Briefing Note

Implementing a Formal Pre-Consultation Step in the Federal Regulatory Process to Inform and Enhance Regulatory Development

Summary:

- The Consumer Products Alliance for Innovation and Growth (CPAIG) is an industry coalition made up of manufacturers and retailers who have come together to work on high-level issues of mutual concern.
- CPAIG members, who have decades of experience as key stakeholders in the development and implementation of government regulatory initiatives, are recommending specific changes to the federal regulatory process to provide for more meaningful input into regulatory development and impact assessment.
- Specifically, CPAIG is recommending that departments be required publish a Notice of Intent (NOI) to Regulate in the Canada Gazette for a 60-day comment period that would include detailed, preliminary drafting instructions.

Issue:

A significant gap exists with the current approach for developing regulations as it relates to the consultation phase for regulatory initiatives. As a result:

- Early consultations on regulatory proposals are carried out in an inconsistent manner.
- Canadians and other affected parties are often not afforded an opportunity to provide meaningful input into the development of regulations prior to the publication of regulations in the *Canada Gazette Part I*.
- Government regulators are missing out on valuable information to fully inform their understanding and analysis of the regulatory impact and operational issues prior to drafting triage statements, developing regulatory impact analysis statements and commencing the drafting of regulations.
- Finite regulatory/drafting resources are utilized inefficiently.

The current review by the Treasury Board Secretariat of the Cabinet Directive on Regulatory Management and its related policies, presents an opportunity to address this gap.

Current Status:

Canada's formal regulatory process assumes that regulatory departments have adequately consulted Canadians and have properly evaluated their policy and instrument choice options. While less formal consultations may be appropriate at the very early stage of policy development such as when identifying issues, consulting on options, and determining instrument choice, formal

consultations on detailed proposals are essential to ensure input is meaningful and informative. For industry, the level of "meaningfulness" of a regulatory consultation correlates directly to the level of detail provided to those being consulted.

The current formal regulatory process jumps from the very early publication of forward regulatory plans by departments, which are lacking in any real scope or detail, to *Canada Gazette Part I*, where regulatory proposals are in a final draft form and where real-world experience of CPAIG members suggests that there is little room for fundamental change. While, the Cabinet Directive on Regulatory Management is clear that "Publishing proposed regulations in the Canada Gazette is not a substitute for meaningful consultations on the development of regulatory proposals"[1], there are no other formal, pre-Gazette requirements for consultations. As a result, there exist significant inconsistencies regarding how pre-gazette consultations are carried out, and those consultations often fail to provide sufficient detail to solicit meaningful and useful input.

This has significant, negative, implications for two important stages in the regulatory development process: the drafting of the Triage Statement and the development of the Regulatory Impact Analysis Statement.

- The Triage Statement is to be developed at the earliest stage of regulatory design in order to determine the requirements to be met at all stages of the regulatory process. The Triage Statement provides an early assessment of the expected impacts of regulatory proposals and helps determine where approval processes can be streamlined and where analytical resources should be focused. [2] However, these Triage Statements are developed without any public consultation or input and are by design based on uninformed and often incomplete analysis by departments.
- "A properly prepared RIAS provides a cogent, non-technical synthesis of information that allows the various RIAS audiences to understand the issue being regulated. It allows audiences to understand the reason the issue is being regulated, the government's objectives, and the costs and benefits of the regulation. It also addresses who will be affected, who was consulted in developing the regulation, and how the government will evaluate and measure the performance of the regulation against its stated objectives. The RIAS is, in effect, a public accounting of the need for each regulation".[3] However, the RIAS is only made public at the near-final stages of regulatory development when regulations are published in the *Canada Gazette Part I*. Industry is frequently asked to opine on costs associated with regulatory initiatives based on incomplete and vague policy proposals that are lacking sufficient detail for industry to provide accurate cost assessments. In addition, the *Canada Gazette Part I* consultation period does not always allow for sufficient time for a thorough assessment of costs.
- It is impossible for affected stakeholders to fully engage in a consultation process without sufficient detail. The smallest nuance can result in unnecessary and often unintended operational impacts. While publication in *Canada Gazette Part I* provides an opportunity for valuable input into detailed regulatory proposals, this step should be reserved for

[1] *Cabinet Directive on Regulatory Management*
[2] Treasury Board Secretariat - Triage Statement Form
[3] RIAS Writers Guide 2009

refinement of specific sections of regulations, rather than large-scale changes that are often required because department's have made drafting decisions without being fully informed of the consequences.

Recommendation:

CPAIG believes issues could be mitigated by implementing a formal consultation step prior to publication of proposed regulations in the *Canada Gazette Part I*. Specifically, we recommend changes to the regulatory process to require the following formal consultation as a pre-condition to getting approval to begin drafting regulations:

- Departments be required publish a Notice of Intent (NOI) to Regulate in the Canada Gazette for a 60-day comment period.
- The NOI could take the form of an early version of a RIAS and include detailed, preliminary, drafting instructions upon which stakeholders would be able to provide meaningful and substantial input as to costs, operational issues, implementation issues etc.
- The Treasury Board Secretariat (and perhaps even Treasury Board itself) should have a role in reviewing the NOI and approving its publication.
- Based on comments received during the pre-consultation, Departments should have to obtain agreement of TBS-RAS before being allowed to engage the Department of Justice drafters in drafting the regulations.

Considerations/Rationale:

This proposed approach would provide regulators with an advanced understanding of costs and operational/implementation issues related to regulatory proposals; it would provide additional rationale for instrument choice, lead to more focused and potentially expedited consultations at Gazette Part I and optimize use of departmental resources including drafting services.

Information gathered from consultations on drafting instructions would provide much more accurate information from all affected parties which could then be used in the drafting of both the Triage Statement (likely preventing the statement from having to be amended during the course of the regulatory development) as well as the RIAS (providing the TBS-RAS and TB Ministers with a far more accurate assessment of the impact of regulatory proposals upon which to base decisions).

Given that drafting instructions must be developed by departments anyway in order to proceed with drafting regulations, little additional work would be required to prepare a NOI for early consultations. Any additional effort would be easily offset by the value derived from obtaining more detailed cost assessments and the ability to further refine drafting instructions prior to engaging finite drafting services.

In addition, the publication of an NOI with preliminary drafting instructions, would also provide more relevant information to other affected departments for their input as well as allowing TBS an opportunity to ensure that regulatory proposals are consistent with other government initiatives such as Regulatory Cooperation before regulations are drafted.

Finally, giving all Canadians an opportunity to provide input on drafting instructions is in line with this government's commitment to a more open and transparent government and allows for more timely constructive dialogue with Canadians and stakeholders.

Background:

Consumer Products Alliance for Innovation and Growth (CPAIG)

- CPAIG is coalition comprised of consumer-focused industry associations that represent the manufacturers and retailers of products that are used everyday by every Canadian. CPAIG industries make enormous contributions to employment and GDP, while providing Canadians with a range of products that impact health, wellbeing, and the enjoyment of life for every Canadian.
- CPAIG members consist of the following associations: Beverages Canada, Consumer Health Products Canada, Consumer Specialty Products Association, Cosmetics Alliance Canada, Food and Consumer Products Canada, Independent Grocers, Neighbourhood Pharmacies Association, Retail Council of Canada
- CPAIG members operate in a highly and tightly regulated environment. How regulations are created, how government consults with industry in the drafting regulations, and the outcomes of that process have an enormous impact on our businesses, the products we make, investment and employment decisions and our competitiveness in global markets.
- CPAIG came together in January of 2017 to work together in addressing issues of common interest. As a first priority, issues with the current regulatory process, in particular the lack of consistency and lack of early input into detailed proposals in the pre-Canada Gazette consultation process was identified.

Appendix A – Case Studies:

1. Self-Care Framework

2. Children's Jewelry Regulations and Consumer Products Containing Lead Regulations

3. Proposed Changes to the Cribs, Cradles and Bassinets Regulations

4. CFIA Modernisation and the *Safe Food for Canadians Regulations*

Appendix A

Case study #1 Proposed Self-Care Framework

Health Canada is currently in the process of developing a proposed new “Self Care Framework” (the Framework) that is aimed at changing how the government approaches the regulation of self-care products. The product categories that are being looked at under this proposed new Framework are: over the counter (OTC) medicines; natural health products (NHP) and cosmetics all of which are currently regulated under the Food and Drugs Act under separate sets of regulations.

In September-October 2016, Health Canada released a high-level framework document for consultation. In 2017, the department has engaged stakeholders in a series of town hall meetings across the country covering some topics in more detail. Health Canada has identified that their next steps will involve further consumer research and targeted consultation sessions. They will also be identifying legislative instruments and developing regulatory drafting instructions.

It is clear from the initial proposals, that the proposed framework will have widespread impacts on manufacturers, retailers, health practitioners and other stakeholders. Among these impacts are the over 3,000 OTCs, 40,000 NHPs and over 30,000 cosmetics marketed in Canada per year that will need to adapt to new manufacturing rules, new processes and requirements for pre-market oversight, and new packaging and labelling. Significant implementation issues have been consistently raised throughout each round of stakeholder consultation, but these details have been largely set aside thus far in favor of keeping the scope of discussions focused on policy development.

In order for the summation of years of policy work and stakeholder consultations to be successful, it is imperative that Health Canada consult as early as possible with stakeholders on the specific details of regulations (e.g. drafting instructions) in order to collect meaningful data on the impacts and implementation not only to inform the future RIAS, but also to ensure that the proposed regulations when drafted do not cause undue burden or other negative consequences. The level of detail and complexity of this initiative, and the fact that the expertise in the areas being impacted by the framework (manufacturing, production, distribution etc.) lies outside of government, highlights the need for early input into the detailed drafting instructions.

Case study #2 Children's Jewelry Regulations and Consumer Products Containing Lead Regulations

In 2017, Health Canada proposed changes to the Children's Jewelry Regulations and Consumer Products Containing Lead Regulations. Concerns quickly emerged that the proposals were developed without consulting with Canada's retail industry. The RIAS indicated that 27 industry stakeholders were consulted on the proposals between November 2013 and March 2014, yet retailers were not consulted, despite the fact that the retail industry is uniquely positioned to provide insights and information to ensure that government objectives are achieved in the most efficient and effective manner.

Because proposals were developed without consulting the affected industry, opportunities were missed, and resulted in the development of unique Canadian requirements that are misaligned with U.S. regulatory requirements and which present significant adaptive challenges. For example, Health Canada proposed the introduction of testing requirements for cadmium limits that are not migrate-able, and imposing made-in-Canada standards that exists in no other jurisdiction. Health Canada proposals failed to align with risk-based U.S. requirements which included different limits and exemptions for specific lower-risk products and parts which are not accessible.

Without a list of exemptions similar to what exists in the U.S., the proposal would result in unnecessary and uniquely Canadian testing on inaccessible products and components, resulting in higher costs and less choice for Canadian Consumers. The proposals put forward by Health Canada further reflected a lack of consultation with business, in the RIAS, because they did not factor in the administrative burden on industry with regards to recordkeeping associated with unique testing requirements.

All of these issues could have been avoided, if the department had been required to publish the details of their proposal (e.g. drafting instructions) in the Canada Gazette, prior to proceeding with the drafting of regulations.

Case study #3 Proposed Changes to the Cribs, Cradles and Bassinets Regulations

Health Canada proposed changes to the *Cribs, Cradles, and Bassinets Regulations* in 2015. The proposed regulations included numerous requirements, many of which aligned with the U.S. Consumer Product Safety Commission (CPSC) requirements for these products. Where joint standards were developed business supported changes. However, the regulations also included requirements that were different from those in the U.S. including different design and testing requirements with regards to stands as well as maximum rest and maximum flatness angles.

Most problematic were new and unique Canadian standards for rest angle where the proposed new requirement imposed an administrative burden on industry with regards to recordkeeping associated with unique testing requirements. Also indicative of a lack of understanding of business realities and costs, the “One-for-One” section of the Regulatory Impact Analysis did not reflect this added administrative requirement and therefore underestimated the costs of compliance. Early consultation with business in the drafting of the regulations could have resulted in Health Canada better anticipating and addressing these impacts.

Case study #3 CFIA Modernisation and the *Safe Food for Canadians Regulations*

The Canadian Food Inspection Agency (CFIA) began its modernisation process using the standard consultation model; the CFIA shared its vision to industry stakeholders without pre-consultation resulting in significant frustration and loss of confidence amongst industry stakeholders.

A small group of subject matter experts approached the CFIA team tasked with modernisation about a new approach that would allow CFIA to share their ideas with experts:

- To ensure regulatory proposals were sound and
- To ensure a better understanding of constraints by both CFIA and stakeholders during more general public information sessions.

This new approach initially involved two separate groups, one which focused on food safety, and one which focused on commodity-specific activities. Eventually the two groups merged into a single advisory body. Sessions were frequent and of sufficient length to have in-depth discussions about proposed regulatory changes and their impact on food safety in Canada, including new requirements for written food safety programs for any importer or food establishment that sells product across provincial, territorial, or to other jurisdictions. As a result of this meaningful discussion, CFIA's proposals resonated with industry; CFIA had insightful responses about constraints to change which were extremely helpful to industry once formal general comment was sought.

In addition to precedent-setting stakeholder outreach, CFIA also responded positively to a stakeholder request for an advance view of the draft *Safe Food for Canadians Regulations*, with the publication of the "progress to date" document; a disclosure of the draft text prior to publication in CGI. This pre-draft publication was extremely useful because it allowed stakeholders considerably more than the typical CGI consultation period to digest a long complex document. Comments on CGI were then further developed by stakeholders resulting in high quality, useful feedback for the CFIA.

This new approach dramatically reduced the time needed to draft new regulation. The drafted text was, generally speaking, less likely to contain unintended consequences, and achieved its objective of consolidating several *Acts* and their supporting *Regulations* in a new modern outcomes-based approach that is based on modern best practices.

We believe that this is a successful model that should be adopted generally by other agencies, such as Health Canada.