

Formulants Program

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PMRA



- ◆ Regulatory Directive DIR2004-01 *Formulants Program* and Regulatory Note REG2004-01 *PMRA List of Formulants* published January 9, 2004
- ◆ New requirements to be phased in over next 3 years with first requirement becoming effective January 2005

- ◆ Guidance document for industry on implementation of Formulants Program to be published

New Requirements

- ◆ Statement of Product Specification Forms (SPSFs) to be submitted with all applications beginning January 2005.
- ◆ Allergens to be disclosed on all product labels by July 2005 and documented through notification

New Requirements (cont'd)

- ◆ Applications for disclosure of formulation preservatives on labels and SPSFs to be submitted by July 2005
- ◆ List 2 formulants to be identified on all product labels by January 2006 and documented through notification

New Requirements (cont'd)

- ◆ Fragrances and Dyes not meeting criteria for acceptability to be replaced and documented by notification or application by December 2006

Other Changes Concerning Formulants Allowable Through Notification

- ◆ Addition, deletion or substitution of colourants and dyes
- ◆ Change in nominal concentration of formulants
- ◆ Change in certified limits of formulants
- ◆ Change in formulation process
- ◆ Change in supplier of a formulant

PMRA Master File on Formulants

- ◆ In final phase of Formulant Request Initiative
- ◆ Requested information on 1500 formulants in Phases 1 and 2
- ◆ Now only 30 formulants for which information is still outstanding



List 1 Formulants

- ◆ Current List 1 formulants are to be out of all pest control products by December 31, 2004
- ◆ Of original 72 products containing List 1 formulants:
 - ◆ 36 products were discontinued
 - ◆ for 27 products List 1 was removed or replaced
 - ◆ 3 product registrations were cancelled and 2 were noneligible for renewal for noncompliance
 - ◆ 4 applications to replace or support continued use of List 1s are currently under review



New Formulants

- ◆ Data/information requirements are under consideration
- ◆ Goal is to be harmonized with USEPA tiered data approach “Methodology for Lower Toxicity Pesticide Chemicals”
- ◆ PMRA to issue regulatory proposal on assessment methodology and requirements for new formulants

Question

- ◆ Does the Council have advice for PMRA concerning the implementation of the Formulants Program?