Canadian Pesticide Regulation Course
Pest Management Regulatory Agency
DRAFT AGENDA

Date: October 28, 29 and 30, 2002
Location: Holiday Inn Select, Kanata
Target Audience: Registrants and other interested parties

Objective: To provide participants with an overview of the Canadian pesticide regulatory process that will assist in the preparation of a complete and accurate pest control submission and consequently facilitate an efficient review

Day 1

Session 1:
- **Overview of the Submission Process for New Products**
- **Formulants Activities**

Time	Topic	Duration	Speaker
8:15	Introduction, Overview of CPRC and Summary of PMRA Structure	15 min.	**Pat Curry**
8:30	Overview	15 min.	**Wendy Sexsmith**
8:45	Single Window for inquiries to PMRA	30 min.	**Margherita Conti**
9:15	Pre-Submission Consultation	45 min.	**Kathryn Adams**
10:00	**Break**		
10:30	Category A & B Submissions • Time lines • Levels of screening and review times	45 min.	**Judie Burke**
11:15	Formatting of Submissions • PMRA • OECD	30 min.	**Judie Burke**
11:45	Product Specific Registration • The Policy and operational perspective	20 min.	**Hang Tang**
12:05	**Lunch**		

Day 1 (continued)

Time	Topic	Duration	Speaker
1:00	**Special Programs** • Joint Reviews	30 min.	**Lisa Lange**
1:30	**Special Programs (continued)** • URMUR • Reduced Risk Products	 10 min. 20 min.	 **Wendy Sexsmith** **Wendy Sexsmith**
2:00	Common Submission Deficiencies	45 min.	**Judie Burke**
2:45	**Break**		
3:00	Category D Submissions: Minor Use - URMULE	30 min.	**Daryl Kindack**
3:30	Category E Submissions: Research Permits	30 min.	**Lynda Austen**
4:00	Emergency Registrations Requirements and Time Lines	30 min.	**Richard Aucoin**
4:30	Wrap-up		**Pat Curry**

Day 2

Time	Topic	Duration	Speaker
8:30	Welcome and Overview for the day	5 min.	**Pat Curry**
8:35	Electronic Submissions Status Update	15 min.	**Valerie Robertson**
8:50	How to complete a Specification Form	40 min.	**Maria Papiez**
9:30	Label Verifications	30 min.	**Frania Marie Granville**
10:00	**Break**		
10:30	Notification Process	30 min.	**Margherita Conti**
11:00	Category C Submissions Amendments • Time lines • Levels of screening and review times	60 min.	**Stéphane Lavigne**
12:00	**Lunch**		
1:00	Category D Submissions: Import for Manufacturing and Exports Program	30 min.	**Shawn Fancy**
1:30	Renewal	30 min.	**Frania Marie Granville**
2:00	**Break**		
2:15	Formulants Activities Joint presentation	180 min.	**Brad Bergen** **Don Wilkinson** **Croplife/CCSPA**
3:30	**Break**		
3:45	Formulants Activities Joint presentation (continued)		
5:15	Wrap-up		**Pat Curry**

Day 3

Session 2: Scientific Evaluation and Decision-Making Process of Pesticides

Goal: Provide an overview of the scientific evaluation and decision making process.

Time	Topic	Duration	Speaker
8:00	Introduction and details on the chosen example	15 min.	**Pat Curry**
8:15	New Products vs Re-evaluation	15 min.	**Jeff Parsons**
8:30	Efficacy Assessment	30 min.	**Pierre Beauchamp**
9:00	Chemistry Assessment	20 min.	**Bernadette Boutin-Muma**
9:20	Health Assessment - Toxicology Assessment	40 min.	**Steve Wong**
10:00	**Break**		
10:15	Health Assessment - Dietary Exposure	30 min.	**Henri Bietlot**
10:45	Health Assessment - Occupational Exposure and Risk Assessment	30 min.	**Dana Bruce**
11:15	Environmental Risk Assessment	30 min.	**Valerie Hodge**
11:45	Overall Risk Assessment - Management and Decision Making	30 min.	**Wendy Sexsmith**
12:15	Compliance and Enforcement of the *Pest Control Products Act*	15 min.	**David Quesnel**
12:30	**Lunch**		

Day 3 (continued)

Session 3: URMULE[1] Submission and Review

Objective: To present an overview of the URMULE process and provide guidance on the effective conduct of data generation trials.

Target Audience: Minor Use Coordinators, Sponsors, Provincial and Federal Research personnel and Registrants.

Time	Topic	Duration	Speaker
1:30	Introduction	5 min.	**Pat Curry**
1:35	Pre-submission Consultation and Submission Package	25 min.	**Daryl Kindack**
Issue Discussion: Pre-submission, Data generation, and Submission Preparation			
2:00	Efficacy/Crop Tolerance	60 min.	**Pierre Beauchamp, Suzanne Chalifour, Najib Malik**
3:00	**Break**		
3:20	Food Residue	40 min.	**Jennifer Selwyn**
4:00	Occupational Exposure	20 min.	**Christine Norman**
4:20	Risk Assessment and Decision Making	40 min.	**Wendy Sexsmith**
5:00	Overall Course Wrap Up		**Pat Curry**

[1]URMULE = User Requested Minor Use Label Expansion

General Definitions

Category A submissions include new technical grades of active ingredients (TGAIs) or integrated system products (ISPs) and their related end-use products (EPs), major new uses, User Requested Minor Use Registrations (URMURs) and the establishment of maximum residue limits (MRLs) for previously unassessed TGAIs. An application to register a new active ingredient must be accompanied by an application to register a related end-use product(s). Category A submissions require either full or substantial data packages.

Category B submissions require evaluation by one or more science divisions based on a change within a use-site category. These include changes in product chemistry, such as sources and specifications for a TGAI, and the following changes for an EP or manufacturing concentrate (MA): guarantee, form of active ingredients, formulation and new combinations of TGAIs. Category B submissions also include label changes resulting from changes in the following: application, level of control, tank mixtures, pests, precautionary statements, and product classification, as well as the conversion or extension of temporary registration and additional import maximum residue limits for previously assessed TGAIs.

Category C submissions include applications without supporting data for new or amended registrations requiring minor label and/or formulation reviews, e.g., product registrations based on precedent.

Category D submissions include applications for new or amended registrations representing special programs, such as Import for Manufacture and Export Program (IMEP) (refer to Regulatory Directive Dir95-05, *Importation for Manufacturing and Export Program*), Own Use Import (OUI), Master Copy (refer to Regulatory Directive Dir93-20, *Master Product/Master Copy Registration Process*), Private Label (refer to Regulatory Directive Dir93-21, *Initial Product/Private Label Registration Process*), and User Requested Minor Use Label Expansion (URMULE) (refer to Regulatory Directive Dir93-23, *User Requested Minor Use Label Expansion*).

Category E submissions include Research Permits (refer to Regulatory Directive Dir93-22, *Chemical Pesticides Research Permit Guidelines*), for new active ingredients, new use(s) of registered active ingredients, and notifications that are required for field research carried out in Canada. Exemptions from data requirements are based on the size and location of treated areas.