Discussion Paper on Bill C-38 – The Omnibus Budget Bill Introduced on March 29, 2012

Prepared by Shawn Buckley, LL.B., president of the Natural Health Products Protection Association on June 17, 2012.

No Review by the Standing Committee on Health

Bill C-38 makes some significant amendments to the *Food and Drugs Act* that will affect consumers and the natural health industry. To date there has been very little awareness of the proposed changes. Even more concerning is that the Bill was referred to the Finance Committee, not the Standing Committee on Health. The Bill is already out of Committee.

We were waiting for confirmation from the Minister's Office concerning the framework of the inevitable regulations that will flow from the proposed amendments. They were not forthcoming and we believe that the public needs to be aware of the proposed changes despite the incomplete analysis that not knowing the structure of the proposed regulations entails.

The following is a Discussion Paper on our initial analysis of the proposed changes. As with all of our Discussion Papers, we look forward to input from others who invariably see things we missed.

This Paper reflects the opinion of its author, Shawn Buckley, and should not be construed as adopted by the NHPPA Advisory Board.

Exempting Pest Control Products from the "Poisonous or Harmful" Substances Protection in Food

Subsection 4(1) of the *Food and Drugs Act* protects against harmful food by prohibiting sale in five different situations. Specifically the section bans the sale of food that:

(a) has in or on it any poisonous or harmful substance;

(b) is unfit for human consumption;

(c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;

(d) is adulterated; or

(e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Currently there is an exemption to these protections which allows for the adulteration of foods if the Minister allows it through what is called an "interim marketing authorization" (see sections 4(2) and 30.2 of the Act). If an interim marketing authorization has been issued, then a food is not considered to be adulterated:

(a) by an agricultural chemical if the amount does not exceed the amount in the interim marketing authorization;

(b) by a veterinary drug if the amount does not exceed the amount in the interim marketing authorization, and

(c) by a pest control product as defined in the *Pest Control Products* Act if the amount does not exceed the limit specified under section 9 or 10 of that Act.

Bill C-38 amends section 4(2) of the *Food and Drugs Act* so that foods with pest control products are no longer to be considered poisonous or adulterated if they have pest control products in amounts that do not exceed the limit specified under section 9 or 10 of the *Pest Control Products Act*.

Under the old section 4(2) food was not considered adulterated if the pest control products were under the limits in the *Pest Control Products Act*, but they could still be considered poisonous or harmful. If amended a person selling a food that is poisonous or harmful due to a pest control product could not be prosecuted providing the limits are below those set out in section 9 or 10 of the *Pest Control Act*.

It is not clear how this change protects the consumer.

This is clearly a positive amendment for persons and companies selling foods containing pest control products as it provides some legal certainty for what is and what is not allowed.

A person comparing the amended subsection 4(2) with the current 4(2) might notice that the exemptions for agricultural chemicals or veterinary drugs in 4(2)(a) and (b) have been removed by the amendment. This is correct, but we are not sure that there will be any practical difference. The new section 30.3 will allow the Minister to grant marketing authorizations that can allow any amount of agricultural chemical or veterinary drug residues that the Minister sets out in the authorization. It is unlikely that Health Canada would enforce the adulteration protection in section 4(2) against a company that was complying with one of the marketing authorizations of the Minister.

Removing the Safety Requirement for Food Marketing Authorizations – Permitting Agricultural Chemicals, Veterinary Drugs or Food Additives that do not have Prescribed Safe Limits – Not Including the Right to Cancel Marketing Authorizations in the Act

Under the current *Food and Drugs Act* the Minister can grant marketing authorization for a food that exempts the food from certain limits such as prescribed safety limits for agricultural chemicals, veterinary drugs, or food additives. However, the Minister can only do this under section 30.2(1) "**if the Minister determines that the food would not be harmful to the health of the purchaser or consumer".**

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Bill C-38 amends the marketing authorization scheme and removes the protection that a marketing authorization can only be granted "if the Minister determines that the food would not be harmful to the health of the purchaser or consumer". There is no explanation for why this safeguard was removed from the Act. We see no benefit to the consumer for this exclusion. Although such a safeguard could be included in the regulations that will follow these amendments, regulations can be changed easily and do not offer the same level of protection as text in an Act which requires Parliament to amend.

Although it is not a "change", the new marketing authorization scheme in Bill C-38 continues to exempt foods with an authorization from sections 6 and 6.1 of the Act. Section 6 prevents the importation, shipping or sale of food that does not meet a prescribed "standard" set for a food, if the food in question is likely to be mistaken as meeting the "standard". "Standards" are set for several reasons, such as safety or to prevent fraud. The continuation of this exemption raises an interesting question as to how it can ever be in the public interest to authorize a food to be sold that can be mistaken as meeting a set "standard" that it does not meet.

Section 6.1 allows the Governor in Counsel to identify a standard for a food as necessary **"to prevent injury to the health of the consumer or purchaser of the food"**. Again, if the Government decides to set a standard for a food as "necessary" to prevent injury, how is it in the public interest to exempt a food from this requirement by granting a marketing authorization? This is not a "change" brought about by Bill C-38. However, whenever an Act is being amended, it is appropriate for comments on the amendments, even if they continue parts of the old scheme.

Under the current *Food and Drugs Act* if a marketing authorization was to provide for a maximum limit of an agricultural chemical, veterinary drug, or food additive, the maximum amount had to exceed the maximum amount that was already allowed by existing regulations. Persons reading this might think that it is risky for the Minister to permit such substances in food above limits that have presumably been set to protect health. That said, the purpose of the marketing authorizations are to exempt specific foods from the limits set out in our regulations.

What is new is that under Bill C-38 technically foods could be allowed to have chemicals, drugs or additives whose safety levels have not been set out in regulations. In effect new chemicals, drugs or additives could be allowed for exempted foods without having been assessed broadly and included in our regulations.

In the current *Food and Drugs Act* it is clear that the Minister can issue a notice cancelling a marketing authorization. There is no such provision in the amendments proposed by Bill C-38. We expect that this will be in the regulations when they arrive.

If Consumers Want to Avoid Foods Granted Marketing Authorizations, They Will Have Trouble Identifying the Foods

Not passing judgment on the safety of issuing marketing authorizations permitting levels of chemicals, drugs and additives that are above those allowed in other foods, some consumers may want to avoid foods granted marketing authorizations.

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Other consumers might want to read the marketing authorizations so that they can make an informed decision prior to consuming such foods. Under the current law all such authorizations must be published in the *Canada Gazette*. They will be relatively easy to find. They are completely public and transparent.

If Bill C-38 is passed, the requirement that marketing authorizations be published in the *Canada Gazette* is removed. We do not know how consumers will be able to easily access this information.

Incorporation by Reference – Are the European Food Claims Regulations Coming and Who do We Lobby for Changes?

Bill C-38 will allow regulations concerning food and also marketing authorizations themselves to incorporate by reference any document regardless of its source. The relevant text includes:

> 30.5(1) A regulation made under this Act with respect to a food and a marketing authorization may incorporate by reference any document regardless of its source, either as it exists on a particular date or as it is amended from time to time.
>
> 30.5(4) For greater certainty, a document that is incorporated by reference in the regulation or marketing authorization is not required to be transmitted for registration or published in the *Canada Gazette* by reason only that it is incorporated by reference.
>
> 30.6 For greater certainty, an express power in this Act to incorporate a document by reference does not limit the power that otherwise exists to incorporate a document by reference in a regulation made under this Act.

The new section 30.6 is interesting as it is written to clearly imply that there already exists under the *Food and Drugs Act* a power to incorporate other documents by reference in the regulations. The only power to "incorporate" by reference that we are aware of is very limited. Section 30(1)(m) permits the Minister to add to or delete from the schedules to the Act. The only schedule that has documents outside of the Minister's control is Schedule B which lists drug standards documents such as the U.S. Pharmacopoeia. Section 10 of the Act prohibits selling, labelling, packaging or advertising a "substance" that is likely to be mistaken for a drug listed in those documents if it does not comply with the standards set out in them. This prevents fraud but does not make those documents part of our regulations.

Bill C-38 gives the Minister power to pass regulations concerning marketing authorizations. We do not know what the proposed regulations will look like, but anticipate that we will be moving to harmonize with the European Union concerning food claims. For anyone interested in the EU document it is Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

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There are dangers to listing other documents as binding in regulations. Those other documents, from other sources, even foreign governments, or trade bodies can be changed without any involvement of our Parliament. Under our current law (see the *Statutory Instruments Act*) we have many procedural safeguards by requiring changes to be made by regulation. These protections include:

1. the public is alerted to all proposed changes which are published in the *Canada Gazette I*;

2. the public is given an opportunity to comment on all proposed changes after their publication in the *Canada Gazette I*;

3. the *Statutory Instruments Act* requires the Clerk of the Privy Council in consultation with the Deputy Minister of Justice to examine all proposed changes to ensure that:

   (a) they are authorized by the *Food and Drugs Act*;

   (b) they are not an unusual or unexpected use of the regulation power under the Act;

   (c) they do not trespass unduly on existing rights and freedoms, and

   (d) they are consistent with the purposes and provisions of the *Canadian Charter of Rights and Freedoms* or the *Canadian Bill of Rights*;

4. all final changes must be published in the *Canada Gazette*;

5. under the *Statutory Instruments Act* all regulations are permanently before committees of both the House of Commons and the Senate who can present resolutions in Parliament to revoke all or part of the regulation, preserving Parliaments' supervision over regulations made by the Government.

We do not see any advantage for consumers or for the industry for these protections to be removed from regulations concerning marketing authorizations and food regulations.

Incorporation of "any document, regardless of its source, either as it exists on a particular date or **as it is amended from time to time**" also creates a significant democratic deficit. For example, the proposed amendment would permit the Minister to incorporate by reference the European Union regulations concerning health claims for foods. How would persons affected in Canada go about seeking changes to those regulations? Would we petition the European Parliament or its Member States? If trade association documents were referenced, would we petition the trade association? Either way, the supervision and relevance of Parliament is excluded.

We do not see these proposed amendments in the interests of either the consumer or the natural health product industry.

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Allowing Schedule A Food Claims

Section 3 of the *Food and Drugs Act* prohibits any health claim for conditions listed in Schedule A of the Act. A list of the conditions can be found at http://laws-lois.justice.gc.ca/eng/acts/F-27/page-13.html#h-18.

Bill C-38 contains the following amendment to the *Food and Drugs Act* to enable the Minister to permit a food to make a Schedule A claim:

> 30.2(1) Subject to regulations made under paragraph 30(1)(r), the Minister may issue a marketing authorization that exempts – if the conditions, if any, to which the marketing authorization is subject are met – an advertisement, or a representation on a label, with respect to a food from the application, in whole or in part, of subsection 3(1) or (2) or any provisions of the regulations specified in the marketing authorization.
>
> 30.2(2) The marketing authorization may be subject to any condition that the Minister considers appropriate.

I believe that the prohibition against Schedule A claims found in section 3 of the Act is unconstitutional for banning all claims, even truthful ones. Consequently, I do not have a concern with this amendment.

Note this amendment does not apply to drugs, or natural health products as a subset of the drug category. This will not allow the Minister to exempt natural health products from the ban in section 3.

Moving Away From Having To Pass Regulations To Amend Prescription Drug Lists

Bill C-38 proposes the following amendments to the *Food and Drugs Act* to permit the establishment of prescription drug lists without the protections afforded by the regulation making process:

> 29.1(1) Subject to the regulations, the Minister may establish a list that sets out prescription drugs, classes of prescription drugs or both.
>
> (2) The list is not a regulation within the meaning of the *Statutory Instruments Act*.
>
> 29.2 (1) A regulation made under this Act may incorporate by reference the list established under subsection 29.1(1), either as it exists on a particular date or as it is amended from time to time.
>
> (2) The Minister shall ensure that the list that is incorporated by reference in the regulation is accessible.

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(3) A person is not liable to be found guilty of an offence for any contravention in respect of which the list that is incorporated by reference in the regulation is relevant unless, at the time of the alleged contravention, the list was accessible as required by subsection (2) or it was otherwise accessible to the person.

The term "prescription drug" is not defined in the Act. Prescription drugs that are governed by the *Food and Drugs Act*, are currently listed in Schedule F of the *Food and Drug Regulations*. Schedule F currently has two parts or "lists". Part 1 lists human prescription drugs. Part 2 lists veterinary prescription drugs.

Currently when Health Canada wants to add or remove a drug from the prescription drug list found in Schedule F, a regulation needs to be passed making the change.

Under the proposed amendments:

1. drugs can be added or removed from a prescription drug list without having to pass a regulation, and

2. the prescription drug list is not a "regulation" and not subject to the *Statutory Instruments Act*.

The amendments in effect remove the listing of prescription drugs from public and parliamentary scrutiny. Under the current law where the prescription drug list is a regulation:

1. the public is alerted to all proposed changes which are published in the *Canada Gazette I*;

2. the public is given an opportunity to comment on all proposed changes after their publication in the *Canada Gazette I*;

3. the *Statutory Instruments Act* requires the Clerk of the Privy Council in consultation with the Deputy Minister of Justice to examine all proposed changes to ensure that:

   (a) the change is authorized by the *Food and Drugs Act*;

   (b) the change is not an unusual or unexpected use of the regulation power under the Act;

   (c) the change does not trespass unduly on existing rights and freedoms, and

   (d) the change is consistent with the purposes and provisions of the *Canadian Charter of Rights and Freedoms* or the *Canadian Bill of Rights*;

4. all final changes must be published in the *Canada Gazette*;

5. under the *Statutory Instruments Act* the list is permanently before committees of both the House of Commons and the Senate who can present resolutions in Parliament to revoke all or part of the regulation, preserving Parliaments' supervision over regulations made by the Government.

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There is a danger to removing the above protections from the regulation of prescription drugs. We can see no advantages for the public and for those engaged in the drug business with these changes. We are concerned about losing the protections listed above when there are no off-setting benefits.

For example, we fully believe former Health Canada scientists such as Dr. Shiv Chopra who has testified under oath about corruption in the drug approval process. The amendments remove Parliamentary supervision over the addition of drugs to the prescription drug list that perhaps should not be added. Conversely, the amendments remove supervision from the failure to add a vital drug to the list.

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