

November 29, 2021

Subsecretaría de Relaciones Económicas Internacionales
Ministerio de Relaciones Exteriores de Chile
Teatinos 180, piso 11
Santiago, Chile

VIA Email: tbt_chile@subrei.gob.cl and productosinfantiles@minsal.cl and US TBT Enquiry Point

RE: Notification G/TBT/N/CHL/575 – Draft Regulation on the safety of products used by children

Dear Sir/Madam:

These comments are provided on behalf of The Toy Association and the U.S. toy industry in response to the notification to the World Trade Organization (WTO/G/TBT/N/CHL/575) of October 4, 2021, regarding the Propuesta de Reglamento sobre Seguridad de los Productos de Uso Infantil (Draft Regulation on the safety of products used by children), proposed by the Ministerio de Salud (“Ministry of Health” or “MINSAL”). We appreciate the opportunity to comment and thank the Ministry of Health for inviting input via the WTO TBT network, consistent with Chile’s obligations under WTO Agreement on Technical Barriers to Trade (TBT).

Toys are sold globally with generally the same specifications, facilitated by an increasingly aligned set of international standards and norms to address the safety of the products, reduce risks to consumers, and reduce the impact on the environment. Safety is a paramount concern of the U.S. toy industry, as evidenced by the fact that the industry and the Toy Association have been global leaders in toy safety for decades. The Toy Association continues to work with medical experts, governments, consumers, and industry to provide technical input to ensure that the ISO 8124, EN71 and the ASTM F963 keep pace with innovation and potential emerging issues.

In response to MINSAL’s proposal, we have several questions and concerns based on the draft regulations detailed under the WTO TBT Notification WTO/G/TBT/N/CHL/575. Several provisions pose a potential barrier to trade and thus may be inconsistent with WTO TBT principles. As part of the WTO TBT obligations, WTO members are committed to “harmoniz(e) technical regulations” and “give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objective of their own regulations.”¹ Our main concerns and recommendations can be summarized as follows:

- **Accepting Foreign Lab Certification** - We recommend that MINSAL allow for a single self-certification based on test reports issued by any ILAC-MLA accredited (to ISO 17025) lab or other appropriate documentation such as a chemical safety review per the EU Toy Safety Directive. As currently proposed by MINSAL’s draft regulation, a “quality certification” will only be accepted if it is issued by an approved (listed) lab and which can only be in Spanish. The International Laboratory Accreditation Cooperation (ILAC) has been in place for over 30 years performing independent accreditation of testing labs for a variety of test methods in hundreds of countries. ILAC labs can be found all over the world. To become an ILAC lab, very strenuous audit procedures and independent evaluations are performed, and recognition arrangements are signed to enhance their effectiveness. This effort has done much to support

¹ WTO TBT Agreement, 2.6-2.7

international trade by helping remove technical barriers to trade.² Because of this, governments and consumers can have confidence in the products tested in these facilities. We would urge the MINSAL to consider these ILAC labs that have gone through a rigorous audit and certification process to provide the necessary test reports detailed under MINSAL's draft regulations and to permit the use of reports in English and Portuguese. In the United States, for example, the Consumer Product Safety Commission (CPSC) authorizes any ILAC-accredited lab to test toys for the U.S. market. Many of these same toys will also be sold in the Chilean market.

- **Burdensome Marketing Certification, QR Code & Sample Certification** - The proposal details a unique marketing/commercialization certification mark, which can only be obtained based on the "quality certificate". Once issued, toy manufacturers/importers must have all product labelled with a unique QR code on the packaging. To require both a quality certificate and a marketing certificate for sale in the Chilean market does not improve the safety of toys but will trigger a lot of unnecessary and costly bureaucracy. Mandating a unique QR code only for the Chilean market would require toy importers to design product packaging specifically for the Chilean market. Further, the proposed regulations also detail a special certification requirement to import a sample for testing. An importer effectively must request and obtain a certification to sample prior to securing the certification of quality. Such measures would impose significant additional costs and delays for imported products, without bringing any added safety benefits to Chilean consumers. We recommend that the MINSAL withdraw its proposal for a marketing certificate and its sample certification and allow application of a certification seal once certification is granted.
- **Equivalent Standards** - The draft proposal suggests a willingness to accept "equivalent" standards to Chilean standards as part of its compliance certification requirements; however, the draft regulations are vague and at times reference multiple supporting standards from Chile, ISO 8124 and others. We would encourage MINSAL to simplify its proposal and explicitly reference EN71, ISO, and/or ASTM F963 as being "equivalent" standards for the corresponding certification requirements detailed under the draft regulations. Leading international regulators allow compliance to any of these three standards which helps allows flexibility without compromising safety.
- **Chemical Assessments** - The proposal appears to merge varying aspects of Chilean requirements with those detailed under EN71, specifically as it relates to chemical assessments. We recommend that the Ministry of Health permit the acceptance of the EN71 standard, as well as a chemical safety assessment (as is accepted in the EU) rather develop a hybrid model with Chilean equivalents. As drafted, the proposed regulations create confusion as to exactly what is required, and likely will result in additional testing costs without any increase in safety.

We have attached an appendix chart outlining more specific issues with the proposal which we would like MINSAL to consider. The Toy Association and our members offer our continued expertise and support as you consider our comments, the impact on consumers and industry, and any revisions to the regulation. Please do not hesitate to contact me or my colleague Joan Lawrence if you have questions or would like further information. I can be reached at akaufman@toyassociation.org and Joan at jlawrence@toyassociation.org.

Sincerely,



Alan P. Kaufman
Senior Vice President, Technical Affairs

² <http://ilac.org/about-ilac/>

About The Toy Association and the toy industry:

The Toy Association is the North American based trade association; our membership includes more than 950 businesses – from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs – all involved in bringing safe, fun toys and games to children. The toy sector is a global industry of more than US\$90 billion annually, and our members account for more than half this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States⁴ and internationally as an effective safety standard, and it serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children.

The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.

APPENDIX

Comments from The Toy Association in response to Chile Draft Regulation on the Safety of Products Used by Children (WTO/G/TBT/N/CHL/575)

These comments are compiled by The Toy Association, in response to the provisions of the Propuesta de Reglamento sobre Seguridad de los Productos de Uso Infantil (Draft Regulation on the safety of products used by children), proposed by the Ministerio de Salud (Ministry of Health).

Line Number (número de línea)	Part Number (número de artículo)	Topics (temas) <i>Wording shown in italics are excerpts from English language translation.</i>	Comment/Recommendation (Comentario/ Recomendación)
55	2 h)	water toy: any article, inflatable or not, intended to transport or support a child to play in the water, not exceeding a depth of 1.40 m;	In the spirit of harmonization with ISO 8124-1, recommend this clause be changed with: <i>aquatic toy - article, whether inflatable or not, intended to bear the mass of a child and used as an instrument of play in shallow water</i> <i>Note 1 to entry: Bathroom toys and beach balls are not considered aquatic toys.</i>
66	2 n)	Product family: set of products from the same manufacturer and country of origin and material, destined for the same age range, which have the same functionality and that they have the same scale of dimensions;	Using "same age range" as a criterion will create unnecessarily narrow families. The age grade is already considered via the "functionality" and should therefore only relate to "intended for children over or under 3 years". Recommend this be changed to: <i>Product family: set of products from the same manufacturer, country of origin and material, with similar functionality and scale of dimensions, and being intended for either children under 3 years of age or children over 3 years of age.</i>
74 to 77	2 q)	q) Marketing Certificate: document issued by the Health Institute Public of Chile, designed to authorize the import, distribution and marketing of products for children's use, which comply with the present regulation;	To require both a quality certificate and a marketing certificate does not improve the safety of toys but causes a lot of unnecessary bureaucracy. The quality certificate will be issued only for toys that comply with relevant standards. <i>Recommend that the requirement for a marketing certificate be removed.</i>
168		Multiple locations	The regulation in several cases refers to " <i>must comply with the requirements of tests defined in the Chilean standard NCh3251 / 1 or equivalent.</i> " It should be clarified in one article that "equivalent standards would be ASTM F963, or the relevant part(s) of the ISO 8124 or the EN 71 standards."
223	11	Article 11- Toys cannot release dangerous magnets after being normal and predictable use, for the purposes of this regulation, a dangerous magnet will be understood as one whose strength magnetic or flux index is greater than 50 kG ² mm ² , and whose size, or combinations correspond to:	To support harmonization with the most recent international requirements for magnets in toys we propose to adopt the text from the current versions of ISO 8124-1/EN71-1/ASTM F963 regarding requirements for magnets.

230 to 233		<ul style="list-style-type: none"> - A cylinder with a length not greater than 32 mm and a diameter equal to or less than 11 mm. - A disc with a diameter equal to or less than 26 mm and a thickness of 5 mm or less. - A sphere 22 mm in diameter or less. 	<p>These dimensions come from an old version of ASTM F963. All international standards today refer to the small parts cylinder and we suggest adopting the text from these standards.</p> <p>Also, it is important to include the current versions of ISO 8124-1/EN 71-1/ASTM F963 include an exemption for magnetic/electrical experimental sets (which are required to have a warning in case they contain strong magnets).</p>
244 to 247	13	<p>Article 13.- The physical, mechanical and magnetic tests, established in the safety requirements of the preceding articles, must comply with the requirements of tests defined in the Chilean standard NCh3251 / 1 or equivalent, "Safety of toys - Part 1: Safety aspects of mechanical and physical properties."</p>	<p>See comment on line 168 (above). Alternatively, update the text in this article to specify which standards are "equivalent":</p> <p><i>Article 13.- The physical, mechanical and magnetic tests, established in the safety requirements of the preceding articles, must comply with the requirements of tests defined in the Chilean standard NCh3251 / 1 or equivalent, such as ASTM F963, ISO 8124-1, or EN 71-1, "Safety of toys - Part 1: Safety aspects of mechanical and physical properties".</i></p>
255 to 257	14	<p>Article 14.- Activity toys must be manufactured in a way that reduces the risk of crushing parts of the body, falls, collisions or drowning. In particular, all surfaces of activity toys that are accessible to that one or more children play on them, they will be designed to support the weight of all of them. These toys must also comply with the test methods in NCh3251 / 4 or equivalent, "Toy Safety - Part 4: Swings, Slides, and Playground similar activities for indoor and outdoor domestic family use "</p>	<p>See comment on line 168 (above). Alternatively, update the text in this article to specify which standards are "equivalent":</p> <p><i>Article 14.- Activity toys must be manufactured in a way that reduces the risk of crushing parts of the body, falls, collisions or drowning. In particular, all surfaces of activity toys that are accessible to that one or more children play on them, they will be designed to support the weight of all of them. These toys must also comply with the test methods in NCh3251 / 4 or equivalent, such as ASTM F963, EN71-81, or SO 8121-4, "Toy Safety - Part 4: Swings, Slides, and Playground similar activities for indoor and outdoor domestic family use "</i></p>
259 to 261	15	<p>Article 15.- Bicycles with a maximum seat height between 435 and 635 mm, intended for young children 4 to 8 years of age, must comply with NCh3276 or equivalent, "Bicycles - Children's Bicycles - Safety Requirements."</p>	<p>Article 15.- Bicycles with a maximum seat height between 435 and 635 mm, intended for young children 4 to 8 years of age, must comply with NCh3276 or ISO EN 4210 or 16CFR Part 1512.</p>
322 to 325	23	<p>Article 23.- The flammability tests, established in the requirements of safety of the preceding articles, must comply with the test requirements defined in the Chilean standard NCh3251 / 2 or equivalent, "Safety of toys - Part 2: Flammability."</p>	<p>See comment on line 168 (above). Alternatively, update the text in this article to specify which standards are "equivalent":</p> <p><i>Article 23.- The flammability tests, established in the requirements of safety of the preceding articles, must comply with the test requirements defined in the Chilean standard NCh3251 / 2 or equivalent such as ASTM F963, ISO 8124-2, or EN 71-2, "Safety of toys - Part 2: Flammability."</i></p>

341-342	25	Article 25.- Products for children's use and their parts must not contain substances classified as carcinogenic, mutagenic or toxic.	<p>There are no exceptions to this requirement, which makes this impossible to comply with for certain materials, and there is no standard to support it.</p> <p>If this requirement is retained, there is a need to introduce the same derogations as in the EU Directive on the safety of toys (2009/48/EC): The requirement does not apply to inaccessible materials nor to contents that are below the generic thresholds in the GHS regulations:</p> <table border="1" data-bbox="1352 472 1814 743"> <thead> <tr> <th></th> <th>C</th> <th>M</th> <th>R</th> </tr> </thead> <tbody> <tr> <td>Cat 1A</td> <td>0,1%</td> <td>0,1%</td> <td>0,3%</td> </tr> <tr> <td>Cat 1B</td> <td>0,1%</td> <td>0,1%</td> <td>0,3%</td> </tr> <tr> <td>Cat 2</td> <td>1%</td> <td>1%</td> <td>3%</td> </tr> </tbody> </table> <p>It does also not apply to CMR substances where the classification is based on exposure scenarios that are not relevant (such as nickel in stainless steel, cobalt in steel, or titanium dioxide in an article or liquid mixture).</p>		C	M	R	Cat 1A	0,1%	0,1%	0,3%	Cat 1B	0,1%	0,1%	0,3%	Cat 2	1%	1%	3%
	C	M	R																
Cat 1A	0,1%	0,1%	0,3%																
Cat 1B	0,1%	0,1%	0,3%																
Cat 2	1%	1%	3%																
344	26	Article 26.- Products for children's use must not contain substances or preparations dangerous in amounts that may harm the health of children who use them.	There is a need to specify this requirement further, i.e. by referring to a standard. Suggest US 16 CFR 1500.3(b): "Any toy, or other article intended for use by children, which is a hazardous substance , or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted"																
381 to 383	29	The migration of monomers and organic solvents in toys and childcare articles made of plastic material, cannot be higher than those maximum limits established in this article.	The limit values have been copied from EN 71-9. However, the requirement does not consider that EN 71-9 has a limited scope when it comes to age grades/types of toys. The requirement should not expand the scope of EN 71-9. Suggest substituting the language immediately above.																
426 to 434		Article 35.- Toys that require an electrical charge greater than 24 volts, to your battery charge, the parts of which may come into contact with a source of electricity capable of causing an electric shock, such as: chargers, transformers and plugs connected to the electrical network (220 volts) must comply with the dimensional requirements established in the Chilean standard NCh2027 / 2 or equivalent, "male and female plugs for domestic and similar uses - Part 2: Dimensional requirements ". Also, cables and other conductors that transmit	<p>We propose to align the requirement in Article 34 with the requirement in ISO EN 62115. Adopt EN 62115 requirements and change the text similar to the below:</p> <p><i>Article 35- Chargers, transformers and plugs connected to the electrical network (220 volts) must comply with the dimensional requirements established in the Chilean standard NCh2027 / 2 or equivalent, "male and female plugs for domestic and similar uses - Part 2: Dimensional requirements". Also, cables and other conductors</i></p>																

		electricity to such parts, they must be sufficiently isolated and protected mechanically to avoid shock hazard.	<i>that transmit electricity to such parts, must be sufficiently isolated and protected mechanically to avoid shock hazard.</i> Alternatively, US 16CFR 1505 or UL 697 compliance is acceptable.
474 to 475	40	Include QR seal of conformity assigned according to the certificate of product marketing.	As noted in comments on lines 70-77 it is proposed to remove the double certification requirement. As proposed, this would create unnecessary administration for manufacturers and importers to not only have to go through a certification process to achieve a quality certificate, but to also have to obtain a product marketing certificate, the number of which has to be included on the package in the form of a unique QR-code. This will cause delays and add cost without adding to the safety of the products.
484 to 491		This warning must be accompanied by a brief indication, which may appear in instructions for use, of the specific hazard for which the precaution applies. The products for children's use that contain small parts, according to the test of small parts of the Chilean standard NCh3251 / 1 or equivalent, "Safety of the toys - Part 1: Safety aspects of mechanical and physical properties ", or the that replace it, that can be ingested and / or inhaled by children under 3years, they should add to the previous warning, the indication: "Contains small parts".	See comment on line 168 (above). Alternatively, update the text in this article to specify which standards are "equivalent": <i>This warning must be accompanied by a brief indication, which may appear in instructions for use, of the specific hazard for which the precaution applies. The products for children's use that contain small parts in the as-received condition, according to the test of small parts of the Chilean standard NCh3251/1 or equivalent such as ASTM F963, ISO 8124-1, EN 71-1, "Safety of the toys - Part 1: Safety aspects of mechanical and physical properties ", or succeeding revisions that replace them, that can be ingested and / or inhaled by children under 3years, they should add to the previous warning, the indication: "Contains small parts".</i>
493 to 495		Article 42- Toys containing dangerous magnets must carry a label hazard warning sign, with the following statement: "WARNING !, Contains dangerous magnets for children under 14 years of age ".	This warning should only be applied when required by the standard. It is unnecessary to warn regarding a condition already prohibited by the standard. It should be clarified that this warning is only applicable for magnetic/electrical experimental sets (see also comment on line 230 – 233).
547 to 548		Keep children under 7 years old away from the area where the experiment is carried out.	Reference should be made to ISO 8124-10 (and possibly -11) which lay down different age grades (not only 7 years) depending on the content of the toy.
573-578	48	Article 48.- Toys with projectiles must be accompanied by instructions for use, in which attention should be drawn to the dangers of using projectiles other than those supplied by the manufacturer and also indicate: "WARNING! Do not aim at the eyes or the face ".	This warning should only be applied when required by the standard. It seems unnecessary to repeat it as a requirement in this regulation. Reference should be made to ISO 8124-1.
579-583	49	Article 49.- Toys that produce high sound levels, as established in the Chilean standard NCh3251 / 1 or equivalent, "Safety of toys - Part 1: Aspects of safety of the mechanical and physical properties ", they must indicate in their packaging	The cases where the application of this warning is relevant is laid down in the standard (e.g., ISO 8124-1). It seems unnecessary to repeat it as a requirement in this regulation.

		the following statement: "WARNING! Do not use near the ear. Such use may cause hearing problems".	
596 to 603	52	Article 52.- They will be applicable to the products regulated in this regulation, likewise, the requirements established in the Chilean standard NCh2788, on "Toys -Labeling Requirements", as far as they do not contravene the provisions of this regulation. The physical, mechanical and magnetic tests, established in the requirements of safety of the preceding articles, must comply with the test requirements defined in the Chilean standard NCh3251 / 1 or equivalent, "Safety of toys - Part 1: Safety aspects of mechanical and physical properties."	See comment on line 168. Alternatively, update the text in this article to specify which standards are "equivalent": Article 52.- They will be applicable to the products regulated by this regulation, likewise, the requirements established in the Chilean standard NCh2788, on "Toys -Labeling Requirements", as far as they do not contravene the provisions of this regulation. The physical, mechanical, and magnetic requirements, established in the requirements of safety of the preceding articles, must comply with the test requirements defined in the Chilean standard NCh3251 / 1 or equivalent, such as ASTM F963, ISO 8124-1, EN 71-1, "Safety of toys - Part 1: Safety aspects of mechanical and physical properties."
606 to 608	Title III	QUALITY CERTIFICATION and COMMERCIALIZATION CERTIFICATION OF PRODUCTS FOR CHILDREN'S USE	Recognizing comments earlier on removing the marketing certification requirement, recommend the title is changed to read: QUALITY CERTIFICATION OF PRODUCTS FOR CHILDREN'S USE
615 to 620	53	Article 53.- Only can be commercialized and distributed, those products of child use who present the commercialization certificate, which will only be granted prior issuance of the quality certificate granted by an institution, laboratory or establishment authorized by the Institute of Public Health of Chile to certify the compliance with the security provisions established in the present regulation.	In line with comments on article 40, we propose that only the quality certificate is required: <i>Article 53.- Only products for children use that present quality certificate can be distributed and commercialized.</i>
748 to 755	70	Article 70.- If the product or products that enter the country have a certification of quality granted abroad, the interested party may submit to the entity certifying the documentation that verifies compliance with the requirements regulated in this regulation and complement, if necessary, with the corresponding laboratory tests using conformity model 1b alluded to in the previous article. Likewise, the documents presented must be legal documents, in Spanish or duly translated under the signature of the legal representative.	It is proposed to add to acceptable languages, Portuguese and English. This would permit manufacturers/importers to use international test reports and quality certificates, including the ones issued in MERCOSUR. Article 70.- If the product or products that enter the country have a certification of quality or test report granted abroad, the interested party may submit to the entity certifies the documentation that verifies compliance with the requirements regulated in this regulation. Likewise, the documents presented must be in Spanish, Portuguese, or English.
765	73	Article 73.- Regarding imported products, the Institute shall allow the entry of a sample for certification purposes, which may not be marketed or distributed; its purpose shall be solely to evaluate the safety requirements established by this	Article 73 suggests the requirement for an importer certification in addition to the quality certification and marketing certification detailed earlier. The draft requirement reads that the importer must request and obtain a certification of sample, without right to use, prior to the

		regulation. For such purposes, the owner of the product shall apply for an "Unauthorized for Use" sample certificate from the Institute, in accordance with the procedures established by the latter and that are available on its website.	certification of quality. Such measures would impose significant additional costs and delays for imported products, without bringing any added safety benefits to Chilean consumers. We recommend withdrawing this proposal and allow application of a certification seal once certification is granted.
772	74	Article 74.- In no case may the holder of the quality certificate advertise the product in a manner that tends to deceive the public as to the nature and purpose of the product.	Does this apply to marketing claims such as "flies over 50 meters" or "washable"? Multi-language packages that may be sold in the U.S. will have "Complies to ASTM F963". Will they apply additional measures to assure compliance to F963?
781 to 785	76	Article 76.- In the event of a modification of the Chilean regulations mentioned in these regulations or equivalent international standards, which serve as a reference for the issuance of the <u>quality certificate and the marketing certificate</u> , the Institute must establish a term, not greater than 1 year, for the adaptation of the regulations in force.	In line with previous comments (article 40), it is proposed to remove the reference to the marketing certificate. <i>Article 76.- In the event of a modification of the Chilean regulations mentioned in these regulations or equivalent international standards, which serve as a reference for the issuance of the <u>quality certificate</u>, the Institute must establish a term, not greater than 1 year, for the adaptation of the regulations in force.</i> Further, this article states a term, no longer than 1 year, for the adaptation of the current regulations in force. This timeline is a concern as it sets both the implementation transition and enforcement within one year. Set 1 year for full implementation is not realistic to the production cycle of imported product and would be very difficult to comply with if there are significant changes in the referenced Chilean standard(s). It is also unclear how this implementation timeline would affect the validity of existing quality certifications, which are set at 3 years as detailed under Article 72.
792 to 797	78	Article 78.- In the event that the certifying entity detects a non-conformity that implies the suspension or cancellation of the quality certificate granted, it must inform the Institute so that it may suspend or cancel the certificate of marketing, if applicable, and inform the Ministry of Health to proceed with the withdrawal of the product (s) involved, without prejudice to the penalties established in the regulations in force.	See comment e.g. on article 40. It appears to be an unnecessary administrative burden to require both quality and marketing certificates. Further, this article suggests that a mandatory recall is required, regardless of the nature of the non-compliance. Therefore, this article should be deleted.
803 to 847	79 to 84		See comment on e.g. article 40 It appears to be an unnecessary administrative burden to require both quality and marketing certificates. Therefore, these articles should be updated.