FORMULANTS POLICY

(Update on Policy Development)

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Key Elements of Formulants Policy:

- Harmonize with EPA by building on their Lists of Inerts (formulants)
- Require updated product specification forms
- Require data to support new formulants
- Apply Toxic Substances Management Policy and Montreal Protocol
- Require data and labelling and/or removal for formulants of concern
- Reclassify and label certain formulants as active ingredients
- Set simple acceptance criteria for dyes and fragrances
- Require labelling of formulants that are allergens
- Will be implemented in a step-wise process
- Reviews of formulants will be done within a NAFTA context

Proposed Time Lines:

- Regulatory Proposal for public comment - Q2, 2000
- Regulatory Directive - Q3, 2000

List 1 - Formulants of Toxicological Concern - Criteria

- Carcinogenicity
- Neurotoxicity or other Chronic Effects
- Adverse Reproductive Effects
- Ecological Effects
- Toxic Substances Management Policy
- Montreal Protocol

List 2 - Potentially Toxic Formulants with High Priority for Testing

- Based on structural similarity or data suggestive of toxicity
- Will use EPA list

List 4A - Formulants of Minimal Risk or Concern

- Commonly consumed as foods, on US GRAS or Minimum Risk Inerts Lists

List 4B - Formulants of minimal concern under specific conditions of use

- Sufficient data to conclude that use pattern will not adversely affect public health or the environment
- Approved by US FDA as food or drug additives
- Polymers

List 5 - Formulants Formerly on List 1 for which Data Support Specific Uses

- Will require large amount of safety data

List 3 - Formulants that do not Meet Criteria for Lists 2, 3, 4 or 5

- Formulants contained in registered pest control products that are not on any other list
- Will likely move to List 4B after being looked at in detail

List 1 - Regulatory Action

- Immediate removal/substitution

OR

- Interim labelling and generation/submission of data to support removal/substitution

OR

- Interim labelling and generation/submission of data to support continued use of formulant of concern
- Goal is to remove List 1 formulants from all products by end of 2002 regardless of which of the 3 options are chosen by the registrant

List 2 - Regulatory Action

- Data call-in with EPA (priority for testing)
- Interim labelling
- Specification forms required by end of 2001

List 3 - Regulatory Action

- Re-classify to other lists as data are available
- Specification forms to be required for renewal after 2002

Proprietary Formulants and Mixtures

- Supplier or manufacturer can disclose composition directly to PMRA

- Components subject to formulants policy

New Formulants

- Subject to data requirements - harmonized with US EPA
- Product chemistry - identity, phys-chem properties
- Toxicology - sub-chronic, genotoxicity
- Ecotoxicology and environmental fate

Minor Formulation Changes Allowable by Notification

- Addition, deletion or substitution of colorants and fragrances
- Change in nominal concentration and certified limits of formulants
- Change in formulation process
- Change in supplier of formulant