EcoLogo™

Environmental Standard - Briefing Note

CCD-170 Instant Hand Antiseptic Products

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Introduction and Results of Stakeholder Survey Questions

On May 20th, 2009, the EcoLogo Program circulated a discussion document for public consultation. Stakeholders, who play a pivotal role in the EcoLogo standard development process, provided valuable feedback to help the Program as it develops an environmental leadership standard for Instant Hand Antiseptic Products. The public consultation involved environmental NGOs and other not-for-profit organizations, academics and other scientific experts, manufacturers, industry associations, government representatives, and purchasing professionals.

This document builds upon the previously circulated *EcoLogo Discussion Document* to reflect stakeholder feedback and views received during the comment period. More specifically, the original discussion document is restated in regular text, new, additional text is formatted in blue and proposed deletions from the original document are formatted in ~~strikethrough~~. This document is designed to transparently convey the instant hand antiseptic products standard development process as it makes clear the rationale in decision-making, and illustrates how stakeholder feedback was incorporated and built upon throughout the process.

The purpose of this document is to present the overall results of the stakeholder consultation, in addition to the rationale behind the criteria statements in the proposed EcoLogo draft standard for Instant Hand Antiseptic Products (see Draft 1: CCD 170). It is important to mention that while every effort has been made to acknowledge and act upon all comments provided by stakeholders, the Program must uphold its premier mandate; balance all stakeholder views while establishing an environmental leadership standard, which is roughly defined as the *20 percent of products/services available in the market at the time of the development or revision of a standard with the lowest environmental impacts across all stages of the life cycle*.

Table 1: Results of stakeholder survey questions (Q1-Q12) per stakeholder category (Stakeholder_Cat), where the value 1 represents agreement with the question and 0 represents disagreement. Note: For confidentiality reasons the names of the stakeholders have been replaced by numbers (Stakeholder_Nb).

Stakeholder_Cat	Stakeholder_Nb	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Academia, Public Health and Safety, and Regulation	S_1	1	1	0	N/A	N/A	0	1	.	1	0	.	.
	S_2	.	.	.	.	.	1	.	.	.	.	.	.
	S_3	0	.	.	.	.	.	.	.	.	.	.	.
	S_4	.	1	.	.	.	.	.	.	.	.	.	.
General Interest	S_5	0	1	0	N/A	N/A	1	1	1	0	1	.	1
Producer	S_6	0	0	0	.	.	.	.	.	0	0	.	.
	S_7	0	0	0	N/A	N/A	0	0	1	0	0	Maybe	.
	S_8	0	.	.	.	.	0	0	.	.	1	.	.
	S_9	0	0	.	.	.	.	0	1	.	.	.	.
	S_10	0	1	0	N/A	N/A	1	0	1	0	1	1	1
	S_11	.	0	.	.	.	.	.	1	.	0	0	0
User	S_12	.	1	0	N/A	N/A	1	1	1	0	0	.	.
	S_13		.	.	.	.	.	.	.	.	.	.	0
	S_14	0	0	0	N/A	N/A	0	0	0	0	0	Maybe	.
Statistics	% agree	11.1	50.0	0.0	N/A	N/A	50.0	37.5	85.7	14.3	33.3	50.0	50.0
	% disagree	88.9	50.0	100.0	N/A	N/A	50.0	62.5	14.3	85.7	66.7	50.0	50.0
	Nb. Votes	9	10	7	N/A	N/A	8	8	7	7	9	2	4

Scope and Category Definition

Question 1: Do you believe that limiting the scope of the standard to Health Care and Food Service is reasonable? Why?

Approximately eleven percent of stakeholders agreed with the proposed scope. In general, stakeholders opposed to limiting the scope to health and food services argued that *Instant Hand Antiseptic Products* should also be used in schools due to research claiming that "the availability of such products would reduce the rate of school absenteeism due to infection." Moreover, it was argued that, "since hand sanitizers are already widely used in educational settings, the introduction and adoption of an environmental standard for this category will have the added value of helping to inform purchase decisions with greater transparency, while protecting vulnerable populations against potentially hazardous, unregulated products."

The use of *Instant Hand Antiseptic Products* in the consumer market was more contentious. Some *Academia, Public Health and Safety, and Regulation* stakeholders were clearly opposed to EcoLogo promoting these products in the consumer market, while some producers mentioned they would like to see the scope extended to all consumer markets. It was also recommended that the appropriate market segmentation rational should be based on the fact that "… a significant amount of these products are used within many other market places not affiliated with either healthcare or food and must not be excluded. This would include all non-consumer based markets, or better defined as the *away from home market*…" This later

suggestion seems to represent a common view where some restrictions are needed, but limiting the use to hospitals and restaurants is too narrow.

The product category of *Instant Hand Antiseptic Products* can also be described as waterless hand sanitizers, waterless hand antiseptics, or professional hygienic hand rubs. For the purposes of this document, an instant hand sanitizer will mean *an antiseptic containing a preparation designed for frequent application, which is intended for use without a water rinse, which reduces the number of microorganisms on intact skin*. Moreover, *instant hand antiseptic products* can be defined as *an antiseptic containing drug product applied topically to the skin to help prevent infection, or to help prevent cross contamination (FDA, 1994)*. Disinfectant soaps, hand sanitizing products that require rinsing, patient preoperative skin preparations, or surgical hand scrubs are outside the scope of this standard.

It is the intention of the EcoLogo Program to restrict the use of EcoLogo certified *instant hand antiseptic products* ~~to settings where care is provided, across the continuum of health care and food service~~ to the "away from home market". This includes settings where emergency (including pre-hospital) care is provided, as well as in hospitals, complex continuing care facilities, rehabilitation facilities, long-term care homes, outpatient clinics, community health centers and clinics, physician offices, dental offices, offices of health professionals, Public Health and home health care. It also includes the Food Service Industry; all establishments, types of businesses, and services that prepare and serve food away from a patrons' home. ~~This includes full-service, limited-service, non-commercial, and catering operations, but not customer restrooms.~~ Schools, offices, daycare services, and all other locations besides the consumer home market will be accepted.

~~As such~~ By restricting the scope of the standard to apply only to the "away from home market", the EcoLogo Program ~~proposes to restrict~~ considers that the use of *instant hand antiseptic products* are not necessary where access to regular hand cleansing products such as soap and water are readily available and sufficient.

It was brought to the attention of the EcoLogo Program that "…the physical forms listed do not include non-aerosol foaming products, which by far have become the product of choice, specifically within the healthcare community. This must be corrected…" and "… in keeping with the concept of an environmental leadership standard, environmental differentiation is clearly possible within the foam category. A clear separation should be made between aerosol and non-aerosol foams. Aerosol foams typically include formulation ingredients (especially propellant systems) and packaging that inherently increase their environmental impact. By contrast, current generation non-aerosol foams typically do not. Segmentation of non-aerosol foams can be made on the basis of the specific chemical used to induce foam. Products that contain fluorinated octanoic acid-based surfactants should be specifically excluded by the standard. These foaming agents are known to present health and environmental risks through their degradation products."

It is the intention of the EcoLogo Program to only consider *instant hand antiseptic products* in the physical forms of gels, liquids, and non-aerosol foams. Aerosols, sprays, and wipes will therefore not be considered for certification. Although some spray products have been positioned as "greener" due to a relatively simple formulation and purported lower use levels, the actual amount needed to achieve antimicrobial

efficacy is no less than with other forms. Sprays have the significant downside of enhancing the exposure of droplet inhalation to the user. Foam products generally do result in less product weight per use, but typically contain more supplemental formulation chemicals (especially propellant systems) beyond the active ingredient. Having said that, a distinction can be made regarding aerosol versus non-aerosol foams, where non-aerosol foams can be distinguished on the basis of the safer chemical used to induce foam. It has therefore been suggested that non-aerosol foam be included, but products that contain fluorinated octanoic acid-based surfactants should be specifically excluded by the standard. Most wipes employ a synthetic nonwoven substrate which adds unnecessary impacts to the environment.

~~*Instant hand antiseptic products* are also available in a wide range of packaging and delivery systems but there are three basic categories: fixed-mount with a refillable dispensing system; bottles; and aerosol cans. There are of two types of fixed mount systems; open, refillable (or "bulk") dispensers, and sealed cartridge systems. Open, refillable systems are contraindicated in many healthcare infection control guidelines, and are seldom used in healthcare due to issues of contamination. Sealed, refillable dispensing systems are typified by "bag-in-box" systems that employ a fixed-mount dispenser and cartridge refills. Plastic bottles, typically PET, are a common package for hand antiseptics in the consumer market, while small size wearable products are mostly used by hospital staff.~~

Background

North American Market Situation

The non-consumer *instant hand antiseptic products* market can be segmented in various ways, but unlike consumer markets, there is relatively little standardized market data for these segments. However, basic segmentation can be approximated from existing information nonetheless.

Healthcare and food handling markets in the United States, Canada and Europe are dominated by alcohol-based hand antiseptics, with a share estimated at 96-97%. Quat based antiseptics comprise most of the remaining products at 2-3%, and a few other active ingredients comprise less than 1% of the market. Regulatory, safety, and efficacy requirements dictate this segmentation.

Healthcare markets have a similar pattern with a large majority of ethanol based products. European markets, and to a lesser extent Canada, are somewhat more diverse from a formulation standpoint with some butanol or propanol containing products, several high (>70%) alcohol formulas, and a number of mixed active systems. There is a clear long-term trend in all markets toward ethanol-based formulations due to the aesthetic acceptance by workers.

Detailed segmentation by packaging is difficult to determine. Wall-mounted, sealed cartridge dispensing systems are widespread but the ratio between this type of packaging and bottles varies widely. Aerosol cans are estimated to capture up to 10% of the U.S. healthcare market, but almost nonexistent in food handling. Canada is estimated to experience similar trends to the U.S. market. They could however, have a lower percentage in healthcare than in the United States.

Laws and Regulations

In Canada:

The regulatory assessment and approval of hand antiseptics are divided between Health Canada's Therapeutic Products Directorate (TPD) and Natural Health Products Directorate (NHPD). The two directorates worked together with industry to harmonize the Antiseptic Skin Cleanser monograph which was published in December 2006. Under this monograph, antiseptic skin cleansers are classified as either natural health products (NHPs) or as a pharmaceutical drug. Alcohol-based instant hand antiseptics are classified as Natural Health Products and are regulated under the jurisdiction of the Natural Health Products Directorate. Antiseptic skin products based upon quaternary ammonium compounds (chloroxylenol, triclosan, triclocarban, and chlorhexidine gluconate) are classified as non-natural based drugs and are regulated under the TPD. In addition, it was reported to the EcoLogo Program that "…the Canadian Food Inspection Agency (CFIA) regulates product usage for food processing/food handling markets by way of issuance of a "letter of no objection", and follows very strict guidelines in cooperation with Health Canada for a manufacturer to comply with. The reference to Health Canada's TPD and NHPD refers more to the Category IV Monograph, which governs consumer products, and neglects to address the new Health Canada draft Guidance Document – Human Use Antiseptic Drugs now under consideration and already affecting such products as Instant Hand Antiseptic Products."

In the United States:

In most cases, regulatory requirements define the primary compositional, performance, marketing and even packaging parameters for *instant hand antiseptic products*. In the United States, *instant hand antiseptic products* fall under the purview of the U.S. Food and Drug Administration and are regulated as pharmaceutical drugs. Hand antiseptics almost exclusively fall under the Over-The-Counter (OTC) Monograph. The latest (U.S. FDA, 1994) OTC Tentative Final Monograph for Healthcare Antiseptics classifies only two active ingredients as Generally Recognized as Safe and Effective (GRASE) for hand antiseptics: alcohol and povidone iodine. Triclosan, triclocarban, benzalkonium chloride, benzethonium chloride, and parachlorometaxylenol are all potential active ingredients for skin disinfectants, which lack either safety or efficacy data sufficient for GRASE classification as hand antiseptics. No natural products' active ingredients, such as thyme, are listed in the Monograph and thus are precluded from legal use in the United States, unless an approved New Drug Application (NDA) is obtained, of which none have been granted.

An additional regulatory consideration in the U.S. is that hand antiseptics used in foodservice situations must conform to State Food Codes, based upon the FDA Model Code. This means the products must meet FDA requirements for both drugs and indirect food contact.

It is important to emphasize that while the EPA categorizes antimicrobials into four categories: (1) Sterilizers, (2) Disinfectants, (3) Sanitizers, and (4) Antiseptics and Germicides, only the fourth category of antimicrobials relate to *instant hand antiseptic products*. Because antiseptics and germicides are used on living humans, they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA). As such, *instant hand antiseptic products* do not sterilize, disinfect, or sanitize hands

according to the EPA definition of these terms (Petru, 2007). Rather, *instant hand antiseptic products*, as defined by the FDA, are an *antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination* (U.S. FDA, 1994).

Activities of Other Standards or Eco-Labels

To our knowledge no standard or eco-label exists for this product category.

Environmental Considerations and Proposed Criteria Statements

In the following section the EcoLogo Program ~~we will~~ proposes specific criteria for *instant hand antiseptic products*. Following each proposed criteria statement is a background rationale explaining the motivation, scientific arguments, and other details required to understand why the proposed criteria statement is necessary.

Raw Materials

It is the intention of the EcoLogo Program that whenever possible, a product be formulated to substitute renewable for non-renewable resources, recycled materials for virgin resources, or use less intrusive exploration or extraction techniques. Currently, the EcoLogo Program has identified two potential areas for leadership within the resource extraction/raw material phase of the life cycle: Biobased Content, and Less Intrusive and Recyclable Materials.

Bio-Based Content

Proposed Criteria Statement:

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

> *To be authorized to carry the EcoLogo, instant hand antiseptic products must:*
>
> - ~~*Contain*~~ *Be formulated or manufactured with at least 73% biobased content per total weight of the formula found inside the product (i.e. packaging is not included).*

Question 2: Do you believe that requiring biobased content is appropriate, and that a threshold of 73% is reasonable? Why?

Fifty percent of stakeholders agreed, in principle, with the proposed criteria statement. However, there were questions as to whether the value of 73% was appropriate and whether the biobased material would be sourced from material "… that rely on resource extraction systems which are sustainable (i.e. do not cause social, environmental or economic hardships in the communities which they are harvested)…" For the moment, the EcoLogo Program has chosen to rely on the final regulations of the BioPreferred℠ program as

a means of establishing the amount of biobased material for hand sanitizers (http://www.biopreferred.gov/ProposedAndFinalItemDesignations.aspx). The 73% value was determined through a series of consultations following a series of steps under the item designation process, manufacturer and vendor guidance, and the procurement process (http://www.biopreferred.gov/files/03-31347.pdf). The EcoLogo Program will closely follow the progress of the BioPreferred[SM] program as to determine whether its regulations are strict enough in regards to promoting biobased materials that follow sustainable best practices. The EcoLogo Program may propose additional requirements in a future revision of the standard if needed to better define environment leadership.

The proposed value of 73% represents the minimum amount of biobased content per total weight of all ingredients found inside the product (i.e. packaging is not included). It is the intent of the EcoLogo Program to ask manufacturers to disclose the exact amount of biobased content so that the Program can inform purchasers and consumers via the EcoLogo's website, and to collect data to establish an environmental leadership threshold at the next revision of the standard.

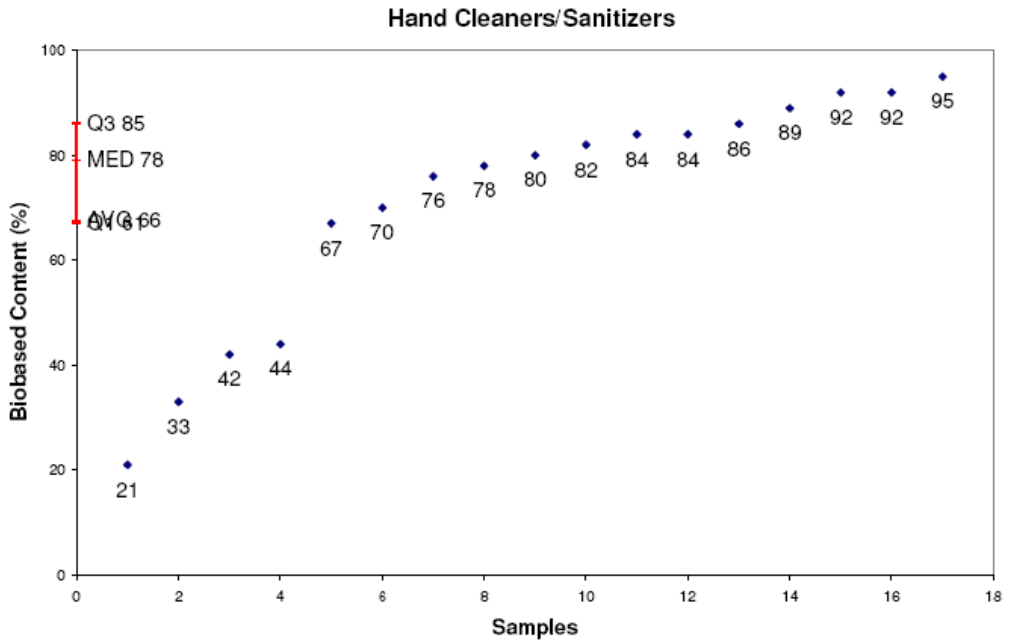
Rationale:

Preliminary research has revealed that approximately 15% of surveyed brands (n=33) using alcohol as active ingredient were biobased (n.b. biobased products determined by label claims) (Table 1). However, the exact amount of the product that is biobased is unknown since many manufacturers do not disclose this information.

Table 1: Research data showing various alcohol-based (% alcohol is reported in the Active Ingredient column) hand antiseptics and whether they are biobased or not biobased.

Manufacturer	Brand	Active Ingredient
1	Brand 1	Isopropyl Alcohol 63%
2	Brand 2	Isopropyl Alcohol 63%
3	Brand 3	Ethyl Alcohol 85%
4	Brand 4	Ethyl Alcohol 72%
5	Brand 5	Ethyl Alcohol 71%
6	Brand 6	Ethyl Alcohol 70% (biobased)
7	Brand 7	Ethyl Alcohol 70%
8	Brand 8	Ethyl Alcohol 70%
9	Brand 9	Ethyl Alcohol 65%
10	Brand 10	Ethyl Alcohol 64%
11	Brand 11	Ethyl Alcohol 62% (biobased)
12	Brand 12	Ethyl Alcohol 62% (biobased)
13	Brand 13	Ethyl Alcohol 62% (biobased)
14	Brand 14	Ethyl Alcohol 62%
15	Brand 15	Ethyl Alcohol 62%
16	Brand 16	Ethyl Alcohol 62%
17	Brand 17	Ethyl Alcohol 62%
18	Brand 18	Ethyl Alcohol 62%
19	Brand 19	Ethyl Alcohol 62%
20	Brand 20	Ethyl Alcohol 62%
21	Brand 21	Ethyl Alcohol 62%
22	Brand 22	Ethyl Alcohol 62%
23	Brand 23	Ethyl Alcohol 62%
24	Brand 24	Ethyl Alcohol 62%
25	Brand 25	Ethyl Alcohol 61%
26	Brand 26	Ethyl Alcohol 60% (biobased)
27	Brand 27	Ethyl Alcohol
28	Brand 28	Ethyl Alcohol
29	Brand 29	Ethyl Alcohol
30	Brand 30	Ethyl Alcohol
31	Brand 31	Ethyl Alcohol
32	Brand 32	Ethyl Alcohol
33	Brand 33	Ethyl Alcohol

The EcoLogo Program is also aware that other alcohol-free *instant hand antiseptic products* found in the marketplace claim to be biobased. Our preliminary research shows the total content of biobased material in hand cleaners/hand sanitizers ranges anywhere from 21 to 95 percent as defined by ASTM D 6866-04 (Figure 1).



~~Figure 1: Biobased content (%) for 17 samples of Hand Cleaners/Sanitizers according to the USDA - BioPreferred℠ Program (Proposed Item for Biobased Designation. 2006-2007. Federal Biobased Products Preferred Procurement Program (FB4P). USDA - BioPreferred℠ Program).~~

Figure 1: Biobased content (%) for 17 samples of hand cleaners/sanitizers according to the USDA BioPreferred Program (Proposed Item for Biobased Designation. 2006-2007)

U.S. Bio-based Legislation and Definition

~~The Farm Security and Rural Investment Act of 2002 (Public Law 107-17), better known as the 2002 U.S. Farm Bill, was signed by President Bush on May 13th, 2002. Section 9002 directs the USDA to create a Designated Biobased Products List (DBPL) and provide purchasing recommendations to federal agencies. The law requires federal agencies to give procurement preference to USDA-designated bio-based products. It is now mandatory to purchase these products and federal agencies are required to develop affirmative procurement programs to purchase these products.~~

~~The term 'biobased product' as defined by the Farm Security and Rural Investment Act of 2002, means a *product determined by the U.S. Secretary of Agriculture to be a commercial or industrial product, that is composed in whole or in significant part, of biological products or renewable domestic agricultural materials (including plant, animal, and marine materials) or forestry materials.* Biobased products are produced from renewable natural resources and are generally more environmentally sensitive than petroleum-based products.~~

~~The EcoLogo™ Program has identified that the current market is capable of offering biobased *instant hand antiseptic products*, for both alcohol-based and alcohol-free formulations. Until a comprehensive data base can be assembled for hand antiseptics, the EcoLogo™ Program proposes to use the *Minimum Biobased Content* specified by the BioPreferred℠ program of the USDA for Hand Cleaners and Sanitizers - Hand Sanitizers (USDA - BioPreferred℠ Program).~~

BioPreferred was created by the Farm Security and Rural Investment Act of 2002 (2002 Farm Bill), and expanded by the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) to increase the purchase and use of biobased products. Biobased products are defined by The USDA secretary as products composed in whole or in large part of renewable agricultural or forestry materials such as plant, animal, and/or marine ingredients.

USDA manages program strategy and implementation. BioPreferred includes a preferred procurement program for Federal agencies and their contractors, and a voluntary labeling program (in development) for the broad scale consumer marketing of biobased products. Under the procurement program, BioPreferred designates items, or generic groupings of biobased products, that are required for purchase by Federal agencies and their contractors. As a part of this process, the minimum biobased content is specified and information on the technical, health, and environmental characteristics of these products are made available on the BioPreferred website. Beginning in 2009, biobased intermediate ingredients and feedstocks will be included in the designation process. These intermediates are used to make finished consumer products. Under the voluntary labeling program, biobased products that meet the BioPreferred program requirements will soon carry a distinctive label for easier identification by government, businesses and consumers.

Less Intrusive and Recyclable Materials

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

For ~~small size wearable~~ bottle products;

To be authorized to carry the EcoLogo, instant hand antiseptic products~~' refill cartridges~~ must:

- *Be sold in bottles of at least 500 ml in size*
- *Not be formulated or manufactured with PVC or Bisphenol A and,*
- *Be made of recyclable materials*

To be authorized to carry the EcoLogo, instant hand antiseptic products must:

- *Not be packaged in secondary packaging and,*
- *Contain at least 25 % post-consumer recycled content in the shipping packaging.*

For ~~bag-in-box products~~ bulk refill products;

To be authorized to carry the EcoLogo, instant hand antiseptic products ~~pouches or bags~~ must:

- *Not be formulated or manufactured with PVC, or Bisphenol A and,*
- *Be made of recyclable materials*

To be authorized to carry the EcoLogo, instant hand antiseptic products must:

- *Not be packaged in secondary packaging and,*
- *Contain at least 25 % post-consumer recycled content in the shipping packaging*

Question 3: Do you agree that the EcoLogo Program should only certify "small size wearable" and "bag-in-box" products? Why?

100% of stakeholders either partially or completely disagreed with the proposed limitation regarding the type and size of dispensing system. In essence, most felt that "small size wearable" dispensing systems where not nearly as popular in hospitals as previously thought, and that "…bottles are a key packaging form leveraged in the healthcare market … Infection Preventionists (IPs) in the Healthcare market are focused on reducing infections and improving hand hygiene compliance. In an effort to make continual progress in these areas, IPs are focusing efforts on increasing access to hand hygiene products, specifically making hand hygiene products available whenever and wherever care is being administered. Under these "Point of Care" applications, having hand sanitizer available at key moments of care (at the bedside, e.g.), during patient transport, off the wall in critical care units, on computer carts, etc., is paramount and requires that facilities leverage bottled hand sanitizing products. These hand sanitizing bottles are often placed in brackets so they can be attached to IV poles, bedrails, wheel chairs, computer carts, etc.; all in an effort to reduce infections, drive compliance and improve patient outcomes. Studies have shown that better access to hand sanitizing product helps to improve hand hygiene compliance…"

Question 4: For "small size wearable" products, what do you believe the percentage of post-consumer recycled content should be? Why?

Small size wearable products will not meet the revised EcoLogo packaging requirements.

Question 5: For "bag-in-box" products, what do you believe the percentage of post-consumer recycled content should be? Why?

Stakeholders have suggested post-consumer recycled content values that averaged to 25% for cardboard shipping packaging. It was also suggested, but not unanimously, that EcoLogo require forestry certification for all paper derived products associated to packaging of the product. At this time, the EcoLogo Program believes that this additional certification may be too stringent based on products currently available in the market.

Rationale:

Post-Consumer Recycled Content & Recyclable Materials

Instant hand antiseptic products are considered an OTC drug regulated by the United States Food and Drug Administration (FDA). In the instance of OTC products, the FDA prohibits the use of post-consumer recycled materials in primary packaging. The FDA Guidance for Industry Document, *Container Closure Systems for Packaging Human Drugs and Biologics* states: "Post-consumer recycled plastic should not be used in the manufacture of a primary packaging component. If used for a secondary or associated component, then the safety and compatibility of the material for its intended use should be addressed appropriately" (U.S. FDA, 1999). There are no FDA constraints regarding the use of recyclable materials such as PET or HDPE, in primary packaging. Secondary packaging is necessary for structural integrity or when primary packaging is not conducive to distribution. There are no restrictions on the use of recyclable materials or materials containing post-consumer content in secondary packaging. However, the strength and durability of secondary packaging should be considered when using post-consumer recycled materials.

~~Small size wearable products~~

~~Larger volume dispensing systems allow for more use from a single package, thereby reducing waste. However, it is important to recognize the value of point-of-care products in compliance markets such as Health Care and Food Service. Small size wearable products are necessary for convenience in patient, food and customer contact. Wearable products typically come with holster, refill cartridges and accessories such as a lanyard and carabiner to help attach the product. The EcoLogo™ Program shall only consider packaging criteria for the holder and refill cartridges.~~

Bag-in-Box Packaging

Traditional bag-in-box (BIB) products include an outer display box around a flexible pouch. Historically, standards have allowed for BIB products as long as the instructions guided the user to separate the display box from the pouch prior to loading the dispenser. Separating the components before use increased the likelihood the display box would be recycled. However, it has been pointed out that to avoid the contamination of the product, "sealed cartridge systems" represent a better alternative, and more importantly, that unnecessary packaging and consideration can be eliminated all together by specifying that only cartridges not using such an outer shell be considered. Most stakeholders agreed with bulk dispensing systems, however to avoid the contamination of the product and reduce the amount of waste, "… "Bag-in-box" is a historical term that today, only describes a sub-set of "sealed cartridge systems". It has been also pointed out that "…some manufacturers utilize rigid or semi-rigid plastic cartridges for their products without aid of an outer cardboard container… This in itself may be considered unnecessary packaging and consideration should be given to specify that only cartridges not using such an outer shell be considered. There are many that would agree that "bag-in-box" is in itself one of the most un-ecologically friendly ways to package any type of hand care product…" In principle the EcoLogo Program agrees that reducing waste

is important, therefore it is proposed that the product primary packaging be recyclable, secondary packaging be eliminated, and shipping packaging contain post-consumer recycled content.

Bottles

Plastic bottles, typically PET, are a common package for *instant hand antiseptic products* in the consumer market. The EcoLogo Program considers that while ~~small size wearable products and bag-in-box~~ bulk dispensing systems may help to reduce waste, typical bottles may be needed for "Point of Care" applications. ~~to be sufficient for both Health Care and Food Service; therefore small sizes bottles will not be accepted.~~ However, in order to reduce the amount of waste the EcoLogo Program proposes to set a limit on the allowable size of bottles.

PVC

Polyvinyl chloride (PVC) has been scrutinized for Health and Safety issues during production and disposal, and reputable organizations such as the U.S. Green Building Council have recognized its' potential to impact human health. Alternative materials are available, and in agreement with numerous organizations such as the Center for Health, Environment and Justice (CHEJ), the use of PVC in packaging will be prohibited.

Prohibited and Restricted Substances

Active Ingredients

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

> *To be authorized to carry the EcoLogo, active ingredients of instant hand antiseptic products must:*

- *Not be formulated or manufactured with:*
  (i) quaternary ammonium compounds
  (ii)chlorhexidine gluconate,
  (iii)chloroxylenol,
  (iv) flurosalan,
  (v) hexachlorophene,
  (vi) phenol,
  (vii) tribromosalan,
  (viii) triclocarban, or
  (ix) triclosan;

~~*have active antimicrobial ingredients that are listed in the FDA Tentative Topical Antimicrobial Drug Products for OTC Human use; Tentative Final Monograph for Healthcare Antiseptic Drug Products (Federal Register, Vol. 59, No. 116, Friday, June 17, 1994) that have been placed in Category I: GRASE (generally recognized as safe and effective).*~~

Question 6: Do you agree that the EcoLogo Program should only certify products that have active ingredients in the GRASE Category-1? Why?

Fifty percent of stakeholder agreed that GRASE Category I was appropriate to distinguish safe and effective active ingredients. The other half who disagreed felt strongly that:

- "…EcoLogo should include products that obtain FDA approval through the New Drug Application (NDA) path as an additional practical alternative and incentive for innovation…"
- "…this section completely ignores components which may be acceptable to Health Canada as a natural health products, drugs or NDS-drugs…"
- "…Restricting certification to actives in the GRASE would only serve to stifle innovation…"
- "…we agree but you should also take into consideration the fact that a company could find a new molecule that is not listed on the GRASE list…"
- "…This would stifle innovation for new & unique active ingredients. In Canada, the safety, quality & efficacy of Medicinal ingredients is assessed and approved by the TPD/NHPD at the time of submission…"
- "…I looked at what was mentioned in there for triclosan. Based on my knowledge of this substance, it makes sense to me that triclosan is not considered as GRASE in the United States…"
- "…would also like to see a specific statement discussion document that only products manfactured in NHPD registered drug registered plants can be considered as is a requirement under Health Canada…"
- "…We agree that EcoLogo should certify products that have active ingredients recognized by the FDA as Category I – GRASE…"

It was also brought to the attention of the EcoLogo Program that, "… in the U.S., alcohol-containing hand sanitizers are regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB regulations require that prior to marketing a formulation it must be submitted for approval to it to assure that it is properly

denatured…" The amount of denaturant needed and which denaturants can be used in alcohol are specified by the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury. More importantly, "… attention needs to be made in terms of what the Biobased ethanol is denatured with… comments here are that the Ethanol should not be denatured with Methanol, IPA or other poisons but with bittering agents only"

Rationale

On September 13, 1974, the FDA published an advance notice of proposed rulemaking in the Federal Register (FR) to establish a monograph for over-the-counter (OTC) topical antimicrobial drug products. The notice incorporated the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial Drug Products (Antimicrobial I Panel). This panel was responsible for evaluating data on the active ingredients in this drug class. The panel prepared a report to the Commissioner of the FDA classifying OTC drug products into three categories: 1) Category I: generally regarded as safe and effective (GRASE) for the claimed therapeutic indication; 2) Category II: not GRASE or having unacceptable indications; and 3) Category III: insufficient data available to permit final classification. On June 17, 1994, the FDA published a notice of proposed rulemaking in the form of an amended Tentative Final Monograph that would establish conditions under which OTC topical healthcare antiseptics are GRASE and not misbranded.

OTC drugs are defined as GRASE for their intended use provided they are not misbranded, nor marketed using false or misleading statements. A manufacturer desiring to market a monographed (therapeutic classes of ingredients that are GRASE) drug need not seek clearance from the FDA prior to marketing. In this case, marketing is not exclusive and all data and information supporting GRASE status are publicly available. Monographs mainly address active ingredients in the product, and in most cases, final formulations are not subject to monograph specifications. Manufacturers are free to include any inactive ingredients that serve a pharmaceutical purpose, provided those ingredients are considered safe, and do not interfere with product effectiveness or required final product testing. In some instances even though the product may contain GRASE ingredients, the final formulation may need to meet a monograph testing procedure. An example would be the antiseptic drug products that are for healthcare personnel hand wash, surgical hand scrub, and patient preoperative skin preparation. These are required to meet in vivo and in vitro efficacy testing requirements to ensure that their formulated products are effective as an antiseptic. Inactive ingredients and emollients, when included in the products, may inhibit the antiseptic action, therefore testing must be performed to show effectiveness. Because the drugs in the monograph system are GRASE, there has been no requirement to report adverse events.

Given the following indications above and the comments provided by stakeholders, reference to OTC drugs as defined as GRASE will be removed. Rather than impose what active ingredients could be accepted via government program lists, the EcoLogo Program has elected to take a restrictive approach. In other words, the EcoLogo Program will add a list of active ingredients that will be prohibited. Prohibited ingredients in the standard will be those that are referenced as drug medicinal ingredients in Health Canada's Therapeutic Products Directorate (*TPD*) and those that are classified as category II (i.e. not GRASE) in the FDA Tentative

Topical Antimicrobial Drug Products for OTC Human use; Tentative Final Monograph for Healthcare Antiseptic Drug Products (Federal Register, Vol. 59, No. 116, Friday, June 17, 1994).

Inactive Ingredients

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

To be authorized to carry the EcoLogo, inactive ingredients of instant hand antiseptic products must:

~~*Have components that are exempt from the requirements of being listed in the U.S. federal food additive regulations as specified in 21 CFR 170.39 threshold of regulation for substances used in food-contact articles OR;*~~

~~*Comply with and be listed in:*~~

- ~~*21 CFR 178 - Indirect Food Additives: Adjuvants: Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, OR,*~~
- ~~*21 CFR 182 Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food.*~~

~~*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*~~

- *Not be formulated or manufactured with endocrine disruptors and heavy metals.*
- *Not be formulated or manufactured with fragrances or dyes.*
- *Not be formulated or manufactured with carbomer thickeners*
- *Not be formulated or manufactured* with fluorinated octanoic acid-based surfactants

Question 7: Do you agree with the product specific requirements for inactive ingredients? Why?

Approximately 63 percent of stakeholders disagreed with the product specific requirements for inactive ingredients. Opposition was mostly directed to the specifications of the Code of Federal Regulations CFR 170, CFR 178, CFR 182, and CFR 186, or the fact that some other aspects have not been dealt with appropriately. As such it was noted that … "This section ignores Canadian requirements. Note that hand

antiseptic products are not marketed in Canada under monograph as in the US and are therefore subject to premarket approval…"

Only one stakeholder objected to the proposed restriction of fragrances. Most agreed that it was appropriate and that dyes also be restricted. "… Some manufacturers add fragrance to their alcohol hand sanitizer formulation. Their logic is that the formulation is more appealing to caregivers and patients. However, a review of advantages and disadvantages listed in Kovach & Associates' annual survey of 120 directors of nursing across the United States would suggest otherwise. Fragrance becomes a problem due to the potential among caregivers and patients for allergic reactions to different fragrances. Directors of nursing cited fragrance as a factor in causing nausea in both patients and caregivers. A fragrance-free product is preferable. Similar survey comments regarding fragrance in the healthcare environment were seen in quotes associated with healthcare personnel hand washes, lotions and liquid body soaps. Hand rinses, healthcare personnel hand washes and lotions are all regarded as having a degree of personal use preference, so high fragrance levels can become a problem for caregivers and patients. We have also heard some objections to the use of dyes in some formulations. These can leave stains or residue on caregiver and patient hands and clothes. It would be best to use a product that has no color additives or dyes in its formulation to avoid staining and possible skin irritation…"
http://www.infectioncontroltoday.com/articles/361feat4.html.

Finally, it was argued "…would also like to see a specific requirement the thickener used for gelled alcohol hand sanitizers be made with 100 % natural thickners which are biodegradable and synthetic/ non biodegradable polymers such as carbomers types specifically excluded…"

Rationale:

Because the EcoLogo Program proposed to include Food Service, all ingredients, including emollients and perfumes that are constituents of *instant hand antiseptic products* used must comply with Title 21, the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration.

Typical alcohol-based *instant hand antiseptic* formulations are relatively simple products, consisting mostly of water, alcohol, and low levels of other ingredients to improve aesthetics and skin compatibility. Similarly, non-alcohol formulations consist primarily of water and low levels of other ingredients. *Instant hand antiseptic products* generally do not contain chemicals of high environmental concern such as endocrine disruptors and heavy metals, however the EcoLogo Program intends to add requirements to assure users that they are free of any of these types of chemicals.

Many products are fragranced to counterbalance the odor of the active ingredients. However, the EcoLogo Program is aware that several "greener" *instant hand antiseptic products* claim to be fragrance-free. Because it is the intent of the EcoLogo Program to reduce the environmental footprint of products, and because fragrances are not absolutely necessary for this category, and because some public places such as hospitals are adopting "fragrance-free" policies (http://www.nontoxic.com/nontoxic/fragrancefree.html), fragrances will not be allowed.

Carbomer products are linear polyacrylates and crosslinked polyacrylates. According to the Basic Acrylic Monomer Manufacturers, Inc., acrylic acid is the base ingredient for linear polyacrylates and crosslinked polyacrylates. It is a highly reactive chemical that is very corrosive and identified as a hazardous chemical. Linear polyacrylates and crosslinked polyacrylates may contain trace amounts of acrylic acid. Primary routes of human epxosure to acrylic acid are skin contact and inhalation.

Health Hazards

The following are examples of the typical types of impacts often included in EcoLogo standards:

- Human toxicity
- Skin and eye irritation
- Respiratory sensitization

Proposed Criteria Statement

EcoLogo ***does not*** **propose** to establish additional criteria regarding health hazards.

Rationale:

The EcoLogo Program assumes the major heath hazards have been covered in the Prohibited and Restricted Substances.

Environmental Hazards

The following are examples of typical types of impacts often addressed in EcoLogo standards:

- Biodegradability/compostability
- Aquatic toxicity (acute/chronic)
- Atmospheric pollution

Biodegradability

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

> *To be authorized to carry the EcoLogo, instant hand antiseptic products must:*
>
> - *Be manufactured or formulated such that all organic ingredients must be readily biodegradable.*

Question 8: Do you agree that *instant hand antiseptic products should* be readily biodegradable? Why?

Rationale

The EcoLogo Program is currently uncertain if requiring active ingredients to be readily biodegradable is technically feasible and/or realistic. The main reason being that ***instant hand antiseptic products*** are designed to kill bacteria, even those involved in the biodegradation process. We also believe that inactive ingredients should not pose a threat to the environment because they must be listed in the federal food additive regulations, and therefore be biodegradable.

Approximately 85% of stakeholder agreed that instant hand antiseptic products be readily biodegradable. First, it was pointed out that "…just because inactive ingredients are listed in the federal food additive regulations, that they are therefore biodegradable…" Second, in regards to the feasibility of testing methodologies it was argued that "… the standard tests do not provide a good way to measure their biodegradability…" However, another stakeholder provided a rationale, solution, and an explanation as to why it would be adequate "…biodegradability is an important criterion for the category despite the fact that these products are intended for leave on skin application. The products ultimately reach the environment

when they are removed from the skin by sloughing or washing, there may be the need to dispose of these products prior to the complete evacuation of the refill container, and manufacturing operations may discharge product into the environment. We have reviewed the commonly accepted test method, OECD 301, "Guideline for Testing of Chemicals-Ready Biodegradability." The primary limitation defined in OECD 301C, D and F is that these test methods are based on biological oxygen demand (BOD). The BOD method is based on the ability of the test organism to consume the organic matter over a five day period. Since the active ingredients used in instant hand antiseptic products are designed to kill microorganisms, this test has the potential to be inappropriate for sanitizer testing, a concern raised in the rationale section of the draft standard document. However, these methods dilute the test solution to concentrations typically in the range of 2 – 10 mg/L or a specific COD (chemical oxygen demand). Based on these test concentrations the test organisms should not be negatively impacted by the sanitizer active ingredient…" For the reasons above, the EcoLogo Program will continue to propose that instant hand antiseptic products be readily biodegradable.

VOC

Proposed Criteria Statement

EcoLogo *does not* propose to establish additional criteria regarding volatile organic compounds.

Rationale

Recently, the California Air Resources Board (CARB) committed to develop a measure for VOCs to be implemented by 2008 and 2010, that would achieve additional VOC emission reductions from consumer products from the already regulated categories and VOC level standards. In the July 19, 2006 VOC Consumer Products Regulatory Amendments, CARB proposed a new regulatory category: Personal Sanitizers with a proposed VOC limit of 1%.

This CARB proposal to limit the VOC content to 1% would eliminate the use of alcohol in no rinse antiseptic hand washes. However, based on strong testimony and evidence, the California Air Resources Board removed instant hand sanitizers from the proposed amendments to the VOC Consumer Products Regulations. By eliminating the use of alcohol as a drug active, CARB would force companies to turn to alternative actives which have not been found by the FDA to be generally safe and effective. This would place companies at a significantly high enforcement risk as well as severely limit public access to these important public health products. CARB also recognized that the effect of this proposal would have a significant impact on public health, and place the California public and its' workforce including healthcare workers, emergency first-aid responders, disaster relief workers, hospitality workers, and food handlers at a significant disadvantage. They would become more vulnerable to the transmission of germs which can lead to infection and disease, as well as limit their preparedness to address emerging pandemics.

The EcoLogo Program is not proposing to regulate VOCs since the requirement would preclude the certification of alcohol-based *instant hand antiseptic products* which have been strongly recommended as a

safe and effective product from most respected public health organizations and agencies worldwide as a key point in hand hygiene compliance to protect public health.

Energy and Water

The following are examples of typical types of impacts often included in EcoLogo standards:

- Renewable energy/RECs/carbon offsets
- Energy reduction/conservation/Energy Star
- Water reduction/conservation

Preliminary research has failed to find relevant data to validate whether Energy and Water conservation are critical aspects of leadership in manufacturing *instant hand antiseptic products*. In other words, it is unclear if the manufacturers of *instant hand antiseptic products* are currently buying RECs and/or carbon offsets, or using technology to reduce energy and water consumption. Without data, the EcoLogo™ Program does not intend to propose such requirements in the standard.

Question 9: Do you believe that in order to distinguish environmental leadership, the EcoLogo Program should establish strict requirements for energy and/or water consumption at the manufacturing site of the product? Why and what criteria statements do you think would be reasonable to establish?

Approximately, 85 percent of stakeholders disagreed that in order to distinguish environmental leadership, the EcoLogo Program should establish strict requirements for energy and/or water consumption at the manufacturing site of the product. It was brought to light that:

- "…The chemical mixing process is not water or energy intensive. Therefore, establishing a requirement in this area would have little to no real impact and thus would not be a critical factor in environmental leadership…"
- "…No, not without data to support it. We have no idea what would be reasonable…"
- "…We do not believe it is appropriate to establish specific threshold values for energy and water consumption at the manufacturing stage for the product. There are multiple reasons for this response, beginning with the difficulty associated with establishing a method for the measurement, allocation, and eventual calculation of the energy and water values that could be applied across the many different facilities associated with the manufacturing of products that might be submitted for certification in this class…"
- "…I feel that requesting energy and water consumptions reports would put the smaller companies at a disadvantage. These may be easily accessible information for large companies but not so for small to medium-sized companies that would need to hire consultants…"

For the reasons mentioned above, the EcoLogo Program is not prepared to require threshold values for energy and water consumption at the manufacturing stage for the product.

Performance and Safety Requirements

Performance

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

> *To be authorized to carry the EcoLogo, instant hand antiseptic products must:*
>
> - ~~Meet the Human Dermatology, Efficacy, and Compatibility performance tests outlined in Table 2~~
> - demonstrate a 3.5 log reduction in viable counts within 30 sec. according to the ASTM E 2276-03 method, when using Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Salmonella spp;
> - demonstrate a 3.5 log reduction in viable counts within 30 sec. according to the ASTM E 1174-06 method, when using Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Salmonella spp;

Question 10: Do you believe the EcoLogo Program should establish strict requirements regarding product performance or that manufacturers should be responsible for meeting industry standards and government regulations? If you believe that EcoLogo should establish requirements, do you think the proposed performance tests in Table 2 are sufficient and adequate?

Approximately 66 percent of stakeholders disagreed with the statement that the EcoLogo Program should establish strict requirements regarding product performance as indicated in the comments below:

- "… the government regulations are already sufficient in this case especially with the GRASE requirements that should take care of safety concerns while Health Canada requirements will make sure about efficacy…"
- "… this is outside the scope of EcoLogo™ environmental leadership standards. We believe that manufacturers should remain responsible for compliance with necessary government standards…"
- "… government already regulates these products, this is sufficient…"

- "… in Canada, efficacy data must be submit and approved pre-market. A DIN# or NPN# should be sufficient for performance & safety requirements. Yes, In the U.S. my understanding is that a company needs only assert compliance with the tentative final monograph. There is no pre-market review or approval. The acceptable efficacy data should be make in vivo data mandatory. As detailed in the Draft Guidelines Human-Use Antiseptic Drugs in vitro data can only be considered as supporting data. In vivo data is mandatory. Environmental Choice should reflect the higher quality standard of in vivo testing…"

- "… Ecologo should not be involved in product performance measurements…"

- "…The only change that we recommend is to modify the testing requirement outlined in Table 2 to require *either* EN 1500 or ASTM E1174 - not both of these tests - since both test methods are well-accepted *in vivo* evaluations of antimicrobial efficacy. We recommend that Table 2 is modified so that the requirements for *in vivo* microbiological efficacy testing are similar to the requirements for *in vitro* efficacy testing, where either ASTM E2315 or EN 1040 and EN 1275 are required…"

The EcoLogo Program has been made aware that Canadian hand antiseptic products that have a DIN# or NPN# meet specified performance & safety requirements. However because the proposed criteria statement that all "inactive ingredients be approved as GRASE in the FDA Tentative Final Monograph" was removed from the proposed EcoLogo standard, in order to ensure consistency across the north American market the EcoLogo Program will require that manufacturers of *instant hand antiseptic products* demonstrate performance/efficacy according to tests cited in Health Canada's **draft guidance document Human-Use Antiseptic Drugs** (*http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/draft_ebauch_antiseptic_guide_ld-eng.php*).

Personal Commercial Use

"Personal commercial use products are those made available to the general public for occasional use and are intended to remove transient organisms from the skin in a commercial or institutional setting. This includes, but may not be limited to, antiseptic products dispensed in washrooms in public buildings (such as daycares and schools) or used in workplaces other than healthcare or food-handling premises These products are commonly used to remove transient organisms from the hands including those organisms that may not necessarily be encountered in a domestic setting. They are intended to provide a superficial and non persistent cleaning effect to reduce microbial load on hands to either augment the effect of soap and water cleaning or for use when soap and water are not available" (PWGSC, 2008).

- Bacterial Test: The *in vivo* ASTM E 2276-03 method is to be used. The products, which demonstrate a 3.5 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM 2276-03 test under practical conditions on the hands of volunteers.

- Mycobacterial Test: The *in vivo* ASTM E 2276-03 method is to be used. The products, which demonstrate a 3.5 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM 2276-03 test under practical conditions on the hands of volunteers.

- Fungal Test: The *in vivo* ASTM E 2613-08 method is to be used. The products, which demonstrate a 2 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E 2613-08 test under practical conditions on the hands of volunteers.

- Virucidal Test: The products, which demonstrate a 2 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E1838-02 test under practical conditions on the hands of volunteers.

Professional Food Premises

"Products for professional food premises are those which are indicated for use by food handlers and are used frequently to remove transient organisms from the skin in a commercial or institutional setting including food processing plants and also includes restaurants, retail supermarkets, and fast food outlets" (PWGSC, 2008).

- The test methods to be used for antiseptic products intended for use by food handlers are the same as those outlined for professional use hygienic hand products (see Professional Healthcare Use below), including when log reduction and organism-specific claims are made. However, given the acknowledged potential for spread of enteric viruses, products for use by food handlers should also demonstrate efficacy against viruses using ASTM 1838-02 in addition to other microorganisms.

Professional Healthcare Use

"Products for professional healthcare use are those which are indicated for use by individuals to remove transient and/or resident organisms from the skin in a healthcare setting (such as hospitals, nursing homes, clinics, dental offices). Healthcare settings typically exhibit a higher presence of transient and/or nosocomial organisms than domestic or other commercial institutions. As such there is an inherently higher safety risk to health if the product is not effective" (PWGSC, 2008). Professional healthcare use antiseptics can be broken down as: professional handrubs and handwashes, surgical handscrubs and patient preoperative skin preparations. Only professional handrubs are part of the proposed EcoLogo standard.

- Bactericidal: The *in vivo* ASTM E 1174-06 method may be used. The products, which demonstrate a 3.5 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E 1174-06 test under practical conditions on the hands of volunteers.

- Mycobactericidal: The *in vivo* ASTM E 1174-06 method may be used. The products, which demonstrate a 3.5 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E 1174-06 test under practical conditions on the hands of volunteers.

- Fungicidal: The *in vivo* ASTM E 2613-08 method is to be used. The products, which demonstrate a 2 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E 2613-08 test under practical conditions on the hands of volunteers.

- Virucidal: The *in vivo* ASTM E1838-02 method is to be used. The products, which demonstrate a 2 log reduction in viable counts within 30 sec. or as specified by the manufacturer are deemed to have passed the ASTM E1838-02 test under practical conditions on the hands of volunteers.

Moreover, each test has several organisms that can be used to verify specific types of efficacy claims. For example, there are test organisms for general kill claims for personal and commercial use products, organism-specific claims for personal and commercial use products, professional food handler use products, or professional healthcare use products. *Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa* are typical test organisms for general kill claims for personal and commercial use products.

Rationale:

Instant hand antiseptic products are very effective antimicrobial products. They are required to be rapidly biocidal and broad spectrum in activity, yet safe when used very frequently (up to dozens of times a day). This requirement for frequent usage makes product aesthetics unusually important because they can directly influence use patterns. An unattractive product will have reduced usage which is contrary to the intended infection control purpose of the products. Thus, key technical performance considerations are antimicrobial efficacy, skin safety and aesthetics; somewhat contradictory objectives that make the fine points of formulation very important.

~~Since hand antiseptics are drug products, the antimicrobial performance requirements are specified by regulations. In the United States, hand antiseptics are required to demonstrate broad spectrum *in-vitro* activity and meet *in-vivo* antimicrobial performance criteria as specified in the FDA Tentative Monograph. The *in-vivo* performance test is a modification of ASTM E1174, and requires that products reduce transient contamination by 99% (2 log10) after one product application, and by 99.9% (3 log10) after ten contamination/wash cycles. A number of comments from leading infection control practitioners have been submitted to the FDA docket strongly questioning the logic of the tenth wash requirement. Further, it is current practice in the industry to test products by the actual ASTM method because of multiple, problematic issues with the FDA method, which can lead to an underestimation of product efficacy. This issue was addressed, but not resolved, at an FDA Nonprescription Drug Advisory Committee meeting in March 2005. The eventual Final Monograph(s) for Skin Antiseptics will likely incorporate E1174 as the required *in-vivo* test method, although the exact performance criteria (log reduction) are unclear. Also, the FDA has announced their intent to publish a notice of proposed rule making (NPRM) for testing methods. In view of this situation, it would be premature to establish the current *in-vivo* TFM test method and performance criteria as a basic requirement for a hand antiseptic. A more realistic approach might be a threshold performance of 2 log reduction after one application using ASTM E1174.~~

~~In Canada, antiseptic skin cleanser products are required to pass antimicrobial testing which is determined based on the product claims to be made. Compendial products (products which conform to the Monograph for Antiseptic Skin Cleansers) must be attested to meet the minimum requirements of the Compendium of Monographs. Products with composition or claims outside of the Monograph are considered Non-Compendial, and must conform to the *in-vitro* and *in-vivo* requirements of the Draft Guidelines for Antiseptic Hand and Skin Disinfectants, which are closely aligned with European Norms.~~

~~Additional performance requirements for hand antiseptics may be set by markets and users. In healthcare settings, hand antiseptics are generally required to show compatibility with latex and chlorhexidine gluconate. Standard tests are available for this determination.~~

~~Below is a table of commonly conducted testing, and the acceptance criteria for superior product performance.~~

~~Table 2: Human Dermatology, Efficacy, and Compatibility tests for instant hand antiseptic products~~ (REMOVED)

In November 2008, Health Canada announced the release of the draft Human-Use Antiseptic Drugs Guidance Document. This document is a guide to help assess whether a manufacturer of an antiseptic product for human use has met the requirements of Section 9(1) of the Food and Drugs Act regarding labeled drug claims made specifically with respect to the "mitigation or prevention of disease". This includes antiseptic products which are regulated as pharmaceutical drugs or natural health products, and applies to antiseptic skin products for human use and intended for use in professional and commercial settings.

The intent of EcoLogo Program is to guarantee that certified products meet some industry performance standards, not the full extent of all possible performance/efficacy tests currently available in the market, or required by government. It should also be noted that manufacturers may choose to go beyond government regulation if they want to have additional claims on their products. Because some tests can be expensive or accredited laboratories difficult to find, the EcoLogo has chosen not to require virucidal tests, for example.

Labelling Requirements and Conditions for EcoLogo Use

Product Information on Label

Proposed Criteria Statement

EcoLogo proposes to include in the *Product Specific Requirements* the following statement:

> *To be authorized to carry the EcoLogo, Instant hand antiseptic products must:*
>
> - ~~*Comply*~~ *Follow the labelling requirement of* ~~*with*~~ *the U.S. Food and Drugs Act* ~~*as well*~~ *OR* ~~*as the Canadian Food and Drug Regulations and Natural Health Products Regulations, whenever applicable*~~. *Health Canada OR the Canadian Food Inspection Agency.*

Stakeholders have commented on the Labelling Requirements and Conditions for EcoLogo use:

- "…Most, if not all, such products will be under the jurisdiction of either the TPD or the NHPD. Both Directorates have specific criteria for labeling. Will they accept the EcoLogo symbol on a drug or natural health product label?…"
- "… in the section attached to this question, the statement in 4.7.1 is inappropriate in that US and Canadian regulations regarding hand antiseptics differ from each other sufficiently that few products are compliant in both countries… *Comply with the U.S. Food and Drugs Act* ***as well as*** *the Canadian…"*
- "…I would also like to draw you attention to the NHPD monograph on Hand Sanitizers. Based on our recent experience environmental claims cannot be made under NHPD label requirements-

claims of bio based content, natural are not permitted. Based on our experience it might be worth Terra Choice getting clarification from the NHPD as to being able to carry the Ecologo on the label. We found the labelling requirements very stringent with no marketing wiggle room either for environmental claims of 62 % natural ethanol and the Ecologo might not be allowed…"

The EcoLogo Program requires manufacturers to follow all labelling requirements subject to the marketing of their products so that EcoLogo certified instant hand sanitizers are not labelled in a manner that is false, misleading or deceptive. All licensees and authorized users must comply with the U.S. Federal Trade Commission's *Guides for the Use of Environmental Marketing Claims*, the Canadian Competition Bureau's *Environmental Claims: A Guide for Industry and Advertisers*, and the EcoLogo Program's *Guide to Proper Use of the EcoLogo*™ regarding the format and usage of the EcoLogo™.

Rationale:

In the United States, regulatory requirements define the primary compositional, performance, marketing, and even packaging parameters for hand antiseptics. In the United States, *Instant hand antiseptic products* fall under the purview of the U.S. Food and Drug Administration and are regulated as drugs. Hand antiseptics almost exclusively fall under the Over-The-Counter Monograph. An additional regulatory consideration in the United States is that *Instant hand antiseptic products* used in foodservice situations must conform to State Food Codes, based upon the FDA Model Code. This means the products must meet FDA requirements for both drugs and indirect food contact.

In Canada, *instant hand antiseptic products* are also regulated as drugs and are subject to the Food and Drugs Act and Regulations. Hand antiseptics are classified as either *non-pharmaceutical drug products* or *natural health products*, depending upon the active ingredient. Both drugs and natural health products must meet established criteria for efficacy and safety, and are required to undergo premarket review and approval by Health Canada prior to going to market.

Sufficient information necessary to support the labelled claim of an antiseptic product for human use should be made available to Health Canada.

This information should include (PWGSC, 2008):

- Evidence of positive supportive results of *in vivo* and *in vitro* testing conducted in accordance with acceptable test methods, and for *in vivo* studies, under the conditions of use prescribed on the label and;
- Evidence regarding the safety of the drug when there is no evidence available that the topically-applied medicinal ingredients are not systemically absorbed to a significant degree.

Finally, as per the Canadian *Food and Drugs Act*, any substance that is used for the "mitigation or prevention of disease" is a drug. Section 9(1) of the *Act* also specifies that a drug must not be labelled "…in a manner that is false, misleading or deceptive or is likely to create an erroneous impression…"

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USDA - BioPreferred℠ Program (web site): http://www.biopreferred.gov/Default.aspx

Interpretation

ASTM E 1174-06 means American Society for Testing and Materials, Standard, Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations;

ASTM E 2276-03 means American Society for Testing and Materials, Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingerpads of Adult Subjects;

ASTM D6866-08 means American Society for Testing and Materials, Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis;

"away from home market" means settings where emergency (including pre-hospital) care is provided, as well as in hospitals, complex continuing care facilities, rehabilitation facilities, long-term care homes, outpatient clinics, community health centers and clinics, physician offices, dental offices, offices of health professionals, Public Health and home health care. It also includes the Food Service Industry; all establishments, types of businesses, and services that prepare and serve food away from a patrons' home. Schools, offices, daycare services, and all other locations besides the consumer home market will be accepted;

"bisphenol A" means is an organic compound with two phenol functional groups such as, inter alia, 2,2-(4,4'-dihydroxydiphenyl)propane, 4,4'-isopropylidenediphenol, or 2,2'-bis(4-hydroxyphenyl)propane;

"biobased" means products that are determined to be commercial or industrial goods (other than food or feed) composed in whole or in significant part of biological products, forestry materials, or renewable domestic agricultural materials, including plant, animal, or marine materials;

"bulk refill products" means a system where a dispensing unit is used with sealed refill cartridges or pouches. Sanitary sealed systems typically use individual bags that come with their own dispensers. The bags are inserted into a casing or "box" — either counter-mounted or wall-mounted — and are simply removed and replaced in full when they are empty. In addition to sealed dispensers, cartridge refill dispensers are also a possible alternative to traditional refill dispensers. Cartridge dispensers are counter-mounted or wall-mounted, and contain all working parts within the refill cartridge, so each refill is really a complete replacing of the working mechanisms within the dispenser. Open refill systems are not accepted since they can lead to product contamination.

"carbomer thickeners" means linear polyacrylates and crosslinked polyacrylates;

"endocrine disruptor" means an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. Candidate endocrine disruptors are listed in Appendix 1 of Towards the Establishment of a Priority List of Substances for Further Evaluation of Their Role in Endocrine Disruption prepared for the

European Union;

"post-consumer" means material that has served its end-use at the consumer level, has been discarded by the consumer, and unless diverted, would enter the waste stream;

"primary packaging" means the material physically coming into contact with and containing the product;

"PVC" means polyvinyl chloride, an industrial plastic derived from the polymerization of vinyl chloride, also known as chloroethene (CH2CHCl);

"quaternary ammonium compound" or "quat" means an active ingredient used in disinfectants, that chemically is an organic nitrogen compound in which a central nitrogen atom is joined to four organic cations and one anionic acid radical. Such compounds include, inter alia, alkyl dimethyl benzyl ammonium chloride and didecyldimethylammonium chloride, benzalkonium chloride, benzethonium chloride, methylbenzethonium chloride;

"recyclable material" means material that can be diverted from the waste stream through available processes and programs, and can be collected, processed, and returned to use in the form of raw materials or products;

"readily biodegradable" for a component, is determined using any of the six test methods described in OECD Guidelines for Testing of Chemicals, 301A-301F; for a whole formulation, is determined using one of the methods described in OECD Guidelines for the Testing of Chemicals, provided that all measurements and calculations are based on the carbon content of the mixture and its degradation, i.e. dissolved organic carbon (DOC) removal (301A or 301E), CO2 evolution (301-B) or oxygen consumption in the presence of an inhibitor of nitrogen metabolism (301C, 301D or 301F);

"secondary packaging" means any packaging material other than primary packaging, including wrappers, boxes, and blister packs, but excluding shipping containers.

Additional Questions

Question 11: EcoLogo™ standards are established so that the top 20-30 percent of products or services within a specific category can achieve certification. Do you believe there is enough separation in the product category of *instant hand antiseptic products* to rationalize the existence of an environmental leadership standard such as EcoLogo™? Why?

Very few stakeholders responded to this question. Most of them did not know or abstained from commenting. Some notable comments were:

- "…While the professional instant hand antiseptic category is defined largely by regulatory requirements, there exists an opportunity for environmental improvements across the life cycle of instant hand sanitizer products that can be addressed with an environmental leadership standard…"

- "…If certain revisions are taken into account during the authoring of this document, it is plausible that there is value to such a standard. However, the standard, as written eliminates any separation in this category. Innovative products will be excluded; and, differentiation between certified products will be impossible…"

- "…-Selon les critères proposés, il n'y a à mon avis que les désinfectants à base d'alcool qui pourront les rencontrer s'ils sont tous maintenus de cette façon…" ***Translation by EcoLogo Program*** "… If the current criteria are maintained, then I believe that only alcohol-based disinfectants will be able to meet the criteria …"

- "… à mon avis cette catégorie n'est pas nécessaire puisque la quantité de produit qui se retrouve dans l'environnement est faible et sous forme d'évaporation volatile qui ne fais même pas partie d'un critère particulier. Les contenants utilisés par l'industrie sont assez standards et les critères proposés n'apportent pas réellement de contraintes sur cet aspect. Le choix d'un produit de ce type, de même que d'un désinfectant, devrait se faire en fonction des besoins en désinfections ou en assainissement et non sur la base d'une certification écologique…" ***Translation by EcoLogo Program*** "… In my opinion this category is not necessary since the quantity of products that ends up in the environment is small and mostly evaporates for which currently no criterion has been proposed. The containers used by industry are standard and the proposed criteria do not really constrain this aspect. The choice of this type of products, as well as disinfectants, should be a function of disinfectant or sanitizing needs and not based on a ecological certification …"

- "… Il y a tellement de rejets nocifs en grandes quantité dans l'environnement, pourquoi perdre du temps à certifier des produits marginaux pour lesquels le respect des critères n'aura que très peu d'effets notables. Ce genre de catégorie risque de faire perdre de la crédibilité aux autres catégories où l'impact est réel et important…" ***Translation by EcoLogo Program*** "… There are so many toxic discharges found in large quantities in the environment, why waste time certifying marginal products for which compliance of criteria will have very little notable impacts. This type of category poses risk to discredit the other categories where impacts are real and important …"

The first published document in the development of an EcoLogo standard for instant hand antiseptic products was a Discussion Document. Following stakeholder comments, and additional research, some changes have been made to the proposed criteria statements, and new criteria have been proposed. The EcoLogo Program will now submit a first draft standard to stakeholders and following comments will re-asses whether the standard represents environmental leadership. This question of will be asked again at every new draft of a potential standard.

Question 12: Do you believe this Discussion Document has addressed the main important aspects that are necessary to establishing an environmental leadership standard for *instant hand antiseptic products?*

Only four stakeholders responded to this question; 50 percent responded yes and 50 percent responded no. Stakeholders provided multiple recommendations that were essential in order to move toward the objective of establishing an environmental leadership standard for *instant hand antiseptic products*. This question of will be asked again at every new draft of a potential standard.