# Draft - Issue Analysis Summary



Security Packaging



## 1. ISSUE

Since the *Natural Health Products Regulations* (NHPR) came into force on January 1, 2004, it has been suggested that the requirement of section 95 (security packaging) of the NHPR may be too onerous for the personal care products industry. Some manufacturers feel that the requirements to place tamper-evident security packaging on all natural health products (NHP) places an unnecessary financial burden on the personal care products industry as their products are generally low-risk in nature. Also, section 95 (3) sets out requirements for the labelling of the security feature if it is not self-evident. Manufacturers of topically applied products using an overwrap security feature state that this adds an unnecessary burden.

Industry has continually requested that the Natural Health Products Directorate (NHPD) review the application of the security packaging requirements and amend section 95 of the NHPR so that topical NHPs be exempted from the tamper-evident security packaging requirements.

## 2. OBJECTIVE

The purpose of this policy development exercise is to provide a recommendation to the Branch Executive Committee of Health Canada's Health Products and Food Branch on the issue of security packaging requirements. Specifically, the objective is to provide a recommendation with regards to our current approach to security packaging for NHPs.

The exemption of lozenges from security packaging requirements however is not in the scope of this analysis.

## 3. BACKGROUND

On January 1, 2004, the NHPR came into force and included explicit requirements to contain all NHPs for sale in Canada in a security package (excluding lozenges). Subsections 1 and 2 of Section 95 of the NHPR clearly state this requirement.

"95.(1) Subject to subsection (2), no person shall sell or import a natural health product that is packaged unless the natural health product is contained in a security package.

(2) Subsection (1) does not apply to lozenges."

In 2005, the Canadian Cosmetics, Toiletries and Fragrances Association (CCTFA) (which represents approximately 175 member companies from the cosmetic and personal care products industry) requested that the NHPD amend the NHPR security packaging requirements for all topical use NHPs such as antiperspirants, acne therapy products and any other product applied topically. The NHPD again reaffirmed its position to CCTFA that Section 95 of the NHPR prevents the tampering with, or the contamination of, NHPs prior to sale, thus ensuring that Canadians have access to NHPs that are safe, effective and of high quality. Therefore the NHPD maintained that the requirements were still appropriate and the security packaging requirements would continue to apply to all NHPs.

The rationale behind mandatory security packaging came directly from the NHPD's mandate: the obligation to ensure access to NHPs that are safe, effective, and of high quality. Mandatory security packaging is one tool used by NHPD to ensure that Canadians are provided with the safest, highest quality product. This emphasis on product quality is mirrored throughout the NHPR, as seen in the quality evidence requirements and Good Manufacturing Practices (GMP), which require that measures be in place to prevent contamination and adulteration as well as appropriate storage conditions that maintain the quality of products.

During the NHP Regulatory Review consultation of 2007, the issue of security packaging was again brought to the attention of NHPD by CCTFA and other stakeholders. It was commented that excluding low risk NHPs from security packaging requirements fits into the risk-based approach to the regulation of NHPs that the NHPD is currently developing. The NHPD has reiterated, through correspondence and stakeholder meetings, that all products must comply with security packaging requirements set out in the Regulations.

### 3.1. Consultation

3.1.1. Regulatory Review

On March 12, 2007, the Natural Health Products Directorate (NHPD) launched its NHP Regulatory Review Initiative, at which time stakeholders were invited to provide feedback on identified issues, to identify any other issues that were not identified and to rank their top 5 priorities based on the issues outlined in the consultation document or Discussion Paper

Since security packaging was not a proposed issue in the discussion paper, most comments received in the e-consultation were in the "additional issues" category or loosely fit with another issue (e.g., lowest-risk products). Each of the comments received regarding security packaging reiterated that security packaging is too onerous for topical NHPs and that it was not in line with other jurisdictions or other product lines.

3.1.2. IAS Shared with Stakeholders

On April 19th, 2010, a version of this document was sent to a targeted group of stakeholders for their comment. The version of the document sent did not include the recommendations however it did include each of the proposed options.

The NHPD received three sets of comments during the 30 day comment period which ended on May 18th, 2010. Comments were submitted by CCTFA, Consumer Health Products (CHP) Canada, as well as Focal Point Research (a consulting firm).

Both CHP Canada and the CCTFA recommended that the NHPD remove the security packaging requirement for topical NHPs while Focal Point Research recommended that the NHPD conduct a risk analysis to determine what, if any, product types should be exempted. Focal Point Research explained that they believe topical use personal care products should be exempted from the security packaging requirements however any exemption should not apply to higher risk topical products such as antibacterial, antifungal, and analgesic creams. It was also noted that there continues to be sterile topical products that exist over the counter and that they should continue to require security packaging to prevent contamination.

The NHPD will discuss the comments received with its Programme Advisory Committee (PAC). Specifically, the NHPD would like to discuss factors affecting risk level which are specific to topical products. For instance, the NHPD would like to have a discussion with its PAC members regarding the risk-level of NHPs intended for use on intact skin and/or non-intact skin.

It should also be noted that although CHP Canada recommended that a policy be developed in the short term to lift the security packaging requirements for topical

products pending a regulatory amendment, a policy could not reverse regulatory requirements.

## 4. ISSUE ANALYSIS

### 4.1. Risk

The primary argument from the cosmetics and personal care products industry has consistently been that their products are low-risk, given that some of their products are topical in nature, and therefore they should be exempt from security packaging requirements. The NHPD is aware that even topical products can present risks to consumers. It may be a reasonable assumption that it is less likely for a consumer to contract a serious disease or have a severe adverse reaction because of a contaminated topical product, but risks still exist. Regardless of risk level of a product, tampering and contamination may occur in the absence of tamper-evident packaging.

A more serious issue is tampering as a deliberate criminal act, as has happened a few times at the distribution or retail level after the package should have been sealed. In the case of Tylenol Extra Strength, cyanide was added to some packages on retail shelves in Chicago in 1982, resulting in some fatalities. While this was an oral product adulterated with a poison that is active orally or by inhalation, there are toxins that are readily available to anyone and that could be used to adulterate topical products.

### 4.2. Environmental Concern

Although relatively minor, there is also the environmental concern of continued packaging requirements creating additional waste. However, given the fact that tamper-evident packaging is quite small and that producers of such packaging take environmental considerations into account, this concern is negligible.

### 4.3. International Comparison

#### 4.3.1. Canada - Other Jurisdictions

Regarding other health products regulated in Canada, most topical cosmetic and personal care products which are not NHPs are exempt from security packaging requirements. In this sense, the NHPR are not aligned with other Canadian jurisdictions with regards to security packaging requirements applicable to other topical commodities in Canada. As set out in Part A.01.065 of the *Food and Drug Regulations* (FDR), security packaging requirements cover only mouthwash, ophthalmic products or those ingested, inhaled or inserted into the body. Therefore, as the FDR do not require security packaging for topical use products, the NHPR do.

Also, in the *Cosmetics Regulations*, the security packaging requirements are only applicable to mouthwash, as set out in Section 28 and there are no guidance documents on packaging requirements. The security packaging requirement for mouthwash was established in 1985, a year after the requirement was put into place for oral and ophthalmic over-the-counter drugs, in response to the Tylenol incident in 1982.

**4.3.2. United States**

The United States Food & Drug Administration (USFDA) has tamper-evident packaging requirements set out in Part 211 of the current GMPs for finished pharmaceuticals. The requirements are for over-the-counter drugs with the exception of dentifrices, insulin, lozenges and, most notably, dermatological products.

With regard to cosmetics, the *Cosmetics Processors and Transporters Cosmetics Security Preventative Measures Guidance* sets out the sorts of preventative measures industry may take to minimize the risk of their product being tampered with. It is important to note however that this guidance document deals only with what industry ought to be doing pre-sale (such as specific transportation measures to prevent contamination) but makes no mention of specific packaging requirements of the finished product.

Upon discussion with the USFDA, it was learned that there is no intention to revise tamper-evident packaging requirements at this time.

**4.3.4. Australia**

The Therapeutic Goods Administration (TGA) in Australia has developed guidance documents for tamper-evident packaging. The *Code of Practices for the Tamper-Evident Packaging of Therapeutic Goods* defines tamper-evident packaging as follows:

"packaging that has an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible or audible evidence to consumers that tampering may have occurred."

However, the code is limited in scope to those products which are administered transdermally, ingested orally, or come into contact with mucous membranes. Topical preparations for local effect are exempt from the code.

**4.3.5. Other Countries**

From what is readily available online, it seems that there are no security packaging requirements for products under the jurisdiction of the Health Sciences Authority (HSA - Singapore) the Medicines and Healthcare Products Regulatory Agency (MHRA - United

Kingdom), the Pharmaceutical and Medical Devices Agency (PMDA - Japan) or the Swiss Agency for Therapeutic Products (Swissmedic - Switzerland). Also the European Medicines Agency (EMEA - European Union) has special packaging requirements only for products determined to be dangerous substances or dangerous preparations.

Based on the information available, it appears that tamper-evident packaging for cosmetic and personal care products, especially those administered topically, is not required by most countries.

4.4. Application of the NHPR

Traditionally, the cosmetics industry has explicitly requested an exemption for cosmetics sold behind a counter (e.g., in large department stores). It should be reaffirmed that, as per Section 2 of the NHPR, only manufacturing, importation, packaging, labelling, storage, distribution and sale is regulated by the NHPD.

4.5. Additional Cost to Industry

Those who consistently request exemptions from the NHPR's security packaging requirements regularly cite the additional costs that tamper-evident packaging entails. It has been stated that a shrink wrap packaging machine costs roughly $250K. This, in turn, raises the cost of the product for the consumer.

Although it is understood that security packaging does add additional costs to the packaging process, it must be understood that these costs may prove to be much less burdensome than if a product were to be contaminated. If contamination occurred the company would likely pay significantly more in terms of recalls and lawsuits.

4.6. Appropriate Regulatory Framework for Cosmetic like Products

Depending on their active ingredients, personal care products can be currently regulated under one of three separate sets of regulations: either as drugs (*Food and Drug Regulations*), NHPs (*Natural Health Products Regulations*) or cosmetics *(Cosmetics Regulations).*

This issue also manifests itself when similar products do not have similar security packaging requirements. For instance, dandruff shampoos containing pyrithione zinc, a medicinal ingredient classified as an NHP are required to have security packaging, while dandruff shampoos containing selenium sulfide, a medicinal ingredient classified as a DIN drug product, do not. Although it is unknown whether this problem could arise, it is not unreasonable to assume that this inconsistency could raise questions in consumer groups.

## 5. OPTIONS ANALYSIS

***Option #1:*** ***Status quo: Maintain security packaging requirements for all NHPs therefore providing no category of NHP with an exemption from security packaging requirements.***

**Pros:**

- NHPD could say confidently that they are fulfilling their mandate to the utmost degree with the aid of security packaging as a regulatory tool, more so than without it.
- Consumers would continue to be assured that an NHP has not been tampered with.
- Would not have to go through the lengthy regulatory amendment process.

**Cons:**

- The cosmetics industry would continue to seek out an exemption.
- By having security packaging requirements encompassing the entire scope of NHPs, the NHPR are not aligned with the Canadian requirements for other health products or with international requirements including the FDR.
- Poses additional costs to industry.
- Would not be received well by the personal care products industry.

***Option #2:*** ***Remove security packaging requirements for topical use NHPs.***

**Pros:**

- Would fit in with the Risk-Based Approach (RBA) to regulation that the NHPD is currently developing.
- Would be aligned with the FDR as there would be no security packaging requirements for topical products.
- Would be more consistent with other current international and domestic norms for other health products.
- Would reduce financial burden on the personal care industry.
- Would be received well by the personal care products industry.

**Cons:**

- In granting any exclusions to Section 95 of the NHPR, the NHPD would be lessening the safety requirements which may or may not be frowned upon by consumers.
- Would have to go through the lengthy regulatory amendment process.

***Option #3:*** ***Conduct risk analysis to determine if the security packaging requirements of the NHPR should be removed for any or all NHPs.***

**Pros:**

- Would fit in with the Risk-Based Approach (RBA) to regulation that the NHPD is currently developing.
- Would be more consistent with the current international norms and the Canadian requirements for other health products if supported by data.
- If results supported the requirements being upheld, NHPD would have data to demonstrate this.

**Cons:**

- Would be a time and resource consuming initiative.

## 6. RECOMMENDATIONS:

Based on this analysis, option #2 is recommended, i.e., that the security packaging requirements for topical-use NHPs be removed.

The NHPR seem to be behind in this issue for most other regulatory jurisdictions. Therefore, security packaging requirements should be removed for topical NHPs so that the NHPR are better aligned both internationally, and in other Canadian commodity areas. With that said, this is a horizontal issue needing support from other Directorates and Branches within Health Canada.

Also, it is recommended that the NHPD develop a consultation strategy with external stakeholders for this issue. This recommendation would hold true under any of the options taken.

## APPENDIX A

**Original Rationale for Security Packaging of all NHPs:**

The following sources were reviewed however no record of found explaining the original rationale for the current security packaging requirements of the NHPR:

1. Early EAC/MAC/BEC meeting records
2. Transition Issue Management meeting records
3. Early regulatory meeting records
4. Drafting instructions
5. NHPR Regulatory Impact Analysis Statement