**May 27, 2004 Teleconference of the Pest Control Products Sector Working Group (PSWG)**

**Discussion Guide For the Acute Toxicity Hazard Class**

## Background

This guide has been prepared to facilitate the technical discussions of the PSWG regarding the implementation of the Globally Harmonized System (GHS) in Canada. The following document describes (1) differences between the GHS and PMRA's current approach (2) options for the adoption of GHS categories and (3) the potential impact of the implementation of GHS. This discussion guide is not intended to be comprehensive of all the options available but presents options that are considered viable at this time.

Acute toxicity is one criterion used to ensure that the more hazardous products are not available in the DOMESTIC market class and that highly hazardous products are limited to the RESTRICTED market class. Market class $LD_{50}$ cut-off values are currently established for acute oral and dermal toxicity, but not for inhalation toxicity. There is, however, a provision that no special precautions or equipment (e.g. respirator) should be needed to mitigate hazard for a product destined for use in a domestic setting. There is a potential for market class realignment with the implementation of GHS.

The sectors have the option of incorporating different categories within the acute toxicity hazard class for each of the three routes of exposure. For example, categories 1-5 can be adopted for oral exposure and categories 1-4 can be adopted for dermal exposure. The following guide presents various options for the implementation of GHS. Refer to **Appendix 1** for a table which summarizes the impact of the options presented below for GHS implementation. Refer to the GHS Situational Analysis Document for Pest Control Products, Table 2, at http://www.hc-sc.gc.ca/ahc-asc/pubs/ghs-sgh/analys/index_e.html for a visual representation of the differences between the GHS cut-off values, signal words, and hazard symbols and the existing system used at PMRA.

## Acute Toxicity - Mixtures: (All Routes of Exposure)

Under the GHS, mixtures are classified according to the same criteria as substances when data are available for the complete mixture and classification will always be based on that data. When data are not available for the complete mixture, bridging principles are then applied. If this approach is not viable, the GHS specifies methods to estimate the acute toxicity of a mixture based on a formula that sums the contribution of each hazardous ingredient. The GHS accounts for the concentration of the unknown only when it is present in a concentration greater than 10%; otherwise it is not included in the formula.

Pesticide petitioners usually produce test data on the active ingredient (substance) as well as the end-use products (mixture) or they bridge to other similar products in order to identify acute hazards and determine the appropriate hazard labelling.

PMRA will consider the formula approach in the absence of toxicological data on the mixture.

**1. Acute Toxicity - Oral Exposure:**

Categories 1 and 2:

An $LD_{50}$ of 50 mg/kg bw is the threshold for category 2 of the GHS and also for the restricted class of products regulated by PMRA. Products within the RESTRICTED class are subject to specific limitations respecting their display, distribution, use or operator qualifications, due to high inherent toxicity or intended use in environmentally sensitive areas.

Category 3:

An $LD_{50}$ of 300 mg/kg bw is the threshold for GHS category 3 requiring the skull and crossbones symbol and signal word DANGER. The comparable threshold for pesticides and consumer chemicals is currently an $LD_{50}$ of 500 mg/kg bw. Products with $LD_{50}$ values between 301-500 mg/kg bw will be classified under GHS category 4 and require a change of signal words from DANGER to WARNING. Such pesticides, currently bearing a COMMERCIAL market class designation, might be considered eligible for the DOMESTIC market class.

In 1998, the PMRA performed an informal in-house analysis of acute oral toxicity data to gain a sense of the potential impact of this change. The assessment revealed that approximately 8% of pesticides bearing a COMMERCIAL market class designation have an acute oral $LD_{50}$ of 200-500 mg/kg bw. The number of products impacted by use of 300 mg/kg bw value is expected to be less.

Category 4:

The $LD_{50}$ values of GHS category range from 301 - 2000 mg/kg bw. Pesticides with $LD_{50}$ values in this range are currently labelled with the Skull & Crossbones symbol and a signal word, either DANGER, WARNING or CAUTION. Under GHS, hazard labelling for products in category 4 will be the exclamation mark symbol and the signal word WARNING.

Category 5:

Currently, PMRA does not have criteria equivalent to category 5 of the GHS.
The signal words "WARNING May be harmful if swallowed" would be required for products in category 5 ($LD_{50}$ 2000-5000 mg/kg bw) which would represent a change from the current PMRA approach (no hazard labelling).

**<u>Options for Acute Oral Toxicity:</u>**

Option 1: Adopt GHS categories 1 to 4 only

Rationale: Option 1 most closely reflects current PMRA practices.

Impact: As indicated above, labelling (signal word, hazard symbol) changes will be required where applicable, market class cut-off values may be realigned and the "formula" approach may be submitted as an alternative to toxicological data.

Option 2: Adopt all 5 GHS categories

Rationale: Option 2 expands the existing classification to include products of relatively low acute toxicity (category 5).

Impact: In addition to the impact of option 1, products which currently do not require hazard communication would require labelling in accordance with GHS. Companies may choose to submit data to demonstrate that their products have $LD_{50}$ values in excess of the Category 5 upper limit (i.e. $LD_{50} \geq 5000$ mg/kg bw). As a result, no hazard labelling would be required for this endpoint.[A]

**2. Acute Toxicity - Dermal Exposure:**

Category 1 and 2:

An $LD_{50}$ of 200 mg/kg bw is the threshold for category 2 of the GHS. The FPT Classification Working Group has proposed that a dermal $LD_{50}$ of 200 mg/kg bw prompt consideration of the RESTRICTED market class (which is currently triggered by a dermal $LD_{50}$ of 100 mg/kg bw). Products within the RESTRICTED class are subject to specific limitations respecting their display, distribution, use or operator qualifications, due to high inherent toxicity or intended use in environmentally sensitive areas.

Category 3:

An $LD_{50}$ of 1000 mg/kg bw is the threshold for category 3 requiring the skull and crossbones symbol and signal word DANGER. The comparable threshold for pesticides is currently an $LD_{50}$ of 500 mg/kg bw. Pesticides with $LD_{50}$ values between 500-1000 mg/kg bw would require a change of signal words from WARNING to DANGER when classified under GHS category 3.

The dermal $LD_{50}$ of DOMESTIC class pesticides must be greater than 1000 mg/kg bw.

[A] Two guiding principles of the GHS implementation in Canada are harmonization to the greatest extent possible between the sectors within Canada and NAFTA countries. It is important to note that the consumer chemical sector working group (CCSWG) anticipates that their NAFTA partners will adopt category 5 because the US Consumer Product Safety Commission originally proposed the inclusion of this category to cover a substance with relatively low acute toxicity but which under certain circumstances may pose a hazard to vulnerable populations such as children.

Category 4:

The $LD_{50}$ values for GHS category 4 are $LD_{50}$ 1001-2000 mg/kg bw. Pesticides with dermal $LD_{50}$ values in this range are eligible for the DOMESTIC market class. For products in GHS category 4, the current symbol and signal word (Skull & Crossbones; CAUTION) would change to the exclamation mark symbol (!) and WARNING signal word.

Category 5:

Currently, PMRA does not have criteria equivalent to category 5 of the GHS.
The signal words "WARNING May be harmful in contact with skin" would be required for products in category 5 ($LD_{50}$ 2000-5000 mg/kg bw) which would represent a change from the current PMRA approach (no hazard labelling).

**Options for Acute Dermal Toxicity:**

Option 1: Adopt GHS categories 1 to 4 only

Rationale: Option 1 most closely reflects current PMRA practices.

Impact: As indicated above, labelling (signal word, hazard symbol) changes will be required where applicable, market class cut-off values may be realigned and the "formula" approach may be submitted as an alternative to toxicological data.

Option 2: Adopt all 5 GHS categories

Rationale: Option 2 expands the existing classification to include products of relatively low acute toxicity (category 5).

Impact: In addition to the impact of option 1, Products which currently do not require hazard communication would require labelling in accordance with GHS. Companies may choose to submit data to demonstrate that their products have $LD_{50}$ values in excess of the Category 5 upper limit (i.e. $LD_{50} \geq 5000$ mg/kg bw). As a result, no hazard labelling would be required for this endpoint.

**3. Acute Toxicity - Inhalation Exposure:**

**Gases and Vapours**

Some pesticides, exist in solid or liquid form but under conditions of use (e.g. fumigants) liberate volatiles or gases when in contact with water or other materials. The acute inhalation hazard classification would be based on the liberated gas which represents the active form of the pesticide. Currently PMRA has no acute toxicity criteria for classifying gases and vapours, however, these pesticides would be restricted in use and the labels stipulate the requirement for the use of personal protective equipment (PPE) to mitigate any inhalation hazard.

Due to the toxic nature, restricted use and limited number of products which involve gases and vapours, PMRA will maintain the current approach. Products which liberate gases will be assessed on a case by case basis. Hazards will be communicated in accordance with GHS labelling and be mitigated with the requirement of PPE.

**Dusts and Mists**

Category 1 and 2:

An $LC_{50}$ cut-off values for GHS category 1 (0.05 mg/l) and 2 (0.5 mg/l) align with those currently used to identify whether a pesticide is labelled with the signal word DANGER or WARNING. Pesticides currently meeting the criteria for inclusion in category 2 would require a change of signal words from WARNING to DANGER.

Category 3:

An $LC_{50}$ of 1.0 mg/l is the threshold for GHS category 3 requiring the skull and crossbones symbol and signal word DANGER. The signal word on pesticides with $LC_{50}$ values of 0.5- 1.0 mg/l would require a change from CAUTION to DANGER. Products with $LC_{50}$ values between 1.1-2.0 mg/l will be classified under GHS category 4.

Category 4:

The $LC_{50}$ cut-off values of GHS category 4 span the range of slightly toxic ('CAUTION') and low toxicity (no hazard communication) products distinguished by PMRA. Products with $LC_{50}$ values between 1.1-5.0 mg/l will be classified under GHS category 4 and would require an exclamation symbol and the signal word WARNING. Currently, PMRA does not require hazard labelling for pesticides with acute inhalation $LC_{50}$ values exceeding 2 mg/l. Routinely, acute inhalation toxicity studies use a limit dose of 2 mg/l.

Category 5:

Currently, PMRA does not have criteria equivalent to category 5 of the GHS.
The signal words "WARNING May be harmful if inhaled" would be required for products in category 5 ($LC_{50} \geq 5.0$ mg/l) which would represent a change from the current PMRA approach (no hazard labelling).

**Options for Acute Inhalation Toxicity:** (Dusts and Mists)

Option 1: Adopt GHS categories 1 to 4 only

Rationale: Option 1 most closely reflects current PMRA practices.

Impact: As indicated above, labelling (signal word, hazard symbol) changes will be required where applicable, market class cut-off values may be realigned and the "formula" approach may be submitted as an alternative to toxicological data. Because GHS cut-off values differ from those used under current practices, products which currently fall above the 2.0 mg/l limit dose and do not require labelling would now require hazard communication for this endpoint in accordance with GHS. Companies may choose to submit data to demonstrate that their products have $LD_{50}$ values in excess of the Category 4 upper limit (i.e. $LC_{50}$ > 5 mg/l). As a result, no hazard labelling would be required for this endpoint.

Option 2: Adopt all 5 GHS categories

Rationale: Option 2 expands the existing classification to include products of relatively low acute toxicity (category 5).

Impact: By default, all products would require labelling due to the technical difficulties in generating a test atmosphere at a high enough respirable concentration to negate the hazard communication requirement. Other impacts noted under option 1 would also apply: the labelling changes, realignment of market class cut-off values and the "formula" approach.

Other:

1. To date aspiration hazard criteria has not been addressed under GHS. This issue will be revisited at a later date.