Briefing Note

Improving regulatory interpretation (guidance) development to enhance regulatory transparency and outcomes

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 that the Cabinet Directive on Regulatory Management be amended to require that, where guidance documents are needed to support regulatory initiatives, they be published along with regulatory proposals in the Canada Gazette.
- We further recommend that departments be required to undertake an internal "audit" of their existing guidance documents to ensure that there are no contradictions between documents and to ensure that all current guidance documents are consistent with existing regulatory authorities.

Issue:

A significant gap exists with the current approach for developing regulations as regulatory interpretation and guidance is generally not developed or published until after a regulation is finalized. As a result, stakeholders, including regulated parties, often lack the information required to fully understand the implications of proposed regulations, including impacts on operations and implementation costs.

In addition, over time, guidance documents have been developed that appear to contradict one another and instances of "regulatory creep" have been noted where requirements laid out in guidance documents are not supported by authority in regulations.

Current Status:

In highly technical regulatory environments, detailed guidance documents are often necessary to ensure the efficient application of regulations and meet policy objectives. These guidance documents are also necessary in order to provide a degree of flexibility that permits regulated parties to comply with government's intended regulatory outcomes without having their ability to innovate stifled by overly prescriptive regulations.

Each department's approach to the development of such guidance is governed by Treasury Board's *Guide for Developing and Implementing Interpretation Policies (the Guide)*, which requires them to publish interpretation policies that outline how they will meet the principles of the *Guide,* including predictability, service, stakeholder engagement, and ongoing improvement. *A*dherence to these principles in the provision of guidance for existing regulations is intended to:

- Ensure consistency in guidance and commitment to plain and clear language;
- Serve Canadians with professionalism and provide accurate, timely and respectful service;
- Engage stakeholders to identify regulatory requirements that require guidance and in developing such guidance; and,
- Seek to improve delivery of interpretation services, based on experience and feedback from Canadians and business.[1]

However, guidance documents are frequently only developed after regulations have been promulgated without any assurances that their interpretations/provisions don't impose additional burden beyond what was anticipated and consulted upon in the regulatory development process. In addition, over time, the proliferation of guidance documents has resulted in inconsistencies between various guidance developed for different aspects of the same regulation/legislation as well as instances where guidance documents impose requirements that are not actually authorized by regulations.

Recommendation:

CPAIG believes that the Federal Regulatory Process should include a requirement to:

1. Identify whether implementation of a proposed regulation would require the creation of a detailed guidance document; and,
2. If it is determined that such guidance would be necessary, publish a draft of the document as part of the *Canada Gazette Part I* consultation.
3. If guidance documents are amended after regulations are published in the *Canada Gazette Part II*, and those amendments result in significant additional requirements, departments should be required to re-publish the guidelines for public comment and Treasury Board review/approval.

CPAIG further recommends that departments be required to undertake an internal "audit" of their existing guidance documents to ensure that there are no contradictions between documents and to ensure that all current guidance documents are consistent with existing regulatory authorities.

Considerations/Rationale:

This proposed approach would provide regulators with an advanced understanding of costs and operational/implementation issues related to regulatory proposals and permit stakeholders, including regulated parties, with the information necessary to provide them with better-informed

[1] Treasury Board Secretariat – Guide for Developing and Implementing Interpretation Policies

and more meaningful input. This input would better inform operational planning in relation to implementation of the regulatory proposal, for both regulators and regulated parties. With the insight into the operational impacts of the regulatory proposal gained from prepublication of the draft guidance, a more meaningful assessment of the cost-benefit analysis and other aspects of the RIAS could be made by respondents to the Gazette notice. This would lead to better decision making in the finalization of the proposal.

Prepublication of draft guidance as part of *Canada Gazette Part I* publication of a proposed regulation should not create an additional burden for regulators, as consultation on such guidance is already Treasury Board policy (for those regulations deemed in need of detailed guidance), and must be completed prior to implementation of the final regulation. Instead, prepublication should make the consultation processes for both instruments more efficient and meaningful. For example, publication of draft guidance could help to ensure an appropriate balance between specificity and flexibility in the regulatory proposal itself, by demonstrating a viable compliance approach that is consistent with Cabinet directives and Treasury Board policy.

As regulators move to more outcome-based regulations, and reliance on guidance increases, it is important to ensure that proper oversight and review of impact follows the lifecycle of a regulatory instrument. As such departments should not have the authority to make significant changes to guidance that would increase costs/burdens significantly beyond what was approved in the original RIAS without having to seek further approvals from Treasury Board.

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 Study: Plain Language Labelling (PLL) Regulations

- In October 2012, Health Canada's Marketed Health Products Directorate MHPD and the Institute for Safe Medication Practices (ISMP) formed an Expert Advisory group to develop the regulatory guidance to support new regulations that were planned to address the need for plain language labelling. The anticipated completion date of this guidance was April 2013.
    - ISMP disseminated three survey questions to industry to gain high level information on industry impacts. ISMP refused industry requests to participate on the Expert Panel developing the guide, which also did not have representatives for consumers, label design houses, the packaging industry or consumer health product manufacturers.
- In December 2012, Health Canada's Office of Regulatory and Legislative Modernization delivered a presentation on the initiative. Later in January 2013, MHPD circulated a seven question survey amongst stakeholders. Industry requests to collaborate early to ensure flexible formatting in guidance were denied.
- In June 2013, the draft regulations were published in *Canada Gazette Part I* [Vol 147. No,. 25, June 22 2013] which included a commitment to consult on the guidance describing the OTC facts table before CGII is published.
    - Regulations were vague, only requiring "adequate directions for use" to be displayed in a "table format" and information to be "prominently displayed"
    - The RIAS stated that "*Because the regulations don't require new information for the Facts panel, are not overly prescriptive regarding the format, the department does not expect any changes in the label or package size as a result."*
    - The RIAS estimated a total one-time impact of $3.5 million in compliance costs for the prescription and non-prescription drug industry, with no ongoing additional costs. This cost was calculated, in part, by applying a factor to cost estimates leveraged from US data from 1990's.
    - Industry estimates that costs for the OTC industry alone will approach $100 million, due to the prescriptive nature of the guidance, which will trigger widespread packaging reconfigurations.
- The PLL Regulations were finalized and Published in *Canada Gazette II* in June 2014 [SOR 2014-158 June 13 2014], bringing prescription drug provisions into force 1 year later, and 3 years later for OTCs (June 2017).
- The Draft Good Label Package Practice Guide (applying to both Rx drug and OTCs) was published in March 2015, 7 months later than expected. Despite early warnings from the OTC industry about the need for a more flexible format, proactively provided specific feedback was not considered.
    - The OTC industry estimated that the format would require 95% of packages to be reconfigured, to meet specific font size restrictions and prescriptive table formats.
    - June 30th 2016: The Final Good Label Package and Practices Guide for OTCs was published introducing graduated flexibilities to address industry concern about packaging impacts. However, by September 2016, after experience applying the final Guide, it was evident these flexibilities did not go far enough to address the concern. As a result of industry consultations from December 2016-Febuary 2017 the Good Label Package and Practices Guide for OTCs was revised on May 31st, 2017 to add further flexibilities and introduce electronic labelling for lower-risk products.
- The Standing Joint Committee on the Scrutiny of Regulations has since completed a review of the PLL Regulations and has written to Health Canada identifying issues that need to be addressed with the vague wording of the regulation and on the use of prescriptive guidance to offset this.
- Should industry have been permitted to be involved early in the development of guidance, accurate cost impacts could have been developed much earlier on to develop workable guidance and regulation for industry.