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Bureau of Program Policy
Risk Management and Stakeholder Engagement
Natural and Non-prescription Health Products Directorate
HPFB, Health Canada

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RE: Canada Gazette, Part I, Volume 155, Number 26: Regulations Amending the Natural Health Products Regulations

The Canadian Celiac Association (CCA) is pleased to provide its submission and comments on the proposed changes to Natural Health Product Regulations by Health Canada as part of the government's ongoing modernization of the Self-Care Framework Initiative under the *Food and Drugs Act*.

CCA appreciated the opportunity to be a part of the stakeholder consultations to help provide guidance on priority allergens and gluten warnings. We are particularly pleased to see the department continue to be global leaders in innovative labelling regulations that supports people with celiac disease and other ingredient sensitivities.

Who Are We?

Since 1973, CCA has been the national charity advocating for people with celiac disease (CD), dermatitis herpetiformis and gluten disorders. Celiac disease is a common disorder that is estimated to affect about one percent of the population. Another two to five percent of the population is at risk for other gluten disorders or sensitivities. CCA's mission is to support Canadians through advocating for access to safe gluten-free food and treatment options, providing evidence-based education and solutions to empower Canadians to minimize their risks related to the disease and to invest in research. CCA has 13 affiliated chapters in major cities and regions across Canada who also provide local supports and resources.

The CCA is also backed by a voluntary world-class Professional Advisory Council (PAC) consisting of experts in celiac disease management and research consisting of Canadian pediatric and adult gastroenterologists, family physicians, registered dietitians and agri-science experts from leading universities, hospitals and clinical research centres.

What is celiac disease (CD)

Celiac disease, one of the most common disorders¹, is estimated to affect one percent of the population and the incidence is increasing. It is a condition in which the absorptive surface of the small intestine is damaged by a substance called gluten. Gluten is a group of proteins present in wheat, rye and barley and their cross-bred grains. The damage to the intestine can lead to a variety of symptoms and result in an inability of the body to absorb nutrients such as protein, fat, carbohydrates, vitamins and minerals, which are necessary for good health. Patients with CD can present with a variety of symptoms.

Gluten is a group of proteins present in wheat, rye, barley and their cross-bred grains.

The classical (typical) symptoms include: chronic diarrhea, abdominal pain, malabsorption and weight loss. However, many patients present with non-classical (atypical) symptoms including: anemia, osteoporosis, extreme fatigue, oral ulcers, liver enzyme abnormalities, constipation, infertility, dental enamel defects, and neurological problems. There is also a form of celiac disease which affects the skin called dermatitis herpetiformis and these patients present with a severely itchy blistering rash.

Why natural health products matter to people with CD

While natural health products containing priority allergens including gluten only account for two percent² of products on the Canadian market, it is important that all Canadian consumers can select and consume products that are safe for them. Gluten-free consumers have the added challenge whenever they shop for consumable products to assess if what they are eating is safe and gluten free. Celiac disease patients, second only to end-stage renal failure, have a high degree of burden because they must monitor, assess, and manage every morsel of food or nutritional content every day because of their chronic illness.³

CCA agrees with the previous findings of the Office of the Auditor General's Commissioner of the Environment and Sustainable Development that labels matter and are the second most important

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[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3496881/#:~:text=Celiac%20disease%20\(CD\)%20is%20one,different%20parts%20of%20the%20world](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3496881/#:~:text=Celiac%20disease%20(CD)%20is%20one,different%20parts%20of%20the%20world)

² Natural Health Products Stakeholder Consultation, Health Canada.

³ [High disease burden in treated celiac patients - a web-based survey - PubMed \(nih.gov\)](#)

factor when people purchase products. In the case of the gluten-free consumer, it's number one.

To support our submission, CCA issued its own consumer survey to its community and received 424 responses in just 24 hours on their feelings about natural health products.

- **53%** said they found current natural health product labels unclear to read.
- **87%** said they found it difficult or sometimes difficult to identify if a natural health product is gluten free.
- **78%** believe the product label when it is clearly labelled gluten free – LABELS MATTER!
- **70%** have not experienced any cross-contamination on NHP labelled gluten free
 - **30%** believed they had experienced cross-contamination of which:
 - 77 individuals have experienced 1-2 times
 - 43 individuals have experienced 2-3 times
 - 37 individuals 3 or more times

Labels Matter

Currently the only effective treatment for CD is with a gluten-free diet (GFD). The adherence to the GFD must be STRICT and LIFE-LONG. A GFD can be challenging and complicated for consumers especially when food, prescription medication, natural health care labelling, retail sales, and dispensing regulations are unclear, inconsistent or inadequate.

Here is just some of our constituent feedback from our survey:

- *“I've purchased medications that appeared to be gluten free only to find the actual ingredients information on the inside packaging included gluten.”*
- *“I appreciate the tightening of identification of gluten and any safety precautions that can be taken to protect us.”*
- *“... ‘Natural Flavors’ It is these products that tend to give me a gluten attack, so I have learned to stay away from them. Over The Counter meds need to be labelled as gluten free also, so we can safely choose a product without having to experiment first.”*
- *“I would really like to have medication labelled gluten free when it is, because I worry about what I give my child. We have to do some much background reading to find that GF medication.”*
- *“Some labels are less clear to read and understand than others. Consistent labelling would be ideal.”*
- *“Would be so helpful if these products required the same labeling laws and practices as food products. I have only been diagnosed a year and a half ago and have given up using most products like these due to not knowing if they are safe.”*

Vulnerable consumers

We have additional concern for the most vulnerable in our community such as individuals in institutional or public care (e.g., hospitals, long term care, outpatient services), newcomers with English as a second language and with vision disabilities.

- *“It's pretty tough trying to read the "challenge font" where gluten may be present.*
- *“My preference is to buy products labelled "gluten free" rather than have to strain to try and read tiny labels.”*
- *“The size of the print is too small...I have not been involved in the business for over 12 years, so am not sure what the minimum size is anymore and as a senior, I find it very difficult reading small print....as a Celiac, size of print of ingredient labels is of utmost importance. Thank you for listening.”*
- *“Another thing that annoys me is the small fonts on labels...sometimes I just can't read ingredients, or if something contains gluten because the font is too tiny. That should be illegal. Why have a label if it's not at least a font that can be read by someone with 20/20 vision.”*

Supplements to support health

For people with active celiac disease, the villus in the small intestine becomes damaged. Individuals are not able to absorb micro-nutrients as easily into their bodies putting them at increased risk of poor or declining health. Many of these individuals are directed to supplement their diet with vitamins and other natural health products. Examples of natural health products used to supplement health are calcium or iron, supplements lessening lactose intolerance, or symptom relievers such as for constipation or diarrhea relief after a gluten contamination.

- *“I'm trying to get pregnant and I know there are some gf prenatal. I just wish it was easier to be sure that what I am taking I won't have a reaction to, which could in turn effect my chances for a healthy pregnancy.”*

Current Consumer Environment

Individuals with CD are required to be vigilant about hidden sources of gluten and cross contamination in products. As a charity, CCA specifically offers free education, resources, and programs to help patients and/or their caregivers to learn how to navigate their lives from grocery shopping for everyday meals, health supplementation, dining outside of the home (restaurant or social gatherings), or travelling.

In the case of Natural Health Products, there is no consistent ingredient listing and information comes in all forms and manners. This inconsistent format creates consumer confusion and anxiety along with incorrect product purchases or buyer avoidance. CCA responds every year to hundreds of posts on its Facebook Support Group with individuals asking, “Is this safe for me to consume?”

Health Canada estimates \$167 million in potential savings to consumers over 15 years through avoided incorrect purchases

We agree with the government's own Cost Benefit Analysis, as part of its justification for the regulation change, estimating the benefits of not only in economic consumer purchasing value (willingness to pay value) of \$157 million but also the potential savings in health and work-loss expenditures at the provincial level. There will be reductions in unnecessary consumer hospitalization and lost time at work or school due to adverse reactions. For people with celiac disease, the effects of consuming gluten contaminated products can result anywhere from one day up to two weeks of symptoms and illness of varying severity. Acute cases can result in lost time at work up to and including doctor or emergency room visits and even hospitalization for symptoms such as severe diarrhea and dehydration from excessing vomiting.

CCA Supports the Changes

CCA supports the proposed modernization of the Natural Health Product Regulation. Health Canada sought feedback on four key areas: modernized contact information; clear prominent label text; labelling of allergens, gluten and aspartame; and standardized Product Fact Table.

1. Modernized contact information

CCA supports the inclusion of company websites and phone numbers on the product label for quicker access to additional information. People with celiac disease often use company contact information to verify food product ingredients. Most consumers have mobile devices that can be used in-store to inform their purchase. In the case where consumers may not have such a device, they may be able to consult with the in-store pharmacist for assistance.

2. Clearly and prominently displayed label text

CCA supports the standardization of font size and black and white contrast to ensure people with lower acuity levels such as seniors or those with visual impairment can read the labels more easily. Currently some manufacturers use colour combinations with little to no text contrast.

3. Clear labelling of food allergens, gluten and aspartame

CCA supports labels which follow the spirit of B.01.010.1 (1) of the Food and Drug Regulation where food allergen and gluten should have the same treatment. People with celiac disease, like other patients with food allergies, are educated to read and follow the labels as recommended by Health Canada. Consistent labels across food and medicine sectors in clear, plain language will allow individual consumers to make informed choices, compare products, and above all, remain safe.



*“Food sold at retail for consumers require any priority allergen or gluten, as identified by Health Canada, be listed as their **common name form either listed or in brackets next to the ingredient** (wheat, barley, rice or triticales) ...”*

CCA supports the regulation change that,

- “If the product contains a food allergen or gluten, an “Allergy alert:”, in bold (followed by the source of the food allergen or gluten)”
- (11) If the natural health product contains a food allergen or gluten, (a) the statement “Allergy Alert / Alerte aux allergies” or the statements “Allergy Alert” and “Alerte aux allergies” shall be shown in bold type under the heading “Warnings / Mises en garde” or under the headings “Warnings” and “Mises en garde”, followed by the source of the food allergen or gluten, also in bold type;
- Where the outer label of an NHP is required to display a Product Facts table, the inner label would have to show allergens, gluten, and/or aspartame including the source of the ingredient (e.g. Wheat, Rye, Barley, Triticale, Oats)

For consumers, a clear warning of an allergy or gluten is key and welcomed. Given the specific clear allergen warning, it should be sufficient for companies to not have to include the allergen in the non-medicinal ingredient section. Due to health literacy concerns, people may not understand the term “non-medicinal” and the potential impact of the ingredient on their health such as anaphylaxis or other acute reactions.

Currently there is inconsistent labelling of gluten sources. For example, some manufacturer’s do not list the source of the ingredient such as “wheat” or “barley”.

Products may additionally use terms such as ‘natural flavourings’ such as malted barley but don’t list the source ingredient. Yeast extracts also can be a concern as they may be derived from barley and should be identified.

For people with wheat allergies, simply listing ‘gluten’ is unhelpful. Using just ‘gluten’ may have deterred consumers from purchasing a safe product as the ingredient may have been derived from perhaps barley versus wheat.

4. Introduction of a Product Facts Table to ensure that key information is shown in a standardized format

CCA supports the regulation change that includes a consistently formatted Products Facts Table in appearance. The guidance provides clear direction on font size and style, appearance, and alignment. This gives consumers predictability and does not allow manufacturer’s discretion on appearance and puts consumer safety first.

Labelling Requirements for Natural Health Products Guidance Document

The consultation asked for the public and stakeholders to comment on the quality of the guidance document for industry to help implement the proposed regulations.

1. *Labelling requirements outlined in the proposed amendments to the Natural Health Product Regulations, in plain language and with additional information for clarity*

CCA believes that the current guidance document is clear and offers strong direction on the expectation of labelling products. The inclusion of the list of priority allergens and gluten in Appendix 1 on Page 45 provides clear direction on adverse ingredients.

CCA also supports the direction provided on use of **Innovative Labels** to avoid the opportunity for important allergen or gluten information to be accidentally removed or torn off. While there is opportunity to provide additional information, key warnings and Allergy Alerts must be available on a label that is adhered to the product's outer container.

The guidance includes specific direction to the FDR section on how to list allergens and glutes:

- Section 6. Product Fact Table
 - “6.d.2 List sources of food allergens and gluten, as per subsection 1(1) of the Food and Drug Regulations (Part B) (B.01.010.1) which has also been included in Appendix 1 of this document. Sources of food allergens and gluten must be in bold.”
- Section 8.c. - Level 2 Flexibilities – Non-Medicinal Ingredients
 - “You may move any “Non-medicinal ingredients” that are not implicated as an allergen from the label to a tag or leaflet attached to the immediate container of the product...”
- Table 9 – Point of Selection vs Point of Use
 - Clearly defines the important information such as allergens and gluten that consumers require when purchasing product.

2. *The introduction of a front-of-pack disclaimer on homeopathic products to inform consumers that these products are based on traditional homeopathic references and not modern science.*

As an organization, CCA is led by science and evidence-based information. We laud the Government for the additional front of package disclaimers for consumers on homeopathic products.

ADDITIONAL CCA RECOMMENDATIONS

Online Purchasing

The use of online websites to order Natural Health Products is growing. In the Auditor General's [survey](#), online retail sales only accounted for six (6) percent of sales. The COVID-19 pandemic has consumers becoming more comfortable with online ordering. But regardless of the percentage, retailers should meet a minimum standard to ensure all consumers are informed and that the risk of harm reduced. There is a lack of regulatory oversight for how online retailers must display both food and natural health products for sale. Another confounding issue is US and International sites available to Canadian shoppers. CCA raised the issue as recently as this past May in recent Health Canada consultations and presentations.

CCA recommends that:

- Online product information needs to be consistent with the in-store retail experience to ensure consumers have access to all ingredient tables, allergen and gluten warnings, and claims.
 - In Health Canada's Guidance Document, Table 9 demonstrates what consumers require for Point of Selection.
- Retailers should not be allowed to make product substitutions without consumer consent.
- Retailers, such as Amazon, have promoted products under a "Gluten Free Category" but shipped product that has a "May Contains" warning.
- There should be both images of the product labels displaying warnings, allergens and product facts table, in addition to a text listing with company contact information for questions or complaints.
 - Label images are key so consumers can verify products once they have been shipped in case of product substitutions or manufacturing ingredient changes.

Testing, Verification and Enforcement

The 2021 Reports 1 and 2 of the Commissioner of the Environment and Sustainable Development found that, "Health Canada did not always verify that manufacturing facilities followed good manufacturing practices before natural health products were marketed for sale in Canada. The department relied on manufacturers' attestations that their facilities followed good manufacturing practices."⁴

In addition, the audit found that,

"Health Canada did not sufficiently monitor whether product label information and advertisements met the product-license conditions. We found that the department monitored product labels and advertisements in response to complaints instead of

⁴ https://www.oag-bvg.gc.ca/internet/English/parl_cesd_202104_02_e_43806.html#hd4a

monitoring the market using a risk-based approach. To gain an understanding of the market, we examined a sample of 75 licensed products for sale on Canadian websites. We found that 88% of these products were advertised with misleading product information.” Included in these violations were “an incomplete list of risks and ingredients.”⁵

Therefore, CCA agrees with the Commissioner’s findings that Health Canada, “develop a risk-based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risks related to products, sites, and problems raised from its follow-up activities.”⁶

In addition, Health Canada should work with patient advocacy groups such as the CCA to promote the steps on how consumers can self-advocate and report if they experience products that are potentially cross-contaminated or poor quality.

Prescription Medications

While not in the scope of this regulation, consumers are still concerned when prescribed therapeutic medications from their healthcare providers. Pharmacists may not have all the information they require in the CPS as companies are not required to list non-medicinal or non-active ingredients. Consumers calling pharmaceutical hotlines are rarely given an informative answer with some minor exceptions. While CCA understands that the risk is low in individual medications, the risk increases with patients who have multiple drugs. The very fact that consumers cannot be told what their medication is unsatisfactory.

- *“Even going to several different pharmacist[s], they won’t help you. If you are trying to see if a cold medicine is safe or a pain killer. The information on the Internet is useless, there [is] too much info to read [through] that is hard to understand.”*
- *“My biggest problems are with fine print and prescription drugs. I have to call the manufacturer, who may want me to read a number stamped on a pill, then find out that it contains gluten or dairy, and then take the opened bottle back to the pharmacy, who isn’t happy that I opened it.”*

In closing, the Canadian Celiac Association agrees with the qualitative recommendations listed in Health Canada’s overview of the proposed changes to the Natural Health Products section of the Food and Drug Act:

- Improved labelling would help reduce consumer confusion and incorrect purchases
- More informed choice, via standardized labels that will allow more efficient and effective comparisons to distinguish among products with similar ingredients, names, and uses
- More informed decisions based on improved legibility and standardization that would

⁵ Ibid.

⁶ Ibid.

reduce incorrect use

- Reduction in prescription drug-NHP and NPD-NHP interactions as well as NHP-NHP interactions of using different products for the same purpose due to unclear or confusing labelling
- Reduction in cases of hospitalization, illness or morbidity as a result of avoidable NHP-related adverse drug reactions
- Reduction in time spent by pharmacists and health professionals in answering questions on NHPs related to confusing or illegible labels
- Improved warnings and risk mitigation measures as a result of improved pharmacovigilance from increased problem reporting with modernized contact information

Again, we appreciate the opportunity to have Canadians with celiac disease and gluten disorders included as part of the discussions of these important regulations.

We trust that Health Canada and the federal government will ensure that once the regulations have passed that they will be enforced with vigour to ensure the spirit of the Act is met as Canadians turn to these products for health benefits in a safe manner.

Respectfully submitted by:



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