

US EPA ARCHIVE DOCUMENT



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Registration Division's Year in Review ---- FY2001 Summary of Major Accomplishments

New Conventional Registrations

A total of 12 new conventional active ingredients (AIs), 4 of which were conventional "reduced-risk" chemicals and 1 which was an OP (organophosphate) alternative, were registered in fiscal year 2001 (FY2001). The average turnaround timeframe for those new registrations was 46 months for non-"reduced-risk" actions and 30 months for conventional "reduced-risk" actions.

Registration Division's Conventional New Chemical Decisions in FY2001

Chemical	Use	# of Tolerances	Pesticide Type	Date of Decision
Picaridin	Insect Repellent	0	Repellent	December 7, 2000
Thiamethoxam	Barley (seed), Canola (seed), Cotton (seed), Sorghum (seed), Wheat (seed)	24	Insecticide	December 21, 2000 OP Alternative
Chlorfenapyr	Ornamentals (greenhouse)	0	Insecticide	January 19, 2001
Ethametsulfuron Methyl	Canola, Crambe, Rapeseed	3	Herbicide	April 6, 2001
Zoxamide	Potatoes, Grapes	5	Fungicide	April 11, 2001 Grapes as Reduced Risk
Flumioxazin	Soybeans (seed), Peanuts	2	Herbicide	April 18, 2001
Mesotrione	Field Corn	3	Herbicide	June 21, 2001; Reduced Risk
Tepraloxym	Canola, Cotton, Soybeans	32	Herbicide	August 2, 2001
Fluazinam	Peanuts, Potatoes	2	Fungicide	September 7, 2001 Reduced Risk
Etofenprox	Crack and Crevice	0	Insecticide	September 14, 2001

Bispyribac-Sodium	Rice	2	Herbicide	September 18, 2001
Novaluron	Ornamentals (indoor, non-food)	0	Insecticide	September 24, 2001 Reduced Risk

Summary:

12	Chemicals
19	Food Uses associated with these chemicals
4	Non-Food Uses associated with these chemicals
19	Crops associated with these chemicals (18 major/ 1 minor)
73	Tolerances associated with these chemicals

Also, 204 conventional new uses were registered in FY2001; of which 77 were conventional “reduced-risk”; 69 were OP alternatives; 3 were methyl bromide alternatives; and, 103 were from IR-4 petitions. The average turnaround timeframe for those new use registrations was 39 months for non-“reduced-risk” actions and 15 months for conventional “reduced-risk” actions.

Note: This information can be found on EPA-OPP’s website at:

<http://www.epa.gov/opprd001/workplan/>

FY2001 Old Chemical and Amendment (Fast-Track and Non-Fast-Track) and EUP Decisions

Type of Action	Number of Decisions Completed in FY2001
Old Chemicals – Fast Track	287
Old Chemicals – Non-Fast Track	214
Amendments – Fast Track	1823
Amendments – Non-Fast Track	445
Notifications/Minor Formulations	1958
Special Local Needs [24(C)s]	411
Experimental Use Permits (EUPs) – New	10
EUPs – Renewals	2
EUPs – Amendments	4

Old Chemical Non-Fast Track backlog decreased by 35% and Amendment Non-Fast Track backlog decreased by almost 10% in FY2001. Old chemical and amendment fast track backlogs were maintained at virtually zero again this year.

Emergency Exemptions

In FY2001, a total of 542 requests were received for emergency exemptions under Section 18 of FIFRA. Of those 542, 470 were granted; 19 were denied; and, 47 were withdrawn. Thirty-three tolerances were established; 47 tolerances were extended; and, 59 crises were declared. The average processing time (for Section 18s) for FY 2001 was 34 days!

FY 2001 SECTION 18s

	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	Total
Receipts	79	254	159	50	542
Issued	43	186	190	51	470
Denied	3	1	7	8	19
Withdrawn	9	10	22	6	47
Tolerances Establishd	6	7	5	15	33
Tolerances Extended	13	2	7	25	47
Crises	0	5	38	16	59

Average Processing Time: 34 days

Emergency Exemptions now eliminated by FY2001 section 3 (new chemical) registrations:

Ethametsulfuron-methyl/canola	1
Fluazinam/pea nuts	4
Bispyribac-sodium/rice	2
Clomazone/rice	2
Fludioxonil/strawberry	1
Chlorothalonil/asparagus	1
Imazethapyr/rice	4
Imidacloprid/edible podded beans	1
Imidacloprid/succ.shelled beans	1
Imidacloprid/tumip greens	1
Imidacloprid/corn (sweet)	3
Imidacloprid/citrus	1
Thiamethoxam/fruited vegs	1
Thiamethoxam/pome fruits	1
Thiamethoxam/cotton	2
Cyprodinil/strawberry	1
Buprofezin/cotton	2
Buprofezin/tomato	1
Paraquat/artichoke	1
Paraquat/pea (dry)	5
Azoxystrobin/leafy brassica	1
Azoxystrobin/pepper	1
Azoxystrobin/strawberry	8
Azoxystrobin/lychee	1
Azoxystrobin/watercress	4
Spinosad/bushberry	3
Spinosad/cranberry	1
Spinosad/sugar beet	1
	<u>56 total</u>

Also, the first ever EPA Exemplary Customer Service Award was awarded to the members of the

Registration Division’s Emergency Response Team in FY2001 because of their exceptional service in meeting growers’ emergency pest control needs and protecting U.S. agriculture and the food supply while implementing the emergency exemption (Section 18) provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). They were commended for developing more efficient and effective processes and procedures for working with the states and with EPA risk assessors. They were awarded for the turnaround response time – which at that time was the shortest in the history of the Section 18 Program – of an average of 44 days! This year, RD’s Emergency Response Team ended FY2001 with their best ever average turnaround time of 34 days!

SEVEN YEARS OF SECTION 18s							
	1995	1996*	1997	1998	1999	2000	2001
Receipts	411	407	422	601	630	549	542
Crises	66	62	121	125	124	71	59
Granted	276	361	384	410	455	458	470
Denied	25	10	17	27	22	34	19
Turn-around, days	57	53	85	56	54	44	34

* FQPA passed in 4th quarter

International (Conventional) Registration Efforts

In FY2001, the first **tri-lateral** NAFTA (North American Free Trade Agreement) review conventional fungicide, Zoxamide, (for use on potatoes and also as a conventional “reduced-risk” pesticide for use on grapes) was registered – by EPA, March 2001; by Canada’s Pest Management Regulatory Agency (PMRA), May 2001; and, by Mexico, July 2001! Workshare efforts were expanded in FY2001 to include OP (organophosphate) alternatives.

Ten new conventional chemicals were in the NAFTA Joint Review (JR) Program in FY2001, 5 of which are conventional “reduced-risk” chemicals [zoxamide fungicide; pyraclostrobin fungicide; EH-2001 rodenticide; acetamiprid insecticide; and, BAS 510F fungicide] and, 2 OP alternatives [thiamethoxam insecticide and clothianidin insecticide] – as well as one conventional non-“reduced-risk” fungicide [famoxadone] and 2 import tolerance only fungicides [iprovalicarb and tolyfluanid]. In addition, new uses for conventional chemicals, including 2 conventional “reduced-risk” chemicals [fenhexamid and pyraclostrobin] also entered the Joint Review process in FY2001, one of which represented another FY2001 expansion of the Program to include new minor uses of previously-registered chemicals (on an IR-4 petition) [fenhexamid fungicide].

In FY2001, EPA initiated a parallel review project with the European Commission, with

Germany acting as the rapporteur (key point-of-contact) country and a workshare review with Canada for two new conventional herbicides [foramsulfuron and iodosulfuron-methyl sodium], in an attempt to explore the feasibility of expanding our work sharing efforts for conventional registration decisions to include European countries. Efforts also began in FY2001 to reach out to other members of the European Community, particularly when we may have information that could assist them with a conventional pesticide regulatory decision (e.g., the herbicide, mesotrione) and/or when they may be able to help us (e.g., with a pending new conventional fungicide).

Also, NAFTA countries began working with stakeholders to investigate the feasibility of a NAFTA conventional label in order to ensure growers a level playing field allowing for the same label on both sides of the borders (e.g., North Dakota-Canada). A number of registrants have expressed interest in the Joint Review program, and both EPA and Canada's PMRA are considering many of those requests as part of planned regulatory efforts for FY2002.

Inert Ingredients

In FY2001, EPA worked to develop a new process for the evaluation of inert ingredients, highlighted by the establishment of the Inert Ingredient Focus Group (IIFG). The IIFG is an interdivisional multidisciplinary team of senior risk assessors and risk managers within the Agency that will have the primary responsibility for the review of pesticide inert ingredients (including both new inerts and inert ingredients subject to tolerance reassessment) as well as selected active ingredients. It is expected that a notice will be published in the *Federal Register* early in FY2002 announcing the availability of this new risk assessment methodology for inert ingredients and soliciting comment from affected stakeholders. In addition to the development of this new methodology, the Agency established tolerance exemptions for eight new food use inert ingredients and approved 72 non-food use inert ingredients during FY2001.

Tolerance Exemptions Established for These Eight New Food Use Inerts:

Modified styrene-acrylic acid polymer
Copper sulfate pentahydrate
Dimethylpolysiloxane
Polybutene
Sucroglycerides
Isoxadifen-ethyl
2-Propenoic acid, polymer with 2-propenamide, sodium salt
2-Propenoic acid, sodium salt, polymer with 2-propenamide

RD Steps Up Its Efforts To Register Methyl Bromide Alternatives

During FY2001, the Registration Division made major strides towards registering several new methyl bromide alternatives. Beginning in January 2001, as required under the Clean Air Act, methyl bromide production has been reduced to 50 percent of 1991 production levels. In January 2003, production will decline to 30 percent of 1991 production levels with a complete phase-out scheduled for January 2005. To ensure that growers have available viable alternatives, the Registration Division has been working closely with EPA's Office of Air and Radiation, USDA's Agricultural Research Service, registrants, growers, and other stakeholders to make available the necessary tools to allow the phase-out to continue.

In April 2001, the Registration Division registered two new products containing the active ingredient 1,3-dichloropropene (Telone) for use as methyl bromide alternatives. The two products, called InLine and Telone EC, allow drip application to tarped soil as a pre-plant soil fumigant, primarily for use in strawberries and tomatoes. For the past several years, IR-4 (USDA's Interregional Project Number 4) has been evaluating these two products as potential methyl bromide alternatives. Results of their research indicate exceptional efficacy. The drip application significantly reduces the amount of fumigant applied per acre, and virtually eliminates worker exposures associated with the more traditional shanked-in method.

Subsequently in September 2001, the Registration Division registered a Terrazole-containing product for use in tobacco. This product, Terramaster, provides an alternative to the use of methyl bromide. Currently, tobacco transplants depend on the use of methyl bromide to sterilize the soil. With the availability of Terramaster, tobacco transplants can be grown in a floatbed production system. Terramaster will control Pythium root rot. The Reregistration Eligibility Decision (RED) for Terrazole had evaluated this use as part of existing special local need (SLN) registrations. The previously-issued 24(c) registrations accounted for upwards of 98 percent of the tobacco-producing acres in the United States. Registration reduces some grower uncertainty and provides an incentive for tobacco growers to move away from the use of methyl bromide in their production practices.

In addition, the Registration Division has been meeting regularly with new potential registrants, providing guidance on the conventional registration process. The Registration Division, along with the Biological and Economic Analysis Division, have formed a Methyl Bromide Steering Committee with the Office of Air and Radiation's Global Programs Division to oversee the development of a Critical Use Exemption Program. This program will allow for certain uses of methyl bromide after the January 2005 phase-out, where no economically or technologically feasible alternatives exist. As articulated under the Montreal Protocol, such uses will need to be approved by the international community.

Partnering to Bring Minor Crop Growers New Tools

Over the past several years, the EPA's Office of Pesticide Programs (OPP) [in particular, the

Registration (RD) and Health Effects (HED) Divisions] has taken extraordinary measures to build a partnership with USDA's IR-4 Program. EPA and IR-4 are working together to bring minor crop growers new tools to work with during the FQPA (Food Quality Protection Act) transition years. A productive working relationship between EPA's Office of Pesticide Programs and IR-4 has been forged, resulting in significant improvements in meeting the goal of providing growers with necessary tools for pest control. In recognition of these achievements, which have resulted in the most productive year in the 30 year history of IR-4 – RD interaction, USDA's IR-4 Program awarded RD the Meritorious Service Award in 2001.

EPA's partnership with IR-4 over the last few years has resulted in many conventional "reduced-risk" alternatives to organophosphate (OP) and carbamate pesticides being made available to minor crop growers. These efforts increased IR-4's level of safer chemistry projects to over 70%. IR-4 and EPA have embarked upon a new era in sharing information, developing problem solving systems and a team-oriented approach which has benefitted growers across the country and nation.

**IR-4 Food Uses Registered in FY2001
(Chemicals – Number of New Uses)**

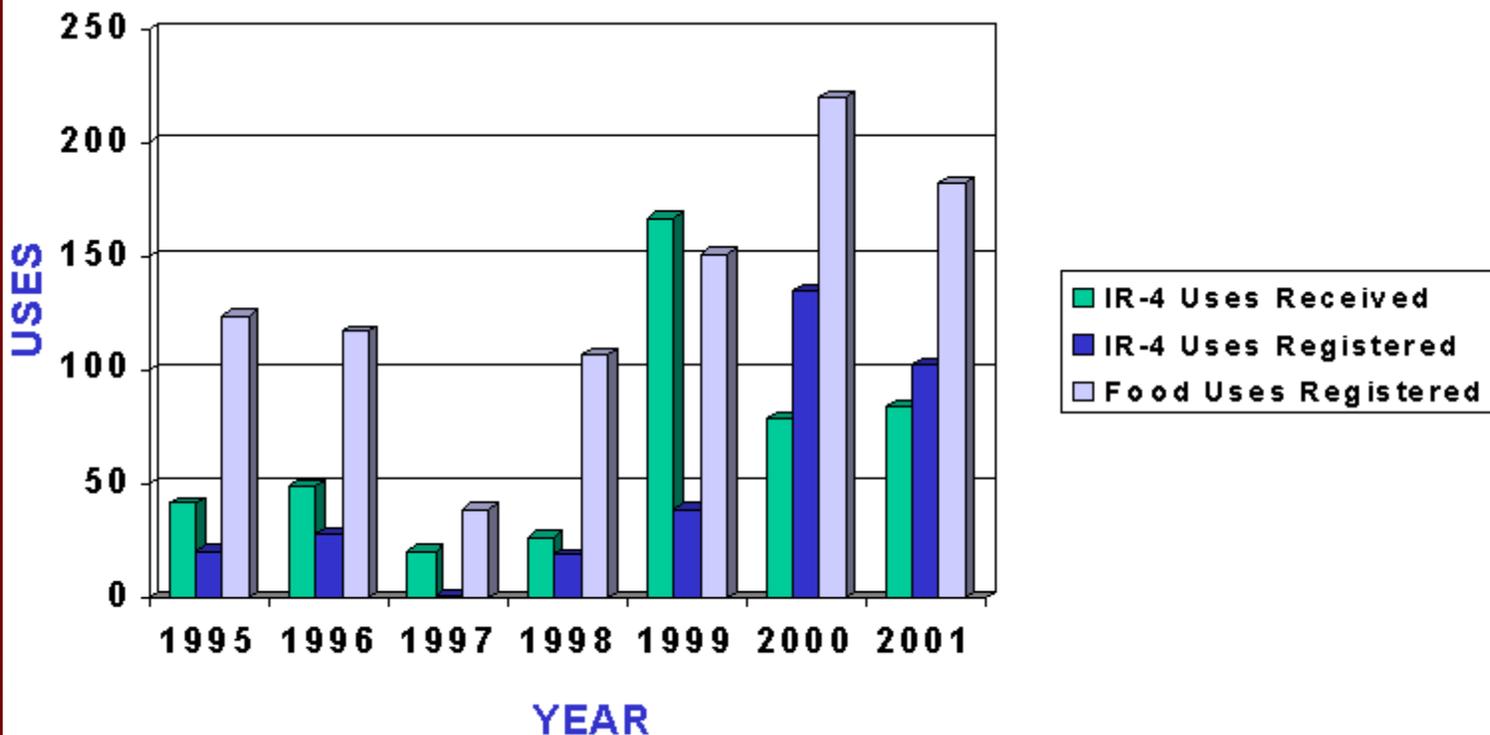
Avermectin -- 1	Fludioxonil – 3
Azoxystrobin – 28	Hexythiazox – 3
Carfentrazone – 1	Imidacloprid – 5
Chlorothalonil – 3	Mefenoxam – 7
Clethodim – 19	Paraquat – 4
Clomazone – 4	Pyriproxyfen – 1
Cyprodinil – 3	Spinosad – 21

103 New Uses

Also, California EPA's Department of Pesticide Regulation's (Cal-DPR) work share program to conduct data review for IR-4 petitions of interest to California growers has expedited Federal and State minor use registrations and strengthened cooperation between the regulatory partners. The work share project utilizes IR-4 residue data reviewed by the Cal-DPR's Pesticide Registration Branch ultimately resulting in the establishment of tolerances by U.S. EPA. The IR-4/ EPA/ DPR partnership, which began July 1, 2000 with one pilot activity, resulted in the establishment of tolerances for fifty-one new uses which, with crop grouping tolerances, will allow registration for approximately 200 crop uses.



Food Use Registration Activities (1995 – 2001)



Partnering to Protect the U.S. Food Supply

Several cases of pesticide misuse in FY2001 resulted in strong partnerships across EPA

organizations including the Regions, and with other federal agencies, as well as state and local government agencies and pesticide manufacturers to protect the U.S. food supply from contamination. In one particular case, the restricted use pesticide zeta-cypermethrin, sold under trade names, Fury and Mustang, was illegally applied to wheat in multiple locations in Mississippi and Arkansas. Faced with the threat of contaminating the entire U.S. wheat supply, EPA-OPP's Registration Division and FDA led negotiations with the registrant which resulted in an unprecedented multi-million dollar wheat buy-back agreement. The EPA-FDA-FMC Fury Wheat Agreement set forth the action plan whereby FMC would purchase all of the adulterated wheat identified by MS and AR state officials; transport harvested adulterated wheat to storage; store the adulterated wheat in segregated and secured facilities; and ensure that adulterated wheat would not be sold or released into interstate commerce until EPA and FDA were satisfied with the wheat's safety following residue testing. This novel agreement covered 47 growers with 18,271 acres of wheat misapplied with Fury in Mississippi and 12 growers with 6,458 acres of wheat (including wheat grown for seed) in Arkansas.

Protecting Children thru Re-examination of Insecticide Products Packaging

In our continuing efforts to be protective of children in and around their homes, in FY2001 the Registration Division's (RD) Insecticides Branch (IB) began to systematically review the regulatory files of already registered residentially-used pesticide products to determine if these products meet today's Child Resistant Packaging (CRP) requirements. This project included research to ascertain if products require CRP and/or revised CRP Certification (as per Pesticide Registration Notice 96-2); or, in the absence of acute toxicity data, the need for such data to be submitted or citation of acute toxicity data (to determine if child resistant packaging is necessary). After a thorough review of files of two companies, over 160 residential pesticide products were found that require further action – either CRP; revised CRP certification; or, submission or citation of acute toxicity data. This effort, which will continue in RD's Insecticide Branch is already making registrants more aware of their child protection responsibilities and has been the means of making residential insecticide product packaging more protective.