Appendix 1: Impact Analysis Document May 17, 2004

Hazard Class	Current Review			Changes required for GHS implementation			
	Hazard		Current Assessment	Symbols	Signal Words	Other	Potential Impact/Issues
	Assessed	Communicated					
Acute oral	✔	✔	-4 hazard categories -3 signal words: Danger, Warning, Caution (Poison) - skull & crossbones (S/CB) contained within 3 border shapes -exposure levels are combined with hazard assessment to determine whether there are risks associated with the use of the product -risk mitigation measures applied	-standardized border shape (♢) -new symbol (!) for many domestic products to replace S/CB	loss of "Caution" loss of "Poison" Retain: "Danger", "Warning"	- as the lowest toxicity category (LD_{50} 2000-5000 mg/kg bw) will now carry "Warning" and hazard statement *vs* none, there may be an ↑ in numbers of submissions as registrants may wish to test out (i.e. $LD_{50} \geq$ 5000 mg/kg bw) - eup: if registrants opt to use "formula" approach in lieu of submitting eup tox data, would be decrease in tox 6-packs but could increase workload for evaluators - Market Class safety criteria: GHS cut-off value for oral toxicity category 4 is slightly lower than PMRA's current cut-off value for eligibility in the Domestic market class; some pesticides currently bearing a COMMERCIAL market class designation would be considered eligible for the DOMESTIC market class	**Option 1: Adopt categories 1-4 only** - Maintains current practices **Option 2: Adopt all 5 categories** - Increase workload due to companies submitting data to "test out" (i.e. $LD_{50} \geq$ 5000 mg/kg bw) in order to negate hazard communication requirement **Regardless of Option:** - Labelling changes are required. - Impact of market class cut-off realignment - Potential increase in workload of "formula" approach option

Hazard Class	Current Review			Changes required for GHS implementation			
	Hazard		Current Assessment	Symbols	Signal Words	Other	Potential Impact/Issues
	Assessed	Communicated					
Acute dermal	✔	✔	-4 hazard categories -3 signal words: Danger, Warning, Caution (Poison) - skull & crossbones (S/CB) contained within 3 border shapes -exposure levels are combined with hazard assessment to determine whether there are risks associated with the use of the product -risk mitigation measure applied	- standardized border shape (♢) - new symbol (!) for many domestic products to replace S/CB	loss of "Caution" loss of "Poison" Retain: "Danger", "Warning"	- as the lowest toxicity category (Dermal LD_{50} 2000-5000 mg/kg bw) will now carry "Warning" and hazard statement *vs* none, there may be an ↑ in number of submissions as registrants may wish to test out (i.e. $LD_{50} \geq$ 5000 mg/kg bw) - eup: if registrants opt to use "formula" approach in lieu of submitting eup tox data, would be decrease in tox 6-packs but could increase workload for evaluators - market class cut-off values may need to be changed to align with those of the GHS	**Option 1: Adopt categories 1-4 only** - Maintains current practices **Option 2: Adopt all 5 categories** - Increase workload due to companies submitting data to "test out" (i.e. $LD_{50} \geq$ 5000 mg/kg bw) in order to negate hazard communication requirement **Regardless of Option:** - Labelling changes are required. - Impact of market class cut-off realignment - Potential increase in workload of "formula" approach option
Acute inhalation	✔	✔	-4 hazard categories -3 signal words: Danger, Warning, Caution (Poison) - skull & crossbones (S/CB) contained within 3 border shapes -exposure levels are combined with hazard assessment to determine whether there are risks associated with the use of the product -risk mitigation measure applied			- as the lowest toxicity category (Inhalation LC50 ≥5 mg/L) will now carry "Warning" and hazard statement *vs* none; by default all products would require labelling (Warning, etc.) due to the technical difficulties of generating a test atmosphere at high enough concentrations OR there may be an ↑ # subs as reg'ts may wish to test out (i.e. $LC_{50} \geq$ 5 mg/L w/ no deaths) - eup: if registrants opt to use "formula" approach in lieu of submitting eup tox data, would be decrease in tox 6-packs but could increase workload for evaluators - market class cut-off values may need to be changed to align with those of the GHS - should PMRA adopt the criteria for classification of gases or maintain status quo? (i.e. due to toxic nature and restricted use, would always require PPE)	**Option 1: Adopt categories 1-4 only** - Cut-Off values differ from current practices -Increased workload due to companies submitting data to "test out" OR test to a limit dose with no deaths in order to negate hazard communication requirement **Option 2: Adopt all 5 categories** - All products labelled **Regardless of Option:** - Labelling changes are required. - Impact of market class cut-off realignment - Potential increase in workload of "formula" approach option