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# MINOR USE PESTICIDES

## PMAC Meeting



**March 27, 2001**

# MINOR USE

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- , A necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada

# **TWO STREAMS FOR MINOR USE APPLICATIONS**

- , User Requested Minor Use Registration (URMUR)
  - Regulatory Directive 1999-05
  
- , User Requested Minor Use Label Expansion (URMULE)
  - Regulatory Directive 2001-01



# URMUR

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- , To facilitate the registration of products, including biopesticides, that are registered in the US or other OECD countries, that due to potential low volume of sales might never be registered
- , Use of acceptable foreign reviews to help ensure that the evaluation of URMUR applications is as efficient as possible.



## URMUR - Some Eligibility Criteria

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- , Active ingredient registered in the US or in another OECD country but not registered in Canada
- , Registration in other OECD country must be less than 5 years old to ensure adequacy of the database and availability of foreign reviews
- , No previously identified health and environmental safety concerns
- , Provision of foreign reviews from OECD countries along with supporting data



## URMUR - Initial Steps

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- , Need identified by sponsor / user group and supported by P/T minor use coordinator
- , Collaboration Manufacturer / Sponsor
- , Presubmission consultation encouraged
- , Manufacturer submits application and serves as liaison between sponsor and PMRA
  - submission for the TGAI and at least one EP



# URMULE

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- , Considers expansion of a label for a new minor use of a pesticide provided:
  - The active ingredient and the end-use product are registered in Canada;
  - The registrant is willing to add the new use to the EP Label;
  - Sufficient information to assess safety, merit and value of the proposed new use.



## URMULE - Initial Steps

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- , Need identified by users
- , Application by Sponsor / User group and supported by Registrant and P/T MU coordinator
- , PMRA Presubmission consultation to verify that criteria are met and to identify data requirements
- , Sponsor submits data in response to presubmission consultation





# MINOR USE - SOME OBSERVATIONS (1)

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- , A cooperative effort
  - Users
  - Registrants
  - Researchers
  - Provinces / Territory
  - Sectoral Departments
  - PMRA

## **MINOR USE - SOME OBSERVATIONS (2)**

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- , Presubmission consultation
- , Quality and completeness of submission
- , Focus on newer products
- , Joint review
  - Joint review and minor uses
  - Minor use joint review



# JOINT REVIEW AND MINOR USES

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- , Increased number of joint review submissions
- , Include a number of minor uses
- , Great benefits - level playing field including for minor uses

# MINOR USE JOINT REVIEW

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- , Pilot identified
- , Criteria same as for other JRs e.g.: active assessed under FQPA; same label, same use, same formulation, same crop, same pests, same gap: sufficient data
- , level playing field for minor uses

# SUMMARY

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- , 2 streams for minor use applications
- , Build on best practices
- , Joint review
- , Cooperation