

Session I

**Registration Production Issues
for Conventional and Biological Pesticides**

July 21, 1999

Presentation to the Pesticide Program Dialogue Committee

OPP Resources Dedicated to the Registration Program

Fiscal Year	FTE	Contract s
FY98	261.6	\$4,970K
FY99	270.7	\$4,054.5K

The Registration Program is comprised of three regulatory areas:

- ! **Biological Pesticides**
(Biochemicals, microbials both naturally and genetically-altered, and plant pesticides)
- ! **Antimicrobial Pesticides**
- ! **Conventional Pesticides**

OPP Resources Dedicated to the Registration of Pesticides in FY99

FTE: 271 FTE are allocated for registration activities:

- ! Antimicrobial Registration Activities: 25 FTE**
- ! Biopesticide Registration Activities: 40 FTE**
- ! Conventional Chemical Registration Activities: 167 FTE**
- ! Program Management and Support: 39 FTE**

Contracts

- ! 4,054.5K in contract dollars have been allocated for registration activities**
- ! In April 1999, the Deputy Administrator allocated an additional \$1 million to the Registration Program to expedite reviews and decisions for reduced-risk pesticides.**
- ! Total FY '99 contract dollars = \$5,054.5**

**HISTORICAL COMPARISON OF NEW ACTIVE INGREDIENT REGISTRATIONS
UNDER SECTION 3 OF FIFRA**

Fiscal Year	Biologics	Conventionals		Antimicrobials	Total
		Regular	Safer		
1988	2	10	0	1	13
1989	3	15	0	0	18
1990	1	5	0	0	6
1991	9	4	0	0	13
1992	6	7	0	1	14
1993	4	12	0	1	17
1994	15	10	2	4	31
1995	17	16	3	2	38
1996	10	6	3	3	22
1997	15	7	4	2	28
1998	12	11	2	2	27

1999 to date	10	5	4	1	20
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Conventional Chemical Registration Program Activities

	FY98 Completions	FY99 Completions (as of 6/30)
New Chemicals	13	9
Tolerances	239	181
Experimental Use Permits	10	11
New Uses for Existing Active Ingredients	144	70
Section 18 Emergency Exemption Requests	504	425
Average Processing Time for Section 18 Requests	56 days	59 days
Section 24(c) Special Local Needs Requests	455	335
Old Chemical Product Registrations (Fast Tracks and Non-Fast Tracks)	621	284

Old Chemical Amendments (Fast Tracks and Non-Fast Tracks)		2,524	1,539
Inerts	Food Use	14	3
	Non-Food Use	94	71
Notifications		1,810	1,218

Biopesticide Registration Program Activities

	FY98 Completi ons	FY99 Completi ons (as of 7/12)
New Active Ingredients	12	10
Tolerance Exemptions	13	10
New or added uses for existing active ingredients*	57	335
Experimental Use Permits	13 new 5 amendm ents	11 new 4 amendm ents
Section 24(c) Special Local Needs Requests	4	6
Existing Active Ingredient Product Registrations (Fast Tracks and Non-Fast Tracks)	47	71
Existing Active Ingredient Amendments (Fast Tracks and Non-Fast Tracks)	136	148

Biotechnology Notifications for Field Trials of Genetically-Altered Microorganisms	3	1
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***An added use requires no new data to be reviewed or a change in the tolerance (exemption). Biopesticide tolerance exemptions are often established for all food commodities and additional uses are added to pesticide labels at a later time.**

What's Currently Pending in the Conventional Chemical Pipeline (as of July 1, 1999)

- ! New active ingredients: 48**
- ! New Food Uses: 455 (involving over 100 active ingredients)**
- ! EUPs: 10**

What's In the Workplan for FY99

- ! New active ingredients: 20 candidates, covering 54 food uses and 4 non-food uses**
 - RD goal for FY99 is to make decisions for 13 new chemicals**
 - Through June 1999, we have registered 9 new chemicals (5 reduced-risk) and received 1 withdrawal**
- ! New Food Uses: 120 new use candidates, covering 35 active ingredients**
 - RD goal for FY99 is to make decisions for 57 new uses**
 - Through June 1999, we've already issued 70 new use decisions**
- ! EUPs: 1**
 - At mid-year, we've issued the 1 EUP listed in the workplan**
 - In addition, we've issued another 10 unscheduled EUPs**

through June 1999.

How Do We Prioritize the Pending Workload

- ! Methyl Bromide Alternatives**
- ! OP Alternatives which are Reduced Risk Candidates**
- ! Other Reduced Risk Candidates**
- ! Non-reduced risk OP Alternatives**
- ! USDA/EPA - vulnerable Crop / pest combinations**
- ! IR-4 Petitions**
- ! Minor Crop Uses Submitted by Registrants**
- ! Trade irritants**
- ! Other Registrant Identified Actions**

Using this priority scheme as guidance, incorporating other identified critical needs, and identifying “low hanging fruit”, RD works with HED and EFED to cull together new chemical, new use, and EUP candidates for decision-making.

Typically, we identify several more candidates in each category than we expect to complete.