

***REGISTRATION
DIVISION
PROGRESS
REPORT
FISCAL YEAR 1995***

**Registration Division
Office of Pesticide Programs
Office of Prevention, Pesticides and Toxic Substances
April, 1996**

FOREWORD

The Registration Division (RD), Office of Pesticide Programs, is pleased to present its annual progress report for Fiscal Year (FY) 1995. The intent of this report is to provide in-depth information about RD's performance not only for FY95, but for preceding years as well for comparison.

RD had a record-breaking year in FY95, exceeding its performance targets in 9 out of 12 registration categories. For new chemicals, RD completed 26 decisions compared to its target of 13. These decisions included 5 reduced risk chemicals, 16 conventional chemicals and 6 biochemicals. On average, RD completed the conventional chemicals in 38 months, reduced risk chemicals in 12 months and biochemicals in 9 months. These decisions were made much faster than the 5 year average decision time for new chemicals in FY91.


In most of the other registration categories, RD greatly exceeded its targets for numbers of decisions. In addition, RD exceeded the target number of product reregistration decisions by about 33%. Numerous reinvention projects aimed at improving the speed and efficiency of registration were completed or initiated. Finally, many other projects were undertaken or finished which further demonstrate new and better ways that RD conducted its business. All of these accomplishments are summarized in Section I (Highlights), while details are provided graphically, numerically and narratively in the remaining sections.

RD's successes can be attributed to its highly dedicated, experienced and hard-working staff. Their continuous efforts to work faster, smarter and more efficiently are evident. They stand fully committed to serving RD's many "customers"--the public, registrants, states, organizations and individuals--who request assistance or submit applications for approval.

We are confident that RD can continue to be highly productive and innovative in carrying out FIFRA's mandate to register pesticides while fully protecting human health and the environment.



Stephen L. Johnson, Director
Registration Division



Peter Caulkins, Deputy Director
Registration Division

REGISTRATION DIVISION PROGRESS REPORT FISCAL YEAR 1995

The Registration Division (RD) of the Office of Pesticide Programs (OPP), EPA is responsible for the registration of all non-biological pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1988. This report summarizes RD's accomplishments for the period of October 1, 1994 to September 30, 1995 as follows:

- ▶ Section I provides highlights of RD's significant accomplishments.
- ▶ Section II presents graphics of registration actions for FY95.
- ▶ Section III provides the detailed information behind the graphics.
- ▶ Section IV describes all of RD's projects.
- ▶ The Glossary defines key terms.

I. HIGHLIGHTS

- ◆ Registered 26 new pesticide active ingredients in FY 1995 consisting of:
 - 5 Reduced Risk Chemicals
 - 15 Regular Chemicals
 - 6 Biochemicals
- ◆ Exceeded annual registration targets in 9 out of 12 categories (see asterisked numbers in table below).

| CATEGORY | TARGET DECISIONS | FINAL DECISIONS |
|----------------------|------------------|-----------------|
| Old Chemicals (FT) | 727 | 524 |
| Old Chemicals (NFT) | 40 | 206* |
| Amendments (FT) | 2,719 | 3,491* |
| Amendments (NFT) | 72 | 182* |
| New Uses | 92 | 102* |
| New Chemicals | 13 | 26* |
| EUPs | 117 | 86 |
| Tolerances | 85 | 116* |
| Temporary Tolerances | 30 | 29 |
| Inerts | 7 | 8* |
| Emergency Exemption | 320 | 400* |
| Special Local Needs | 150 | 472* |

- ◆ Exceeded annual target for product reregistration decisions--405 decisions completed vs. target of 298. Cumulatively, 747 products have been reregistered and 2,242 decisions have been made to date.

◆ Reinvented the registration process to make it faster and more efficient while protecting human health and the environment:

- PR Notice 95-2--Notifications, non-notifications and accelerated minor formulation amendments.
- Section 25(b) exemptions rule was proposed, public comments were evaluated and a final rule is nearly ready.
- Entered into an agreement with California to share acute toxicity and certain label amendment reviews.
- PR Notice 94-8 allowed water soluble packaging to be included under the same registration number as other packaging.
- PR Notice 95-1--Exemption of small containers from effluent discharge labeling statements.
- Explored ways to allow registrants to "self-certify" acute toxicity and product chemistry studies.

◆ Adopted new ways of doing business:

- Section 18 exemption for potatoes used European data.
- Section 18 on cotton permitted a use of a pesticide which was "triggered" when a certain level of infestation occurred.
- Sec. 24c for carbofuran on canola was approved with a temporary tolerance based on Canadian data.
- A new chemical (tebufenozide) was jointly registered with California and Canada (CUSTA).
- Section 18 regulations were revised to allow EPA and states greater flexibility.

◆ Other special projects are listed in Section IV of this report.

II. VISUALS

Registration Targets vs. Completions: Actions and decisions (completed vs. planned) in FY95.

Actions vs. Decisions: Ratio of actions to decisions.

Backlogs: Registration backlogs for FY95 vs. FY94.

Workload (Actions): Pending plus backlog actions awaiting processing.

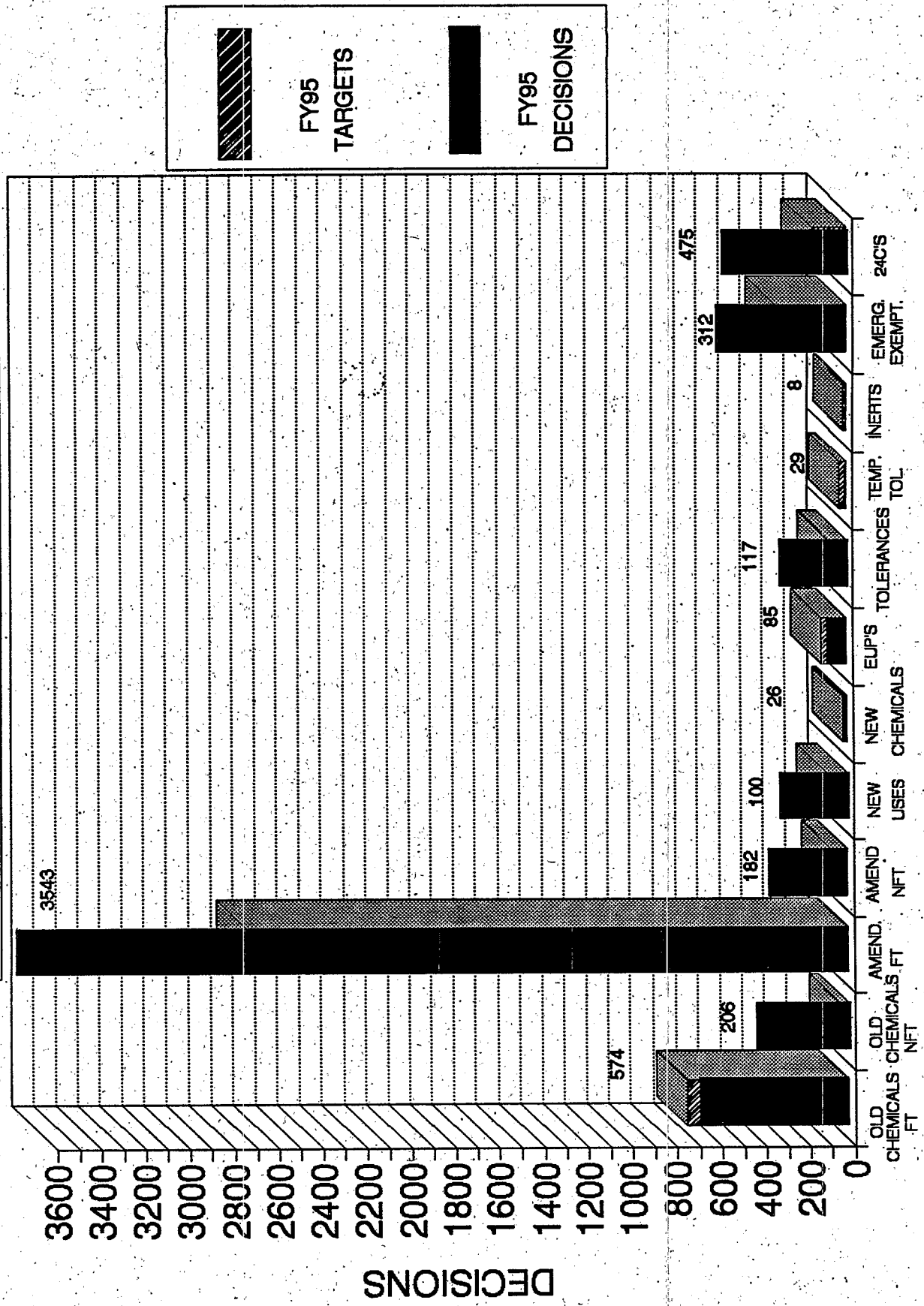
Workload (Decisions): Estimated number of decisions (pending plus backlogged) awaiting processing.

Resources Spent vs. Planned: Resources used vs. planned in FY95.

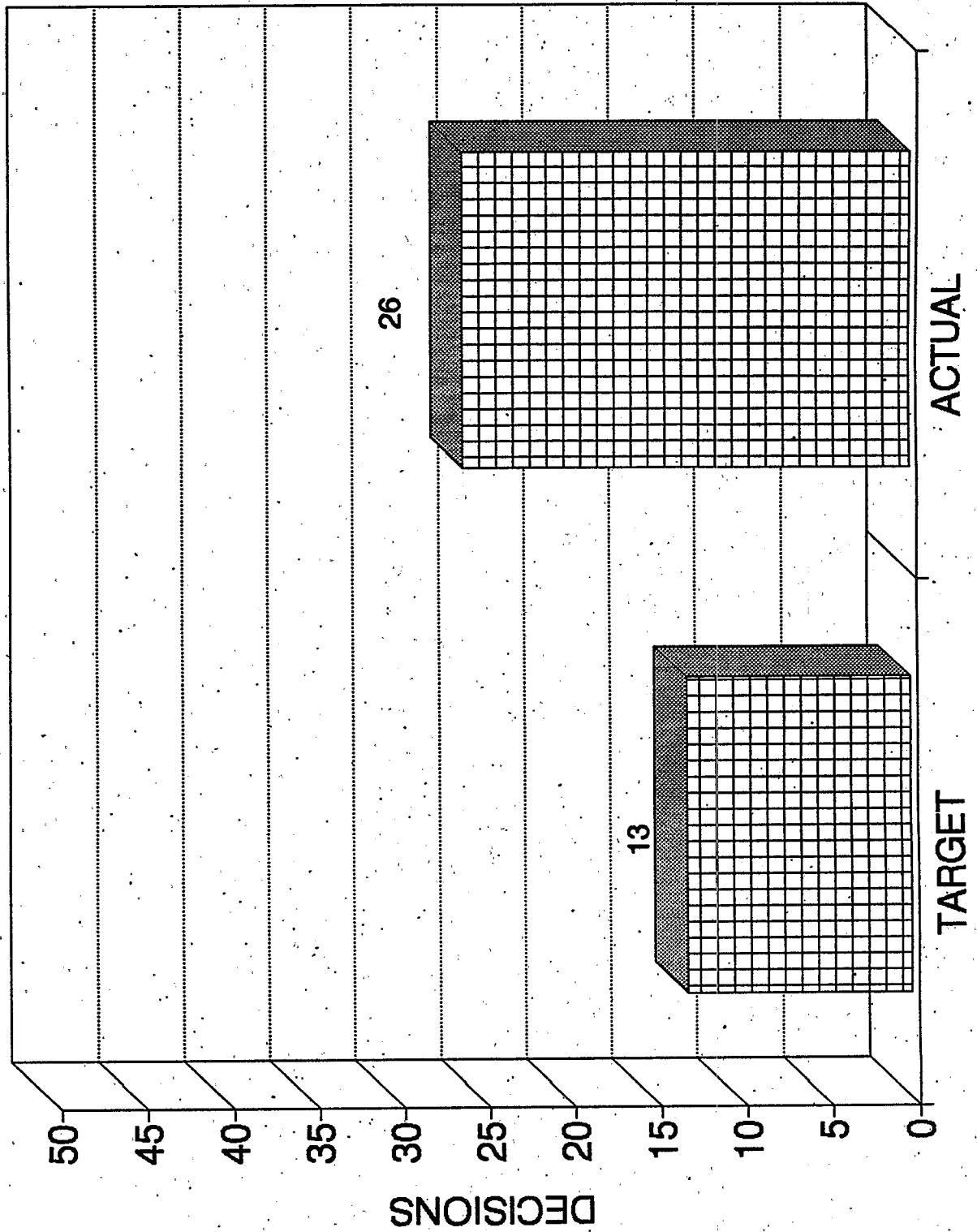
Total Resources Spent vs. Planned on Registrations: Resources used vs. planned across OPP in FY95 for processing registration actions.

Product Reregistration Status: Cumulative status of current and future decisions as of October, 1995.

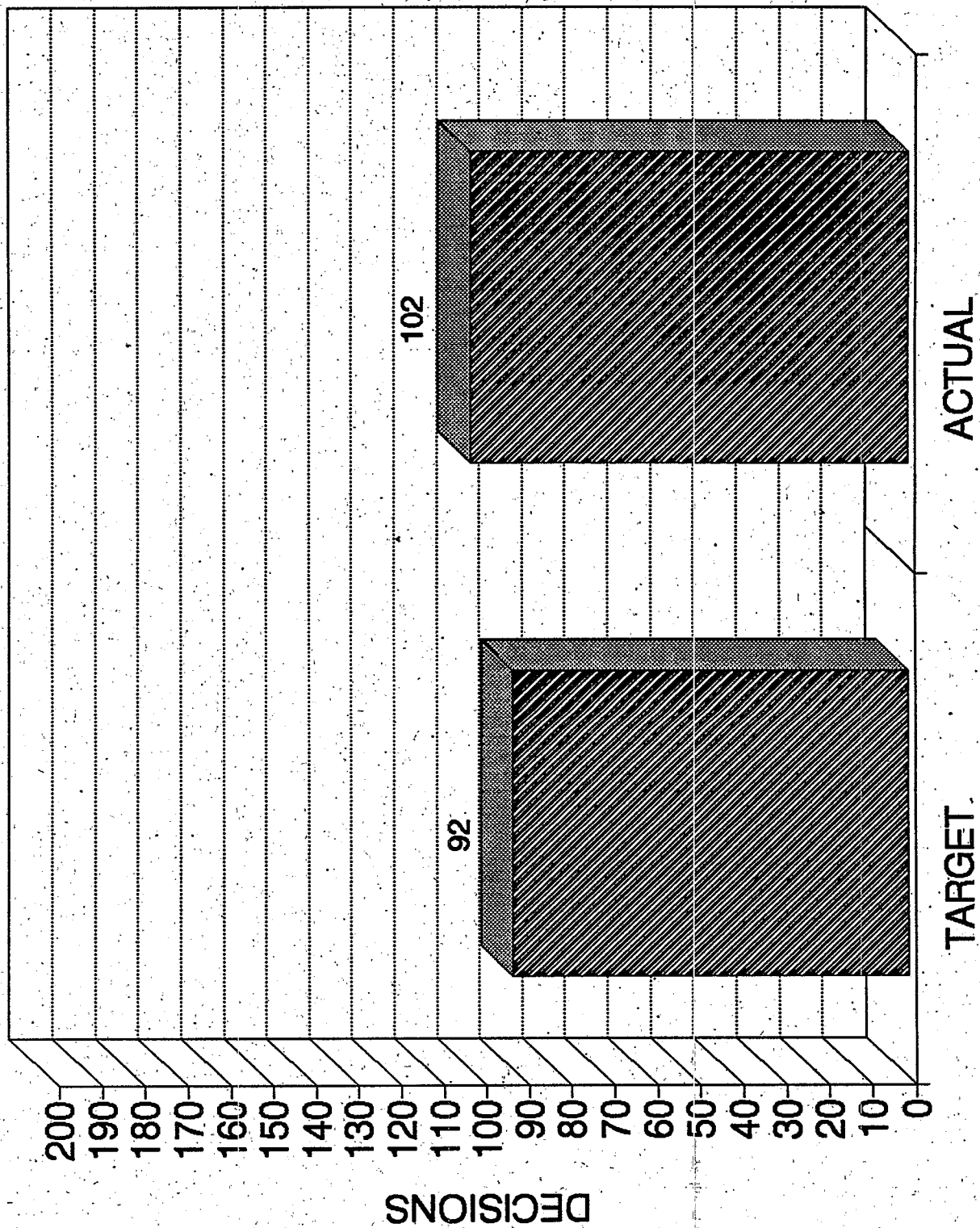
FY95 PPA TARGET VS. DECISIONS



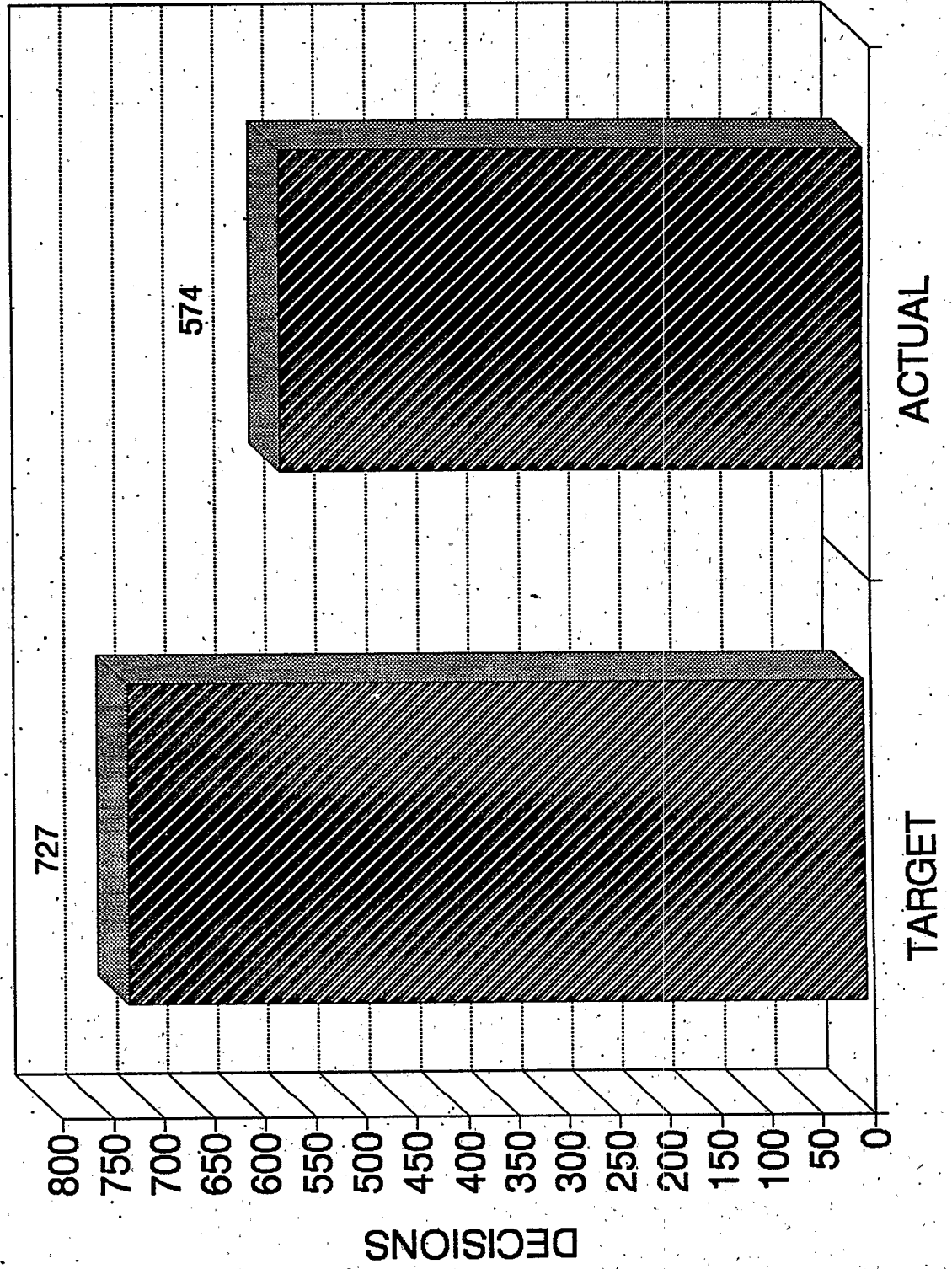
NEW CHEMICAL FY95 TARGET VS. ACTUAL



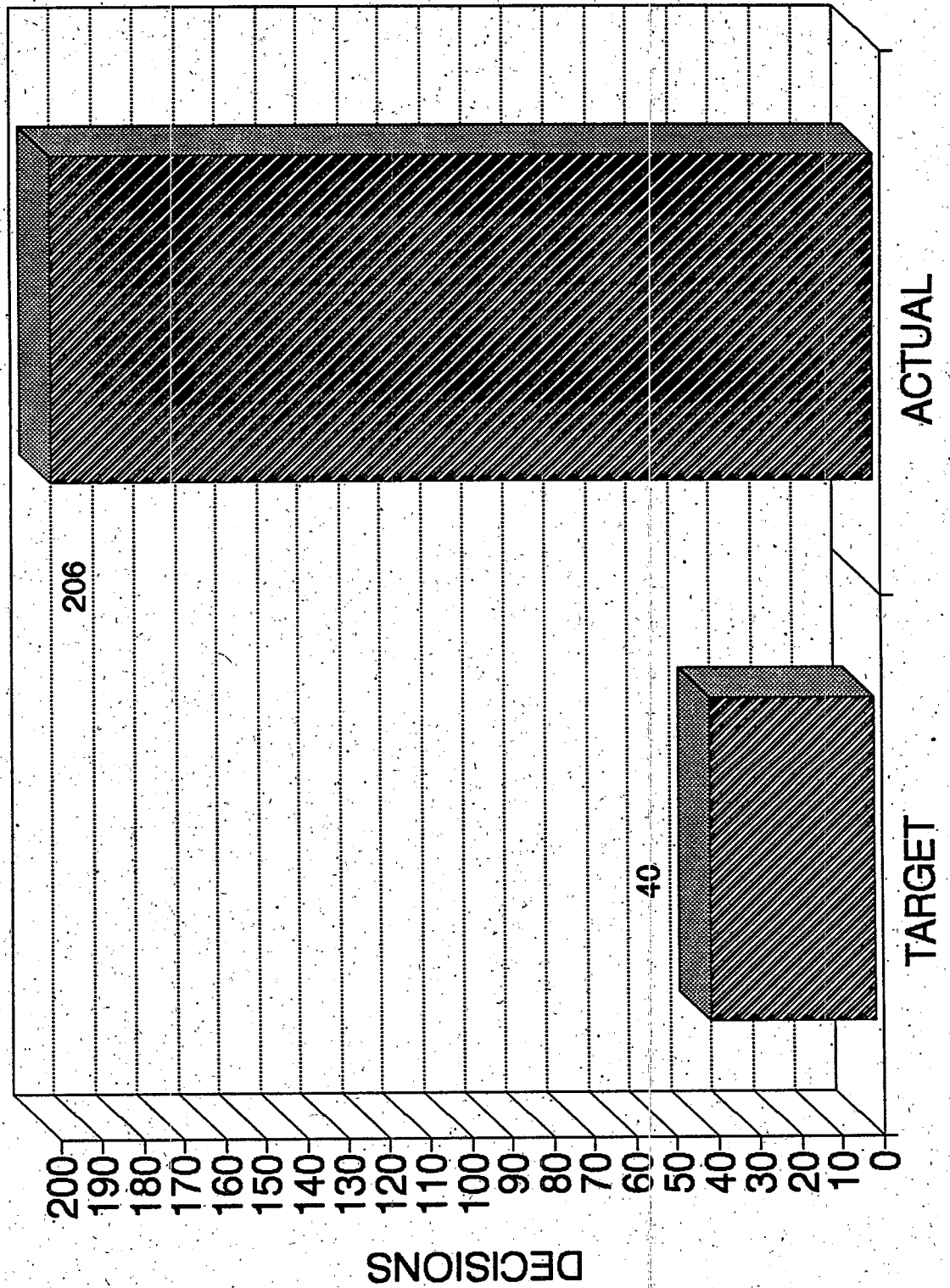
NEW USE FY95 TARGET VS. ACTUAL



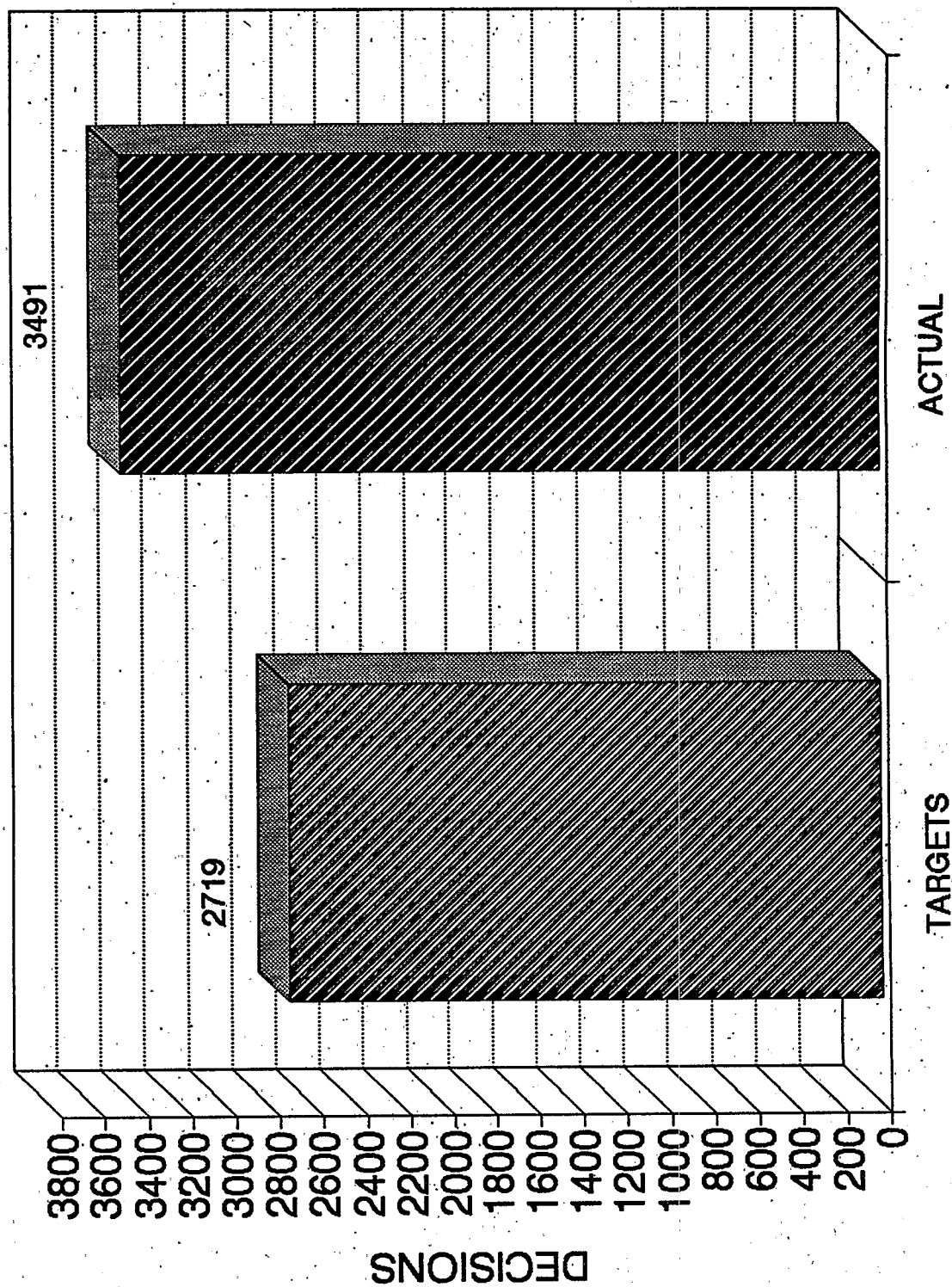
OLD CHEMICALS FAST TRACK
FY95 TARGET VS. ACTUAL



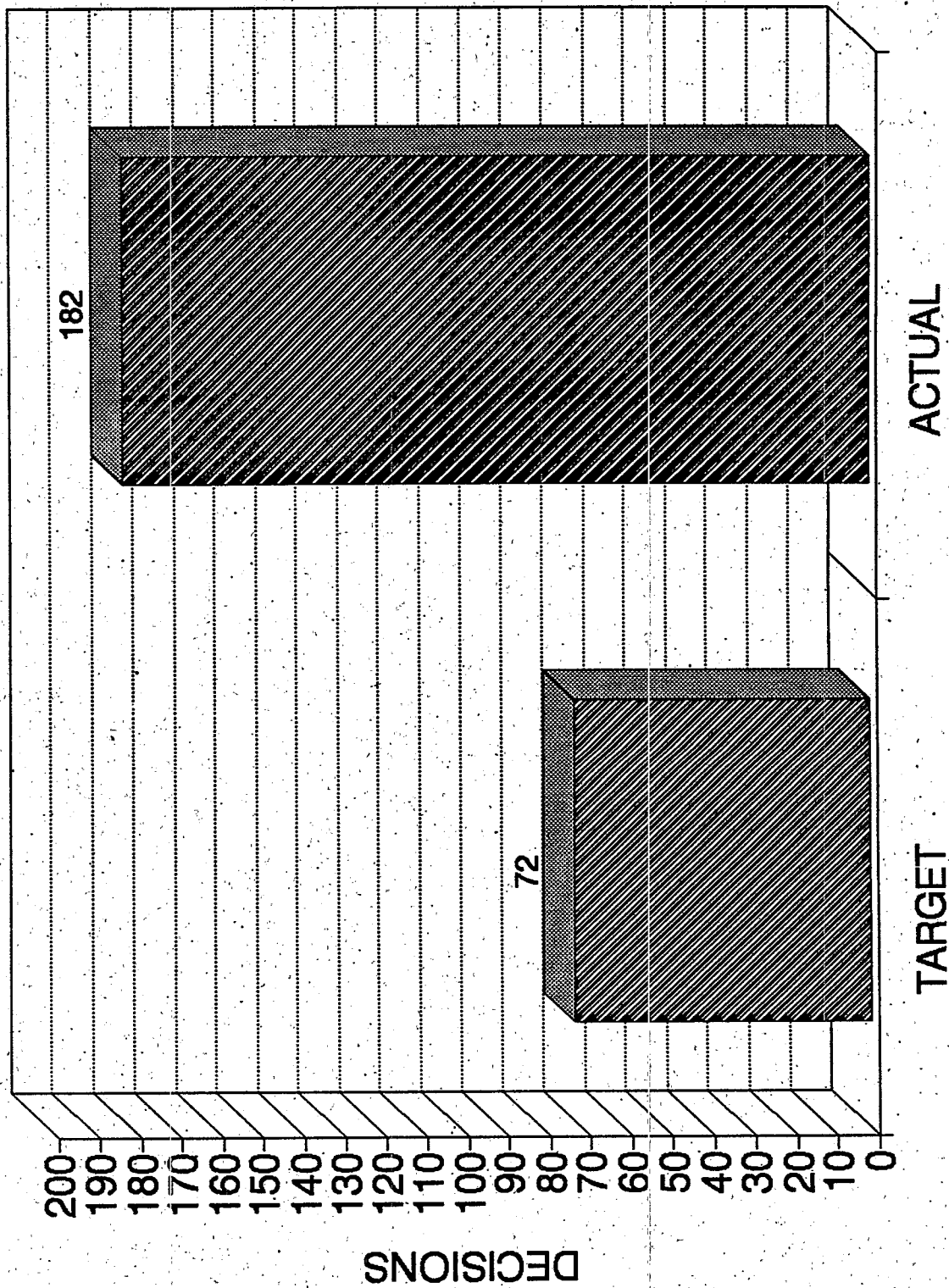
OLD CHEMICAL NON FAST TRACK
FY95 TARGET VS. ACTUAL



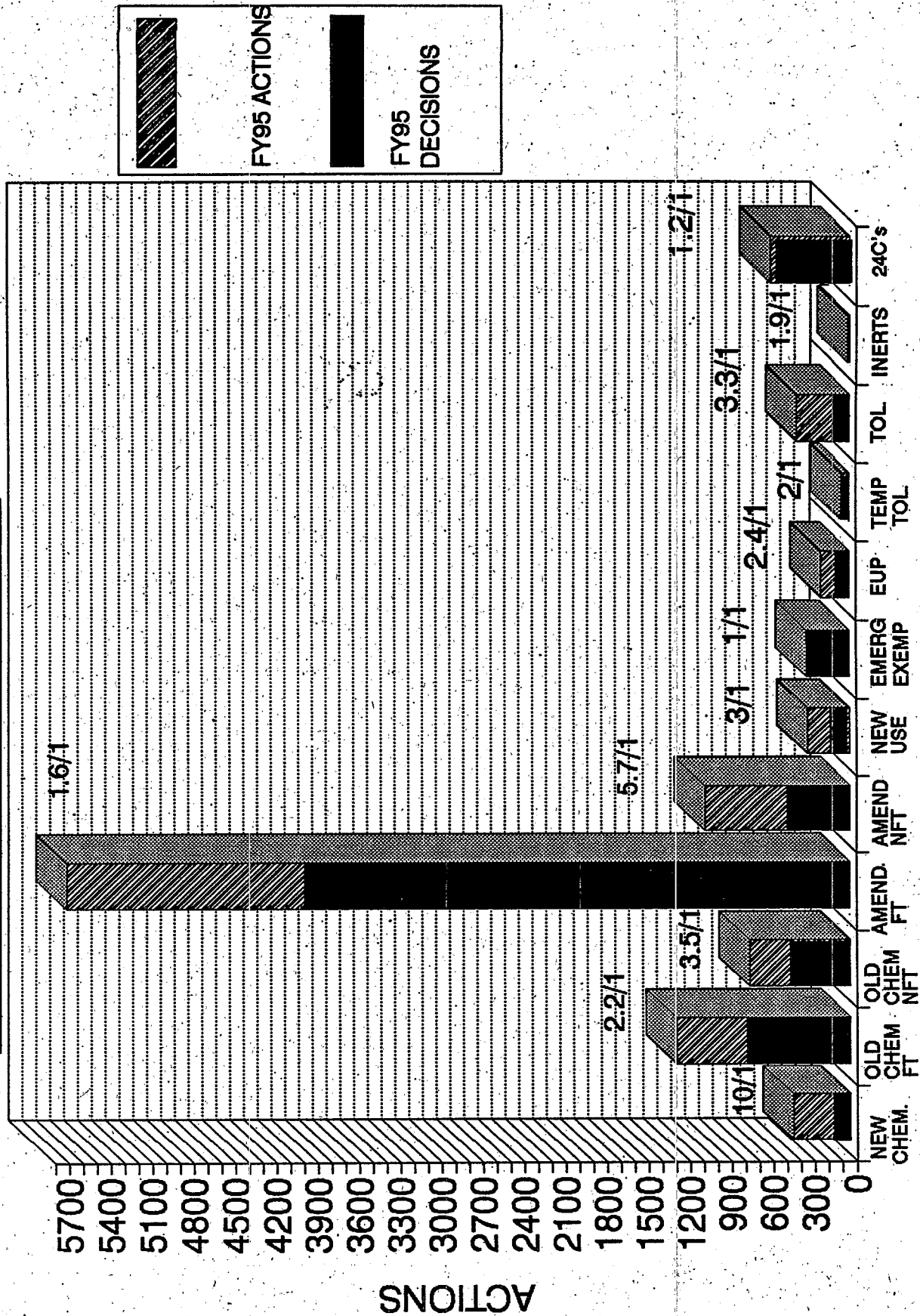
AMENDMENTS FAST TRACK
FY95 TARGETS VS. ACTUAL



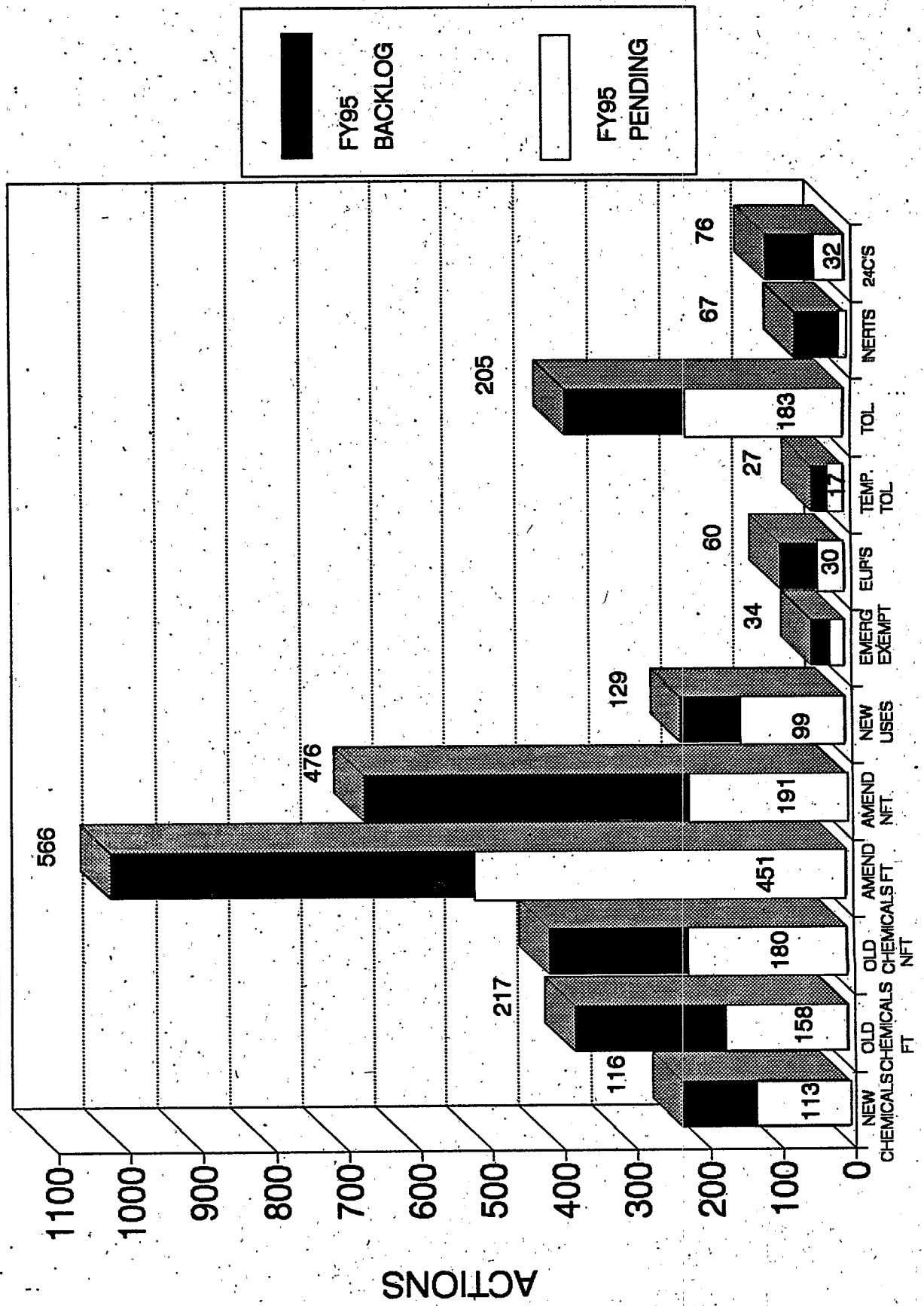
AMENDMENTS NON FAST TRACK
FY95 TARGET VS. ACTUAL



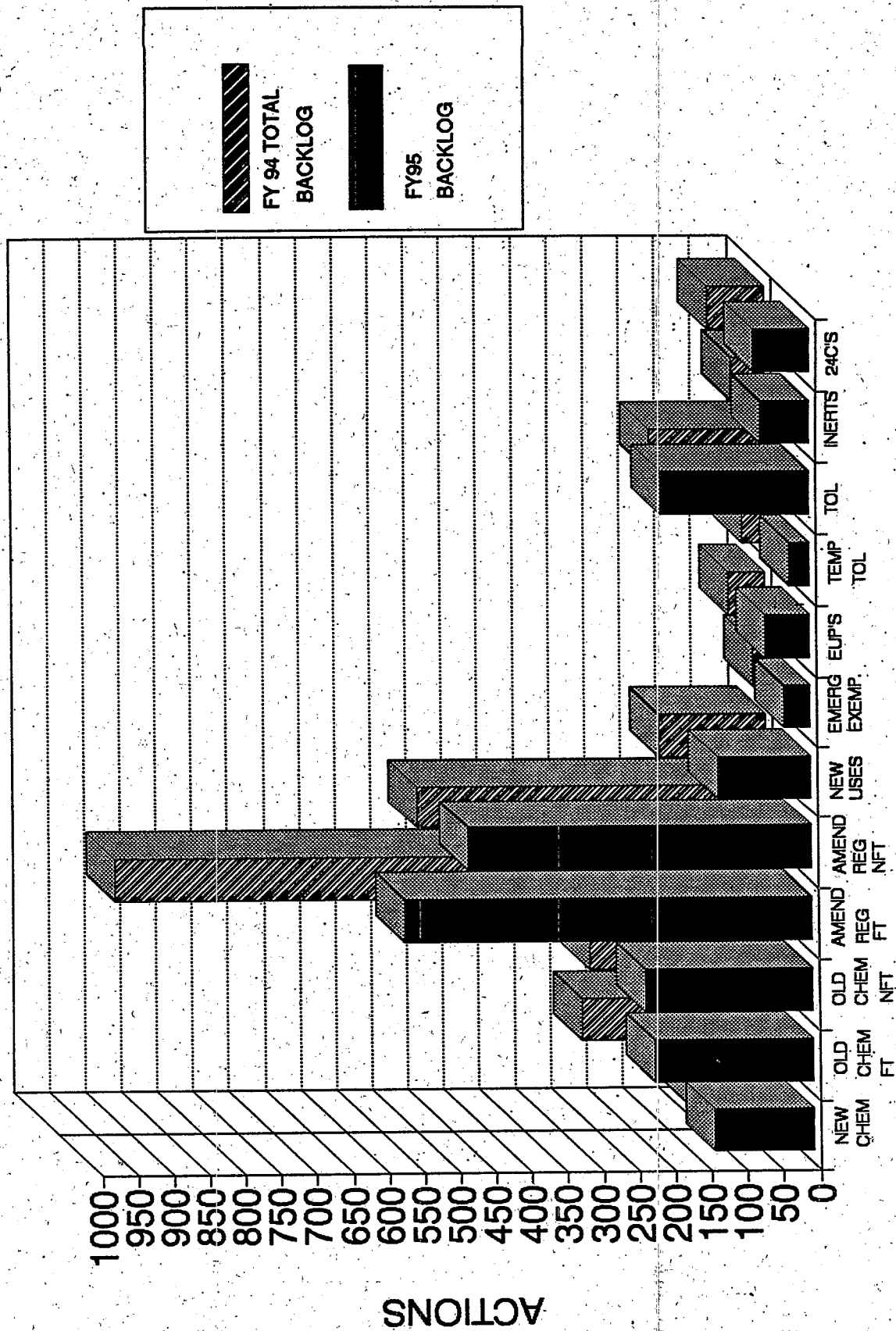
FY95 ACTIONS vs. DECISIONS



WORKLOAD (ACTIONS) AT END OF FY95

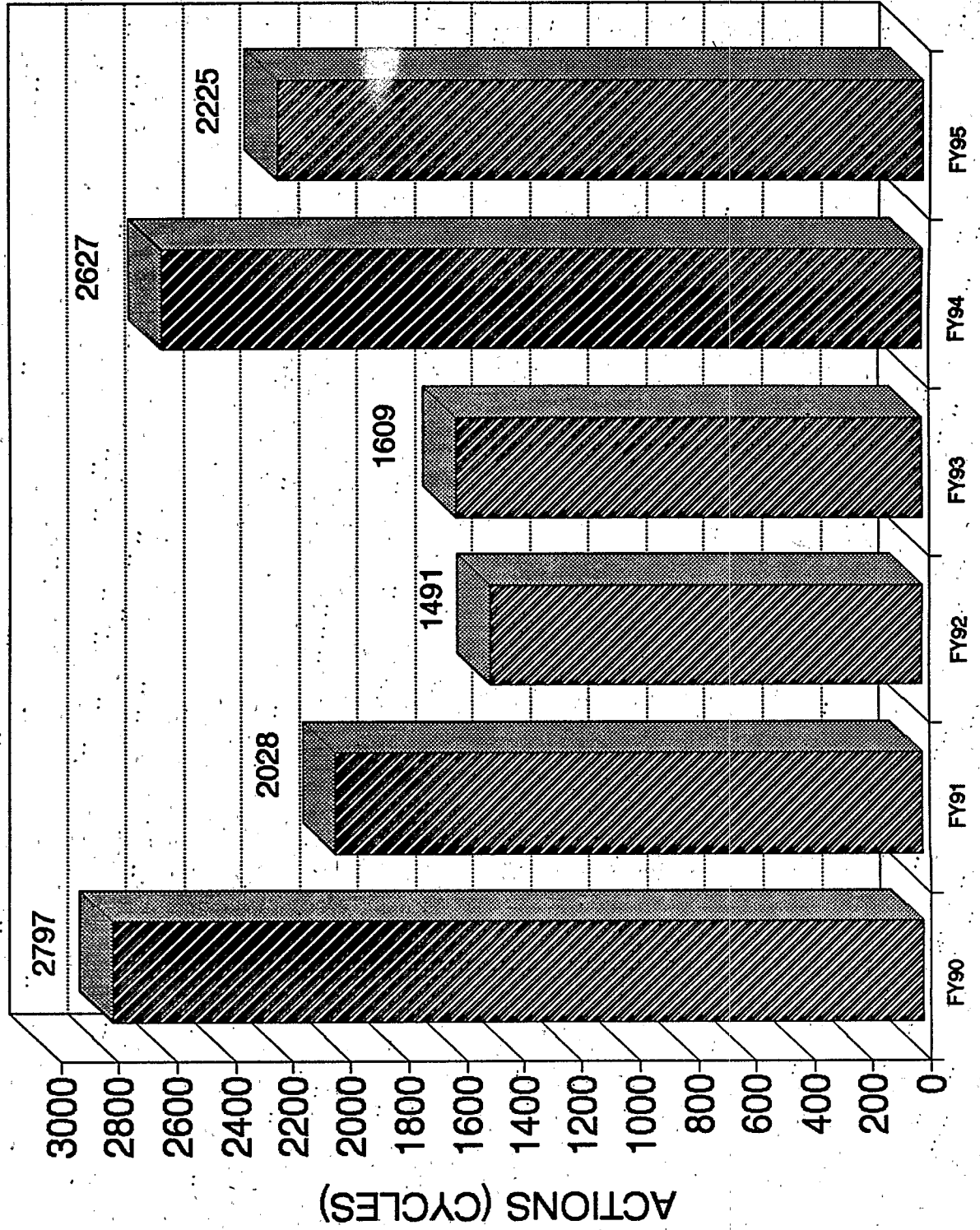


RD REGISTRATION BACKLOGS

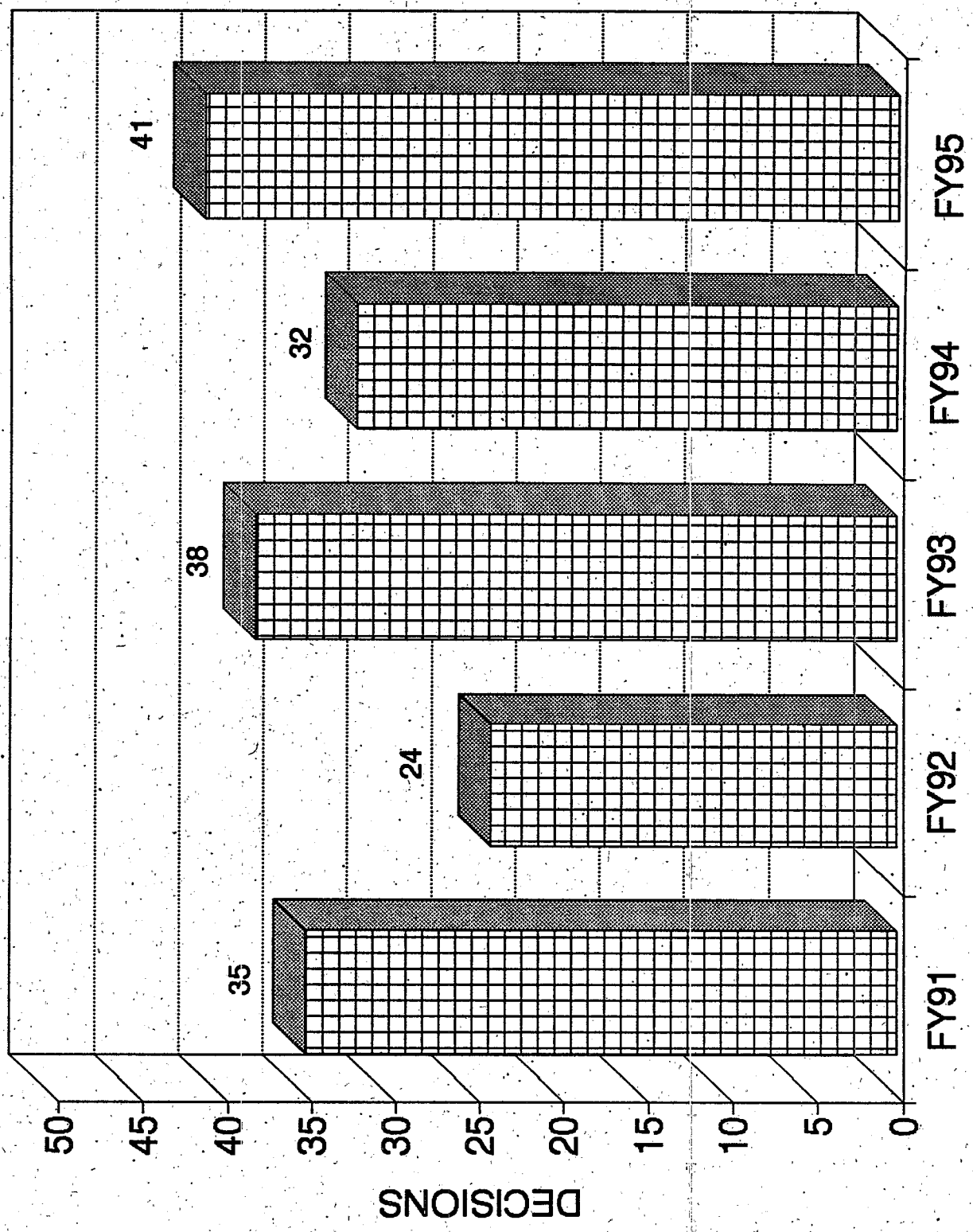


This figure compares the backlog (actions older than a target turnaround time) at the end of FY94 to that of the backlog at the end of FY95. In some cases backlog has decreased and in some case it has increased.

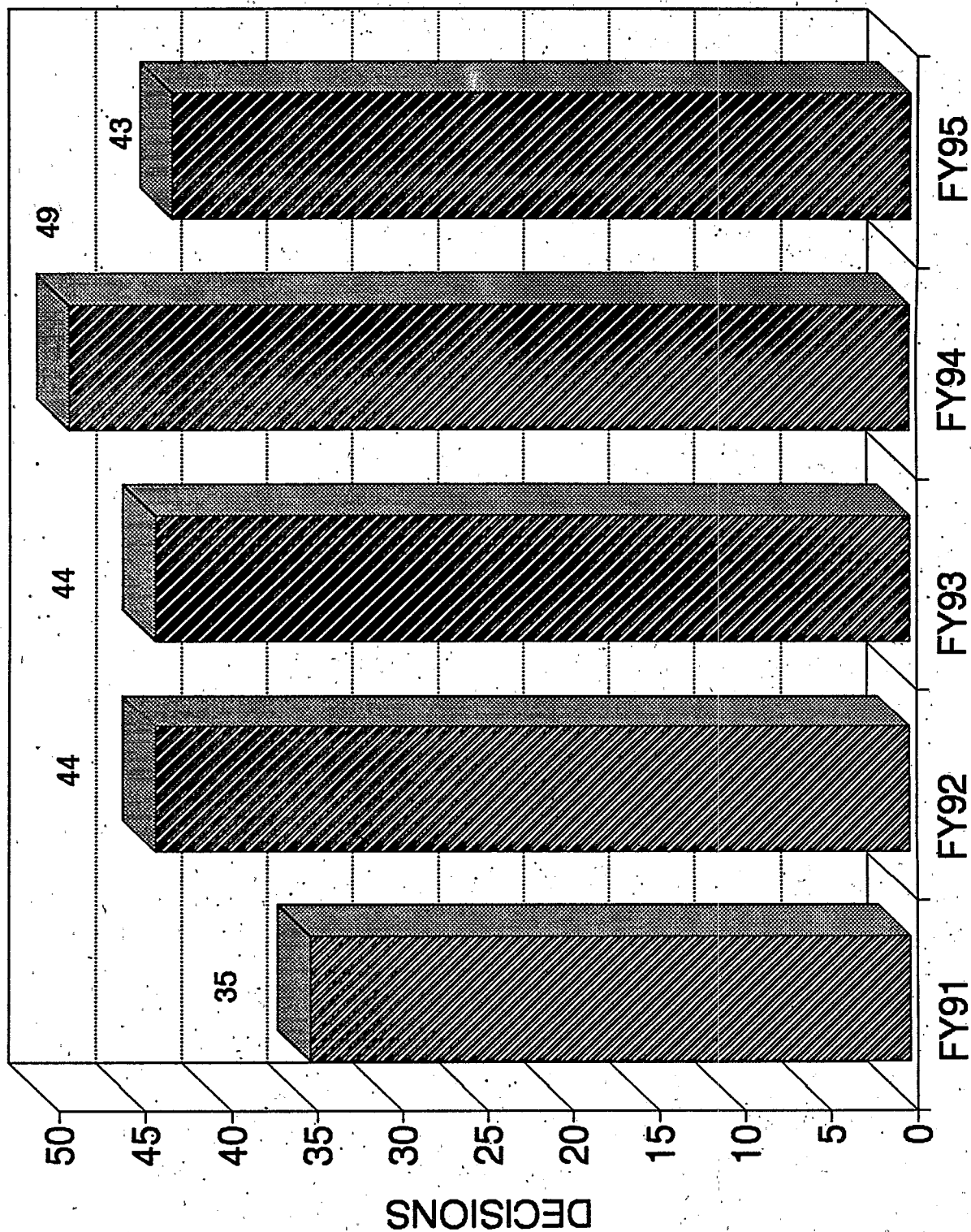
FY90-FY95 TOTAL BACKLOG



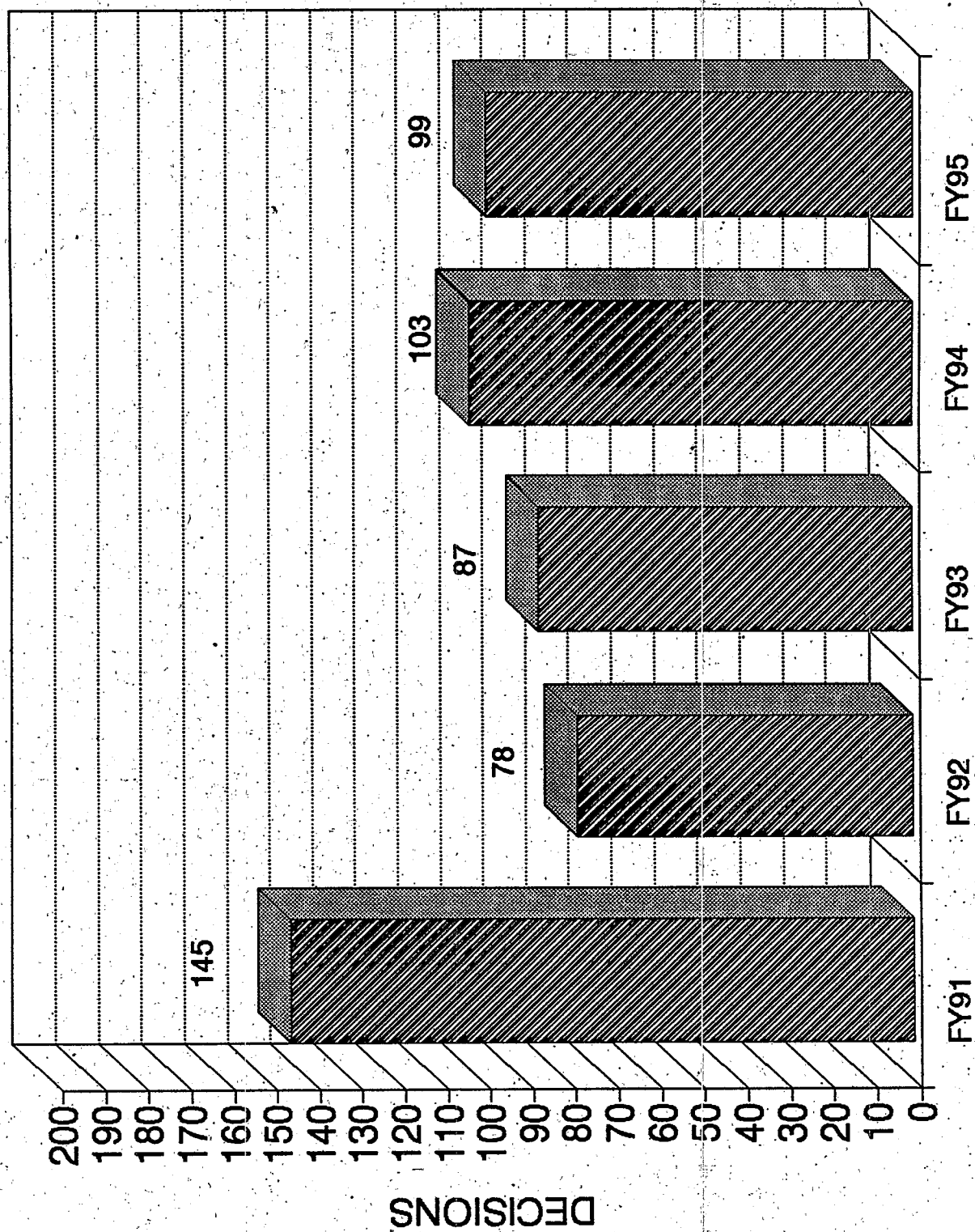
NEW CHEMICALS FY91-95 BACKLOG



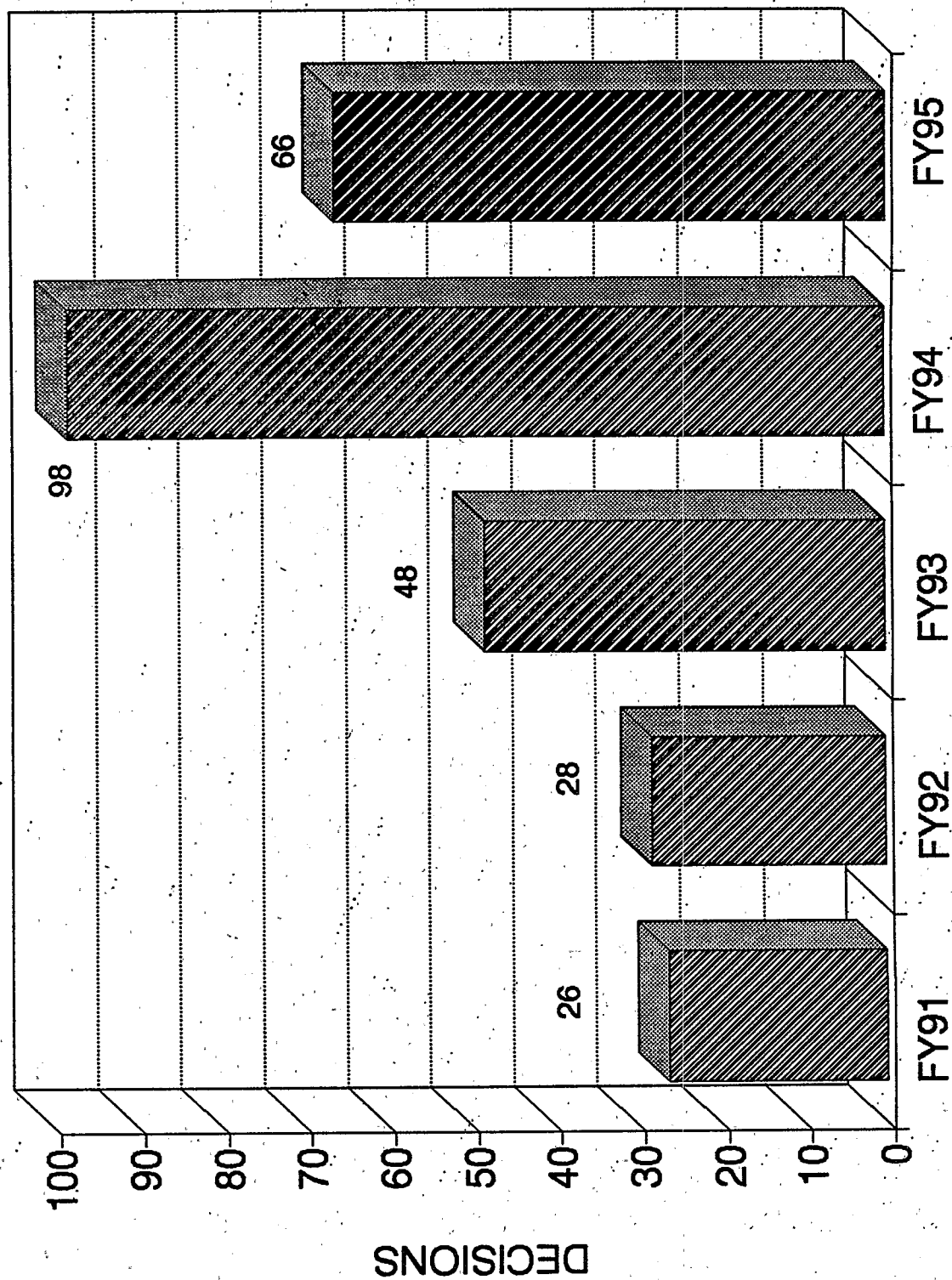
NEW USES FY91-95 BACKLOG



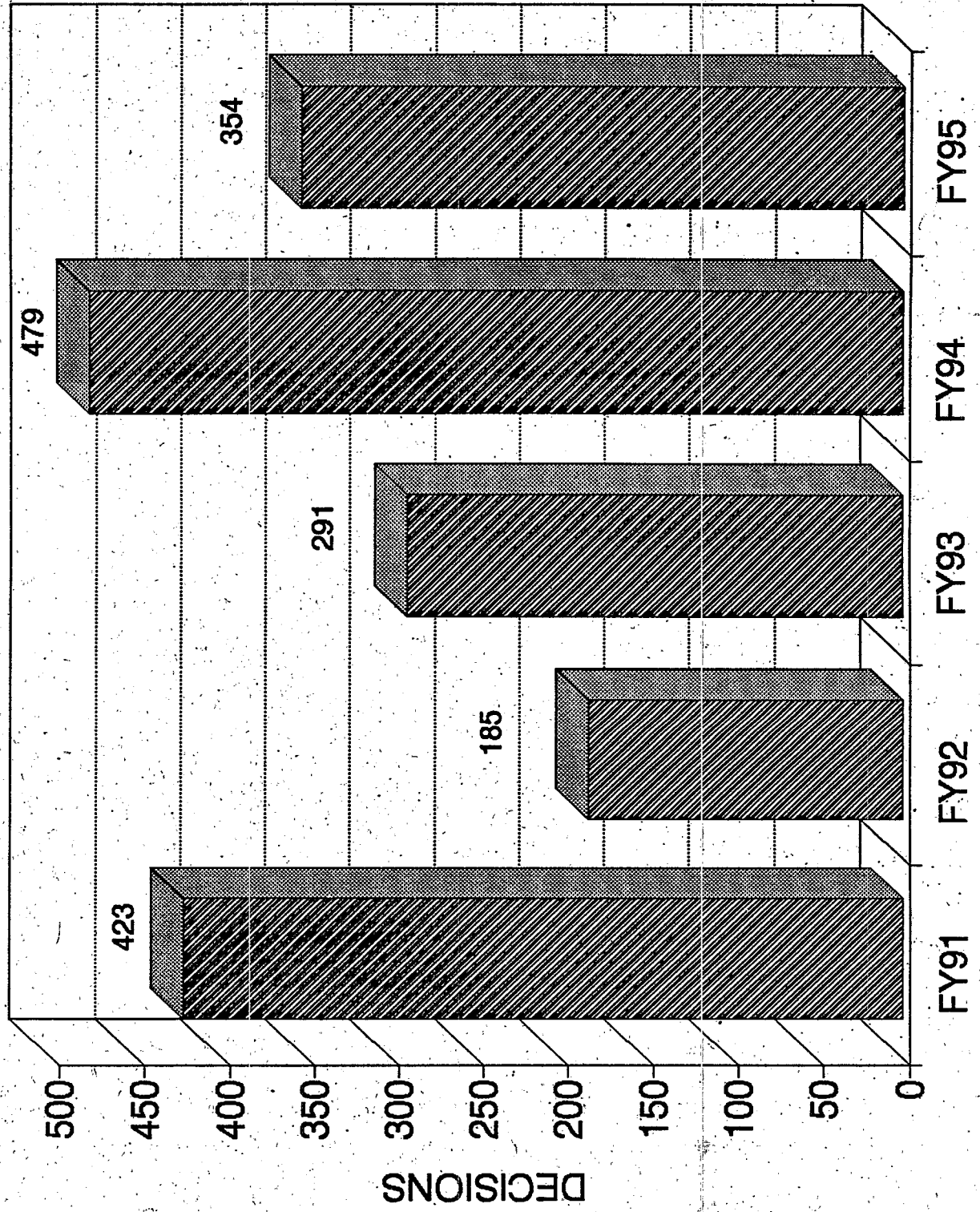
OLD CHEMICAL FAST TRACK FY91-95 BACKLOG



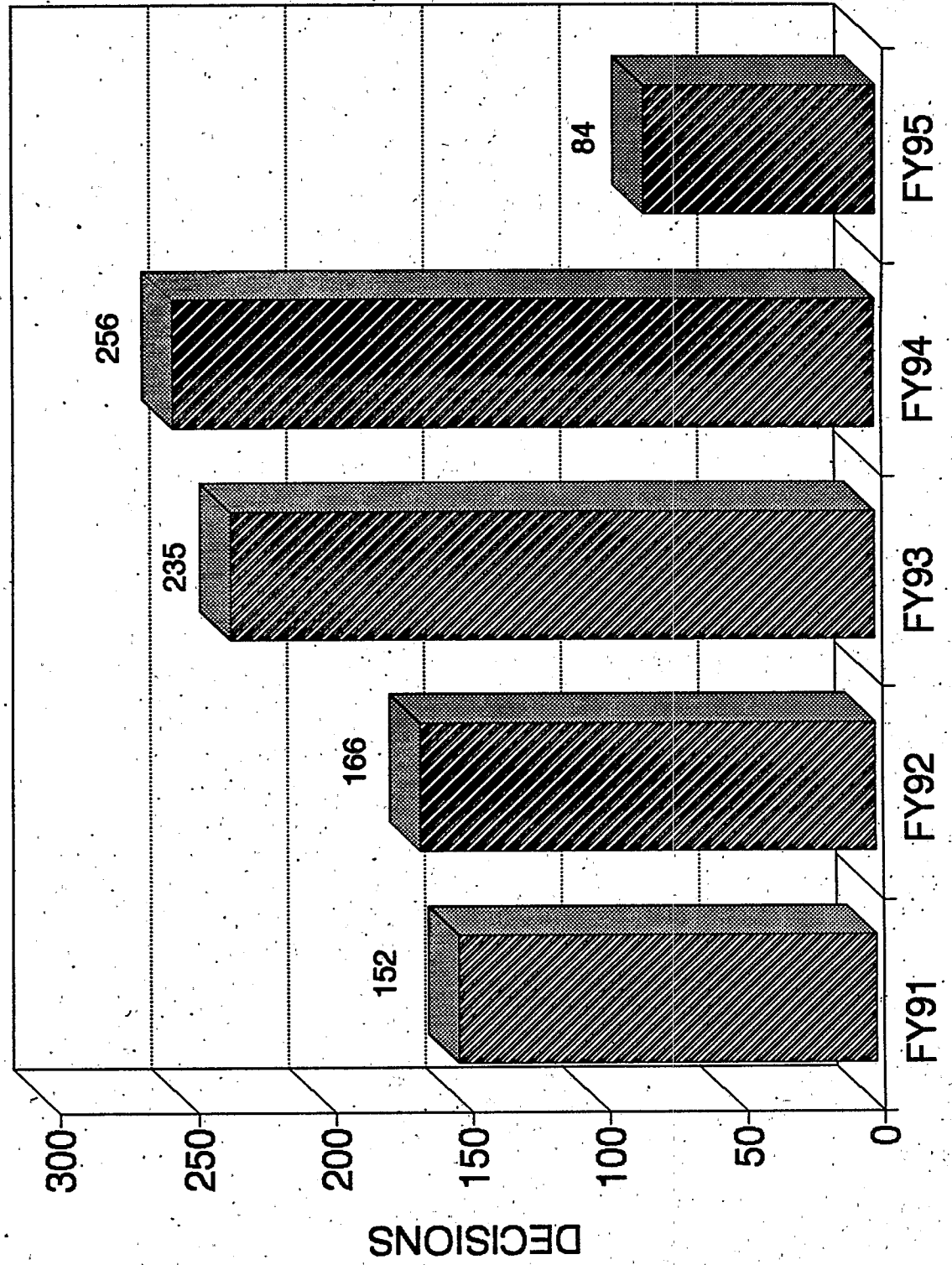
OLD CHEMICAL NON FAST TRACK
BACKLOG FY91-95



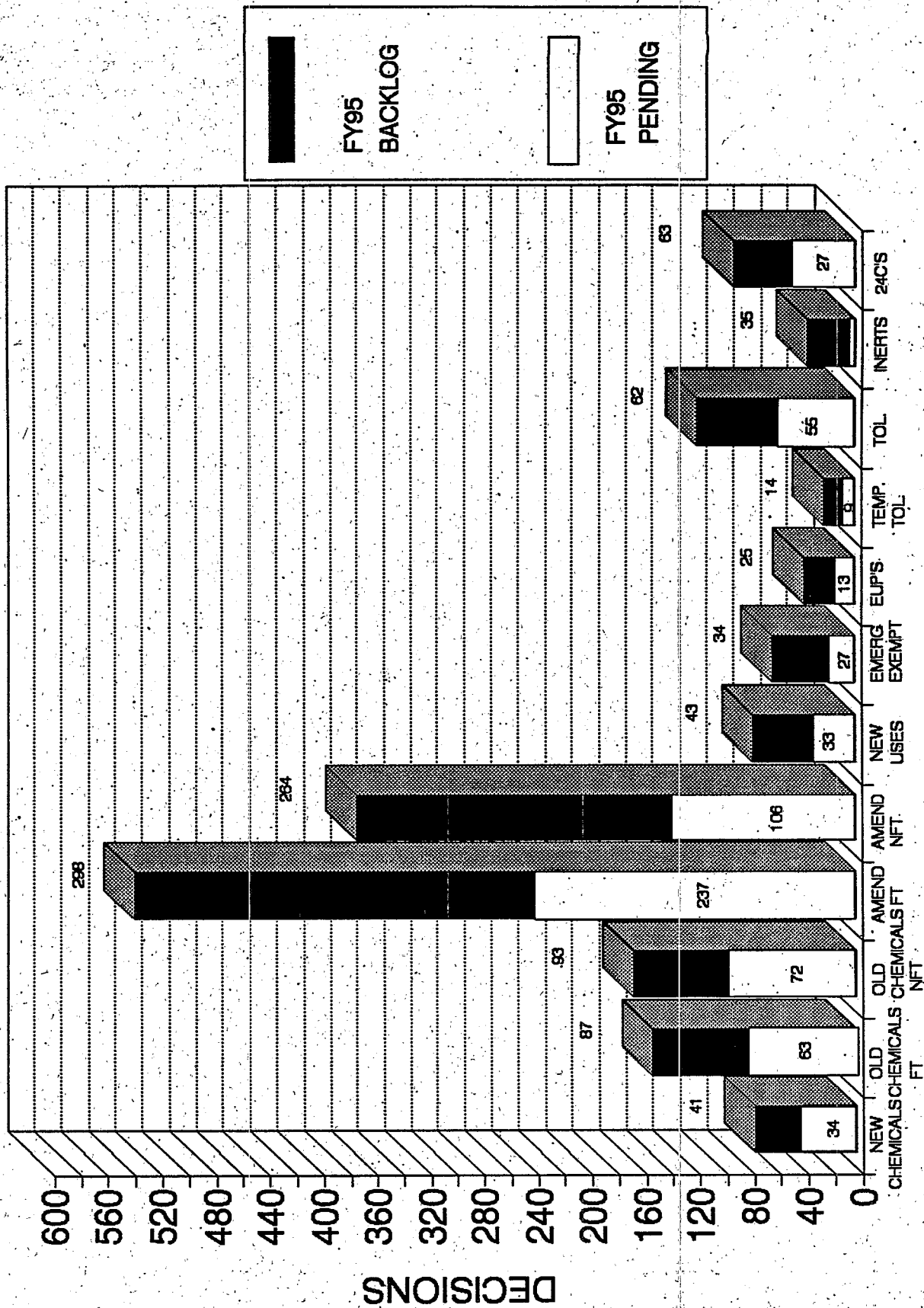
AMENDMENTS FAST TRACK BACKLOG FY91-95



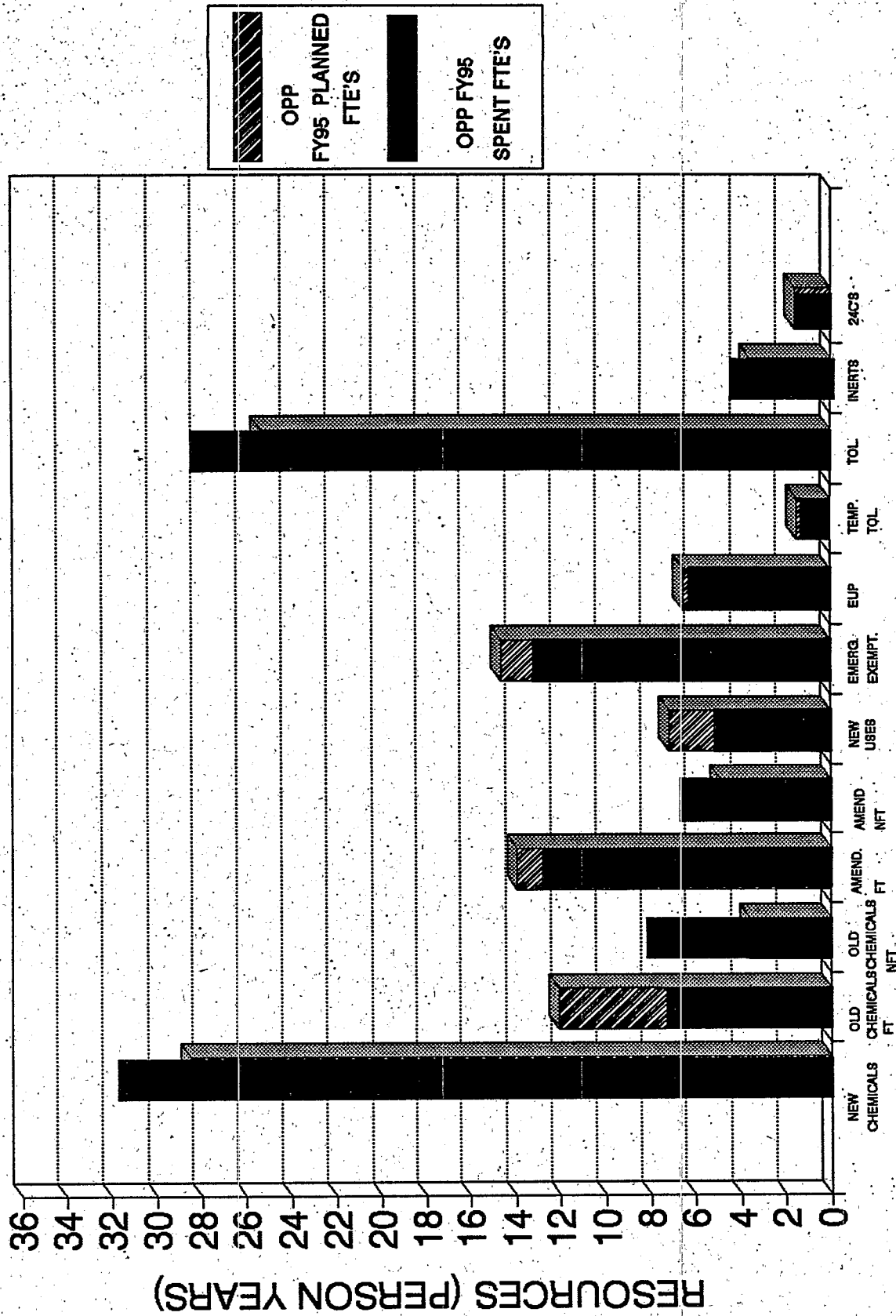
AMENDMENTS NON FAST TRACK
FY91-95 BACKLOG



WORKLOAD (DECISIONS) AT END OF FY95

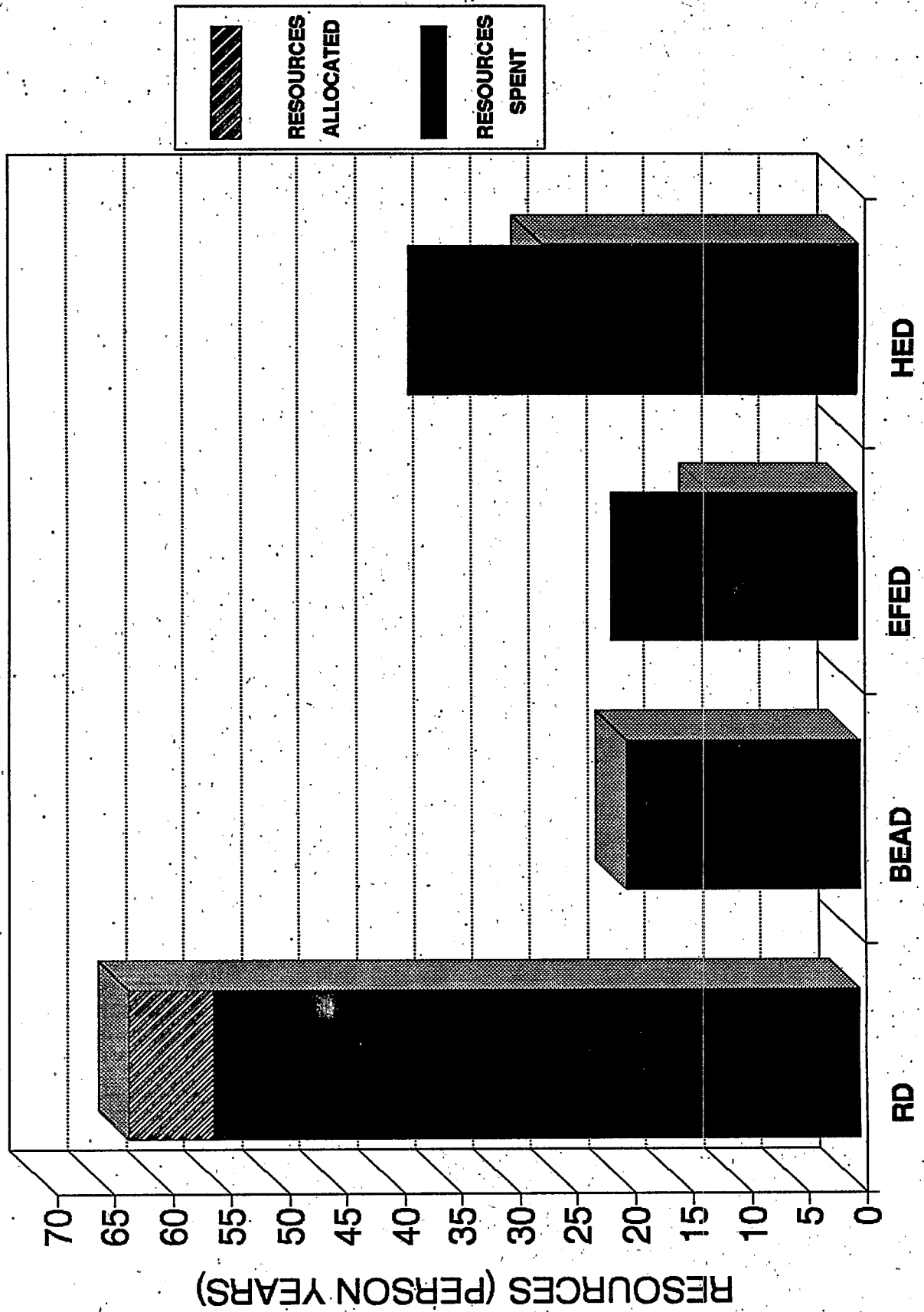


OPP FTE'S SPENT VS. PLANNED FY95



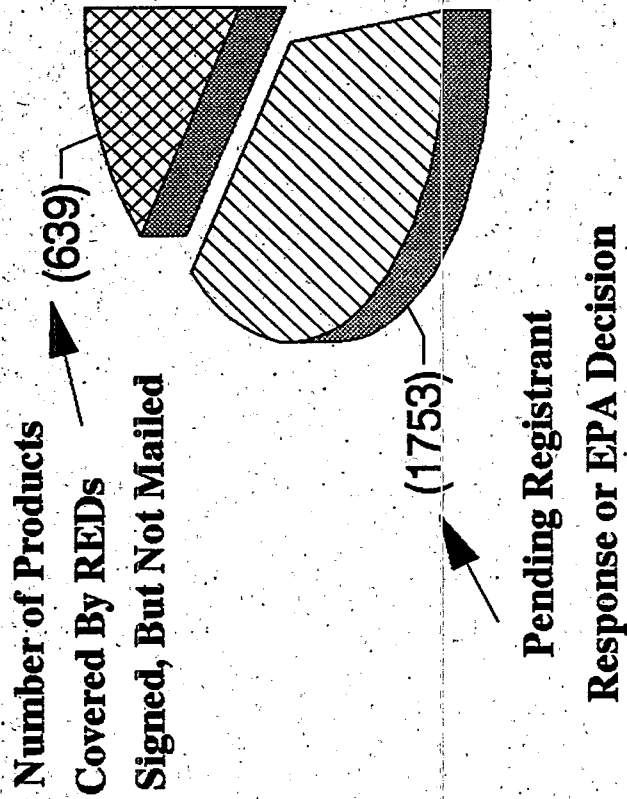
This chart shows FY95 Allocated resources vs. FY95 resources spent in each PPA category. Registration Division appears to be underburning resources in some categories, overburning in some and on track in the remaining categories.

OPP FY95 ALLOCATED RESOURCES VS SPENT

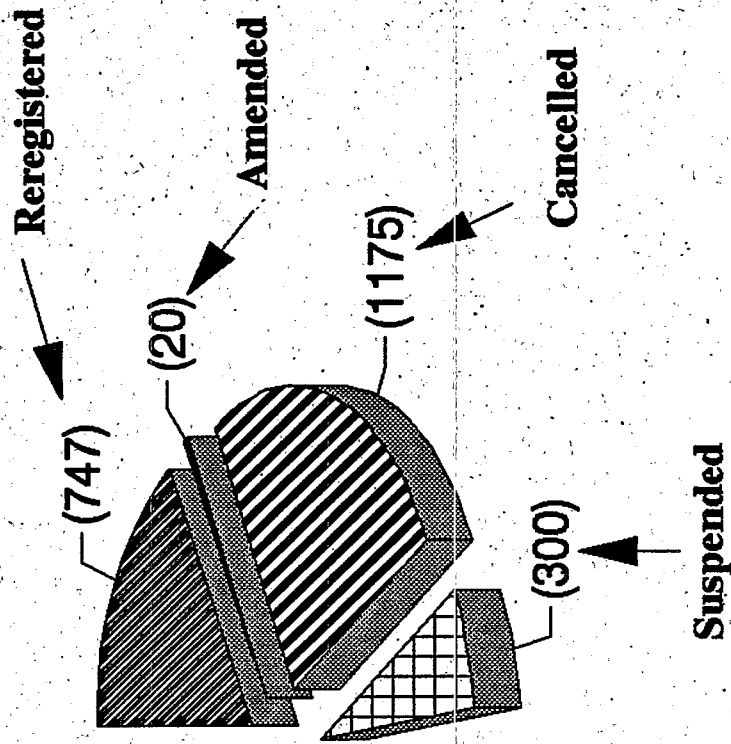


PRODUCT REREGISTRATION STATUS OF 4634 PRODUCTS FOR 121 REDS AS OF OCT 19 1995

FUTURE DECISIONS (2,392)



CURRENT DECISIONS (2,242)



III. DETAILS

New Active Ingredients Registered in FY95: New chemicals, biochemicals and reduced risk (chemical) active ingredients.

Actions and Decisions Completed: Numbers of completed actions and decisions for each registration category in FY95.

Workload: Pending and backlogged actions for each registration category at the end of FY95.

Resources: Resources spent vs. planned by registration type during FY95.

NEW PESTICIDE ACTIVE INGREDIENTS FY 95

| Pesticide Name and CAS Reg. No. | Registrant | Pesticide Type | Use(s) | Active Ingredient Type |
|---|------------------------------------|---------------------------|-------------------------|------------------------------|
| Prallethrin (23031-36-9) | Sumitomo | Insecticide | Non-food/feed areas | Chemical |
| Halosulfuron (100784-20-1) | Monsanto | Herbicide | Corn/ornamental | Chemical |
| Potassium Bicarbonate (298-14-6) | Church & Dwight Co. | Fungicide | Formulating Uses | Biochemical |
| Sodium Bicarbonate (144-55-8) | Church & Dwight Co. | Fungicide | Formulating Uses | Biochemical |
| Pyridaben (96489-71-3) | Nissan Chemical | Insecticide Miticide | Non- food/ornamental | Chemical |
| Resource (87546-18-7) | Valent | Herbicide | Corn | Reduced Risk Chemical |
| Rimsulfuron (122931-48-0) | DuPont | Herbicide | Corn/Potatoes | Chemical |
| Sodium Carboxymethyl- cellulose (9004-32-4) | Creative Services Inc. | Insecticide | Ornamental | Biochemical |
| 1,4 Dimethyl- naphthalene (571-58-4) | D-I-1-4 Inc. | Plant Growth Regulator | Potatoes | Biochemical |
| Fenbuconazole (114369-43-6) | Rohm and Haas Company | Fungicide | Pecans/Small Fruits | Chemical |
| Sodium 5-Nitro- guaiacolate (67233-85-6) | Asahi Chemical Manufacturing | Plant Growth Regulator | Cotton/soybeans rice | Biochemical |

| | | | | |
|---|---------------------------------------|-------------------|-----------------------------|--------------------------|
| Diethyl Sulfide (352-93-2) | Bear Country Products | Bear Deterrent | Non Food | Chemical |
| A0-159 (58842-20-9) | DuPont | Insecticide | Farm Animals/Pets | Chemical |
| Isobardac | Lonza, Inc. | Antimicrobial | Water treatment | Chemical |
| Primisulfuron Methyl (86209-51-0) | Ciba-Geigy | Herbicide | Corn | Chemical |
| Difethialone (104653-34-1) | LiphaTech, Inc. | Rodenticide | Home | Chemical |
| Tebufenozide (112410-23-8) | Rohm and Haas Company | Insecticide | Walnuts | Reduced Risk Chemical |
| Methyl Anthranilate (134-20-3) | Dolphin Trust | Bird Repellent | Small Fruits/ ornamental | Reduced Risk Chemical |
| Hymexazol (10004-44-1) | Sumitomo Chemical | Fungicide | Seed treatment | Reduced Risk Chemical |
| Diocetyl Sodium Sulfosuccinate (1639-66-3) | Safe and Sure Products | Insecticide | Dogs/Cats | Chemical |
| Undecylenic Acid (112-38-9) | Safe and Sure Products | Insecticide | Dogs/Cats | Chemical |
| Pyriproxyfen (95737-68-1) | Mclaughlin Gormley King Company | Insecticide | Dogs/Cats | Chemical |
| Maxim (131341-86-1) | Ciba-Geigy | Fungicide | Seed Treatment | Reduced Risk Chemical |
| Chlorethoxyfos (54593-83-8) | DuPont | Insecticide | Corn | Chemical |
| Pyriethionac-sodium (123342-16-8) | DuPont | Herbicide | Cotton | Chemical |
| Poly (N,N-dimethyl diallyl ammonium chloride) (26062-79-3) | Calgon | Antifoulant | Water treatment | Chemical |

FY95 TARGETS VS. DECISIONS

| | FY95 TARGETS (CYCLES) | FY95 COMPLETIONS (CYCLES) | | FY95 TARGETS (DECISIONS) | FY95 COMPLETIONS (DECISIONS) | |
|-------------------|--------------------------|------------------------------|--|-----------------------------|---------------------------------|--|
| OLD CHEMICALS FT | 1600 | 1255 | | 727 | 574 | |
| OLD CHEMICALS NFT | 140 | 724 | | 40 | 206 | |
| AMENDMENTS FT | 4350 | 5670 | | 2719 | 3491 | |
| AMENDMENTS NFT | 410 | 1045 | | 72 | 182 | |
| NEW USES | 240 | 301 | | 92 | 102 | |
| NEW CHEMICALS | 275 | 417 | | 13 | 26 | |
| BIOLOGICALS | 0 | 11 | | 9 | 19 | |
| EUP'S | 280 | 204 | | 117 | 86 | |
| TOLERANCES | 280 | 387 | | 85 | 116 | |
| TEMP. TOLERANCES | 60 | 58 | | 30 | 29 | |
| INERTS | 13 | 15 | | 7 | 8 | |
| EMERG. EXEMPTIONS | 320 | 312 | | 320 | 400 | |
| 24C's | 180 | 570 | | 150 | 472 | |
| TOTALS | 8148 | 10969 | | 4381 | 5711 | |

TABLE 1

BACKLOGS FY90-95 DECISIONS

| | FY91 | FY92 | FY93 | FY94 | FY95 |
|------------------|------|------|------|------|------|
| OLD CHEMICAL FT | 145 | 78 | 87 | 103 | 99 |
| OLD CHEMICAL NFT | 26 | 28 | 48 | 98 | 66 |
| AMENDMENTS FT | 423 | 185 | 291 | 479 | 354 |
| AMENDMENTS NFT | 152 | 166 | 235 | 256 | 84 |
| NEW USES | 35 | 44 | 44 | 49 | 43 |
| NEW CHEMICALS | 35 | 24 | 38 | 32 | 41 |
| BIOLOGICALS | 0 | 0 | 0 | 0 | 0 |
| EUP'S | 26 | 27 | 26 | 21 | 25 |
| EMERG. EXEMPT. | 28 | 47 | 15 | 16 | 34 |
| TOLERANCES | 26 | 42 | 51 | 49 | 62 |
| TEMP. TOLERANCES | 9 | 10 | 10 | 16 | 14 |
| INERTS | 3 | 7 | 6 | 24 | 36 |
| 24C'S | 62 | 32 | 54 | 65 | 63 |
| TOTALS | 970 | 690 | 905 | 1208 | 921 |

TABLE2

| | FY91 | | FY92 | | FY93 | | FY94 | | FY95 | |
|----------------|--------------|------------------------|--------------|------------------------|--------------|------------------------|--------------|------------------------|--------------|------------------------|
| | TURN TIME | % ACTIONS COMPLETED | TURN TIME | % ACTIONS COMPLETED | TURN TIME | % ACTIONS COMPLETED | TURN TIME | % ACTIONS COMPLETED | TURN TIME | % ACTIONS COMPLETED |
| OLD CHEM. NFT | 183 | 65.2 | 222.5 | 59 | 153.7 | 74.3 | 175.1 | 63.7 | 202.6 | 62.2 |
| OLD CHEM. FT | 171 | 47.9 | 137.1 | 50.5 | 109.6 | 59.8 | 126.6 | 55.6 | 145.9 | 49.3 |
| AMEND NFT | 232 | 45.8 | 156.1 | 59.3 | 138.5 | 69 | 180.4 | 61.5 | 193.5 | 57.7 |
| AMEND FT | 179.2 | 49.5 | 110.9 | 60.7 | 81.6 | 72.6 | 97.9 | 68 | 119.7 | 63.4 |
| NEW USES | 222.2 | 59.5 | 288.3 | 45.8 | 271.6 | 53.8 | 263 | 57.5 | 246.7 | 62.5 |
| EMERGE. EXEMPT | 51.8 | 52.3 | 83.4 | 35.9 | 86.7 | 42.1 | 58.7 | 51.7 | 62.6 | 45.5 |
| EUP | 126.1 | 65.3 | 167.2 | 58.6 | 116.8 | 66.4 | 160 | 51.5 | 170.3 | 58.3 |
| TEMP. TOL. | 140.3 | 56.5 | 206.6 | 43.9 | 171 | 52.2 | 209.3 | 37.1 | 225.9 | 41.4 |
| TOL. | 292.8 | 51 | 256.4 | 61.3 | 276.3 | 52 | 304.3 | 50.4 | 262 | 58.7 |
| INERTS | 0 | 0 | 0 | 0 | 452 | 0 | 355.4 | 0 | 237.6 | 6.7 |
| 24(C) | 125.1 | 67.2 | 99.4 | 69.5 | 146 | 69.7 | 117.8 | 69.9 | 101.5 | 69.3 |
| NEW CHEMICALS | 207.3 | 55.6 | 239.7 | 50.4 | 224.4 | 57.6 | 250.7 | 52.1 | 192.1 | 68.6 |
| NEW BIOLOGICAL | 171.1 | 77.4 | 192.7 | | 138.4 | | 208.1 | 54 | 117.7 | 72.7 |
| MISC | 228.8 | 0 | 208.8 | 0 | 141.2 | 0 | 179.8 | 0 | 177.7 | 0 |

TABLE 3

| | FY95 PENDING PLUS BACKLOGGED ACTIONS | | FY95 PENDING ACTIONS | FY95 PENDING DECISIONS | FY95 BACKLOGGED ACTIONS | FY95 BACKLOGGED DECISIONS |
|----------------------|---|--|-------------------------|---------------------------|----------------------------|------------------------------|
| NEW CHEMICALS | 249 | | 113 | 34 | 136 | 41 |
| OLD CHEMICALS FT | 375 | | 158 | 72 | 217 | 87 |
| OLD CHEMICALS NFT | 412 | | 180 | 51 | 232 | 93 |
| AMENDMENTS FT | 1017 | | 451 | 282 | 566 | 298 |
| AMENDMENTS NFT | 667 | | 191 | 34 | 476 | 264 |
| NEW USES | 228 | | 99 | 33 | 129 | 43 |
| EMERGENCY EXEMPTIONS | 61 | | 27 | 27 | 34 | 34 |
| EUP'S | 90 | | 30 | 13 | 60 | 25 |
| TEMP. TOLERANCES | 44 | | 17 | 9 | 27 | 27 |
| TOLERANCES | 388 | | 183 | 55 | 205 | 62 |
| INERTS | 70 | | 3 | 1 | 67 | 35 |
| 24C'S | 108 | | 32 | 27 | 76 | 63 |
| TOTAL | 3709 | | 1484 | 638 | 2225 | 1072 |

TABLE 4

IV. PROJECTS

Following is a listing of RD projects with a brief status report on each as to what has been accomplished to date. The projects are grouped according to the branch or office having the lead, and then listed alphabetically.

FRONT OFFICE

EXEMPTION OF EFFLUENT DISCHARGE STATEMENTS FOR CERTAIN PRODUCTS. On May 1, 1995, OPP issued PR Notice 95-1 to exempt containers under five gallons (liquid) or 50 pounds (dry weight) from bearing the effluent discharge labeling statements specified in PR Notice 93-10. PR Notice 95-1 will reduce the burden which would have fallen on small container products because their labels lack space, but will continue the effluent discharge statements for larger containers where the impact is minimal and where users are in the industrial/commercial sector.

EXPEDITED REGISTRATION. RD is developing guidance for PM teams concerning how to process "fast track" applications. The Fast Track Work Group presented recommendations to the RD Director and is working on a guidance document for the PM teams. This guidance is intended to speed up processing of fast track registrations through standardizing and simplifying current procedures.

NOTIFICATIONS, NON-NOTIFICATIONS AND ACCELERATED REVIEW OF MINOR FORMULATION AMENDMENTS. PR Notice 95-2, issued on May 31, 1995, expands the categories of low risk, minor amendments which may be accomplished by notification (self-certification) or non-notification. In addition, the PR notice creates an accelerated process for reviewing minor formulation changes in 45 days instead of 90 days. As many as 10% (i.e., 500 annually) of current non-fast track amendments may be done by notification, saving about 1.2 FTE and eliminating the current 3-6 month wait for EPA approval. The expedited process for minor formulation changes should reduce unit costs and cut EPA's turnaround time in half (45 days vs. 90 days) for about 5% of fast track amendments (250 per year). EPA will make minor revisions to its regulations to be consistent with the PR notice.

SECTION 25(b) EXEMPTIONS RULE. EPA issued a proposed rule on September 9, 1994, to exempt 31 possible active ingredients from regulation under FIFRA. These ingredients will only be exempted when used alone or in formulation with List 4A inert. Many of the comments received were critical, but we believe they can be adequately addressed without major revisions in the final rule. The final rule should be promulgated at the end of 1995. The Agency is considering proposing another 25(b) rule to deregulate a number of additional chemicals and/or uses such as in the antimicrobial area, including sodium hypochlorite, bacteriostatic water filters and products which control odor-causing bacteria.

SELF CERTIFICATION OF ME-TOO PRODUCTS. OPP is exploring the concept of self certification of registration of fast track, me-too products. An issue paper is being drafted which develops and evaluates several options. The draft paper will be made available for public comment and meetings may be held with stakeholders. After considering the public inputs, OPP will decide whether to proceed with this concept.

VOLUNTARY REDUCED RISK PESTICIDE INITIATIVE. Since the introduction of EPA's voluntary reduced risk pesticide initiative in July of 1993, Registration Division has received twenty reduced risk pesticide applications. Of the 20 applications requesting reduced risk status, nine candidates have been accepted, while six of these candidates have been registered. Seven candidates have been denied, and currently there are four applications pending reduced risk status. RD is committed to make a decision one year after the candidate has been granted reduced risk status. OPP has also issued a draft PR Notice expanding the initial voluntary reduced risk PR Notice to include new uses of those pesticides that have been granted reduced risk status. This PR Notice should be finalized by December 1. The primary goal of this PR Notice is to grant expedited reviews to those new use applications of reduced risk pesticides.

WATER SOLUBLE PACKAGING (WSP): On September 27, 1994, PR Notice 94-8 allowed water soluble packaging to be included under the same registration number as other packaging; this change may be done by notification. The notice streamlines and encourages the approval of WSP, reduces risks for pesticide handlers and decreases the number of pesticide containers requiring cleaning prior to disposal.

ANTIMICROBIAL PROGRAM BRANCH

STRATEGY TO IMPROVE THE ANTIMICROBIAL PROGRAM.

- o The benchwork has been completed on three of the five cooperative agreements which are conducting studies to improve or revise the existing test methods used for registration of antimicrobial pesticides. The Sporicidal Coop has completed its Tier 1 collaborative study. The Virucidal and Tuberculocidal Coops are in the process of preparing for their collaborative studies. The Howard University cooperative agreement, involved in researching injury to bacterial cells, is in the final stages of its benchwork. All of these coops are due to be completed between December 31, 1995 and the end of FY 96. The Statistical Cooperative is undergoing final negotiations for conversion to a contract. This cooperative supports the research performed by the other four by analyzing the data and assisting with the design for the collaborative studies. The Statistical Coop/Contract will be completed approximately one year beyond the completion of the other coops.
- o The Antimicrobial Complaint System (ACS) handles inquiries or complaints concerning EPA registered antimicrobial pesticides. This function was transferred from Texas Technical University, which handled over 1074 inquiries during FY 95, to Oregon University during the second quarter of FY

96. Oregon University is currently in the initial setup phase (hiring and training personnel).

WATER PURIFIER PROTOCOL.

- o The Water Purifier Protocol has been removed from the regulatory agenda. It was decided that a policy for handling water purifier claims could be published without going through the rule making process. OPP is currently awaiting final advice from OGC on the most appropriate means for publication of the policy.

STRATEGY FOR TESTING ANTIMICROBIAL PRODUCTS.

- o The FDA/EPA Interagency Agreement for testing EPA registered sterilant products is in the process of final closeout procedures. All testing of sterilant products was completed in September 1993. Products which failed to show effectiveness as sterilants were referred to the Toxics and Pesticides Enforcement Division (TPED) for enforcement action.
- o The Disinfectant Testing Program was converted from an ORD contract to an in-house OPP managed program in FY 95. Staff from the Antimicrobial Program Branch in RD and the Biological Analysis Branch in BEAD are co-managing the testing program. BEAD/BAB laboratory technicians, at the EPA-OPP-Cincinnati Microbiology Laboratory, are currently in the process of resuming testing of tuberculocides and hospital disinfectants. Due to current resource constraints (both budgetary and personnel related) being faced by many programs in OPP, the overall strategy for testing disinfectant products is undergoing revisions so as to address the issue of removing inefficacious products from the market in the most resource effective manner possible.

EPA/FDA MEMORANDUM OF UNDERSTANDING--25(B) STERILANT EXEMPTION.

- o Under the EPA/FDA Memorandum of Understanding, as amended, for regulation of liquid chemical germicides used on medical devices/medical equipment surfaces, efficacy data required for sterilant products is being reviewed by FDA. All other antimicrobial pesticides which require efficacy data, will continue to have their data submitted to and reviewed by EPA.
- o As part of the EPA/FDA Memorandum of Understanding, each agency will be responsible for their respective rule makings to eliminate the dual regulation of liquid chemical germicides. A draft proposed rule, exempting sterilant products from registration under FIFRA section 25(b), is in the process of undergoing revisions by the Office of General Counsel and the Antimicrobial Program Branch.

FUNGICIDE HERBICIDE BRANCH

ACETOCHLOR NEGOTIATIONS. FHB/EFGW completed negotiations with the Acetochlor Registration Partnership dealing with the 7A provisions of the March 8, 1994 conditional registration of acetochlor.

AUTOMATION" OF CERTAIN PM TEAM DOCUMENTS. Three kinds of documents are being put into electronic form to facilitate the work of the Product Manager Teams: (1) electronic TAIS forms, (2) FR tolerance documents and correspondence, and (3) standard response letters.

EXPERIMENTAL USE PERMITS. Reviewed the regulations and recommended that unutilized reporting be dropped and the 10 acre limitation be increased to 250 acres.

MOU WITH CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION (CDPR). On May 7, 1995, OPP and CDPR agreed to conduct a pilot in which registrants submit simple amendments to CDPR for review; CDPR forwards the amendment and its review to OPP, and OPP accepts CDPR's review and issues approvals to registrants. This pilot is in progress.

METAM SODIUM SEWER LINE ROOT CONTROL MANUAL. As of March 1, 1996, metam sodium products, used for sewer root control, will be reclassified as restricted use pesticides. A manual is now in place to provide assistance to State education and regulatory agencies in introducing sewer root control into their training and certification programs. The manual is being distributed to the regions, state pesticide lead agencies, and state cooperative extension offices. The manual was crucial to the negotiations between the Agency and Arrigation in conjunction with the Notice of Intent to Cancel issued earlier this year.

PMAT (PM AUTOMATION TEAM). The purpose of the PMAT is to streamline the way PM teams function by establishing new ways of conducting our day to day activities via pilot projects and/or best available software. The PMAT assisted in the FHB TAIS pilot project. By doing the TAIS forms electronically we have improved our accuracy by reducing the number of errors normally reported. PMAT has also established macros and boilerplates which allow RD personnel to easily pull up registration notices, fact sheets, federal register notices, and other forms used regularly, saving us time and allowing us to perform more efficiently. The PMAT is currently participating in two pilot projects, the automated labeling project and the Lotus Notes Pilot Project.

REGISTRATION ELIGIBILITY DOCUMENT. As part of the living chemical pilot project, RD issued the first Registration Eligibility Document. This document is similar to a Reregistration Eligibility Decision (RED) document in that it contains a fact sheet, science chapters, and a regulatory chapter. The living chemical document also functions the same as a Living RED document in that it is updated as new regulatory decisions are made.

SECTION 24(c) GUIDANCE DOCUMENT. This document was drafted and sent out for public comment. The document should be issued in December 1995.

WORKER PROTECTION STANDARD LABELING. PR Notice 95-5 which provided guidance to retailers and distributors of agricultural pesticides on how to bring non-complying WPS products into compliance was issued.

INSECTICIDE RODENTICIDE BRANCH

CANADIAN-U.S. TRADE AGREEMENT (CUSTA). A parallel review of tebufenozide was conducted by EPA and Canada. The goal was to identify, through a real example, the similarities and differences between the Canadian and U.S. pesticide regulatory systems.

RODENTICIDE PACKAGING PR NOTICE. A draft PR Notice will be issued for public comment in the Fall of 1995 and issued final in FY 1996. A PR Notice will be proposed which permits placepack products of different sizes to be marketed under a single registration number rather than under separate registrations for each size. This approach would give registrants some relief from Federal and state fees and an opportunity to coordinate packaging of the various placepack sizes with the correct labels for the outer packages. The policy change would be implemented via the amendment process under a "master label" framework. The notice being drafted would delineate OPP's historical policies regarding the consideration of rodenticide baits as distinct products and other administrative matters. This document would also provide a "streamlining" benefit by enabling applicants to "get it right the first time."

TERMITICIDE LABELING PR NOTICE. A workgroup was formed in 1995 to finalize the July 1994 Pesticide Regulation Notice on Termiticide Labeling. The workgroup includes members from the Insecticide-Rodenticide Branch/RD, Occupational and Residential Exposure Branch, HED, State and Regional Operations Branch and Certification and Training Branch/FOD, the Office of Enforcement and Compliance Assurance, and the state regulatory Association of Structural Pest Control Regulatory Officials. The purpose of the notice is to address a number of issues which have evolved over the years due to the highly specialized nature of termiticides, including: use limitations, precautionary statements, use directions, and longevity of termiticide treatments. In conjunction with these efforts a one-day workshop was held at the headquarters of the National Pest Control Association in Dunn Loring, Virginia which included seminars on termite biology, behavior and control strategies, a field demonstration of a post-construction termiticide application and a video demonstration of a pre-construction termiticide application. The workgroup's goals is to finalize the notice by December 1995.

REGISTRATION SUPPORT BRANCH

ACUTE TOXICITY RELATED EFFORTS. OPP currently has a backlog of 357 submissions, down from 522 in December 1994. OPP receives approximately 900 new submissions per year. A submission can be a single study, a six pack of studies, a rebuttal to a previously rejected submission or any combination thereof. New submissions are about equally divided between registration and reregistration. With current practices and resources, OPP is able to review about 70 submissions per month. Currently, without a change in practices or resources, companies must wait upward of 12 months to receive a review of

product specific acute tox data.

SHARE ACUTE TOXICITY REVIEWS WITH CDPR. OPP and CDPR have determined that their review procedures are sufficiently harmonious to allow the sharing of reviews and workload. To date, the MOU has not translated into significant resource savings. We have received a handful of reviews from California that we used for reregistration. However, we have begun a process that will lead to considerable savings. We have contacted registrants who have submitted acute toxicity data packages since October 1994 to determine if they plan to register the product in California and/or Canada. By the end of September 1995, we will determine the overlapping data and distribute reviews equitably among the regulatory agencies. Using an SOP developed by CDPR, we will then share the data packages with CDPR (and Canada), with an agreed time frame for completion of the reviews. We will then exchange reviews. EPA reviewers will do a cursory review of the CDPR reviews and labeling and the packages will be forwarded back to the PMs for action. We expect that this will shorten the time in-house awaiting a review by at least 25%.

SELF-CERTIFICATION OF ACUTE TOXICITY STUDIES. RD has created a work group to explore the possibility of allowing registrants to self-certify product specific acute toxicity test results. This work group consists of members of RD, SRRD, OECA, and OGC. The work group also has a subcommittee working on the acceptance criteria for the six required studies.

COMPUTER SOFTWARE TO STANDARDIZE "PRECAUTIONARY" LABELING. EPA has begun to develop a computer program which displays the correct precautionary labeling statements for a product based on the results of the acute toxicity studies for that product. This system could be used by both EPA staff and registrants to assure accurate and appropriate precautionary labeling for new or existing products. It would also enable registrants to submit correct labeling and help EPA staff to assure that labeling is acceptable. This program could result in a reduction in review time and help unnecessary rejections of applications with incorrect labeling. Computer software is anticipated to be produced and distributed in early calendar year 1996.

OTHER REINVENTION PROCESS CHANGES FOR ACUTE TOXICITY.

Acceptance Criteria. The Precautionary Review Section (PRS) is now making decisions about the acceptability of a study with respect to its acceptability for labeling. Previously, PRS decisions about acceptability were based on whether it conformed with guidelines.

Reregistration. Studies accepted after 1989 (with two exceptions) will be considered acceptable for registration purposes. If multiple products in a batch have studies submitted as part of the 8 month response, PRS will perform a thorough review of one six pack and a cursory review of all other studies submitted in the same batch.

ELECTRONIC LABELING. The Labeling Unit (LU) will conduct a limited pilot project to test the concept of electronically capturing, accessing and reviewing product labeling. The pilot will involve up to 25 products. The LU has done some preliminary work, has been contacted by interested parties such as ACPA and intends to begin the pilot in the Fall 1995. Further activities in this area will be proposed for 1996 based on progress demonstrated in the pilot.

LABEL AVAILABILITY. The LU is working closely with the Program Management Support Division to convert the compact label file to CD-ROM. This will streamline both RD and FOD by reducing requests for stamped, accepted labels and will vastly improve service to OPP's customers including the state enforcement programs. The conversion is also the first step toward making label images available to PM reviewers through the LAN. The conversion project has begun and will continue into FY 96.

LABELING COORDINATION. RD has issued a draft PR Notice for comment which (1) establishes an annual compliance date for implementing most EPA mandated labeling changes and (2) describes the LU's role in coordinating all labeling issues and related streamlining efforts. The LU reviewed comments and has also met with several trade organizations including ACPA, CMA, CSMA and CPDA. Most comments have focused on the channels-of-trade provisions specified in the Notice. LU currently reviewing the comments received and our stocks in trade policy.

LABEL REVIEW MANUAL: In December 1994, RD's Labeling Center for Excellence (assisted by the Labeling Unit) completed an extensive document to be used by EPA staff in reviewing and determining the acceptability of pesticide labeling. The Manual is on OPP's Local Area Network and is publicly available.

LABEL POLICY DIRECTORY: In October 1994, RD's Labeling Center for Excellence and the Labeling Unit initiated an electronic "on-line" Labeling Policy Directory that allows OPP staff to quickly search and access labeling policy information via their computer. The Directory is available on OPP's LAN. Portions of the policy directory will be made available to the public soon.

GLOSSARY

Action: Any application or correspondence submitted by a registrant is an "action." Each submission is logged into the Pesticide Action Tracking System (PRATS); upon completion of review, EPA issues a response, closes out the action on PRATS and ends the "cycle" for that submission.

Amendment: An application to change an existing registration (such as its formula or labeling) is an "amendment."

Amendment, Fast Track: An amendment which requires no data and qualifies for expedited handling is a "fast track" amendment.

Amendment, Non-Fast Track: An amendment application which requires submission of data (such as exposure data to support a new method of application) is a "non-fast track" amendment.

Backlog: An action which has been awaiting review longer than the target turnaround time has reached "backlog" status. OPP has set target turnaround times for reviewing each type of registration.

Decision: When an application meets all requirements for approval, EPA makes a registration decision by issuing either an approval or a denial. Such a decision may occur after the first submission (one action) or after 10 submissions (10 actions), depending on when the entire application is acceptable.

Emergency Exemption: Under Section 18 of FIFRA, EPA may approve a state's request to use an unregistered pesticide when no registered product is available. This type of action is an "emergency exemption."

Experimental Use Permit (EUP): A permit required to conduct field trials (residue tests) to support the registration of a new active ingredient.

Inerts: All inert ingredients used in pesticide products must be cleared by EPA before registration. To obtain approval for new inerts, the producers must submit toxicology data to EPA for review. Such submissions are called "inerts."

New Chemical: An application for registration of a product containing an active ingredient (a.i.) not contained in a currently registered product is called a "new chemical."

New Use: An application for registration of a use not currently registered is called a "new use." A new use is "significant" if additional data are required.

Old Chemical: Refers to an application for a new product which contains an active ingredient (a.i.) contained in a currently registered product. Hence, an application for a new product similar to an existing, registered product is an "old chemical."

Old Chemical, Fast Track: An application for a new product containing an old chemical which requires no data review and qualifies for expedited handling is an "old chemical, fast track."

Old Chemical, Non--Fast Track: An application for a new product which requires data review is an "old chemical, non-fast track."

Pending: An action which has been waiting for EPA review less than the target turnaround time is "pending."

Tolerance: When a pesticide is used on a food crop, a pesticide residue level or "tolerance" that is safe must be established before a product may be registered for that crop.

Tolerance, Temporary: When an unregistered pesticide is tested under an EUP on a food crop, a temporary tolerance must be established if that crop will be consumed.

24(c): Under Section 24(c) of FIFRA, a state may issue a registration for an unregistered use of a currently registered product within that state when a "special local need" exists.