



NAFTA TWG Meeting

December 3–5, 2003



Formulants Program

- ◆ Based on US EPA approach to inert ingredients
 - ◆ Formulants categorized into lists according to level of concern with respect to human health and the environment.
 - ◆ Lists 1,2,3,4A,4B
 - ◆ Removal of List 1 Formulants
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Formulant Lists

- ◆ List 1 - formulants of toxicological concern
 - ◆ List 2 - potentially toxic formulants
 - ◆ List 3 - formulants that don't meet criteria for other lists
 - ◆ List 4A - formulants of minimal risk or concern
 - ◆ List 4B - formulants of minimal concern under specific conditions of use
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Disclosure Labelling

- ◆ Under Paragraph 43(5)(b) of the new PCPA a list of formulants and contaminants that are considered to be of health or environmental concern will be established.
 - ◆ The PCPA list will comprise formulants on Lists 1 and 2, allergens, and contaminants of concern found in active ingredients.
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Disclosure Labelling (cont'd)

- ◆ As a result products containing List 2 formulators and allergens will require disclosure labelling
 - ◆ Products containing Formulation Preservatives that meet the definition of active ingredient under the PCPA and Regulations will require disclosure labelling
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Formulant Reassessment

- ◆ Formulants will be reassessed and reclassified to List 1 or 4
 - ◆ List 2 and 3 are priority
 - ◆ Reassessment will be coordinated with EPA inert tolerance reassessment
 - ◆ EPA reviews will be utilized where available
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New Formulants

- ◆ Goal is to be harmonized with EPA tiered data approach “Methodology for Lower Toxicity Pesticide Chemicals”
 - ◆ PMRA to issue regulatory proposal on methodology and requirements for new formulants
 - ◆ Proposed methodology is not appropriate for higher toxicity formulants which will likely require a full data package (as for active ingredients)
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PMRA Master File on Formulants

- ◆ Initiative being completed to update master file
 - ◆ Involves verification of trade name formulants and mixtures
 - ◆ Will lead to improved internal formulants database
 - ◆ Information being used in creation of PMRA List of Formulants
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