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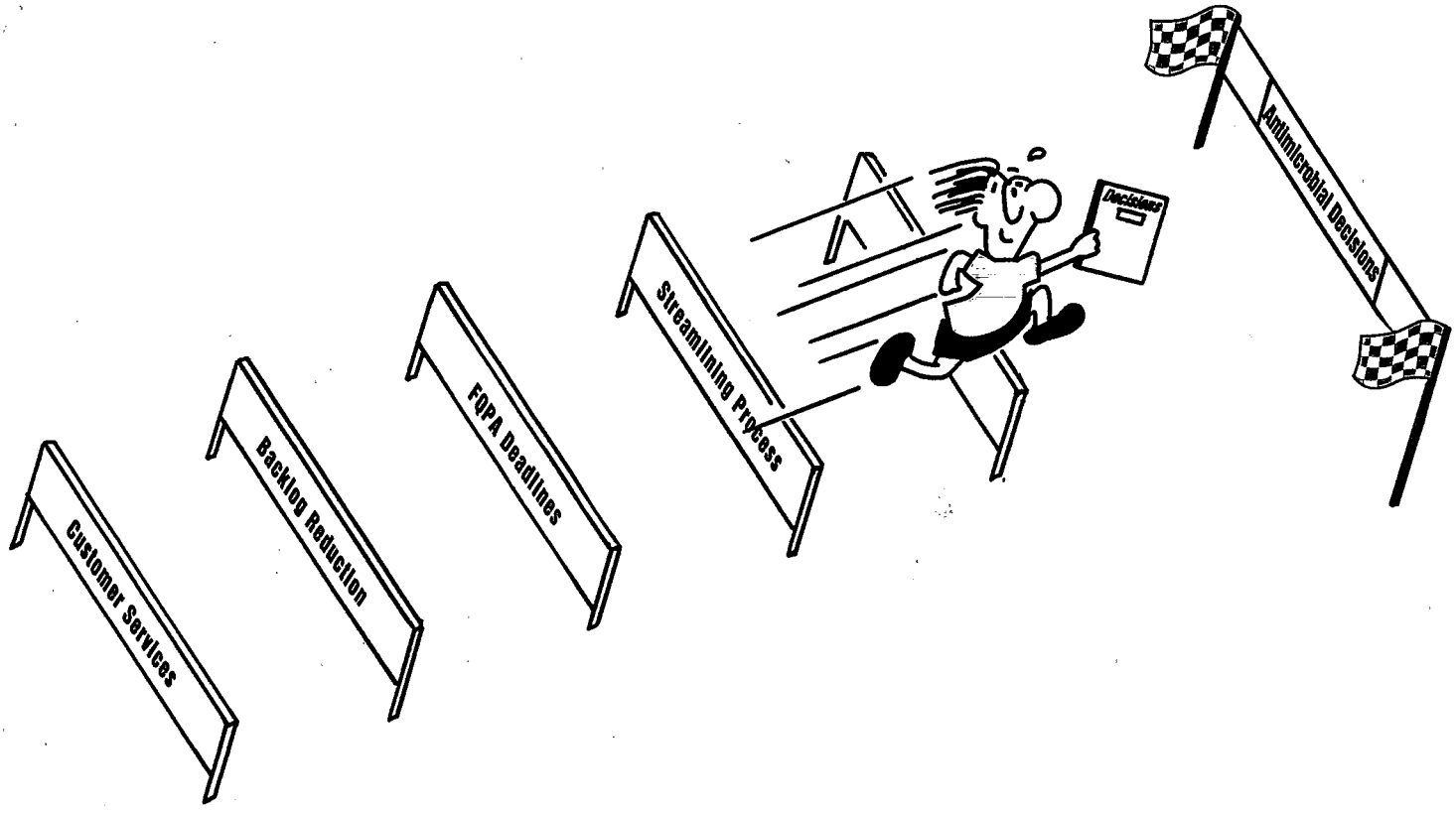
1997 EPA Progress Report



STREAMLINING REGISTRATION of ANTIMICROBIAL PESTICIDES

1997 EPA PROGRESS REPORT

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC

October 1997

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EXECUTIVE SUMMARY

On August 3, 1996, President Clinton signed the landmark Food Quality Protection Act, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 3(h)(4) of the amended FIFRA requires EPA to prepare an annual report to two Congressional committees explaining what measures the Agency has taken to reduce the antimicrobial registration backlog, its progress in achieving antimicrobial process reforms, and what further registration-related changes it recommends. This report responds to the three topics mentioned in Section 3(h)(4) of FIFRA, but goes much further in describing the far-reaching changes the Agency is making to streamline antimicrobial registrations.

A turning point in improving antimicrobial pesticide registrations occurred with creation of a self-contained Antimicrobials Division in the Office of Pesticide Programs. This new division provides "one-stop shopping" for all antimicrobial regulatory services. After this reorganization, EPA reduced the antimicrobials registration backlog from 388 at the end of December 1996 to 90 by June 30, 1997, a decrease of 77%. EPA's goal is to eliminate the antimicrobial backlog during 1998. At the same time as reducing the backlog, EPA has met all the fast track review goals mandated by the amended FIFRA. (Fast track actions are those that need to be completed within 90 days.) These accomplishments were possible largely because the new division can control its own workflow, and because it created a dedicated Expedited Review Team that ensures that fast track actions and certain other activities are completed on time. In addition to meeting the new FIFRA review goals, EPA has fulfilled all its other regulatory responsibilities related to antimicrobial pesticides.

To continue its streamlining activities, EPA is meeting regularly with antimicrobial pesticide stakeholders to obtain their suggestions for lessening the registration burden both on EPA and on registrants, while ensuring the continued safety and efficacy of registered pesticides. EPA and registrants are working together to develop standardized reporting forms for various types of submissions. In the antimicrobial rule--developed with extensive input from stakeholders--EPA is proposing to streamline certain registration steps and to develop a tiered system of required tests so that the results of initial tiers determine the need for additional tests. In the near future, EPA hopes to approve faster and more dependable efficacy tests for public health antimicrobial pesticides.

With many successful streamlining activities in progress, it would be premature for EPA to make recommendations for further improving antimicrobial pesticide registration at this time. The Agency expects to include such recommendations in its 1998 progress report, after it has had more experience with ongoing changes.

STREAMLINING REGISTRATION of ANTIMICROBIAL PESTICIDES:

1997 EPA PROGRESS REPORT

I. INTRODUCTION

The landmark Food Quality Protection Act of 1996 (FQPA), Public Law 104-170, was signed on August 3, 1996 by President Bill Clinton. Its major goals were to better protect the public--especially children--from exposure to harmful pesticides in foods and to improve registration processes related to non-food pesticides. The FQPA provisions became amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 3(h) of the amended FIFRA (see Attachment A) addresses Antimicrobial Pesticide Registration Reform and requires EPA to submit an annual progress report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate that covers three topics related to registration of antimicrobial pesticides. The yearly reports, required until specified statutory goals are achieved, "shall include a description of--

"(I) measures taken to reduce the backlog of pending registration applications;

"(ii) progress toward achieving reforms under this subsection [subsection describes new review deadline goals and types of streamlining processes EPA should consider to speed up antimicrobial pesticide registration decisions]; and

"(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations."

This EPA report describes the Agency's recent activities in the three areas identified above. But the report goes further, by showing how EPA is responding to both the statutory requirements and the spirit of the law. Since the FQPA was passed, significant changes have occurred in the way EPA manages antimicrobial registration activities. A new Antimicrobials Division was formed to provide the structure and staff needed to respond to the law. Under the new division, the backlog of applications for registration activities has been greatly reduced; fast-track statutory deadlines are being met; registration submissions are being processed more quickly than in the past; and outreach activities are involving stakeholders in an ongoing dialogue about the best ways to protect human health and the environment while streamlining registration procedures.

Uses of Antimicrobial Pesticides

According to the new FIFRA amendments, an antimicrobial pesticide is a pesticide that is intended to "(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime." This category does not include certain pesticides intended for food use, but does encompass pesticides with a wide array of other uses. For

example, antimicrobial pesticides act as preserving agents in paints, metalworking fluids, wood supports, and many other products to prevent their deterioration.

Antimicrobials are especially important because many are public health pesticides. They help to control microorganisms (viruses, bacteria, and other microorganisms) that can cause human disease. Antimicrobial public health pesticides are used as disinfectants in medical settings, where they are present in products used in cleaning cabinets, floors, walls, toilets, and other surfaces. Proper use of these disinfectants is an important part of infection control activities employed by hospitals and other medical establishments. According to the most recent data available from the Centers for Disease Control, more than 2,000,000 infections per year occur when individuals are in a hospital rather than at home or elsewhere. A substantial decrease in that number would be a significant public health accomplishment. EPA also registers many consumer products as disinfectants, which consumers use to decrease the number of microbes on surfaces such as toilet bowls or sinks. Because microbes are invisible and users cannot determine if the disinfectant is working, EPA reviews public health pesticides for efficacy as well as safety.

Amounts of Antimicrobial Pesticides Used in the United States

The approximately 5,000 antimicrobial pesticide products registered with EPA contain one or more of 256 active ingredients. The Antimicrobials Division (AD) of the Office of Pesticide Programs (OPP) is responsible for regulating these ingredients and products. Table 1 shows the current share of responsibility for pesticide registration held by the Antimicrobials Division compared with the responsibilities of the entire Office of Pesticide Programs.

Creation and Structure of Antimicrobials Division.

EPA has created an Antimicrobials Division (AD) in the Office of Pesticide Programs that allows "one-stop shopping" for regulation of antimicrobial pesticides. For pesticides under its jurisdiction, the division carries out the full range of regulatory activities, including registration, reregistration, notifications, tolerance-setting, experimental use permits, and oversight of State-registered products. When fully staffed, it will have the needed personnel and expertise to conduct and manage virtually all reviews within the division, thus helping to ensure that AD meets its deadlines and quickly responds to the needs of stakeholders. The division consists of two Regulatory Management Branches, each with a projected ceiling of 13 people, and a Risk Assessment and Science Support Branch with more than 20 technical staff (see Figure 1 and Attachment B). The Regulatory Management Branches manage all aspects of the review, technical integration, and decision-making related to submissions. The technical branch reviews all incoming data related to AD registration actions. It includes experts in the fields of microbiology, toxicology, biology, chemistry, ecology, and risk assessment.

Table 1. Portion of Total EPA Pesticide Registration Activities Managed by Antimicrobials Division

Category	Antimicrobials Division	Office of Pesticide Programs, Total	% Antimicrobials Division
Active ingredients registered (number)*	256	883	29%
Active products registered (number)*	5,000	21,000	24%
Active ingredients used per year in U.S. (pounds)**	**Total: 3.3 billion pounds.** **2.3** billion pounds hypochlorite/ chlorine chemicals for disinfecting water, including drinking water. **0.7** billion pounds wood preservatives. *** **0.3** billion pounds "other," including public health pesticides such as disinfectants and sanitizers used in medical facilities and swimming pools; preservatives for metalworking fluids, paints, and coatings.	**Total: 4.5 billion pounds** **1.0** billion pounds conventional pesticides used in agriculture or on lawns, gardens, etc. **0.2** billion pounds "other." **3.3** billion pounds antimicrobials	73%

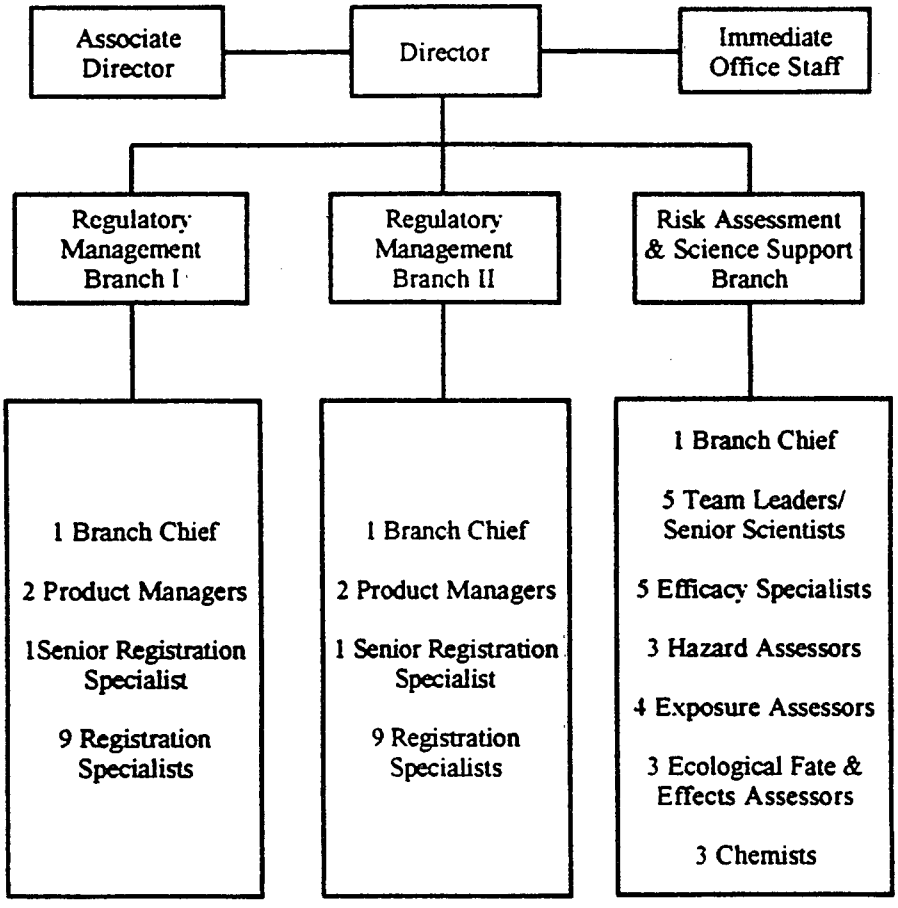
* Data as of July 1997
** Data for 1995
*** Excludes water treatment chemicals with hypochlorite/chlorine

In addition to the Division Director and Associate Division Director, the Immediate Office consists of nine people, four of them constituting an administrative team. Others in the immediate office are a senior advisor, two special assistants, a communications specialist, and an ombudsman. The ombudsman role is especially crucial in AD, where many applicants are small companies that lack in-house expertise or that have limited experience with registration of antimicrobial pesticides. Because the ombudsman is available to solve problems and to answer a variety of questions, remaining AD staff can focus on completing registration actions assigned to them.

Figure 1.

Antimicrobials Division

Office of Pesticide Programs
U.S. Environmental Protection Agency



Total AD staff is 60 full time employees (FTEs) (October 1997). Depending on the workload, the division may add a second risk assessment and science support branch.

II. MEETING NEW REGISTRATION DEADLINES

Review Periods Under the 1996 Amendments to FIFRA

A major goal of the 1996 amendments to FIFRA is to ensure that pesticide registration actions occur in a timely manner. Section 3(h) of the amended FIFRA establishes goals for the length of time EPA can take to review and reach decisions on different types of pesticide applications. These new review periods are months to years shorter than the length of time often taken in the past (see Tables 2a and 2b). Except as explained below, EPA is required to meet these new review times for submissions received after implementing regulations are in place (21 months after enactment of the Act, or May 1998).

However, two shortened review periods for antimicrobials registration activities are already in effect. The first shortened review period concerns Notifications for labeling changes unrelated to pesticidal claims; a 30-day review period for disapproval of notifications became operable the day the Food Quality Protection Act became law. The second is the 90-day review period for expedited ("fast-track") submissions.

Although the review period goals of longer than 90 days are not yet in effect under the provisions of FQPA, AD is processing applications received after November 1, 1996 as though all the review goals already apply. Under this self-imposed standard, AD has met all FQPA review times for submissions received since FQPA was enacted, and expects to continue to do so. Meeting these goals has required significant changes in the way AD processes different types of submissions. Some administative changes, such as creation of an Expedited Review Team, have been crucial in ensuring that AD meets the shortened time goals for reviewing and making decisions on applications.

Table 2a. Registering Antimicrobial Pesticides: Comparison of Historical Elapsed Times with New Review Time Goals under FIFRA Amendments

Type of Registration Application	**Historical Elapsed Time (months)**	**Review Time Goals under New Amendments to FIFRA (months)**
A. Product with a new active ingredient	36-84	18
B. Product with new use	24-36	9
C. Product identical or substantially similar to one already registered	Not Available	3
D. Other new product	18-36	4

Table 2b. Acting on Amendments for Antimicrobial Pesticides: Comparison of Historical Elapsed Times with New Review Time Goals under FIFRA Amendments

Type of Amendment	**Historical Elapsed Time (months)**	**Review Time Goals under New Amendments to FIFRA (months)**
E. New use (significant amount of data review)	6-30	9
F. Amendment (no data review except product chemistry)	Not Available	3
G. Other amendment (some data review)	Not Available	3-6

Types of Submissions

Registration

As shown by Tables 2a and 2b, several types of applications come to the Antimicrobials Division. Below is a brief description of the categories of submissions, with review time goals specified by FIFRA amendments in parentheses.

A. New active ingredient (18 months (540 days)): Application for registration of a new product containing any active ingredient not contained in a currently registered product.

B. Product with major new use (9 months (270 days)): Application for new registration that also proposes a "major new use."

C. Substantially similar product (3 months (90 days)): An application for new registration that meets the following three criteria: 1) the product formulation contains the same active ingredients as, and is substantially similar in composition to, a cited currently registered product; 2) the proposed uses are substantially similar to the uses on the label of the cited substantially similar products; 3) the application relies solely on data already submitted, with the exception of certain product chemistry data, and does not require submission or citation of efficacy data.

C. Identical product (3 months (90 days)): Application for registration where 1) the formulation is identical in composition to a cited currently registered formulation. Typically a product is being repackaged or being produced by a different entity; 2) the proposed uses are identical to those on the cited product.

D. Other new product (4 months (120 days)): Application for new registration that does not fit into any of the categories already described. These products usually require submission of data.

Amendments

The three categories of amendments, which are changes to a product's existing registration, are described below:

E. Major new use (9 months (270 days)): An application for amended registration to add a major new use that is not currently registered for one or more of the active ingredients in the product. Data review required.

F. Minor amendment (3 months (90 days)): An amendment to an existing registration that does not require scientific review of any type, and does not contain any new data that need to be reviewed.

G. Other amendment (3-6 months (90-180 days)); A substantive amendment that is not a major new use, and that requires scientific review, often of more than efficacy data.

What is a Fast Track Submission?

A fast track submission is the name that EPA has given to submissions that FIFRA section 3(c)(3)(B) specifies must be reviewed and a decision made within 90 days of EPA's receiving a complete application. The following three types of applications are fast track applications:

1) Registration of an end use product that is identical or substantially similar in composition and labeling to a currently registered product, and that does not require scientific review of data other than product chemistry data (Item C in Table 2a);

2) Registration of an end use product that differs from a currently registered product in composition and labeling only in ways that do not substantially increase the risk of unreasonable adverse effects on the environment (Item C in Table 2a);

3) Amended registration of an end use product that does not require scientific review of data other than product chemistry data (Item F in Table 2b).

III. MEASURES TAKEN TO REDUCE BACKLOG

The Antimicrobials Division has made substantial progress in reducing its backlog. This backlog reduction occurred while AD met all of the new FIFRA review time goals for applications submitted after FQPA took effect. Thus, the antimicrobials backlog consists of the following two categories of applications:

1) applications submitted before FQPA took effect and which were not completed under EPA's self-imposed deadlines, and

2) applications received after FQPA took effect in categories for which FQPA does not set review time goals; most of these applications are for antimicrobial pesticides with food uses.

For categories B-G in Table 3 (next page), which encompass more than 95% of antimicrobials registration actions, EPA reduced the backlog between December 1996 and July 1997 by almost 80%. The backlog in Category A, new active ingredients, is decreasing more slowly for two reasons. First, these are the most complicated applications to review, and EPA's self-imposed deadlines were exceeded. EPA has not completed the reviews for these backlogged submissions since FQPA was passed. Second, the number of items in the backlog in category A increased slightly (from 11 to 14) during early 1997 because that is when EPA's self-imposed deadlines were exceeded.

Table 3 shows the numerical reductions in individual backlog categories from January to June 1997. Amendments that are fast track, which have accounted for the largest share of the backlog, were reduced by 85% during the January-to-June period. Fast track new products were reduced by a similar percentage.

The Antimicrobials Division took specific actions to reduce the backlog. It created an Expedited Review Team to process the majority of fast track submissions, thus giving other reviewers time to work on the backlog. In some cases it consolidated multiple actions on the same product. To ensure that new submissions do not enter the backlog, AD has strengthened its tracking system so that submissions move quickly from one stage to the next and staff can readily identify approaching deadlines. Additional staff who can help reduce the backlog have recently joined the division. AD's goal is to eliminate the backlog for categories C, D, F, and G by the end of December 1997, and to eliminate the backlog for categories A, B, and E during 1998. The division plans to continue making timely decisions on all incoming submissions so that no new actions enter the backlog.

Table 3. Number of Items in Antimicrobials Division Backlog at End of Various Months

Month Ending	New active ingredient [A]	New use [B] [E]	New product, fast track [C]	New product, not fast track [D]	Amend-ment, fast track [F]	Amend-ment, not fast track [G]	TOTAL *
December 1996	10	16	69	50	178	60	388
January 1997	10	17	52	37	127	49	297
February 1997	11	16	44	37	114	49	276
March 1997	14	12	26	34	94	47	232
April 1997	14	9	15	30	69	26	167
May 1997	12	8	11	23	35	20	112
June 1997	12	8	7	20	25	17	90

NOTE: "Fast track" refers to submissions for amendments or new products for which FIFRA requires a decision within 90 days (C and F). "Not fast track" refers to similar submissions with longer FQPA review periods or not subject to FQPA (D and G).
* Total for each month includes up to 5 backlog items in a miscellaneous category.
[ ] Bracketed capital letters refer to categories in tables 2a and 2b.

IV. STREAMLINING ACTIVITIES

To meet the statutory goals for decision-making based on the review period goals in the FQPA amendments to FIFRA, the Antimicrobials Division needs to ensure that it uses efficient processes and that it clearly lays out its policies in new rules and guidelines. The division has made significant progress in improving its processes and in developing a new antimicrobial rule.

Processes

Expedited Review Team

The Expedited Review Team is one of the innovations that AD introduced to streamline its activities and meet the new FIFRA review goals while maintaining high standards for decision-making. This dedicated team handles registration actions that need to be completed within 90 days, as well as Notifications, for which the Agency is required to make a disapproval finding within 30 days of receiving the proposed labeling modifications. Although the statute only requires a written response in the case of disapprovals, AD decided that it would be more efficient to respond to all notifications--approvals as well as disapprovals--within the 30-day timeframe. The Expedited Review team also processes minor formulation changes (45-day review period goal as established by PR Notice 95-2), although this deadline is not part of the FIFRA review goals. This committed team has helped AD meet all of the FQPA 90-day registration deadlines for submissions filed after November 1, 1996, and also has processed all notifications and minor formulation changes within the FIFRA-established time goals.

Registrants have been pleased with turnaround times as short as two weeks for simple actions such as minor label changes.

In addition, by lessening the burden on other staff, the Expedited Review Team has allowed AD to reduce its backlog of registration actions. Another advantage, from AD's perspective, is that new members of the division can begin learning about the division's activities by starting with the relatively simple fast track actions. Thus, they can contribute significantly to the division's work soon after joining the staff, a result that is beneficial both to the new individual and to the division as a whole.

Other Process Changes.

Many of the suggestions for process change have come from registrants, including members of trade associations such as CMA (Chemical Manufacturers Association); CSMA (Chemical Specialties Manufacturers Association); and ISSA (International Sanitary Supply Association), whose member companies tend to be relatively small compared to most members of the larger trade associations. To help applicants submit complete, correct applications the first time, the trade associations have suggested that the Antimicrobials Division develop standard forms for submitting different types of applications, and for submitting toxicity, efficacy, and other types of data. EPA is developing appropriate forms and guidance. In addition, EPA is considering organizing and publicizing periodic registration training sessions for registrants and potential registrants.

As a related activity, registrants have suggested that AD develop more standard forms for some of AD's activities, such as reviewer summaries, decision documents, and certain types of registrant communications. Such increased standardization would help EPA and registrants avoid misunderstandings regarding what registrants need to do to correct inadequacies and move their applications forward.

AD has developed performance measures so that it can track improvements in making decisions on time and can identify bottlenecks where more staff training or improved processes could enhance performance. A training program has been developed to orient the many new staff who are joining AD.

In the mid-to-long term, AD plans to expand its use of electronic technology to improve its performance, for example, by continuing to computerize and automate the registration process. Meanwhile, AD will make increased use of electronic communications wherever feasible. An antimicrobial registration handbook is being developed, which will be available in both paper and electronic forms.

Policies

Minor Changes in Labels or Formulations

In 1995, EPA issued a Pesticide Registration Notice [PR Notice 95-2] designed to streamline certain registration actions. The Notice allowed EPA to process minor, low-risk registration amendments quickly through notification, non-notification, or as accelerated amendments, rather than through the usual amendment process. The Notice addressed policies related to: a) Notifications; b) Minor Formulation Changes.

Notifications. The portion on notifications described the type of labeling changes and product chemistry changes for which registrants could use the notification process. Only proposed changes that did not affect pesticidal claims or activity were allowed. Registrants could add or delete such label claims as "Cleans faster;" Package recyclable;" "Prevents odors;" "Stays fresh longer" using a notification. Registrants also could use a notification if they were

changing the source of active or inert ingredients, or the composition of the product so long as it remained within specified limits and none of the changes altered pesticidal activity. No review period was mentioned in PR Notice 95-2.

The FQPA amendments to FIFRA set a 30-day review period deadline for EPA to disapprove notifications, measured from the date EPA received the notification. However, the amendments limit this expedited notification process to non-pesticidal label changes for antimicrobial pesticides only (i.e., the statutory provisions do not apply to other types of pesticides). The notification process also applies to changes in antimicrobial product chemistry that do not relate to any pesticidal claim or activity. The Antimicrobials Division has met this 30-day deadline for all notifications it has received since passage of the FQPA on August 3, 1996, with an average review time of 24 days for all notification actions. Tables 4 and 5 provide more detailed analyses for the notifications received and processed between November 1, 1996 and June 30, 1997.

Table 4. Numbers of Decisions Made by the Antimicrobials Division on Notifications and Minor Formulation Changes Submitted and Completed between November 1, 1996 and June 30, 1997.

Category of Submission	**Number Accepted**	**Number Rejected**	**TOTAL**
Notification (labels and product chemistry)	236	59	295
Minor formulation change	78	28	106
TOTAL	314	87	401

Table 5. Average Staff Time (in Minutes) Required to Review Notifications and Minor Formulation Changes Completed by the Antimicrobials Division between November 1, 1996 and June 30, 1997.

Category of Submission	**Change Accepted**	**Change Rejected**
Notification--requires label review	40 minutes	240 minutes
Notification--does not require label review	20 minutes	20 minutes
Minor formulation change	240 minutes	240 minutes

Minor Formulation Changes. The second part of PR Notice 95-2 provided that EPA would have a 45-day target review period goal for registration amendments concerning certain types of minor formulation changes. Although this part of PR Notice 95-2 was not

reflected in the provisions of the Food Quality Protection Act amendments to FIFRA, OPP has decided, on its own initiative, to process minor formulation change amendments in 45 days whenever possible. The Antimicrobials Division has met the 45-day target for the 106 minor formulation change submissions it received and completed between August 3, 1996 and March 31, 1997, with an average review time of 36 days.

As part of its streamlining effort, AD is looking closely at suggestions from registrants that would help them to prepare successful applications the first time, thereby saving themselves and EPA many hours per year. As noted in Tables 4 and 5, the Antimicrobials Divison fails to approve almost 30 % of total submissions of notifications and minor formulation changes. AD staff spend 240 minutes (4 hours) to review a label that is eventually disapproved, compared with 40 minutes for a label that is approved. Following a disapproval, both registrants and EPA need to spend additional time on the resubmission.

Because the notification process has proven so successful, an OPP-wide team is exploring additional areas where notifications might replace the more cumbersome amendment process. Stakeholders are active participants in these discussions. Expanding the use of notifications would allow registrants to implement changes more rapidly in product characteristics that do not relate to any pesticidal claim or activity and would free EPA staff to focus on activities that are critical to protecting public health and the environment.

Proposed Procedural Rule and Data Requirements

Under the FQPA amendments, EPA must issue a rule to aid in streamlining the registration process for antimicrobial pesticides. This streamlining is necessary for EPA to meet the new shorter statutory review and decision deadlines specified for different types of registration actions. In cooperation with other parts of the Office of Pesticide Programs, and in a process that includes ongoing consultation with stakeholders, the Antimicrobials Division is developing two rules to help meet the streamlining requirement: a procedural rule (40 CFR 152) and a data requirements rule (40 CFR 158).

40 CFR 152 (Procedural Rule). A new part 152 will lay out a variety of procedural requirements for applications to register antimicrobial products, although some provisions will apply to all pesticides. The major contents of Subpart W, which is being developed, are:

- General (introductory material);
- Applicability;
- Consultations with EPA (required in certain instances, encouraged in others);
- Types of applications (new chemicals, identical, new product with new use, etc);
- Contents of application (describes what constitutes a complete application);
- Action on applications (describes what EPA will do with an incomplete application, and the approval and denial responses. A basic premise, designed to help registrants, is that the Agency may stop the clock in the midst of the review period to allow time for an applicant to remedy easily correctable deficiencies; if the applicant can respond quickly, the clock restarts close to where it stopped and the Agency's decision should come sooner than if the application had to begin the review process again or encounter rejection.)
- Time frames for response to applications (contains the time frames identified as statutory goals).

40 CFR 158 (Data Requirements). Part 158 currently contains data requirements for all types of pesticides. Because many of the issues related to registering antimicrobial pesticides are different from those for agricultural pesticides, the Agency has decided to develop

a new subpart of 158 that is specific to uses of antimicrobial pesticides. The current draft organizes these new data requirements of Part 158 into the following 12 antimicrobial use sites:

1. Agricultural premises and equipment (e.g., stalls, barns, shovels, halters, feeders, troughs, and milking equipment);

2. Food handling/storage establishments premises and equipment (e.g., food processing plants; restaurants and cafeterias; food shipping and storage containers; food stores).

3. Commercial, institutional and industrial premises and equipment (e.g., ceilings, stairs, woodwork and light fixtures in hotels, theaters, airports, factories, schools, offices, auditoriums).

4. Residential and public access premises (e.g., homes, shelters, public buildings and public areas).

5. Medical Premises and Equipment (includes premises and non-critical equipment in hospital or medical environments such as clinics and nursing homes; non-critical medical equipment includes items such as furniture, carts, bedpans, and other items that do not contact the patient or generally contact only the patient's intact skin).

6. Human drinking water systems (e.g., public water systems, individual water systems, water purifier systems).

7. Materials preservatives (e.g., industrial process intermediate materials such as dispersions, and emulsions, as well as the resulting products including paints, coatings, textiles, paper).

8. Industrial processes and water systems (includes antimicrobials applied to freshwater supplies for commercial and industrial systems and processes, and similar specialized applications such as cooling towers, heat exchangers, wastewater systems, and photo processing wash water).

9. Antifouling coatings for submerged structures and objects (e.g., boat hulls, crab and lobster pots, and underwater structures or equipment).

10. Wood preservatives (includes products used on newly cut wood surfaces, kiln dried wood, milled wood, and other building materials, which are then used in playground equipment, lawn furniture, dwellings, containers, fences, and many other products).

11. Swimming pools (encompasses swimming pools, jacuzzis, hot tubs, and other such structures that are lined with impermeable materials and do not connect directly with environmental bodies of water).

12. Aquatic areas (encompasses use sites that are mostly outdoors, including lakes, ponds, reservoirs, and irrigation systems).

Testing requirements for antimicrobials are generally arranged in tiers so that the results of earlier tiers determine the need for additional testing. Especially in the areas of human health and exposure, a registrant must provide sufficient data for EPA to evaluate the safety of the product in its intended use, but EPA can still minimize the testing burden on registrants. To further protect public health and the environment, AD not only plans to specify exposure measurement testing under conditions of pesticide application, but also is identifying situations where post-application exposure testing should be done. For example, AD is concerned about the level of exposure of swimmers, as well as applicators, to swimming pool disinfectants.

Drafts of 40 CFR 152 and 158 have been made available to stakeholders and others through meetings and a public docket, and are undergoing pre-proposal discussions with stakeholders. AD expects to issue a proposed rule for Part 152 in the first half of 1998. The data requirements proposal is more complex and may take somewhat longer.

V. OUTREACH

As the Antimicrobials Division develops improved rules for registering antimicrobial pesticides, it is maintaining an open dialogue with stakeholders. Industry is making helpful suggestions for revising the rules, and will be able to submit better applications because they will understand how the rules were developed. A non-adversarial relationship with industry will enable AD to use its limited resources most efficiently in making timely decisions while continuing to protect human health and the environment. In addition to pesticide registrants, other stakeholders include consumer, environmental, and public health groups. To show how important AD considers communications and outreach, the division includes a full-time communications specialist to inform registrants and the rest of the public about AD activities and about ways to use antimicrobial products safely and effectively.

First National Antimicrobial Workshop--January 1997

On January 8 and 9, 1997, the Antimicrobials Division held the first National Antimicrobials Workshop on the Regulation of Antimicrobial Pesticides. The workshop was set up to provide registrants with an overview of OPP's new Antimicrobials Division and to discuss the requirements and potential impacts of the 1996 Food Quality Protection Act on registration of antimicrobial pesticides. More than 300 people attended.

The workshop was also the first step in opening an ongoing cooperative dialogue between registrants and the Antimicrobials Division. Industry representatives helped develop the agenda for the workshop. They presented their suggestions for how EPA could handle antimicrobial registration actions more quickly at lower cost. In her opening speech, Dr. Lynn Goldman, EPA Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances, emphasized the importance of antimicrobial pesticides to public health and the need to ensure that they were efficacious as well as safe..

Frank Sanders, Director of the Antimicrobials Division, set the participatory tone for the workshop as he made the following points:

- Industry is AD's partner--not an adversary.
- We prefer compliance to enforcement, and will work to help industry comply.

- We will be responsive to inquiries and will work to keep registrants informed about the status of registration packages.
- We will listen to industry and work with them to streamline registration actions and meet deadlines.
- We understand that industry needs credible information from EPA about when decisions will be made.
- Standard Operating Procedures (SOP's) will be developed and implemented quickly to help ease uncertainty for industry.

Plenary and breakout sessions covered such topics as:

Applying for a Registration
Reinventing the Registration Process
Data Requirements
Self-certification of Data
Harmonization with States and the International Community

Participants indicated that they were especially pleased with the opportunity to meet EPA staff and to participate in informal discussions. More than 97% of attendees who responded to an anonymous evaluation survey indicated that the workshop had met their needs and that they would find a similar workshop useful in the future.

As a followup to the successful workshop, the Antimicrobials Division and the workshop attendees arranged to set up regular stakeholder meetings, which have been held approximately monthly since February 1997. Participants at stakeholder meetings represent several diverse groups besides pesticide registrants. These meetings are providing stakeholders with an opportunity to make their views known as OPP develops the antimicrobial rule and puts new procedures in place.

Stakeholder Meetings

The Antimicrobials Division is holding meetings with stakeholders every three to four weeks to address the issues that most concern registrants and others. Their input has been useful in shaping the direction that AD is taking on the procedural rule and on development of Part 158 (data requirements). Invitees to these meetings have included members from diverse groups such as industry trade associations (Chemical Manufacturers Association; Chemical Specialties Manufacturers Association; International Sanitary Supply Association), user groups (Association for Professionals in Infection Control) and environmental and consumer groups (Natural Resources Defense Council; National Coalition Against Misuse of Pesticides). The agenda for each meeting is based primarily on suggestions made by participants at the previous meeting. Draft language for developing section 152 (procedural rule related to registration) and section 158 (data requirements for various antimicrobial site uses) have been distributed for discussion and comment. Stakeholder input at this early, pre-proposal stage has been helpful to AD as it proceeds to develop an effective new antimicrobial rule.

EPA has taken several steps to help publicize these meetings and make associated documents widely accessible. EPA has opened a docket (OPP #00473) that contains information about these meetings and development of the antimicrobial rule. The meetings are announced in the Federal Register, and summaries of the meetings and copies of materials handed out are distributed electronically.

National Antimicrobial Information Network
of the National Pesticide Telecommunications Network

Under a cooperative agreement with Oregon State University, the Antimicrobials Division supports a telecommunications information service called the National Antimicrobial Information Network (NAIN), which is part of the National Pesticide Telecommunications Network. Until recently NAIN was known as the Antimicrobials Complaint System, although almost all of the 700+ phone calls it received in 1996 requested information about how to use antimicrobial products safely and whether specific antimicrobial substances were registered with EPA. Therefore, in early 1997 the network's name was changed to NAIN to reflect its information role. NAIN responded to more than 800 calls in the first six months of 1997. To help satisfy the public's need for reliable information, NAIN is developing fact sheets to answer the most common questions it receives. (NAIN can be contacted in the following ways: phone 800-447-6349; fax 541-737-0761; e-mail nain@ace.orst.edu ; website http://ace.orst.edu/info/nain/

VI. OTHER RESPONSIBILITIES OF THE ANTIMICROBIALS DIVISION

Earlier sections of this report described short-term activities that the Antimicrobials Division is undertaking to comply with FIFRA as amended by the Food Quality Protection Act. AD has put special effort into finding ways to streamline registration processes and to make decisions within the new review period goals. AD has met all statutory review deadline goals for applications received after November 1, 1996, and plans to continue meeting all statutory and self-imposed deadlines. However, AD performs many activities in addition to those already described. Although AD can continue functioning in the short-run without giving these other items needed attention, for the longer term AD will need to devote a significant share of its resources to fulfilling its responsibilities for reregistrations, tolerance setting, and efficacy testing, as well as considering possible new initiatives on laboratory accreditation and self-certification for submitted data.

Reregistration Eligibility Decisions (REDs)

Many older pesticides were registered when scientific knowledge and testing for safety were less advanced than now. Under FIFRA, EPA is required to undertake a comprehensive review of pesticides containing active ingredients registered before November 1, 1984 to ensure that they meet current safety standards. Reregistration is a two-step process. The first involves a Reregistration Eligibility Decision (RED) for the active ingredient, in which EPA thoroughly reviews all the data associated with the ingredient and identifies changes in the registration requirements that would better protect public health and the environment. The second step involves issuing the reregistration for specific products containing that active ingredient. Some active ingredients cannot meet current standards, and products containing them cannot be reregistered.

EPA is organizing its reregistration review to give priority to the active ingredients that potentially present the greatest risk to human health or the environment. The FQPA amendments to FIFRA provide funding for EPA to complete review of these pre-1984 active ingredients in the next few years. The Antimicrobials Division is responsible for issuing Reregistration

Eligibility Decisions by the year 2002 on 45 active ingredients or classes of active ingredients registered before November 1, 1984.

The new FIFRA amendments carry the review of registered pesticides a step further than the 1988 FIFRA amendments. The new amendments make provision for ongoing review of pesticide registrations every 15 years, beginning with review in the year 1999 of pesticides registered in 1984. The following year EPA would review pesticides registered in 1985, and so on. However, there are no special funds authorized for this new activity.

Setting Tolerances

A tolerance is the maximum legal residue of a pesticide chemical that is allowed to remain in or on a human or animal food. EPA and FDA have shared responsibility for setting residue limits that ensure that the U. S. food supply is safe, with each agency responsible for certain categories of substances. FDA has sole responsibility for **enforcing** the tolerances, that is, for monitoring the amounts of pesticides and other selected substances in food and for taking action to prevent unsafe foods from reaching consumers. EPA will not register a pesticide intended for use on food or expected to enter the food supply unless it has a tolerance or has been exempted from the need for a tolerance.

Setting a tolerance is resource intensive, requiring expert review of large amounts of data. When a manufacturer wants to register a pesticide that may leave residues in food, the manufacturer submits a petition containing data that allows EPA to determine whether a tolerance is needed and what a safe tolerance will be, taking into account amounts of food people eat, concentrations of pesticide residue, toxicity of the residue, and other factors. The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA) require that tolerances be examined more closely than in the past, for example, by requiring EPA specifically to consider exposures and other factors that may make children and other identified groups more vulnerable to potential adverse effects of food pesticides. The amended FFDCA also requires that the approximately 9,000 existing pesticide tolerances be reviewed within the next 10 years to ensure that they meet the new safety standards.

Under the new amendments to FIFRA, the Antimicrobials Division will be assuming additional responsibilities for setting tolerances. Prior to FQPA, EPA was responsible for setting food tolerances only for pesticide residues that appeared in raw agricultural commodities, or that had been used on raw agricultural commodities and were still present after the food had been processed. For example, if EPA set a tolerance for a pesticide in raw apples, it was also responsible for setting a tolerance for the pesticide in applesauce, if pesticide residue from the raw apples would become more concentrated in the processed food.

EPA and FDA are discussing how to divide jurisdiction for antimicrobials used in or on food contact articles to satisfy the FFDCA amendments. Although final agreement has not been reached, recent discussions suggest that FDA will be responsible for antimicrobials in or on food packaging materials and for antimicrobials intended to exert an antimicrobial effect in processed food. Under the current discussions, EPA would retain jurisdiction over antimicrobials intended to exert an antimicrobial effect in or on raw agricultural commodities (RACs). EPA would become responsible for setting tolerances for antimicrobials intended to exert an antimicrobial effect in or on finished articles or surfaces, such as cutting boards and conveyor belts, that are in contact with food; previously, FDA was responsible for regulating these residues.

FDA and the Antimicrobials Division of EPA are working together to ensure that the changes in responsibility occur smoothly, and that there is minimal delay for tolerance petitions now with FDA. Where possible, EPA will use existing FDA data evaluations in reviewing new

petitions. AD will carefully monitor the resources that these new tolerance responsibilities take to ensure that other goals and activities stay on schedule.

Ensuring Efficacy of Public Health Antimicrobial Pesticides

Most public health pesticides are designed to help limit human disease by preventing the spread of infectious organisms found on inanimate surfaces. Because the user generally cannot tell if the pesticide is working as claimed, and there are potentially serious public health consequences if a product does not work, EPA reviews data demonstrating the efficacy as well as the safety of these pesticides before it registers them for public health uses. It also has a program to evaluate the efficacy of products after registration. Obtaining dependable efficacy data depends largely on the validity of the tests and the ability of laboratories to carry out the tests.

Efficacy Testing.

The new FIFRA amendments address ways that EPA could better ensure the efficacy of antimicrobial public health pesticides. The law requires EPA to "ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness" after they are registered.

Since the early 1990s, EPA has taken steps to ensure that public health pesticides are efficacious as well as safe. In particular, the Agency has funded multi-year research studies to develop better and faster tests for determining the activity of public health antimicrobial agents against spores, viruses, and the tuberculosis bacterium. This research has led to better tests, which EPA expects to make part of standard test method guidelines in the near future.

To ensure that products remain efficacious after they are registered, EPA is in the process of testing more than 800 hospital disinfectants on the market, including the 150 hospital disinfectants with tuberculocide claims. As of October 1997, efficacy evaluations have been completed for a total of 26 of the 38 high priority hospital disinfectant products chosen for early evaluation. Preliminary results indicate that 19 of the 26 products with hospital disinfection claims passed the efficacy testing and 7 failed. Of the 16 hospital disinfectants that also made tuberculocide claims, 12 passed the efficacy testing and 4 failed. EPA is reviewing the results to determine appropriate regulatory and enforcement responses for the products that failed the efficacy tests.

Laboratory Accreditation (Certification)

EPA is examining proposals to establish laboratory accreditation programs to improve the scientific integrity, reliability, and accuracy of antimicrobial efficacy data developed to support public health claims. FQPA amendments mention that use of certified laboratories might help EPA speed up the review process. This outcome could occur in several ways. Data from accredited laboratories might not need as rigorous review as data from other laboratories. Registrants might prefer to have accredited laboratories perform their efficacy testing because they believe the results might be reviewed more quickly if the laboratories have a good track record with EPA. If use of accredited laboratories made reviews less time-consuming for EPA staff, then EPA would have additional resources for other activities. EPA is working with industry to see whether accreditation could help streamline registration activities for antimicrobial pesticides.

Self Certification of Data

To streamline its registration processes, the Antimicrobials Division is also considering industry proposals to examine areas where, with appropriate safeguards and minimal risk, it could allow applicants to certify both the results and regulatory consequences of certain required toxicology or studies. As usually conceived, self-certification would allow EPA to make a decision on an application before reviewing selected data that the applicant has submitted. However, such data might be reviewed after registration to "spot check" compliance. AD is approaching this possibility cautiously, however, since it is concerned with maintaining the scientific integrity of submitted data and decisions based on those data.

VII. SUMMARY AND RECOMMENDATIONS

While continuing its ongoing activities, the Antimicrobials Division of the Office of Pesticide Programs, EPA, has made significant progress in meeting the new requirements imposed by the Food Quality Protection Act. The Antimicrobials Division has a structure designed to function efficiently and to be responsive to registrant needs while protecting public health and the environment. The division is maintaining a dialogue with stakeholders, who include public health users and environmental groups as well as pesticide registants. It is streamlining its operations, one of its most successful innovations being creation of a dedicated Expedited Review Team to ensure that fast-track registration actions are completed within 90 days. During the first six months of 1997, the division met the review time goals set by new FIFRA amendments while it reduced its backlog by almost 80%.

This report has described actions that EPA is taking to streamline antimicrobial registration activities and to reduce the backlog of antimicrobial pesticide actions. With many regulatory activities undergoing change, it would be premature to make recommendations for further improvement in antimicrobial registration activities. The Antimicrobials Division is beginning to implement important new streamlining and process changes while continuing to explore and develop others. It is facing many new challenges as it attempts to integrate its streamlining activities with new responsibilities for addressing reregistration, reexamining existing tolerances, and upgrading the scientific foundation of its regulatory programs. After the Agency has had experience with these ongoing and new activities, it expects to be in a position to develop useful recommendations for its next antimicrobials progress report.

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Attachment A. 1996 FIFRA AMENDMENTS RELATED TO ANTIMICROBIAL PESTICIDES

(h) REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.—

(1) EVALUATION OF PROCESS.—To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) REVIEW TIME PERIOD REDUCTION GOAL.—Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) IMPLEMENTATION.—

(A) PROPOSED RULEMAKING.—

(i) ISSUANCE.—Not later than 270 days after the date of enactment of this subsection, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) REQUIREMENTS.—Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) COMMENTS.—In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) FINAL REGULATIONS.—

(i) ISSUANCE.—The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) FAILURE TO MEET GOAL.—If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) REQUIREMENTS.—In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) EXPEDITED REVIEW.—This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) ALTERNATIVE REVIEW PERIODS.—If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) WOOD PRESERVATIVES.—An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(mm) is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) NOTIFICATION.—

(i) IN GENERAL.—Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) FINAL DECISION.—If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5, United States Code.

(iii) EXEMPTION.—This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection.

(4) ANNUAL REPORT.—

(A) SUBMISSION.—Beginning on the date of enactment of this subsection and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall include a description of—

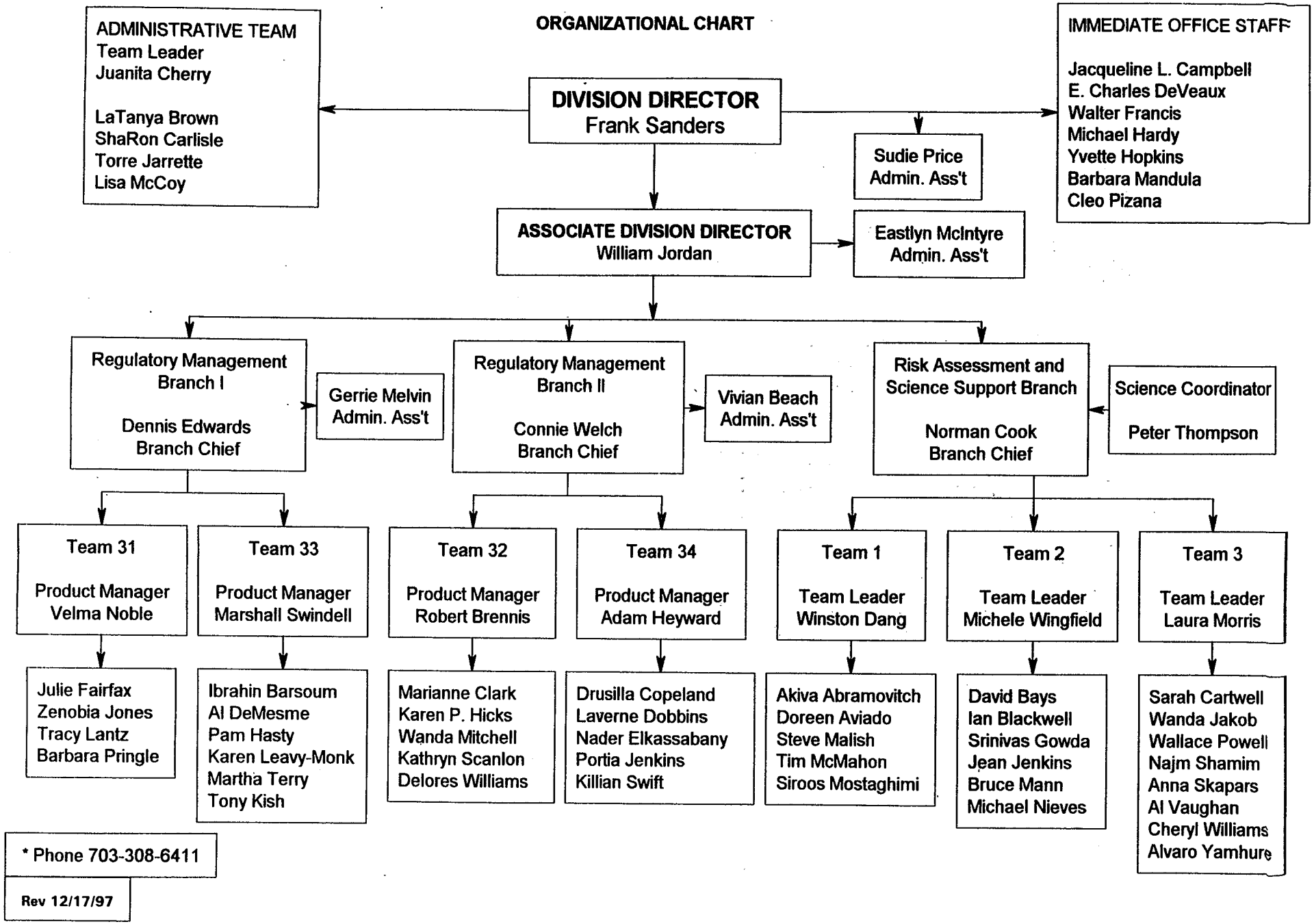
(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

ANTIMICROBIALS DIVISION *

ORGANIZATIONAL CHART



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