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Consultation on Regulations Signals the Canada Consumer Product Safety Act is Moving Forward

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In June 2010, the proposed *Canada Consumer Product Safety Act* (CCPSA) was given its first reading in the House of Commons as Bill C-36 (see our June 2010 Blakes Bulletin on Life Sciences: *Third Time Lucky? Canadian Consumer Product Safety Bill Reintroduced*). The proposed CCPSA is, for the most part, a reintroduction of Bill C-6, which died on the Order Paper when Parliament was prorogued in December 2009. The CCPSA would apply to all consumer products, including components, parts or accessories and packaging that can be reasonably obtained by an individual for non-commercial (including domestic, recreational and sports) purposes. Certain products currently regulated under specific legislation such as food, drugs, medical devices, natural health products, cosmetics, pest control products and vehicles would be excluded from the CCPSA.

If passed, the CCPSA will radically revamp Canada's existing consumer product regulatory regime through the enactment of a variety of measures including: broad application to most consumer products; new obligations to report product "incidents"; new government authority to issue mandatory recalls; mandatory record-keeping obligations; widespread investigatory power of government inspectors; and substantial penalty provisions. Health Canada is currently in the midst of a consultation period, during which the public and other stakeholders have the opportunity to voice opinions concerning the Ministry's proposed interpretation of certain provisions within the proposed CCPSA, as well as certain regulations that would accompany the CCPSA. Specifically, Health Canada is seeking input regarding its interpretation of the legislation's mandatory reporting requirement, proposed product exemption regulations, and proposed administrative monetary penalty (AMP) regulations. The current proposals in respect of these policies and regulations are discussed below.

MANDATORY REPORTING

The proposed CCPSA outlines reporting duties for manufacturers, sellers or importers in the event of a product-related "incident". The proposed CCPSA defines the term "incident" to include: an actual or potential serious injury caused by the product that occurs anywhere in the world; a defect or characteristic in the product that may lead to serious adverse health consequences for a product user, and incorrect or insufficient information on a label or in instructions (or lack thereof) that may lead to serious adverse health consequences for a product user. Under the proposed CCPSA, manufacturers, importers or sellers would be expected to report an incident within *two days* after the day on which they become aware of any "incident".

Health Canada's "mandatory reporting" consultation document provides that the two-day timeline is started when a "responsible person" becomes aware that an "incident" has occurred with respect to a product that they supply in Canada. Health Canada proposes to interpret "responsible person" as referring to the directing mind of an organization, and the question of who is a directing mind may be determined on a case-by-case basis having regard to relevant qualities of a particular organization such as its size and structure. Further, a product would meet the definition of "supplied in Canada" if it has been manufactured, imported, sold or otherwise distributed in Canada.

In addition to the two-day incident reporting report, the proposed CCPSA states that a manufacturer or importer would be expected to provide a written report to Health Canada within 10 days of becoming aware of an incident. However, the proposed legislation provides for Ministerial discretion to specify an alternative period of time.

Health Canada is currently consulting with stakeholders to be notified of capacities, policies, processes and procedures that stakeholders currently have in place which may facilitate the reporting process. This information may be used to develop criteria by which the Minister is able to determine situations in which he or she should specify a different written reporting period

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than the 10 days currently set out in the proposed legislation. Interested parties have until October 1, 2010 to make submissions on these matters.

EXEMPTION REGULATIONS

Exemptions for Consumer Products Non-Compliant with Requirements in Regulations

Under the proposed CCPSA, the manufacture, importation, advertisement and/or sale of a non-compliant consumer product would be prohibited in Canada unless certain exemption requirements are met. Under the exemption regulations that have been proposed by Health Canada, the following products would be exempted from compliance with the proposed CCPSA in addition to those products already exempted by virtue of their regulation under other existing legislation:

i) products that are manufactured domestically or imported into Canada and then exported for sale;

ii) products imported from elsewhere that are not compliant at the time of importation, but that can be brought into compliance; and

iii) products that are manufactured, imported or advertised for testing, research or exhibition, but not for sale to consumers.

Under Health Canada's exemption regulations proposal, a formal exemption would have to be requested and granted prior to the initiation of any of the above activities that would otherwise result in a non-compliant product entering the Canadian supply chain. A request for an exemption would require the submission of a formal application that provides information including:

- reason for the exemption;
- activity requested;
- establishment information;
- responsible person/contact information;
- product and shipment information;
- start date/end date for which the exemption is required; and
- compliance status.

Further, an exemption could be revoked in the event of non-compliance with the proposed exemption regulations. A person or business could, however, submit a new application if measures had been taken to ensure that non-compliance would not re-occur. Health Canada is consulting on a variety of issues concerning the exemption regulations, including the circumstances in which an exemption should be granted, and the nature of the application process. Interested parties have until October 19, 2010 to make submissions on these matters.

Exemptions for Preparing and Maintaining Documents

The proposed CCPSA contains a requirement that anyone who sells consumer products for commercial purposes prepare and maintain documents that indicate the name and address of the person from whom they obtained the consumer products, where they sold the consumer products, and the period during which they sold the consumer products. Concerns have been raised by establishments that receive donated products from unknown sources that it would be virtually impossible for them to comply with these provisions.

In light of these concerns, Health Canada is considering situations in which certain persons or companies would be exempt from the obligation to prepare and maintain documents. Under Health Canada's exemption regulations proposal, a recipient of a consumer product would be exempted from the record-keeping obligation where:

i) the consumer product is donated, that is, given for no consideration; and

ii) the donation is from a person other than a manufacturer, importer, distributor, or retailer.

However, if an item is being donated by a manufacturer, importer, retailer or distributor, then the record-keeping obligation would apply. Interested parties have until October 19, 2010 to make submissions on these matters.

ADMINISTRATIVE MONETARY PENALTY REGULATIONS

Under the proposed CCPSA, compliance with the legislation would be enforced through a variety of measures including: product seizures; injunctions; criminal charges; and AMPs. AMPs would be specifically available for use against persons or businesses who fail to adhere to an Order from the Minister of Health to comply with the terms of the CCPSA.

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Health Canada's AMP regulations proposal provides detail on matters related to the calculation of penalties including: gravity factors; weighting; and penalty values. The penalty amount would be determined by adding "historic gravity value" to "risk gravity value". "Historic gravity value" points would be assigned based on the person or business's number of previous violations. "Risk gravity value" points would be assigned based on the magnitude of the health risk posed by the violation. One gravity value point would result in a C$1,000 penalty, and the maximum 10 gravity value points would result in a C$25,000 penalty. However, penalties could be issued for every day that a person or business fails to meet an Order, so an initial C$1,000 penalty could be inflated over a period of days to become much more significant.

Under the proposed CCPSA, persons or businesses would have an opportunity to request review of a Ministerial Order prior to being made subject to an AMP. Under Health Canada's AMP regulations proposal, penalties would have to be paid within 15 and 30 calendar days after the assessment of the penalty. If the penalty is paid earlier than 15 calendar days following the assessment, then the amount of the penalty would be reduced by half. If the penalty is not paid after 30 calendar days, then the debt would be referred to the Receiver General of Canada for collection. Interested parties have until November 7, 2010 to make submissions on these matters.

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