September 21, 2023

Consumer & Hazardous Products Safety Directorate
Healthy Environments & Consumer Safety Branch
Health Canada
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VIA Email: ccpsa-lcspc@hc-sc.gc.ca

To Whom it May Concern:

Re: Notice of Intent to amend the *Toys Regulations*

On behalf of the Canadian Toy Association and the Toy Association in the U.S., we are writing in response to the Notice of Intent to amend the *Toys Regulations* published on June 23, 2023. As industry leaders for the North American toy sector, we very much welcome Health Canada's proposed initiative to update and modernize specific provisions of the *Toys Regulations*.

The Canadian Toy Association (CTA) supports over 100 members consisting of manufacturers, importers, and distributors of toys. Many CTA members are small and medium enterprises operating across Canada; however, the bulk of Canadian sales come from larger multinational toy companies, most of which are based in the United States. The Toy Association is a not-for-profit trade association for producers and importers of toys and youth entertainment products sold in North America, representing over 800 companies. The mission of our members is to bring fun and joy to children's lives and in that mission toy safety is paramount – it is our industry's number-one priority.

The toy industry operates in a global regulatory environment. As an industry, we remain highly focused on encouraging greater alignment of Canadian toy standards/regulations with leading international standards/regulations. The toy industry has long advocated for coordinated safety standards globally that are based on sound science. Avoiding unnecessary divergences is a very important objective towards ensuring effective product safety. It improves compliance and coordinates enforcement amongst regulators, a goal already recognized by Health Canada and the U.S. Consumer Product Safety Commission (CPSC) through their commitment to collaborate on toy safety.[1] This is in addition to the obvious economic benefits conferred by reducing technical trade barriers, especially those which do not significantly enhance safety or health.

In response to the questionnaire included within Health Canada's consultation notice, we have appended to this letter our answers along with additional context to each response. We are also including general comments as part of our overall position and support of Health Canada's working efforts to modernize its *Toys Regulations*, which include:

[1] US Consumer Product Safety Commission and Health Canada's Commitment to Collaboration on Toy Safety (2012) – Website: http://www.hc-sc.gc.ca/cps-spc/advisories-avis/info-ind/ccts-cmsj-eng.php

- **Toy Product Safety:** When it comes to chemical testing, the use of safe and approved chemical substances in the manufacturing of toys has always been strictly regulated. In addition, well-established production controls ensure harmful substances are prevented from entering the manufacturing process. Consumer safety is a paramount goal for our industry, and we are proud of our decades of work with governments and product safety experts around the world to ensure toys remain as safe as possible for children. All toys sold in Canada, regardless of where they are made or imported from, must comply with strict toy safety regulations, tests, and other requirements. Toys are one of the most regulated products in the marketplace and undergo both testing and review before they are placed on the shelf. As Health Canada understands, the *Toy Regulations* under the *Canada Consumer Product Safety Act* make it illegal to sell toys or children's products containing substances harmful to children to which they might be exposed. As part of this ongoing commitment, our members also recognize the importance of continually monitoring current standards and enhancing toy safety when risks emerge. This approach applies to chemical substances used in the manufacturing of our products. Toy manufacturers use substances and materials that have been subject to science and risk-based assessments and are approved by Health Canada as administered under the *Toys Regulations*. Our members have no interest in using unsafe substances or materials in the manufacturing of their products.

- **Safe & Responsible Chemical Testing:** Health Canada's consultation notice highlighted a focus to explicitly eliminate the use of animal testing from the guiding terms when assessing chemicals to ensure compliance under the *Toys Regulations*. We strongly support this intent. As an industry, we have long stopped relying on toxicological tests that would have involved animals. There are over 100 standards and tests for toy safety, but none involve testing on animals. Our industry relies on published toxicology and irritation data and/or reviews provided by a toxicologist. Health Canada's proposed amendment on this topic is welcomed and is well supported by our industry.

- **Modernizing Boric Acid Testing:** We are pleased to see Health Canada embrace the intent to modernize its approach to boric acid. This has been a topic of concern for our industry for many years due to misalignment of leading safety standards. Based on years of data and studies, the toxicology is clear that the limit should be focused on elemental boron, with an acceptable presence depending on product type up to a level of ~7,500 ppm. It is also important to keep in mind that although there has been a variation in approaches applied by ISO and the EU, the toxicology has been consistent and a limit of ~7,500 ppm limit is based on leading sound-science. If Health Canada plans to update its regulation of boron in toys, we recommend alignment to harmonize with the latest ISO soluble metals list and supporting protocols as represented in ISO 8124-part 3.[2]

- **Ambulatory Incorporation by Reference**: We support the proposed approach of incorporating changes to the *Toys Regulations* through incorporation by reference of other leading toy standards. This will allow for the greatest flexibility and ensure Canada's toy safety regulations remain up to date with the leading science and product safety measures applied internationally.

- **Opportunity for Enhanced Alignment of Safey Requirements:** Recognizing that increased regulatory alignment with Canada's major trading partners is a stated goal for these proposed changes to the *Toys Regulations*, we wanted to take the opportunity to profile other regulatory considerations that could readily be addressed during this initiative. Our recommendations for consideration are as follows:

[2] ISO 8124-3:2020/Amd1:2023 Migration of certain elements – Amendment 1: Limits for boron and other elements in slime, and barium in modelling clay (Website: https://www.iso.org/standard/82627.html)

- Canada's total mercury requirement for toys is out of alignment with the soluble mercury requirement applied per ASTM F963, EN71-3 and ISO 8124-3. The toy industry recommends that Health Canada considers aligning with ASTM F963 or ISO 8124-3 on the migration limits, which are considered to provide an acceptable and reliable level of safety for toys.
- In conjunction with the current scope under consideration, a clarification on the *Phthalate Regulations* would be a beneficial area for updating, specifically as it pertains to how the regulation applies to "accessibility", in that only accessible materials fall under the scope of the requirement, and whether certain materials may be considered to be out of scope due to the fact that phthalates would not be present in them. We would recommend Health Canada clarify this requirement of the regulation and look to align the language relating to scope and accessibility with 16 CFR 1307 and 16 CFR 1308.
- We would also ask Health Canada to consider aligning its C34 series of testing methods for phthalates with the CPSC method CPSC-CH-C1001-09.4 or ISO 8124-6, or to accept the result from these methods as acceptable alternative test methodologies for compliance, similar to what is being considered for the heavy elements migration testing method(s).
- Finally, we have been receiving questions from member companies regarding the update on the *Surface Coating Regulations* (SOR/2022-122), specifically due to Health Canada's decision to treat all stickers as a surface coating, which is not in alignment with ASTM. It is unclear what Health Canada means by "films". Further clarification would be beneficial as to whether this relates to clear film laminated on the label or to the sticker itself.

We appreciate your consideration of our comments and responses to the questionnaire as outlined in our appendix to this letter. Our associations and supporting members remain committed to working with Health Canada as it eventually details out its proposed amendments to the *Toys Regulations*. In the meantime, should you have any questions regarding our submission, please do not hesitate to contact us directly.

Yours sincerely,

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Enclosed: Appendix – Questionnaire – Notice of Intent to Amend Toys Regulations

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APPENDIX

Questionnaire - Notice of intent to amend the Toys Regulations – Survey

Contact information

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Stakeholder interest information

- Do you represent a business that manufactures toys in Canada?
  - *YES*
- Do you represent a business that manufactures toys in other countries?
  - *YES*
- Do you represent a business that imports toys into Canada?
  - *YES*
- Do you represent a business that distributes toys to wholesalers or retailers in Canada?
  - *YES*
- Do you represent a business that sells toys directly to consumers (brick and mortar or online) in Canada?
  - *YES*
- Do you represent a government or regulatory body?
  - *NO*
- Are you a consumer, or do you represent a consumer interest group?
  - *NO*

Question 1

Health Canada is considering amending the requirements addressing toxic substances (Section 25) and stuffing materials (Section 29) with 1 of these options:

1. By including additional sources of toxicity data in Schedule 2, including human experience data, and data from tests conducted using the product in accordance with the OECD Test Guidelines, which would include NAMs that are published in these guidelines, or
2. By repealing Schedule 2 and only allow substances that aren't classified for the acute toxicity health hazard class in the GHS

Do you prefer 1 of these options for the requirements addressing toxic substances? Please include information to support your opinion.

- **I am in favour of Option 2: only allow substances that aren't classified for the acute toxicity health hazard class in the GHS**
  - We would support this option as it would most likely facilitate the least amount of administration.

Question 2

Health Canada is considering amending the requirement for corrosive, irritant or sensitizing substances in Sections 26 and 29 with 1 of these options:

1. By amending Schedule 3 to allow for specific corrosive, irritant or sensitizing substances testing methods, or
2. By repealing Schedule 3 and replacing it with a requirement that the corrosive, irritant or sensitizing substances assessment be performed in accordance with good scientific practices

Do you prefer 1 of these options for the requirements addressing corrosive, irritant or sensitizing substances? Please include information to support your opinion.

- **I am in favour of Option 2: requirement that the assessment be performed in accordance with good scientific practices**
    - We would support Option 2.

Question 3

Health Canada is considering amending the requirements addressing boric acid and salts of boric acid with 1 of these options:

1. By establishing requirements in the regulations consistent with the current enforcement policy (0.91%)
2. By adopting the requirements from the EN 71-3 standard for liquid or sticky materials, dry, brittle, powder-like or pliable toy materials, and scraped-off toy materials, or
3. By adopting the requirements from the ISO 8124-3 standard for slimes, putties and modelling clays

Do you prefer 1 of these options for the requirements addressing boric acid and salts of boric acid? Please include information to support your opinion.

- **I am in favour of Option 3: requirements from the ISO 8124-3 standard.**
    - As noted in our cover letter, it would be desirable to harmonize with the latest ISO soluble metals list/protocols. Health Canada requirements set an absolute ban on boric acid and its salts, with a 0.91% total content action limit. The toy industry is working through the ISO 8124-3 to set an acceptable migration requirement for boron. The proposed updated ISO standard will limit the restrictions to slimes and putties, which the toy industry supports, as these are the categories in which boron is most likely to be found in significant quantities. However, there are a few points that are still outstanding, and we would hope Health Canada will consider them as part of its own internal review of the chemical requirements in the *Toys Regulations*. The primary issue is that the ISO proposed boron limits are too low by a factor of two. This has more to do with the EU approach to managing chemical limits than to the science. Secondly, the dewaxing procedure requires additional guidance as some product manufacturers have seen artifact failures created on some slimes when dewaxing was inappropriately applied. We look forward to review specifics on Health Canada's proposed intent once made public.

Question 4

Health Canada is considering amending the requirements for mercury with 1 of these options:

1. By maintaining the limit for total mercury in stickers, films or other similar materials that can be removed, or surface coating materials, and requiring compliance to the ISO 8124-3 migration limits for other substrates by an ambulatory incorporation by reference
2. By maintaining the limit for total mercury in stickers, films or other similar materials that can be removed, or surface coating materials, and requiring compliance to the ASTM F963 migration limits, for other substrates by an ambulatory incorporation by reference
3. By maintaining the limit for total mercury in stickers, films or other similar materials that can be removed, or surface coating materials, and requiring compliance to the EN 71-3 migration limits, for other substrates by an ambulatory incorporation by reference
4. By changing the limit for total mercury to a migration limit for all substrates through the incorporation by ambulatory reference of the ISO 8124-3 migration limit for all substrates
5. By changing the limit for total mercury to a migration limit for all substrates through the incorporation by ambulatory reference of the ASTM F963 migration limit for all substrates, or
6. By changing the limit for total mercury to a migration limit for all substrates through the incorporation by ambulatory reference of the EN 17-3 migration limit for all substrates

Do you prefer 1 of these options for the requirements addressing the migration of certain elements? Please include information to support your opinion.

- **I am in favour of Option 4, Option 5 and Option 6**
    - We assume Health Canada is proposing one of these options and not all three. In other words, it should be “Or” instead of “and”. We propose Health Canada looks to align with the definition of surface coating in ISO 8124-3 and ASTM F963 and apply that to stickers and films to determine surface coating or substrates. We would also propose that Health Canada includes an exemption for materials with sample sizes that are less than 10 mg.

Question 5

Health Canada is considering amending the requirements addressing the migration of certain elements with 1 of these options:

1. By amending the requirements for antimony, arsenic, barium, cadmium and selenium, and adding new requirements for chromium by requiring compliance to the ISO 8124-3 migration limits, by an ambulatory incorporation by reference
2. By amending the requirements for antimony, arsenic, barium, cadmium and selenium, and adding new requirements for chromium by requiring compliance to the ASTM F963 migration limits, by an ambulatory incorporation by reference, or
3. By amending the requirements for antimony, arsenic, barium, cadmium and selenium, and adding new requirements for aluminium, boron, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, strontium, tin, organic tin and zinc, by requiring compliance to the EN 71-3 migration limits

Do you prefer 1 of these options for the requirements addressing the migration of certain elements? Please include information to support your opinion.

- **I am in favour of Options 1 and 2**
    - We would be in favour of either option. Again, we assume Health Canada means “or” and not “and” for this selection. These approaches would help strengthen alignment with US/CAN testing requirements. Further, it would simply be too complex to adopt EN 71-3 migration limits for all 19 elements listed. It would make practical sense to adopt ISO 8124 and ASTM F963 migration limits. Further we would not support the limit for the total mercury for the same reasons. Instead, we would recommend Health Canada modify the limit for total mercury to the migration limit for all substrates and surface coating materials under ISO 8124-3 and ASTM F963.

Question 6

Health Canada is considering amending the requirements addressing finger paints with 1 of the following options:

1. By adopting the proposed toxicity, irritation, sensitization and corrosivity requirements (see sections 1 and 2) for finger paints and by requiring compliance to the ISO 8124-7 standard
2. By adopting the requirements from the ISO 8124-7 standard that prohibit finger paints that are classified under the GHS for acute toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity (single exposure and repeated exposure) and aspiration hazards
3. By adopting the requirements from the ISO 8124-7 standard for the colourants, preservatives, and impurities finger paints might contain. Under that standard, these products cannot be sweetened, flavoured or fragranced, and an embittering agent shall be added to discourage and minimize the ingestion of paint
4. By adopting the requirements from the ISO 8124-7 standard for binding agents, extenders, humectants, surfactants, and N-nitrosamines contained in finger paints
5. By adopting the requirements from the ISO 8124-7 standard for the containers, so they are not mistaken with containers of foodstuffs or drinks
6. By adopting a limit for total mercury in finger paints, in addition to requiring compliance to the ISO 8124-7 standard, or
7. By adopting the requirements from the ISO 8124-3 standard regarding the migration limits for antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium that apply to finger paints

Do you prefer 1 of these options for the requirements addressing finger paints? Please include information to support your opinion.

- **I am in favour of Option 2, Option 3, Option 4 and Option 5**
  - We would recommend this approach. It would streamline product safety requirements by incorporating 8124-7 without any other complications.

Question 7

Health Canada is considering adding requirements for liquids, pastes, putties, gels, powders and items of avian feather origin by requiring compliance to ASTM F963.

Do you agree with these additional requirements for liquids, pastes, putties, gels, powders and items of avian feather origin? Please include information to support your opinion.

- **I am in favour of these additional requirements.**
  - Yes, we would be in favour of this proposed change. The toy industry has long advocated for coordinated safety standards globally that are based on sound science and have been particularly supportive of aligning Canadian and U.S. toy safety requirements. Further, as noted under our response to Question 3, we would also encourage Health Canada to consider the upcoming revisions to the ISO 8124-12 as another possible approach for alignment. Avoiding unnecessary divergences is a very important objective to ensuring product safety.

Question 8

Health Canada is considering adding requirements for chemical toys (sets) other than experimental sets by requiring compliance to ISO 8124-11.

Do you agree with these additional requirements for chemical toys (sets) other than experimental sets? Please include information to support your opinion.

- **I am in favour of these additional requirements.**
    - Yes, we would be in favour of this proposed change. The toy industry has long advocated for coordinated safety standards globally that are based on sound science.