16 May 2007

Canadian Implementation of the
Globally Harmonized System of Classification & Labelling of Chemicals

Ad hoc Expert Group for Chronic Hazards for Consumer Chemicals

2007 Summary of Expert Group Deliberations For Chronic Hazards for Consumer Chemical Products

Issue

1. As part of the implementation of the Globally Harmonized System of Classification and Labelling (GHS) in Canada, consideration must be given to whether chemical products[1] under the *Consumer Chemicals and Containers Regulations*, 2001 of the *Hazardous Products Act,* should include consideration of the GHS chronic hazard classes, i.e., respiratory or skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity, and target organ toxicity – repeated dose (UN GHS document, Chapters 3.4, 3.5, 3.6, 3.7, 3.9 respectively). Currently, consumer chemical products are not classified for these hazard classes.

Current Canadian Regulatory System and approach to chronic labelling:

Hazardous Products Act: Consumer Chemical and Container Regulations, 2001

2. The *Consumer Chemicals and Containers Regulations, 2001, (CCCR, 2001),* do not currently address the chronic or subchronic toxicity hazards posed by consumer chemical products.

3. During the review and development of the CCCR, 2001, it was recommended that a Working Group or some other group be established to continue work on the development of chronic and subchronic toxicity criteria.

4. In 1993, the Canadian Centre of Occupational Health and Safety (CCOHS) was contracted to examine the chronic and subchronic toxicity for consumer chemical products. The final report concluded that product usage patterns in some product areas posed a potential for chronic and subchronic exposures. The product areas were arts and crafts materials, home repair, maintenance and renovation and automotive and boat repair and maintenance.

[1] Part II of Schedule I of the *Hazardous Products Act* includes chemical products as defined in the *Consumer Chemicals and Containers Regulations, 2001*.

5. Further work related to chronic and sub-chronic toxicity hazards for consumer chemicals was put on hold until the finalization of the GHS criteria for respiratory and skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity, and target organ toxicity – repeated dose.

Current International Situation

US: Consumer Product Safety Commission

6. The *Federal Hazardous Substances Act* (FHSA, July 12, 1960) 15 U.S.C. 1261-1278 includes all chemicals in home and schools except: Pesticides (FIFRA), Food, Drugs, and Cosmetics (FDCA), Tobacco and Tobacco products, and Nuclear material (AEA). The FHSA defines a hazardous substance as: Any substance or mixture of substances which
   (i) is toxic,
   (ii) is corrosive,
   (iii) is an irritant,
   (iv) is a strong sensitizer,
   (v) is flammable or combustible, or
   (vi) generates pressure through decomposition, heat, or other means,
   if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children."

7. Concerning the classification of substances or mixtures, the FHSA incorporates likelihood of harm and therefore risk consideration is needed for carcinogenicity, including mutagenicity, reproductive toxicity, target organ toxicity - repeat exposure, respiratory and skin sensitization

European Union

8. In the European Union, hazard information through labelling is provided on consumer chemicals. This hazard information includes the following chronic hazards: mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitization, and target organ systemic toxicity – repeated dose. The European Substances and Preparations Directives are applicable to both consumer and workplace chemicals.

Considerations

9. The ad hoc Expert Group was formed to examine whether the regulations for consumer chemical products should include consideration of the GHS chronic hazard classes i.e., mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitization, and target organ systemic toxicity – repeated dose? If so, which hazard classes and categories should be covered? And how should these be covered?

10. The objectives of the Canadian implementation of the GHS include:

    a. Harmonization to the greatest extent possible between the sectors; and
    b. Harmonization to the greatest extent possible between the NAFTA partners.

Options

11. For each hazard class and hazard category within each hazard class, the options for assessment include:
    1. Risk-based approach
    2. Hazard-based approach

Risk-Based Approach

Description:

12. The GHS (Hazard Communication: Labelling Chapter 1.4; Annex 4 of the GHS document provides the option for consumer product labelling based on the likelihood of injury. The following describes an integrated approach using both the results of hazard classification and predicted consumer exposure that occurs as a result of proposed and foreseeable product use to determine the hazards to be communicated on consumer product labels. The approach is based on knowledge about how the product is used by the consumer and the likelihood that harm could occur under proposed and foreseeable use conditions. The approach is consistent with the current principles used by US CPSC in determining hazards, and determining likelihood of harm, and labelling of hazardous consumer products. Additionally, the basic principles employed in determining the likelihood of harm are consistent with the risk-assessment approaches used nationally in Canada (CEPA chemical reviews) and internationally in making decisions about the safe use of chemicals.

3 Step Approach

Step 1: Classification

13. The approach starts by determining whether or not the consumer product meets the GHS criteria for classification for any specific chronic endpoint based on the properties of the product and/or its components.
    - If the consumer product does not meet the classification criteria, the product is not classified per GHS, and hazard communication is not required.
    - If the consumer product meets the criteria for hazard classification for one or more of the chronic endpoints, the product is classified accordingly and one proceeds to Step 2 of the proposed approach.

Step 2: Determining the Likelihood of Injury

14. The purpose of this step is to determine the likelihood of injury for each of the chronic endpoints for which the consumer product is classified based on GHS criteria. This step has a number of critical components:

a. **Determine consumer exposure to the classified consumer product including the exposure to the classified substance.**

A stepwise approach for determining consumer exposure to the classified substance in a classified consumer product is suggested.

- The first step is a qualitative assessment to determine whether or not there is relevant exposure to the classified substance, based on the route of exposure or the physical properties of the classified product or the classified substance. If there is no relevant exposure then one can conclude that GHS hazard labelling is not required. For example if a chronic effect is produced only by a specific route of exposure and there is no potential for that route of exposure to occur or due to the physical chemical properties of the classified product or substance exposure will not occur then one can conclude that GHS hazard labelling is not required. If it is determined that relevant exposure occurs, then one can either proceed to step 2 or go directly to step 3.
- In step 2 it is assumed that the consumer is exposed to the total amount of the classified substance in the container in a single day and that all the substance is absorbed (this is extremely unrealistic for many consumer products) and then one determines whether or not there is a likelihood of injury under these assumptions. If it is concluded that likelihood of injury will not occur then one can conclude that GHS hazard labelling is not required. If it cannot be concluded under these highly unrealistic conditions that likelihood of injury will not occur then one proceeds to step 3 to determine consumer exposure under realistic exposure conditions.
- In step 3 consumer exposure is determined based on specific knowledge about actual use of the product (amount of product used per day, length of exposure, exposure route etc.). If it can be determined that likelihood of injury will not occur under foreseeable consumer use conditions then no hazard labelling is required. If it is determined that likelihood of harm will occur in step 3 then GHS hazard labelling of the product is required.

b. Determine the exposure level (based on the general, scientific risk-assessment principles employed nationally and internationally) that is unlikely to cause injury/ harm to humans (e.g., Allowable Daily Intake-ADI, Tolerable Daily Intake-TDI).

c. Determine whether or not the exposure to the classified product under conditions of proposed or foreseeable use is greater than the exposure that is unlikely to cause injury/ harm in humans (ADI, TDI). For exposure greater than the ADI,

TDI, proceed to Step 3: Hazard Labelling. If the exposure is below or equal to the ADI, TDI, no hazard labelling is required.

Step 3: Hazard Labelling

15. Communicate on the label information about any inherent hazards in the product as designated by authoritative agencies.

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16. Use the GHS the standardized label elements (symbols, signal words, hazard statements) as well as the other required label elements and the principles outlined in the GHS document.

Note: Risk assessment standards would need to be developed and agreed. This could include consideration of internationally agreed risk assessment standards, risk assessment standards used elsewhere (e.g. CPSC) and CEPA risk assessments (as they become available).

Hazard-Based approach

Description

17. Chemicals are classified according to the GHS classification criteria for mutagenicity, carcinogenicity, reproductive toxicity, respiratory sensitization, skin sensitization, and target organ toxicity – repeated dose effects.

Classification

18. The approach starts by determining whether or not the consumer product meets the GHS criteria for classification for any specific chronic endpoint based on the properties of the product and/or its components.
    - If the consumer product does not meet the classification criteria, the product is not classified per GHS, and hazard communication is not required.
    - If the consumer product meets the criteria for hazard classification for one or more of the chronic endpoints, the product is classified accordingly and labelling is required.

Labelling Options

19. Use the GHS the standardized label elements (symbols, signal words, hazard statements) as well as the other required label elements and the principles outlined in the GHS document.

Hybrid Approach

Description

20. Chemicals are classified according to the GHS classification criteria for mutagenicity, carcinogenicity, reproductive toxicity, respiratory sensitization, skin sensitization, and target organ toxicity – repeated dose effects. If exposure thresholds exist, GHS hazard labelling requirements can be supplemented with a risk statement regarding likelihood of injury.

Classification

21. The approach starts by determining whether or not the consumer product meets the GHS criteria for classification for any specific chronic endpoint based on the properties of the product and/or its components.

- If the consumer product does not meet the classification criteria, the product is not classified per GHS, and hazard communication is not required.

- If the consumer product meets the criteria for hazard classification for one or more of the chronic endpoints, the product is classified accordingly and labelling is required.

- If substance/mixture can be classified, labelling based on GHS requirement

Labelling

- Use the GHS the standardized label elements (symbols, signal words,hazard statements) as well as the other required label elements and the principles outlined in the GHS document.
- If exposure thresholds exist, GHS hazard labelling requirements can be supplemented with a risk statement regarding likelihood of injury.

Summary of Expert Group Discussions

Agreements

23. The agreements reached to date include:

- Chronic hazards should be considered for consumer products.
- Risk assessment is not appropriate for germ cell mutagenicity, i.e. no exposure thresholds exist and therefore, this hazard class will use the GHS criteria and hazard communication elements.
- If a risk assessment cannot or is not conducted, then by default, the labelling will be hazard-based according to the GHS

24. No consensus whether exposure thresholds exist for carcinogenicity, reproductive toxicity including developmental toxicity.

Stakeholder Positions

Labour Sector

Chronic Hazard Labelling: Canadian Labour Congress

Background:

The Canadian Labour Congress (CLC) is the largest democratic and popular organization in Canada with over three million members. The Canadian Labour Congress brings together Canada's national and international unions, the provincial and territorial federations of labour and 136 district labour councils.

With roots everywhere in Canada, the labour movement plays a key role in ensuring that Canadians enjoy a quality of life that is the envy of the world.

Active in every aspect of the economic, social and political life of Canadians, we speak for our millions of members as both workers and consumers. Consumer right to know what hazardous chemicals they may be exposed to in their home environment is as important to our members as our hard fought for and won rights to know in the workplace.

Labour position

The committee reviewing the labeling of chronic hazards came to a basic agreement that hazard based labeling should be required when exposure thresholds could not be confidently determined. It was agreed that this would apply to germ cell mutagens, genotoxic carcinogens, and sensitizers.

It was also the position of two stakeholder groups, namely labour, and the Non-governmental Public Interest Sector, that thresholds cannot be accurately or confidently determined for GHS classified carcinogens category 1&2 which includes many so-called "non genotoxic" carcinogens, for example "epigenetic" carcinogens, where thresholds have not been determined. (It is useful to remind ourselves that dioxin is not a "genotoxic carcinogen" yet all responsible authorities would ban or restrict its use and certainly respect public right to know. Similarly with ASBESTOS, where bans and product labeling are required)

In addition, thresholds for certain GHS classified reproductive hazardous chemicals cannot be adequately determined, for example endocrine disrupting chemicals.

Therefore the essence of the disagreement between labour and the public interest NGO compared to the chemical producers stakeholders is over the issue of thresholds of exposure for certain end points, namely CMRS.

The CLC proposes that in order to move forward, we consider a hybrid system: for CMRS, adopt the GHS classification and labeling elements and where there is test data available demonstrating a threshold of exposure for that endpoint, a risk based label statement will be added.

Where the data cannot demonstrate this, such a statement would not be allowed.

If one understands the threshold discussion, it becomes clear that the risk-based approach is not appropriate for certain hazard classes. Calculation of Allowable Daily Intake (ADI's), for example, cannot be meaningful for carcinogens, mutagens, sensitizers, and endocrine disrupting chemicals. In addition, consumer use and exposure varies substantially, with some using multiple containers of these products over a lifetime, some using these products daily, and some, for example housecleaners, using these products multiple times per day.

To capture the general principle, the agreement of the committee should be properly worded:

> Risk assessment is not appropriate for categories where exposure thresholds cannot be accurately determined or do not exist and therefore, these hazard categories will use the GHS criteria and hazard communication elements.

GHS communication criteria are based on an inherent hazard classification system. A strictly GHS application to consumer chemical products would require full disclosure of all hazardous ingredients meeting the classification criteria established, if concentration cut-offs were met. In addition, standard hazard phrases would be used, as will be done on workplace chemical labelling. Responsible authorities have the option to develop an application of GHS in this area also using risk based systems of labelling. These two options are often seen as contradictory and irreconcilable. However it is possible to blend both GHS hazard based classification with a communication strategy that combines inherent hazard identification with risk management assessments.

Consumer chemicals and chemical mixtures would initially be classified according to the GHS criteria. For acute hazard classes, the current CCCR addresses both the nature of the potential health hazard and the risk. This is because for most acute hazards, clear thresholds of exposure can be determined. This is not the case for chronic endpoints of concern. For chronic hazard classes a combined approach is possible.

Canada has endorsed the precautionary principle for a number of years, as elaborated in both national and international fora. See for example the NREE, CEPA, and the Best Practices Review of the Canadian Strategy for Cancer Control:

Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. CSCC 2005[b])

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[b] Resolution of the European Council of Nice, December 2000 COM (2000) 1, 2.2.2000

For certain chronic health endpoints and chemicals, exposure thresholds cannot be (or have not been) reliably established as discussed above for CMRS. In addition, there exist internationally applied classification lists for many chemicals where there is scientific evidence that they are known, or presumed, CMRS.
The European Community has applied these lists to consumer chemicals the most systematically. However, other jurisdictions have also moved towards greater disclosure and selective prohibitions.

Application

A Canadian application of GHS to consumer chronic chemical hazards should refer to entries from the following lists when considering the disclosure, supplemental information, and restrictions on use:

- IARC (Category 1 and 2) known, presumed, and suspected human carcinogens
- ACGIH 1/2)
- CEPA Toxics
- EC Directives and Schedule on restricted chemicals and consumer products
- EU and U. S. State jurisdiction listings for developmental toxicants and sensitizing agents
- HC (with an expert advisory committee representing stakeholders) would review these lists and establish a Canadian equivalent.

For CMRS disclosure supplemental information would be required. Supplemental information should utilize standard hazard and risk phrases. Where there exists reliable scientific evidence that certain thresholds of exposure exist, this would be disclosed. Where this cannot be established further restrictions would be considered. This may range from concentration limits, to restrictions from certain classes of consumer products (e.g., those products where children may be particularly exposed, and personal care products. A Canadian example is the restriction on lead in toy jewellery, arsenicals in playground and domestic use wood structures.

It has been argued that risk assessment is the basis for assessments currently done by Health Canada under CEPA. However, it must be stated that Health Canada has designed its assessment protocols and strategies for another purpose: determining if a chemical should be restricted from use. Assessment for the purpose of respecting simple disclosure to the public, i.e. public right to know should be hazard based, along with appropriate precautionary statements based on reliable scientific evidence of potential harm. This position is in consensus with the approach taken by the European Community and a number of US State jurisdictions.

Conclusion

In summary this proposal accomplishes a number of objectives. It:

- Effectively addresses concerns regarding chronic health hazards, (exposure to CMRS)
- Moves towards international harmonization with respect to classification, communication standards, and precautionary restrictions
- Utilizes internationally referenced classification and disclosure standards
- References risk assessments ,where reliable and available
- Proposes a stakeholder advisory committee
- Allows for supplemental information reflecting precautionary approach to hazard communication as well as risk assessment information where reliable and available
- Demonstrates Canadian leadership in application of GHS to consumer product sector

Risk based consumer product labelling is a status quo that is unacceptable from both a public and scientific perspective. Canada has given international leadership to the development of the GHS. It must continue to give leadership through the implementation stage…especially within Canada itself.

On Behalf of its Affiliated Trade Unions and over Three Million Members,

Canadian Labour Congress
May 01.07

Non-governmental Public Interest Sector

Position submission to Health Canada
Chronic Hazards for Consumer Chemical Labeling
May 11, 2007

Submitted by Mae Burrows
Non-governmental public interest sector

Background
Health Canada has been managing a consultation process with various expert stakeholders from labour, public interest, and chemical manufacturers and distributors with a goal to find consensus on labeling chronic hazard chemicals in consumer products in Canada. This process has been called the Ad Hoc Expert Working Group: Chronic Hazard Implementation of Global Harmonization System: Chronic Hazards for Consumer Chemicals. The Labour Environmental Alliance Society (LEAS) through Mae Burrows has been representing the non-governmental public interest sector.

The group has arrived at consensus on the need to label products for chronic health hazards but could not arrive at consensus as to whether labeling would occur only when there was a *proven risk* to the consumer when exposed to the chemical in the product (*risk based management*) or if labeling was to occur if there was a *known hazardous chemical* (carcinogen, reproductive or developmental toxicant, or sensitizer) present in the product (*hazard based* labeling). The exception to this was consensus that germ cell mutagens would be labeled because safe thresholds of exposure cannot be determined.

Since the working group could not arrive at consensus on risk or hazard-based labeling, the sectors are submitting their views in a position paper. These position papers will be sent to Health Canada, as well as the Consumer Products Sectoral Working Group.

Public interest position
Recent public surveys by LEAS clearly show that Canadians are demanding that they are able to exercise their right to know by having labeling that informs of known and potentially toxic materials in consumer products. It is the view of the Non-Governmental Public Interest sector, as represented in the following signed organizations that products containing hazardous chemicals should have:

- Full ingredient disclosure and hazard labeling of hazardous chemicals contained in consumer domestic-use manufactured products
- *Hazard labeling, using distinct symbols or letters for each hazard class, for all ingredients designated as carcinogens (labeled "C"), reproductive toxicants ("R) and mutagens ("M") according to IARC (Group 1, 2A, 2B) or the OEHHA (P65), reproductive and developmental toxicants' ("D") according to P65 or the EU CMR list, as well as endocrine disrupting chemicals ("EDs") listed EU and EPA, and sensitizers as listed in the EU directives and other reviewed lists acceptable to the international community. This would be in addition to current hazard labelling that indicates*

corrosive, flammable or explosive ingredients. In the alternative, Canada may consider adoption of the GHS standard symbols and hazard phrases for all these categories

- Plain English and French prescribed risk phrases to accompany hazard symbols, such as "the ingredient methylene chloride in this product has been designated as a possible human carcinogen."

The rationale

- Consumers should have the same rights as employees in the workplace when it comes to exposure to hazardous chemicals in products. In the workplace, employees have a right to see full disclosure of ingredients in products that contain hazardous chemicals. They also have the right to be informed if any of those ingredients are classified as carcinogens, reproductive or developmental toxicants or sensitizers. Consumers should have that same right. MSDS are not available to consumers, nor required. Further, there is no system in place to ensure MSDS accuracy, nor education and training in their use. Consumer label information needs to address these gaps through full disclosure of hazardous ingredients and clear symbols.
- Health Canada's priority should be to develop and enforce regulations to protect the health of Canadians. Ingredient and hazard labelling fulfills consumers' right to know what chemical ingredients they may be exposed to and the potential health hazards associated with using them; however Health Canada's obligation to protect Canadians does not end with labeling hazardous chemicals in products. Control and bans of hazardous chemicals would be the next direct and required step.
- Hazard-based labeling would follow the Precautionary Principle that states "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically"
- Disclosure of potentially toxic ingredients allows for consumer education about ingredient safety and toxicity as well as environmental sustainability and helps encourage the market for safer, environmentally preferable products.

Signed by:
Mae Burrows, Labour Environmental Alliance (LEAS) and CancerSmart Consumer
Kathleen Cooper, Canadian Environmental Law Association
Dr. Warren Bell, Canadian Association of Physicians for the Environment
Angela Rickman, Prevent Cancer NOW Coalition
Andrea Reimer, Western Canada Wilderness Committee
Deena Dlusy-Apel, Breast Cancer Action Montreal
Heather Logan, Canadian Cancer Society (sign-on by way of attached letter)

May 8, 2007

Ms. Mae Burrows, Executive Director
Labour Environmental Alliance Society
1203-207 West Hastings Street, Vancouver, BC
Canada V6H 1H7

SUBJECT: HAZARD BASED LABELLING

Dear Mae,

Thank you to learn more about the work of Health Canada's Multi-Sectoral Expert Advisory Committee and your role as a non-governmental Public Interest Representative on that group. The Canadian Cancer Society is aware of the position paper regarding hazard based labeling that was drafted by the Labour Environmental Alliance Society for submission to Health Canada, and offers the following comments in support:

1. The Canadian Cancer Society is supportive of hazards based labeling of all manufactured consumer based products in Canada. The announcement of Cosmetic Regulations in November 2006 was an important step forward in providing clear, understandable information for Canadians to enable them to make informed choices. The Society strongly believes that this approach must be expanded to include all manufactured consumer based products in Canada that informed consumer choice.

2. The Canadian Cancer Society's comments and support are limited to that part of the LEAS position paper that related to carcinogenicity and endocrine disruption, given that they are both within the mandate of the Canadian Cancer Society to address. While important to overall health, comments regarding the appropriateness of reference lists and labeling products with known mutagenic agents and/or reproductive toxins are outside the mandate of the Canadian Cancer Society.

The Canadian Cancer Society is committed to consumer product labeling and to identifying, in partnership with organizations like the Labour Environmental Alliance Society and the National Committee on Environmental and Occupational Carcinogens, potential models for a pan-Canadian approach to labeling. A single best practice has not yet been identified or endorsed by the Canadian Cancer Society.

Thank you for the opportunity to comment on the draft position paper on hazard based labeling and to contribute to your efforts to ensure informed consumer choice. If there are opportunities to engage in this discussion with Health Canada's multi-sectoral Expert Advisory Committee in the future please do not hesitate to let me know.

Sincerely,

Heather Logan
Director, Cancer Control Policy
Canadian Cancer Society

Industry Sector

CCSPA CANADIAN CONSUMER SPECIALTY PRODUCTS ASSOCIATION®
ACPCS L'ASSOCIATION CANADIENNE DE PRODUITS DE CONSOMMATION SPECIALISÉS®

May 11, 2007

Kim Headrick
International Harmonization and Senior Policy Advisor
Health Canada, Policy and Program Services
123 Slater Street
Ottawa, Ontario K1A 0K9
Fax: (613) 946-1100

Dear Ms. Headrick,

Following our April 3, 2007, teleconference to discuss the issue of GHS chronic hazard labeling, we resolved as a group to submit our respective positions concerning the need and manner in which chronic hazard labelling of consumer chemical products should be implemented in Canada. Please consider this letter and attachments as representative of the position of the industry members of the Ad Hoc Chronic Hazard Labelling Expert Work Group.

CCSPA is a national trade association that represents over 40 member companies across Canada, collectively a $20 billion industry directly employing 12,000 people. Our companies manufacture, process, package and distribute consumer, industrial and institutional specialty products such as soaps and detergents, pest control products, aerosols, hard surface disinfectants, deodorizers and automotive chemicals.

CCSPA's position on implementation of GHS for chronic endpoints for consumer is that the option to consider likelihood of injury as provided in the official GHS text be employed. Additionally, our position is based on the overall assumption that all of the principles embodied in the official GHS text will be included in Canada's implementation of the GHS for chronic endpoints. These include, for example, use of a weight–of–evidence approach, maximum use of existing data, precedence of human experience, self classification and meeting the needs of the different users/target audience.

I trust that our comments will be helpful and informative. If you require clarification on any of the comments we have provided, please contact me.

Sincerely,

Bruce Rebel
Director, Regulatory Affairs

Industry members of the Ad Hoc Chronic Hazard Labelling Expert Work Group

Stephen Rathlou	SC Johnson & Sons Canada
Karen Kohrman	Proctor and Gamble Inc
Jacqui Jenskey	Quixtar Canada
Bruce Rebel	Canadian Consumer Specialty Products Association

CCSPA and Industry Position Supporting a Risk-Based Approach to Labelling

After having reviewed the deliberations and comments provided by the work group and considered external expert documents regarding labelling of consumer products it is our opinion that the risk-based approach (i.e., likelihood of injury option - as provided in the official GHS text - to the labelling of chronic hazards for consumer products) is the best approach for informing consumers/users of the hazards a product poses.

We support the following areas and recommend that the government adopt them in its implementation of GHS for consumer chemical products in Canada:

- Chronic hazards should be considered for consumer products.
- Use the risk-based approach – likelihood of injury option – as provided in the official GHS text to determine labelling for chronic hazard whenever possible.
- When a risk assessment is not done (e.g., when exposure cannot be determined or when there is no threshold, like for germ cell mutagenicity), then use hazard as the basis for determining the labelling.

A risk-based approach provides for the integration of hazard and exposure that occur as a result of normal and foreseeable product use. This, in turn, determines the hazards that need to be communicated on consumer product labels. This approach is based on knowledge about how the product is used by the consumer and the likelihood that harm could occur under proposed and foreseeable use conditions. Risk-based approaches are scientifically robust because they integrate both hazard and exposure information. By utilizing a risk-based approach, relevant and actionable information is placed on the label, thereby enhancing comprehensibility and encouraging proper action by the consumer. Risk-based labelling prevents unnecessary labelling that erodes consumers' attention to critical warnings on the label, resulting in a lessening of protection.

Several studies have demonstrated that the more information placed on a label, the more crowded and cluttered it becomes, and the more difficult it will be for consumers to determine the hazards a product may pose (Vi scusi, 1991; Frantz et al., 1999). At the WHMIS Central Issues Committee meeting held on March 15, 2007, a representative of the Canadian Centre for Occupational Health and Safety (CCOHS) shared the preliminary results of a study they had conducted which demonstrated:

1. the amount of print located on a label is an issue for comprehensibility and
2. the need for white space (blank space surrounding the hazard information and symbols) was just as critical to the ability of consumers to accurately absorb the hazard information being conveyed.

Chronic hazard-based labeling without regard to risk does not provide the consumer with information that will enable them to distinguish between products that are likely to cause harm from those that are not. Thus, the consumer is unable to make better informed decisions about the products they choose to use. Basing the labelling on hazard alone will lead to excessive hazard warnings on product labels, which can lead to a decrease in the effectiveness of warnings that truly enhance protection. Consumers become desensitized to warning labels and caution statements because of their proliferate use.

One aspect that must be reinforced is that GHS is a system for the classification and communication of hazard. It is not a chemical management system. Canada has a comprehensive process for dealing with legacy and new chemicals in the *Canadian Environmental Protection Act* (CEPA). The process utilized in the assessment of chemicals under CEPA is based on the same principles of risk assessment (hazard + exposure = risk) that we are proposing as a means of implementing the chronic hazard labeling component for GHS. By utilizing the risk-based approach in our implementation of GHS, we would be consistent with other Canadian government initiatives and within Health Canada itself.

CCSPA has previously written to both the Minister of Health and officials within Health Canada for the need to harmonize our implementation of GHS with the United States of America, our major trading partner. In February 2006, the U.S. *Consumer Protection Safety Commission* released a policy statement reaffirming their commitment to implementing a risk-based approach to the labellling of consumer products, *"In particular, with respect to the labeling of chronic health hazards in the consumer product setting, the Commission intends to follow the risk-based labelling option specified under Annex 5 of the GHS."* (http://www.cpsc.gov/phth/GHSpolicy.html) Both countries have mature hazard communication systems in place. To replace each of our current hazard communication systems with a non-harmonized GHS system would be of no benefit to consumers given the highly integrated North American market place for consumer products.

Appendix I – Risk-based Approach Model

Description:

The GHS Hazard Communication: Labelling Chapter 1.4; Annex 4, of the GHS document provides the option for consumer product labelling based on the likelihood of injury. The following describes an integrated approach using both the results of hazard classification and predicted consumer exposure that occurs as a result of proposed and foreseeable product use to determine the hazards to be communicated on consumer product labels. The approach is based on knowledge about how the product is used by the consumer and the likelihood that harm could occur under proposed and foreseeable use conditions. The approach is consistent with the current principles used by the US CPSC in determining hazards and the likelihood of harm and the labelling of hazardous consumer products. Additionally, the basic principles employed in determining the likelihood of harm are consistent with the risk assessment approaches used nationally in Canada (CEPA chemical reviews) and internationally in making decisions about the safe use of chemicals.

Step Approach

Step 1: Classification

The approach starts by determining whether or not the consumer product meets the GHS criteria for classification for any specific chronic endpoint based on the properties of the product and/or its components.

- If the consumer product does not meet the classification criteria, the product is not classified per GHS; and hazard communication is not required.

- If the consumer product meets the criteria for hazard classification for one or more of the chronic endpoints, one proceeds to Step 2 of the proposed approach.

Step 2: Determining the Likelihood of Injury

The purpose of this step is to determine the likelihood of injury for each of the chronic endpoints for which the consumer product is classified based on GHS criteria. This step has a number of critical components:

a. Determine consumer exposure to the classified consumer product including the exposure to the classified substance.

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- The first step is a qualitative assessment to determine whether or not there is relevant exposure to the classified substance, based on the route of exposure or the physical properties of the product or the classified substance. If there is no relevant exposure, then one can conclude that GHS hazard labeling is not required. For example, if a chronic effect is produced only by a specific route of exposure and there is no potential for that route of exposure to occur, then one can conclude that GHS hazard labeling is not required. If it is determined that relevant exposure occurs, then one can either proceed to step 2 or go directly to step 3.

- In step 2, it is assumed that the consumer is exposed to the total amount of the classified substance in the container in a single continuous use session and that all the substance is absorbed (this is extremely unrealistic for many consumer products). One then determines whether or not there is a likelihood of injury under these assumptions. If it is concluded that

likelihood of injury will not occur, then one can conclude that GHS hazard labeling is not required. If it cannot be concluded under these highly unrealistic conditions that likelihood of injury will not occur, then one proceeds to step 3 to determine consumer exposure under realistic exposure conditions.

- In step 3, consumer exposure is determined based on specific knowledge about actual use of the product (amount of product used per day, length of exposure, exposure route, etc.). If it can be determined that likelihood of injury will not occur under foreseeable consumer use conditions, then no hazard labeling is required. If it is determined that likelihood of harm will occur in step 3, then GHS hazard labeling of the product is required.

- If consumer exposure cannot be determined, a hazard-based labeling approach needs to be employed.

b. Determine the exposure level (based on the general, scientific risk assessment principles employed nationally and internationally) that is unlikely to cause injury/harm to humans (e.g., Allowable Daily Intake-ADI, Tolerable Daily Intake-TDI).

c. Determine whether or not the exposure to the classified product under conditions of proposed or foreseeable use is greater than the exposure that is unlikely to cause injury/ harm in humans (ADI, TDI). For exposure greater than the ADI/TDI, proceed to Step 3: Hazard Labelling. If the exposure is below or equal to the ADI/TDI, no hazard labelling is required.

Step 3: Hazard Labelling

Communicate on the label only those hazards that are likely to cause injury during use as per the assessment above. Use the GHS standardized label elements (symbols, signal words, hazard statements) as well as the other required label elements and the principles outlined in the GHS document.

Note: Risk assessment standards would need to be developed and agreed. This could include consideration of internationally agreed risk assessment standards, risk assessment standards used elsewhere (e.g. CPSC) and CEPA risk assessments (as they become available).