Chapter 8

Summary and Options

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Regulatory laboratories analyze pesticide residues in food by one of two ways:

. multiresidue methods (MRMs) or
• single residue methods (SRMs)

Both the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS) rely on MRMs for the bulk of their testing. These methods provide quantitative data on a large number of pesticides. FDA supplements its MRM testing with SRMs that also provide quantitative data. A potential third way to analyze residues in food is by using rapid semi-quantitative and qualitative methods. Currently, the majority of such tests developed for pesticides are for nonfood matrices, e.g., water, and are not yet applicable to food.

REASONS FOR NEEDING ADDITIONAL METHODS WORK

If analytical testing is to remain the basis of Federal pesticide residue regulatory programs, then new and improved analytical methods will be needed to carry out the mandate of preventing illegal residues in food from reaching the consumer. The need for improved methods arises from constraints on existing methods used today by regulatory agencies in the following areas:

- Coverage: the ability to test for all significant pesticides.
- Resources: the availability of sufficient resources (e. g., personnel, instrumentation, and laboratory facilities) necessary to test for all significant pesticides.
- *Confirmation:* the ability to verify that a violation exists.
- *Regulatory action:* the ability to analyze samples in a timely manner so that violative commodities can be stopped before they reach the marketplace.
- *Metabolizes, new pesticides, and inert ingredients:* the ability to test for pesticide metabolities and breakdown products, for new pesticides having different characteristics than those analyzed using existing methods, and for significant inert ingredients (if determined necessary).

Analytical methods exist today to analyze for each pesticide residue on the food for which a tolerance has been established. These methods, almost all SRMs, are contained in the *Pesticide Analytical Manual Volume II* (PAM II). SRMs are not suitable for everyday monitoring of the food supply for several reasons: a large number of pesticides are commercially available, more than one pesticide is commonly applied to a particular commodity, a pesticide residue may occur on a commodity for which the commodity has no tolerance, and regulatory laboratories work with samples whose pesticide history is unknown (14).

To maximize coverage with given resources, FDA and FSIS rely on MRMs for the majority of their analyses. These MRMs can detect only certain pesticides that may occur in food, including some pesticides of primary concern to Federal agencies (31). FDA's and FSIS's MRMs can test for no more than half of the currently known pesticides. In addition, development of MRMs has not kept pace with the number of new pesticides approved for use on food and feed (14). The five MRMs[1] used by FDA can detect 163 out of 316 pesticides with EPA tolerances and a number of pesticides with temporary or pending tolerances, pesticides with no tolerances, and metabolizes that could be found in food (8, 22, see table 3-1 in ch. 3). FSIS's four MRMs can detect approximately 40 pesticides and metabolizes of the 227 FSIS lists for consideration (1, 10).

[1]In addition to FDA's five primary MRMs, several additional MRMs exist that can analyze a small number of similar pesticides (e.g., chlorophenoxy acetic acids or phenylurea herbicides).

Some pesticides do not require routine monitoring because they pose low risk to human health. But not all higher health hazard pesticides can be analyzed through MRMs. Pesticides that can be analyzed by MRMs are linked through similarities in chemical structure and behavior, not through the degree of health hazard they pose. The General Accounting Office found that FDA's MRMs could not detect 33 pesticides with moderate to high health risks (3 I). FSIS has identified 10 highly ranked pesticides it would like **to** monitor routinely but cannot with its MRMs (11). A number of other highly ranked pesticides exist that cannot be analyzed using the MRMs but FSIS considers them less likely to appear in meat (11).

Many pesticides not detected by FDA's and FSIS's MRMs require the use of specific SRMs for analyses. SRMs can be as time-consuming and costly to conduct **as** MRMs, making them comparatively expensive and inefficient for routine monitoring. Thus, they are used sparingly, usually **to** test for a pesticide known or suspected **to** be a problem, to confirm the results of an MRM, or to conduct special surveys that monitor one-time levels of a specific pesticide residue in food. For some pesticides, practical SRMs do not yet exist.

When a violation is found, it must be analytically confirmed before enforcement action is taken. Confirmation is done by analyzing the sample with **a** different method or with the same method originally used but technically modified. A confirmatory method generally exists for an MRM because modifications can be made by using a different column and/or detector. Confirmation methods do not exist for some SRMs and so may constrain their use.

Existing analytical methods, when combined with sampling and reporting requirements, generally do not provide results fast enough to prevent perishable commodities from reaching the market even after violations are found. Frequently, it takes considerably more than 2 days from the time a sample is collected to the time analytical results are available (31). In many cases, the food is sold during this interval.

Some pesticides may break down to metabolizes or degradation products hazardous to human health. Analyzing for the parent compound and its metabolizes (or only its significant metabolizes) may be outside the capability of existing methods or the available resources of regulatory agencies. For some older pesticides, the metabolism data is flawed and significant metabolizes have not been identified (30). In addition, existing MRMs are not designed to detect many polar (water soluble), nonvolatile, and nonpersistent compounds. Many new pesticides are designed to be less persistent in the environment than older ones; therefore, they metabolize or degrade more quickly, producing breakdown products that are more polar and thus more difficult to detect using existing methods. New classes of compounds, such as synthetic pyrethroid insecticides and sulfonylurea herbicides, also are not easily analyzed by existing methods, although they should not be too difficult to detect using available technology (20). This trend suggests that current MRMs will need to be modified or that new MRMs be developed to analyze new pesticides coming on the market.

In addition, pesticides contain a number of chemicals used for purposes other than pest control, e.g., colorants and drift control agents. Currently, these chemicals are categorized under Federal regulation (CFR 180.1001) as "inert ingredients" and are exempted from the tolerance process and Federal monitoring. In some cases, inerts are potential or known toxic substances, and increasing attention is being paid to them as possible health hazards. If Federal monitoring for inerts—or for only those considered a health risk—is determined necessary, existing MRMs will have to be modified to address the larger number of chemicals requiring monitoring.

EXAMPLES OF WHAT CAN BE DONE

Multiresidue Methods

MRMs will remain the foundation of regulatory analysis. They are superior in terms of cost, coverage, and quantified data they provide. Several ways exist to improve the use of MRMs:

- Expand the number of pesticides and commodities that existing MRMs can analyze.
- Develop new MRMs for pesticides not detected by existing MRMs.
- Use new technologies to reduce the resources necessary to perform an MRM.

Existing MRMs can be expanded to analyze additional pesticides as well as additional commodities. The research has not yet been done to determine whether an existing MRM can be used to detect a large number of pesticides without modification. Both FDA and USDA are currently conducting research in this area. For example, FDA's Los Angeles laboratory is determining if the Luke method can be used to analyze an additional 80 older, domestic pesticides and 50 foreign ones (15). And FSIS is trying to adapt its MRMs to analyze an additional seven pesticides (l). The expansion of an MRM to analyze other pesticides and foods may also require some methodology modification. In some cases, subtle modifications such as substituting one solvent for another can increase the number of pesticides an MRM can determine.

Adding new technologies into an existing MRM can also expand the number of pesticides that can be analyzed. For example, new detectors, such as photoconductivity for high performance liquid chromatography (HPLC), can detect additional pesticides, and capillary columns for gas chromatography (GC) can separate individual pesticides that normally might be seen as one peak on a chromatogram from a packed column. Theoretically, immunoassay could be used on an extract prepared for an MRM to identify pesticides the MRM cannot detect. Thus, immunoassay would function as an additional detector for the MRM.

Current MRMs might also be expanded by using different combinations of existing technologies. For example, the ability of the Luke method to detect a large number of pesticides is based in part on the use of two to six combinations of packed columns and detectors (15). Smaller laboratories, however, may not have the equipment for such combinations. Further work on other combinations of technologies could lead to increased coverage of pesticide-matrix combinations.

Another way to expand an MRM might be to develop ways to analyze those parts of the sample now discarded, e.g., the water and cellulose fractions. Theoretically, some highly polar compounds might end up in the water and thus would not be analyzed. FDA's Los Angeles laboratory found daminozide in the water released during extraction of fruits and vegetables (15). Herbicides can be bound to plant material, not extracted with existing methods, and lost when cellulose is discarded. The importance of these bound pesticides to human health has not been established, although initial work shows that the majority are of little concern (34). The relative merits of spending resources for this type of research have not been determined, but developing techniques for the extraction of bound herbicides is seen as an expensive research project (34).

Developing new MRMs can help address the problem of pesticides that cannot be analyzed by existing MRMs. New MRMs are applicable to fewer residues than existing MRMs because such residues will be from pesticides with widely varying chemical structures. In short, new MRMs will analyze smaller groups of chemically related pesticides (25). For example, FDA's Pesticide and Industrial Chemicals Research Center (PICRC) is researching how to expand the use of high performance liquid chromatography (HPLC) to develop new methods that can identify small groups of pesticides not easily detected through GC (32).

New methods may also result from emerging technologies. For example, supercritical fluid extraction (SFE) may simplify sample extraction and cleanup, and supercritical fluid chromatography (SFC) may improve chromatographic separation. The coupling of SFE/SFC could lead to new MRMs capable of detecting small groups of pesticides that are thermally labile or polar (13). Although not now in regulatory use, SFE/SFC is being researched under FSIS contracts for use on pesticides and drugs in meat products.

New technologies may also reduce the time necessary to perform an MRM, thereby freeing up time for analysis of additional samples, a broader analysis of each sample, or additional research. Automated gel permeation chromatography (GPC), autoinjectors, and data processors are already routinely used to free analysts from time-consuming and tedious laboratory activities. Solid phase extraction (SPE), automated evaporators, and other technologies are being developed and used for their ability to save time during sample cleanup.

Robotics is an emerging automation technology that might free large segments of analysts' time now spent on repetitive laboratory procedures; robots are expensive, require substantial design modification, and work best for large numbers of similar samples undergoing the same analysis. Health and Welfare Canada is evaluating the use of a robot in a milk survey for 32 pesticides, metabolizes, and PCBs to carry out the extraction and cleanup steps. Early results show that the robot can contribute to a doubled weekly sample output, in part due to its ability to work at night (17). Some U.S. private companies are also using robots for pesticide residue analysis.

In addition to new technologies, new approaches may also reduce analysis time. For example, ongoing FDA research on reducing the size of the sample prepared for analysis could cut extraction and cleanup times.

Single Residue Methods

SRMs will be required to test for pesticides that cannot be analyzed by MRMs, especially those pesticides with significant health hazards. SRMs can be made more practical for regulatory analysis through improvements in their accuracy, cost, and timeliness.

A first step could be to determine if existing SRMs (listed in PAM II) are practical and effective. Those SRMs found wanting would be candidates for improvement or replacement through Federal research or potentially by the petitioner who submitted the method. To ensure that new PAM 11 methods did not suffer from the same problems, EPA could tighten its requirements for acceptable methods and increase the testing of such methods (for more details, see Finding 3).

Many of the same technologies available for improving MRMs or developing new MRMs could also be used to improve or develop new SRMs. Technical advances have taken place since many SRMs were developed. In some cases, technologies may be more applicable to SRMs than MRMs. For example, SPEs reduce cleanup time but may also cause the loss of pesticides; newer SPEs suffer less from this problem than older ones. Reducing the loss of pesticides can improve the usefulness of a technology for an MRM but not for an SRM, since SRMs only detect one pesticide at a time. Automation and robotics can also be used in SRMs, especially if an SRM is used to analyze large numbers of similar samples for a particular pesticide, as in the case of a special survey. Because of insufficient research resources, the need for improving an individual SRM could be evaluated on the basis of the pesticide's health hazard and the possibility that an MRM could be adapted to test for the pesticide.

The quantitative immunoassay is an emerging technique that could lead to important new SRMs, particularly for those pesticides that do not need extensive cleanup and that cannot be detected easily by existing analytical techniques

or when large numbers of samples need analysis. Quantitative immunoassays' potential to analyze more samples in the same period of time than conventional methods, to lower training and equipment costs, and to potentially lower analysis costs combine to make their development attractive for analyzing those health hazardous pesticides that cannot be analyzed by MRMs. Currently, Health and Welfare Canada is taking steps to implement the regulatory use of an immunoassay SRM on food that will give quantifiable results in its field laboratories.

Semiquantitative and Qualitative Tests

Development of semiquantitative and qualitative tests promises to complement existing approaches while also changing them. Qualitative rapid tests identify a residue if it occurs at concentrations above a pre-established level, while semiquantitative methods identify residues over a pre-established concentration and determine the range of their concentrations. Both may test for a single pesticide residue or a group of related ones. In the latter case, the test can identify only the pesticide group, not the specific pesticides. The advantages of such methods are that they can provide fast results at lower cost than conventional methods and may be portable. Their disadvantages are that they usually analyze only a small number of pesticides, and they do not provide quantitative data.

The lack of quantitative data is a major institutional drawback. Regulatory agencies like FDA use methods that can detect and quantify pesticide residues at below-tolerance levels to collect data on the incidence and levels present in food. Such quantitative data are used by EPA in special reviews of pesticides, in pesticide tolerance revocations, and in re-registration of pesticides and are of interest to other groups. FDA is concerned that the use of such tests would adversely affect its data-gathering responsibilities, especially to EPA. To overcome the quantitative data obstacle, FDA could meet with EPA to determine EPA's actual data needs, how such tests could take place without affecting those needs, and what other data needs might be filled by such tests (e.g., identifying that a pesticide residue commonly exists in a specific food that was thought to be pesticide free).

A number of possible uses exist for these tests, which make use of such technologies as thin layer chromatography, enzyme inhibition, and immunoassay. In cases of a widespread residue problem in a commodity, these tests might identify violative samples more quickly and less expensively.

Secondly, such tests could be used to analyze large numbers of samples for a particular pesticide or small group of pesticides that are expected to have low violation rates. The small number of samples identified as violative could then be analyzed by quantitative methods to confirm and measure the violation. In this way, significantly hazardous pesticides could be routinely monitored while minimizing the use of more expensive SRMs. Along these lines, FSIS is evaluating a commercial immunoassay kit for qualitatively analyzing triazines; this kit could complement a new conventional method for analyzing triazines that provides quantitative results (l). Where applicable, these tests might also be applied to sample extracts prepared for an MRM to analyze additional pesticides. FSIS is developing and evaluating several such tests to analyze triazines, synthetic pyrethroids, and organophosphates in meat products, and FDA is developing a method using thin layer chromatography for organotins (1, 32).

Semiquantitative and qualitative tests may prove applicable for non-laboratory testing if scientific obstacles can be overcome. The benefits of such an approach would include reducing the costs associated with laboratory analysis (including transporting the sample to the laboratory) and speeding up identification of violative samples. Drawbacks would include the training and equipment needs for the in-

specters who would do the testing and the additional time they would need to carry out tests. FDA has evaluated one commercial kit for on-site use, but the kit produced an unacceptable number of false negative results (33).

For all these uses of such tests, conventional methods would have to be used to confirm any violation detected and to provide assurance that the tests were not providing unacceptable levels of false negatives or false positives. Nevertheless, given the pressure for broader monitoring with fixed resources, the appropriate role of semiquantitative and qualitative rapid tests in Federal monitoring programs needs to be determined.

Validation: Important for Technology/Methods Adoption

Validation is an important consideration for the adoption of any new technology or method (see ch. 6). Validation is the verification that a technology or method provides useful analytical data and operates within acceptable performance parameters (for a description of these parameters see ref. 4). There are several levels of validation including the following: intralaboratory, interlaboratory, and a collaborative study. FSIS requires a minimum of three analysts and two collaborating laboratories for validation. FDA requires at least two collaborating laboratories to test the method or technique but in some cases maybe forced to use an intralaboratory validated method if no other is available. Validation requires time and trained personnel—two scarce components of regulatory work.

Collaborative study involves six to eight laboratories under the auspices of the Association of Official Analytical Chemists (AOAC) and is the most rigorous form of validation. (Methods that have been validated in this way are termed ‘‘official” by the AOAC.) The length of time involved to carry out this type of validation (1 to 3 years) (26) and the difficulty in finding enough laboratories to volunteer their resources restrict the number of methods validated in this way. Even the most widely used FDA MRMs are official for only some of the commodities. FDA, in particular, emphasizes the use of official methods where possible. The emphasis on official methods and the limits on performing collaborative studies may make it difficult to adopt a new technology or method if an official one already exists.

To avoid delays in adopting new technologies and ensure the availability y of resources for validations, Federal agencies and non-Federal organizations, such as the AOAC, could jointly determine how the speed of official validation could be increased and how to expand participation of additional laboratories. For example, private or academic laboratories could take a greater part in interlaboratory studies.

Immunoassay (discussed in ch. 4) pose a specific validation need. They will require rigorous validation as a new technology for analyzing pesticide residues, and as they are unfamiliar to most analytical chemists. At the same time, pesticide chemists’ unfamiliarity with the technology may make it difficult to find the necessary number of analysts needed to perform collaborative studies. In addition, collaborative studies designed for conventional methods may not be applicable to certain immunoassay applications. Therefore, Federal agencies and organizations such as AOAC could determine the protocol for immunoassay validation for pesticide analysis and promote means to overcome obstacles to their validation.

FINDINGS AND OPTIONS

OTA has identified specific options for improving the capability of Federal programs to analyze pesticide residues in foods. The options are summarized in table 8-1 and organized under four categories:

- improving Federal agencies’ pesticide methods research, development, and adoption;
- increasing research coordination and cooperation;
- improving the regulatory usefulness of ana-

Table 8-1.—Summary of Options to Improve Federal Detection of Pesticide Residues in Food

Improve Federal agencies' pesticide methods research, development, and adoption	• FDA[a] and FSIS[b] could establish long-term research plans including priority lists of pesticides requiring improved methods. • FDA could improve the organization of its research. • GAO could conduct an evaluation of Federal analytical methods research programs for analyzing pesticides in food.
Increase research coordination and cooperation	• Federal agencies could create a methods research and development advisory committee for pesticide residues in food. The committee could include appropriate non-Federal representatives. • FDA, FSIS, and EPA could establish a methods workgroup for pesticide residues in food. • Federal laboratories could increase coordination with State pesticide residue laboratories. • Federal agencies could improve their use of private sector expertise. • Federal agencies could increase coordination with appropriate agencies of foreign governments.
Improve the regulatory usefulness of analytical methods submitted to EPA as part of the tolerance-setting process	• EPA[c] could require an independent test of pesticide analytical methods before their submission to EPA. • FDA and FSIS could validate submitted methods. • EPA could require the testing, development, or adaption of a multiresidue method for any pesticide requiring a tolerance. • EPA could revise its regulations and guidelines for submitted methods. • FDA and FSIS could review and revise existing methods cataloged in PAM II.[d]
Maintain the quality and quantity of the analyst workforce	• Federal agencies could revise their hiring practices and find ways to give laboratories increased flexibility in hiring new recruits. • FDA and FSIS could increase continuing education and training programs for Federal analysts. • FDA and FSIS could sponsor analytical methods training workshops for State analysts.

[a] FDA: Food and Drug Administration of the U.S. Department of Health and Human Services
[b] FSIS: Food Safety and Inspection Service of the U.S. Department Of Agriculture
[c] EPA U.S. Environmental Protection Agency
[d] PAM II: *Pesticide* Analytical *Manual*, Volume II, Washington, DC: Food and Drug Administration)

lytical methods submitted to EPA as part of the tolerance-setting process; and
- maintaining the quantity and quality of the analyst workforce.

Although the options could require congressional action, most of the options can be implemented by the relevant Federal agencies without new or amended legislation. However, a number of these options would require budget increases or realignments in agencies' priorities. In addition to improving analytical methods, the effectiveness of monitoring pesticide residues in food could be enhanced by addressing related issues (box 8-A).

In general, the barrier to expanding the detection of pesticide residues in food seems to stem less from the scientific arena than from the policy one. Individual agencies have given lower priority to such research because of pressing demands to address other matters. In addition, lack of adequate incentives and resources slows progress in this area, including the detection of moderate to high health hazard pesticides not now detectable by existing MRMs.

FINDING 1: Federal Agencies' Pesticide Methods Research, Development, and Adoption Could Be Improved.

Option 1.1: FDA and FSIS could establish long-term research plans including priority lists of pesticides requiring improved methods.

Box 8-A.—Related Issues

In the processor assessing technologies for the detection of pesticide residues in food, certain other issues arose that influence the effectiveness of Federal agencies' monitoring of pesticide residues in food. Although these issues were outside the scope of this OTA study, they warrant brief discussion because they affect the technical capability and research direction of the Federal pesticide regulatory programs. They are the following:

- Intelligence data on pesticide use
- Sampling
- Perception of food safety

Intelligence Data. Analytical chemists can focus their analysis better and improve their ability to detect pesticide residues if they know what pesticides have been used on the crop. For instance, FDA's most widely used MRM, the Luke method, comprises six different column/detector combinations to detect a range of pesticides. Without intelligence data, each of the six combinations would have to be used to check the food sample. With intelligence data, the number of combinations used can be reduced to focus on those pesticides thought or known to have been applied to the crop. Having such intelligence data thereby can free equipment for analyses of additional samples.

The lack of intelligence data today is greater for imports than for domestic foods. FDA laboratories obtain information on domestic pesticide use, for example, from State agencies, land grant universities, USDA's extension service, domestic growers, and pesticide applicators. Information on foreign pesticide use is more scarce. FDA uses the Battelle World Pesticides Program database, which provides country-level data on fungicide, herbicide, and insecticide use in 22 countries. Information may also be obtained from such sources as foreign agencies making pesticide application recommendations and weather reports. Improvements in intelligence data, especially for imports, would increase the analytical effectiveness of regulatory analyses while improving the use of fixed laboratory resources. Improved intelligence data would require additional funds and raise the question of who—regulatory agencies or the private sector—should bear the increased costs.

Sampling. Decisions on how much sampling should take place and what type of commodities should be sampled affect analytical methods development. For example, a decision to increase sampling could lead to an emphasis on making current methods faster, introducing new and more rapid methods, and using semiquantitative or qualitative methods to screen out nonviolative samples quickly. A decision to increase sampling might also lead to requirements for private testing to reduce the burden on Federal regulatory laboratories. Such a step could require Federal quality control and assurance programs for private laboratories performing the analyses. The resulting increase in private testing could lead to increased private development of analytical technologies and methods suitable for regulatory testing.

Correspondingly, a decision to maintain the current level of sampling but increase the number of pesticides analyzed could promote research on expanding the scope of existing MRMs and on developing new MRMs and more practical SRMs. A decision to sample a wider variety of commodities might require increased work on adapting existing methods to new commodities.

Perception. A difference of opinion exists with regard to the actual importance of pesticide residues in food in relation to human health. A significant level of consumer concern and congressional interest exist on the issue. However, the regulatory agencies, FDA and FSIS, do not consider pesticide residues as a high priority issue for food safety. Most regulatory chemists and laboratory directors OTA spoke with believe the food supply is safe with regard to the level of pesticides residues present, and other areas of food regulation should have priority for any new funding. The regulatory agencies' stand on this point has led to their allocation of fewer resources and incentives for the development of improved methods for the detection of pesticide residues in food.

Federal methods research for pesticide residues in food suffers from a lack of long-term planning. For example, neither FDA nor FSIS has a long-term pesticide methods research plan. Instead, each relies on annual research plans that include multiyear projects directed toward short-term program needs. A percentage of research is necessary to address short-term emergency-oriented research. But regulatory work could benefit from long-term planning designed to provide research direction to overall needs and monitoring goals. More specifically, a long-term plan would identify potential future problem areas (e.g., emerging pesticides), develop strategies to address the problem areas, and forecast resources (i.e., skills, time, and funds) necessary to carry out the strategies. Currently, FDA's Center for Food Safety and Applied Nutrition (CFSAN) is developing a long-term research plan to be completed in 1988.

An important element of such a research plan would be the development of a list of top-priority pesticides requiring improved analytical methods. To generate such a list would require developing a formal means to rank pesticides for regulatory action, ranking the pesticides, and then identifying those pesticides that cannot be easily detected by existing methods and those pesticide-matrix combinations for which existing methods are unsatisfactory. By gathering this information, Federal agencies could then develop long-term methods research plans to help identify and measure the most important pesticides of health concern. This list would also assist State and private researchers in setting research priorities. The priority list would be subject to continual revision as new pesticides and new uses were introduced, older pesticides and their uses were ended, and new pesticide data (e.g., metabolism and toxicological) were developed. FDA and USDA may need separate lists because of the different food matrices with which they work. A comparison of those lists with an EPA list of pesticides in environmental matrices would reveal areas of mutual concern and offer an opportunity for coordination of research.

Much of the work needed for development of such a list has already been done by the three agencies. FDA and FSIS have taken steps toward developing such a list, but a list of top-priority pesticides requiring methods development is not available to other agencies nor to the private sector.

FDA began ranking pesticides on its Surveillance Index (S1) in 1981 based on such factors as pesticide toxicity, production and usage, human exposure, and environmental fate (23). Under the SI, pesticides are placed in one of five categories of health hazard. The SI was developed primarily to help set monitoring priorities but has also been used to highlight methods research needs. Currently, 205 pesticides of approximately 316 pesticides with tolerances have been ranked, with the remainder still to be considered (9). An additional 120 pesticides that could be in food will not be ranked because they have low toxicological effects, do not produce residues in food, are no longer manufactured, or are used only in foreign countries on foods not intended for export to the United States (23). Ranking the remaining pesticides with tolerances (and those pesticides that do not have tolerances but have high potential to occur as residues in food) is of some concern because only 10 pesticides per year were ranked in 1986 and 1987 vs. the proposed 30 to 50 (9, 23). FDA also has set up a database, Pestrak, to identify those pesticides that cannot be analyzed through its MRMs.

FSIS has listed 227 pesticides and metabolites of concern and has given each a letter ranking that represents the potential for harmful residues to occur in animals at slaughter. In 1985, FSIS instituted a new ranking system for pesticides, the Compound Evaluation System (CES), using a letter-number ranking code to represent potential toxicity and human exposure. Of the 227 pesticides, 39 have been ranked under the CES, though none have been ranked so far in 1988 (24). Ranked pesticides are then checked for suitable analytical and confirmatory methods. If highly ranked pesticides are found not to have suitable methods for their

identification and quantification, research priorities can be adjusted to address the problem. Although the CES is being used to help set research priorities, it is currently too small to provide an overall priority list.

EPA's need for a list of priority pesticides in foods is less because its regulatory responsibilities concern the environment, not food (although it has responsibility for some game animals). A similar listing for the pesticide matrices EPA regulates, however, could be useful to support internal EPA coordination of methods work as well as coordination with other agencies.

Option 1.2 FDA could improve the organization of its research.

Recent studies of deficiencies in pesticide monitoring programs point to the need for an aggressive methods research and development program (28, 31). FDA conducts the majority of Federal research on pesticide residue methods for food. OTA has observed that problems in the organization of FDA's methods research adversely affect the agency's research program.

The basis for OTA's observations was interviews with persons inside and outside the FDA. within the timeframe and mandate of this work, OTA was unable to evaluate FDA's pesticide methods research program in depth. Because OTA's observations raise significant concerns about the FDA research program, *a more detailed evaluation of the program as well as those of FSIS and EPA conducted by the General Accounting Office would be useful* to gauge the importance of OTA's observations and, if necessary, to identify remedial actions. While OTA did not make similar observations of FSIS's or EPA's programs, an analysis of FSIS's decentralized research approach, EPA's methods evaluation process, and the level of coordination with FDA would be important to obtain an overall picture of Federal methods research on pesticide residues in food.

Pesticide methods research is conducted by four organizational bodies within FDA:[2]

- CFSAN laboratory, which has six FTEs for pesticide methods research.
- Two research centers, the Pesticide and Industrial Chemicals Research Center (PICRC) and the Total Diet Research Center (TDRC), which together have six FTEs for pesticide methods research.
- The 16 field laboratories, which together have approximately seven FTEs for-pesticide methods research.

CFSAN has the greatest concentration of research personnel in one place. Research at CFSAN has led to development of four of the five MRMs used by FDA. OTA observed that FDA field laboratories considered CFSAN's current research not geared to regulatory needs, including the timeliness needs, of field laboratories. Little field involvement seems to exist in setting CFSAN's research agenda, which primarily addresses current problems rather than upcoming issues. CFSAN is the proper body to prioritize overall pesticide methods needs, and it does so annually but not in a fashion easily accessible by other Federal agencies, State programs, or the private sector.

FDA's research centers—PICRC and TDRC–were established in 1980 to address the research needs of field laboratories in analyzing pesticides and industrial contaminants. TDRC's primary function is to support the Total Diet Program, and PICRC's is to support other regulatory field laboratories. These centers have developed a number of methods in support of the field laboratories' needs, and a number of specific cases exist of individual field laboratories benefiting from this work.

OTA observed that field laboratories consider a large part of the research centers' work as not being applicable to their regulatory needs. Again, it seems that field laboratories have little involvement in setting the centers' research agendas especially compared to CFSAN. This lack of field laboratory appreciation for the centers' work may in part stem from a failure of the field laboratories to devote the resources needed to work with the centers on appropriate research agendas.

[2]Pesticide methods research is conducted in conjunction with industrial chemicals methods research, e.g., PCBS and dioxin, Therefore, the total research FTEs given overstate the number of persons working solely on pesticide methods.

Pesticide methods research at field laboratories is done primarily through short- and medium-term projects. The strength of field research is its immediate relevance to problems at hand. Field research may also significantly improve FDA's analytical work. For example, the Luke MRM was developed at the Los Angeles laboratory, and in 1987 was used in approximately 80 percent of all FDA pesticide analyses. One weakness of field research is that the first priority of field laboratories is regulatory work, and if the need arises, research time will be sacrificed to deal with emergencies. As noted earlier, field laboratories may not be making the effort to help set relevant research agendas for the research centers. Field research also may not be well coordinated between laboratories, leading to duplication of effort or lack of productive interchange.

Although the current structure of FDA research (CFSAN, research centers, and field research) seems to be workable, OTA believes that modifications in the responsibilities of each research body might lead to increased productivity results. As mentioned earlier, a long-term research plan for pesticide methods research would help FDA address the most important needs of its regulatory program, develop improved coordination inside and outside the agency, and address the research responsibilities of FDA's research organizations. Any plan should be based on significant input from FDA field laboratories and from outside experts and should be subject to modification as new needs arise.

CFSAN's research capabilities may be required to address the immediate needs of the regulatory laboratories. If so, then modifications could help make that work more appropriate for meeting field needs. Possible approaches would be to increase field pesticide staff involvement in setting CFSAN's research agenda or to have CFSAN research staff periodically spend time at the field laboratories to improve their understanding of field needs.

On the other hand, CFSAN, as a central laboratory with no line authority over the field laboratories and removed from daily regulatory work, could focus on addressing some longer-term and broader-scope research issues. CFSAN has the time and resources to identify and evaluate new and existing technologies for their application to pesticide residue analysis. Where in-house expertise is lacking, such work might be done through contracts. Contracting allows access to specific expertise but it needs to be done in ways that ensure the work is geared to regulatory needs and is transferable into the FDA system.

CFSAN also has a key role to play in the area of methods development for new pesticides. Changes in the types of new pesticides are seen as making regulatory work more difficult. By tracking the development of new pesticides and addressing the analytical needs for them, CFSAN could help FDA keep up with its regulatory responsibilities and avoid possible future crises.

If CFSAN were to be less involved in research for immediate regulatory needs, then the research centers or the field laboratories might need additional research resources. Ranking pesticides that require methods development research and then coordinating that research are functions that a central laboratory may be best able to accomplish. CFSAN's location enables it to tap EPA's and USDA's pesticide data and research agendas easily, a factor necessary to carry out coordination of priority setting.

The research centers' primary purpose is to support the field laboratories, to be involved in the day-to-day regulatory needs. One way of helping to ensure that research centers are doing so would be to involve field laboratory staff more formally, especially the pesticide specialists, in setting the research centers' agendas. In addition, research center personnel could interact more with field laboratory staff through personnel exchanges, workshops, and increased visits to field laboratories, The centers could assume increased responsibility in technology adoption by adapting and disseminating to the field new methods development work done at CFSAN, at the centers, and at individual field laboratories.

Field laboratories seem best suited to conduct research that meets their individual regulatory responsibilities, such as extending existing methods to analyze additional pesticides and commodities. They are also able to refine new technologies or methods for their own particular situation and validate new methods or techniques. In one case, field laboratories have demonstrated the capability of developing new MRMs. The modifications detailed above would demand increased field participation in setting research agendas for the research centers and possibly for CFSAN and could require additional research to be carried out by field laboratories. Such a redirection of resources would require a corresponding increase in pesticide laboratory personnel to maintain the current level of regulatory work. Therefore, the expansion of field research would require an overall increase in FDA's pesticide methods research expenditures or an internal redistribution of research resources.

FINDING 2: Research Coordination and Cooperation Could Be Increased.

The amount of resources available for methods research for pesticide residues in food increases the importance of coordination between research organizations. Failure to share research plans and results makes it difficult for agencies to be familiar with each others' ongoing work and to benefit from that work. Knowledge of what other agencies are doing can help minimize gaps in pesticide monitoring coverage, facilitate information transfer, provide early warnings of upcoming concerns, and reduce duplication of efforts. For example, FDA let a contract to develop monoclinal antibodies for immunoassay without consulting experts at EPA and Health and Welfare Canada. Antibodies, albeit polyclonal, had already been developed for two of the pesticides included in the contract by Health and Welfare Canada and the University of California at Davis.

Coordination could be increased at all levels: among Federal agencies; among Federal, State, and the private sectors; and between the United States and other countries, in particular, Canada. Resources would have to be redirected in support of measures to increase coordination. Means of increasing coordination include the following:

Option 2.1: Establish a methods research and development advisory committee for pesticide residues in food.

This committee could include representatives of Federal and State regulatory programs as well as representatives of private companies, agricultural producers, consumers, environmental organizations, academic institutions, and pesticide registrants. This committee could include two subgroups: one to deal with policy issues, which would include the chemistry program administrators, and one to deal with scientific issues, which would include the principal chemists. This committee could be mandated to advise the Federal government on current problem areas, support the exchange of results of ongoing government-sponsored projects, and recommend areas of methods research. Another approach that could stand alone or complement the advisory committee would be to follow the Canadian approach of holding workshops with participants from the relevant groups to address specific methods needs when a problem emerges (3).

Option 2.2: FDA, FSIS, and EPA could formally establish a methods workgroup on pesticide residues in food.

Currently, research coordination takes place on a formal and informal bases between EPA, FDA, and FSIS. For example, FDA and USDA use information provided by EPA to help make decisions on what pesticides should be monitored.

Currently, a pesticide analytical methods advisory group with a representative from each of the three agencies meets on an irregular basis. Past meetings led to improvements in the methods program, for example, the inclusion of a user review form in the PAM II to encourage chemists to report problems they had with specific methods. Overall, the advisory group does not have authority, resources, nor commitment to coordinate the pesticide residue methods research of the agencies.

Therefore, a more formal workgroup meeting on a regular basis could improve coordination of the methods research of the three agencies. Effective coordination already exists between FSIS and FDA in another area of regulatory research—animal drugs. FDA's Center for Veterinary Medicine and FSIS have a formalized system for coordinating their work on veterinary drugs through a 2%-year-old working group that puts research needs in priority, and coordinates methods research and validation of new methods (6). In addition, FDA has established project advisory groups with FSIS participation to address veterinary drugs for which residue methods are not available, to contract methods research, and to review the resulting methods (2). Similar coordination on developing research priorities and carrying out methods research and validation could be established between FSIS and FDA in the area of pesticide residue methods.

As part of the workgroup, EPA could continue to supply data for priority setting and increase its use of FDA and FSIS input to ensure that methods submitted during tolerance setting are practical for regulatory work. EPA's role in coordinating research with the other two agencies may be smaller but still important. This is because EPA's methods research does not address food and thus may be of less value to the other agencies. EPA's extraction and cleanup processes may not be applicable to food, especially fatty foods. But since all three agencies use similar detection equipment, advances in such instruments could be used by all three agencies (16). Also, immunoassay research on pesticides can be used by the three agencies because once a pesticide-specific antibody is developed, each agency can then conduct application research to adapt the antibody to matrices of particular concern. Currently, FSIS has an interagency agreement with EPA's Las Vegas laboratory to promote coordination on antibodies of mutual interest.

Option 2.3: Coordination between Federal and State pesticide residue laboratories could be increased.

State regulatory personnel, like Federal analysts, have firsthand knowledge of the needs of field laboratories and could provide guidance for appropriate methods research. Currently, some Federal-State coordination exists. For example, in some FDA districts, FDA and State laboratories divide monitoring responsibilities for certain foods. FDA laboratories also use State pesticide-use data to decide which pesticides and commodities to test. EPA provides pesticide standards to State laboratories and conducts methods training workshops on nonfood matrices for 52 State laboratories. Currently, the California Department of Food and Agriculture (CDFA) and FDA's Pacific Coast Region are developing a Memorandum of Understanding that may include coordination of methods development and quality assurance procedures. Further coordination could include FDA use of State-generated residue data and training of State personnel in pesticide residue methods for food by FDA, similar to the program now run by EPA.

Since most State programs are too small to conduct methods research, opportunities for Federal-State coordination of research on residue methods may be small. But those States with small programs are still knowledgeable of regulatory needs, and their analysts could be consulted. Several States have large-scale pesticide residue monitoring programs and at least one, California, has a significant methods research program. The CDFA recently established a three-person research group to evaluate emerging technologies. It also gave out contracts for developing three immunoassay for pesticide residues in the environment. Increased Federal coordination with State programs like CDFA would expand the scope of overall methods research efforts. It also would help ensure that California establish an effective and efficient program that would complement rather than duplicate the Federal programs.

Option 2.4: Federal agencies could improve their use of private sector expertise.

A tremendous amount of research and development on technologies for detecting pesticides in food is conducted by the private sector. The private sector's contribution to improve analytical methods for regulatory use could be increased in the following ways:

- Creating incentives to stimulate private research and development of methods.
- Tapping the technical expertise of private industry and academia through training and technology transfer.

In addition to the private sector's provision of analytical methods, primarily SRMs, as part of the tolerance-setting process, the private sector also develops new and innovative pesticide residue techniques in response to the market. Analytical instrument makers innovate partly in response to Federal analysts' needs. The development of biologically based technology for the analysis of chemicals has led to private development and marketing of testing kits.

Federal agencies could promote private sector involvement by making clear their own needs. Commercial firms would more likely venture into analytical methods development for pesticides in food if they perceive that a market exists for their products. By making available a list of what methods are needed (e.g., pesticide-matrix combinations) and the type of method needed (qualitative, semiquantitative, or quantitative) for regulatory work, Federal agencies would provide the private sector with needed research direction and some assurance that commercial products indeed have a market among regulatory agencies. For example, FSIS is trying to tap and stimulate the private development of rapid test kits, although these efforts may not be focused enough to convince the private sector that an assured market exists (18). In addition, a common validation procedure would help assure the private sector that acceptance of the technology would require one validation study, not several, for new technologies that are to be used by several Federal agencies.

Along with stimulating market development of methods, the agencies can provide the private sector with seed money in the form of contracts to encourage increased methods research and development. With initial seed money for methods research, the private sector may then be willing to expend its own money for further development. Contracts also will allow agencies to take advantage of expertise not found in-house. FSIS has much of its research done through contracting, while FDA relies primarily on in-house expertise. With the development of new technologies, however, agencies like FDA will need either to increase their contracts to address new developments or bring the expertise in-house, which may be an expensive process. The downside of contracting is that agency personnel must often spend significant amounts of administrative time developing and monitoring the contract, It is sometimes difficult to transfer the results directly because of the nature of regulatory work and lack of in-house expertise.

A large amount of methods development research occurs at U.S. universities, but much of it is devoted to the analyses of environmental matrices, e.g., water, soil, and air, in part because funding is available for such types of work. These methods are of potential use for food analysis. Redirection of university research to food might take additional Federal funding. FDA might improve their use of the four university laboratories funded by USDA to develop methods for pesticides requiring tolerances for use on minor crops (27).

In addition to providing seed money for methods development in the private sector and markets for products, Federal agencies can also tap the expertise that exists in the private sector. Private sector laboratories of pesticide manufacturers and food processors are ahead of Federal regulatory agencies in the use of certain technologies, e.g., robotics and capillary columns. They also may have made improvements in existing methods or developed new techniques of which the Federal agencies are unaware. In some cases, these advances may not be applicable to regulatory usage. On the other hand, Federal and State laboratories have turned to the pesticide manufacturer for advice on methods after encountering difficulty in pesticide analysis.

Federal agencies could obtain additional methods expertise from the private sector through joint public/private sponsorship of technical "hands-on" laboratory workshops. A model may be the annual pesticide residue workshops

sponsored by the State of Florida or the EPA method workshops held for State analysts and often taught by private sector personnel using privately supplied equipment. FDA does tap the academic community through contracting science advisers from universities at the field laboratories. The majority of science advisers, however, are not experts on pesticide analytical methods.

Option 2.5: Federal agencies could increase coordination with foreign agencies.

FSIS and FDA have programs whereby foreign scientists work at Federal laboratories to gain experience in analytical methods and to pass on their expertise to Federal analysts. Foreign government pesticide regulatory agencies may have certain methods, research expertise, and knowledge that might be relevant to the United States and vice versa. For example, Health and Welfare Canada has a small pesticide methods research program that seems to be advanced in several areas such as immunoassay and robotics. Yet little interaction exists between that agency and U.S. agencies in the area of immunoassays. Canada has developed seven immunoassay for use on fruits and vegetables. U.S. agencies could take advantage of this expertise and avoid duplicating Canada's work. One easy way to facilitate information transfer between the two countries would be for U.S. agency personnel to attend the Fall *1988* workshop on immunoassay held for personnel from Canada's regional laboratories.

FINDING 3: Pesticide Methods Submitted for Tolerance Setting Could Be Improved for Regulatory Use.

All pesticides used *in* the United States must be registered by EPA. If a proposed use of a pesticide may result in residues in food or feed, a tolerance (or exemption from tolerance) is required. As part of the tolerance-setting process, EPA requires that the person or organization (known as a petitioner) requesting a tolerance provide an analytical method that can be used to enforce the tolerance set for each pesticide/food combination. To meet this requirement, SRMs, commonly developed to generate data required for pesticide registration and tolerance setting rather than to meet regulatory needs, are submitted. In some cases, these methods have not been laboratory tested by EPA. Thus, some submitted methods have proved complex, time-consuming, costly, and sometimes cannot be replicated by another laboratory, thus rendering them impractical for regulatory work.

Several courses of action exist that could be taken to ensure that methods submitted for the tolerance-setting process are more useful for enforcement purposes. The majority of these actions, noted below, include stricter EPA requirements on submitted methods to make them more practical for regulatory work. In conjunction with any of these actions could be improved communication between EPA and the pesticide manufacturer as to what kind of methods or information would be most useful for the government. Improved communication could save the company time by focusing its chemists' time, and it could provide agencies with methods more appropriate for regulatory work.

Option 3.1: EPA could require an independent check of pesticide analytical methods before their submission to EPA.

This requirement would increase the likelihood that a submitted method really works. The petitioner could contract with an independent laboratory or have an in-house laboratory carry out the evaluation (if the in-house laboratory were not involved in the development of the particular method). The results from the independent test would be used by EPA in its own evaluation of the method. This action places the cost of additional testing on the person petitioning for a tolerance.

EPA has just implemented this requirement for the first tolerance petition for a pesticide and for any tolerance petition using a new method or a significantly changed method. Beginning August ***1, 1989,*** such petitions are required to include the results of *an independent* evaluation of the submitted method on six samples (two control samples, two samples fortified with the pesticide at the proposed toler-

ance, and two samples fortified at 2 to 5 times the proposed tolerance). If more than one commodity is being proposed for a tolerance, the independent evaluation of the method must be on the commodity most difficult to analyze (7).

Option 3.2: FDA and FSIS could validate methods submitted for tolerance setting.

Increased Federal validation would increase the likelihood that a submitted method would be practical for regulatory use. FDA or FSIS could, in addition to EPA, provide a desk review or laboratory evaluation of all or a selected number of submitted methods. Criteria for selecting certain pesticides could be based on such factors as the health hazard of the pesticide, degree of difficulty of the method, or the use of a new technology or procedure. FDA or FSIS could evaluate petitioners' methods as to their applicability to regulatory work, provide EPA with results of the evaluation, and if necessary, EPA could require the appropriate modification of the method before a tolerance was granted.

This action would place an additional resource burden on FDA and FSIS. FDA probably would disagree with the redirection of resources (staff time and funds) for such work, in part because it depends primarily on MRMs not SRMs, and thus probably would not consider validation of petitioner methods a high priority.

Option 3.3: EPA could require the testing, development, or adaptation of a multiresidue method for any pesticide requiring a tolerance.

FDA and FSIS do not have the needed resources to use SRMs routinely and so depend upon MRMs for the bulk of their testing. Therefore, it may be reasonable to have petitioners address the development or adaptation of an MRM to analyze their pesticide. In *1984,* EPA added the requirement to its tolerance-setting regulations that petitioners must determine whether their pesticide can be analyzed by FDA's and USDA's MRMs (40 CFR: part 158.125). In 1986, FDA made method protocols available for four of its MRMs, which were needed before such testing could be done and the new regulation became practical (Federal Register, *51(186): 34249,* Sept *26, 1986).* None of the four MRMs have to work for the pesticide but the results must be provided to EPA, which gives them to FDA. As of May *1988, 12* pesticides had gone through this procedure. As part of re-registration, EPA requires registrants to supply similar testing data on older pesticides if they are not already available. USDA has not published method protocols for its MRMs, and therefore methods submitted for tolerances for meat products have not been tested through FSIS's MRMs.

This requirement could be taken one step further by requiring that for all tolerances, or some subset such as tolerances for new pesticides, an MRM be developed or adapted for the analysis of the pesticide. While this requirement would increase the capability of Federal monitoring of pesticide residues in food, it could also lead to new problems with the regulation of pesticides and could increase costs for pesticide development.

First, if this requirement applied to all pesticides requiring tolerances, a decision would have to be made on pesticides now having tolerances that cannot be analyzed through existing MRMs. In some cases, new pesticides that might have lower health hazards and fewer adverse environmental effects than existing pesticides might not be able to be analyzed through existing MRMs. The requirement could thereby slow down or prevent the introduction of safer pesticides.

Second, the additional research to develop or adapt an MRM would increase the cost of pesticide development and might increase the time before registration is approved. Changes could be made, however, to prevent the delay in the pesticide's entry into the marketplace. A "conditional registration" could be granted based on submission of an SRM with the proviso that the registrant submit an MRM within a given time period. Because it can take several years for a new pesticide to achieve widespread distribution, the MRM would be developed in time for the routine analysis for that pesticide. Another time-saving alternative is for EPA to expedite its review process. Currently, it takes

EPA about 12 to 18 months to respond to a submission. Expeditious review, whether through additional staffing or improvements in efficiency of the review process, could compensate for the additional time required to develop an MRM.

Option 3.4: EPA could revise its regulations and guidelines for submitted methods to ensure that these methods are practical for regulatory work.

EPA has both regulations and guidelines concerning the submission of methods during the tolerance-setting process. EPA could review these regulations and guidelines and make appropriate changes to increase the regulatory usefulness of submitted methods.

EPA's regulations require the following: a method be submitted whenever a tolerance is required (or for most exemptions to a tolerance), the method must not be confidential, and the pesticide be tested through FDA and USDA MRMs (**40** CFR: part 158.125). EPA's guidelines (EPA, "Pesticide Assessment Guidelines, Subdivision O," Oct 1982) include certain technical requirements for submitted methods but do not carry the same legal weight as the regulations.

The regulations and guidelines could be tightened in a number of ways to make submitted methods more practical and more appropriate for enforcement work rather than research. For example, the regulations could address the need for practical regulatory methods and either define what is meant by practical or refer to the guidelines for that explanation. The guidelines could be rewritten to set stricter limits on the cost of using a method and the time required for analysis (possibly to the point of setting maximum times for extraction, cleanup, and detection), and the need to analyze for significant metabolizes. They could also require improved and more detailed writeups of the methods, require the use of U.S. measurements, and require the use of technology easily available to U.S. regulatory agencies. Currently, revision of regulations and guidelines is not a priority at EPA and so resources are not available to carry it out.

Option 3.5: FDA and FSIS could review and revise existing PAM II methods.

PAM II contains the methods submitted during the tolerance-setting process and approved by EPA. Regulatory analysts have found that PAM II methods can be impractical to use. The usefulness of PAM II is further compromised by a recent EPA decision to discontinue funding (as of FY 1988) for the provision of submitted methods by EPA to FDA for publication in PAM II.

Several steps could be taken to increase the utility of PAM II. First is the continuation of funding at EPA and FDA for PAM II work. Second would be the updating of PAM II by FDA (which maintains PAM II) and FSIS to winnow out impractical methods, possibly through desk reviews and user comments. A further step would be the replacement of existing methods with up-to-date methods that are sometimes available from the pesticide manufacturer. This work would require FDA and FSIS to redirect resources. Updating could concentrate on methods for those pesticides that cannot be analyzed by MRMs and possibly those pesticides of moderate to high health hazard in order to be more cost-effective for regulatory needs.

FINDING **4:** The Quantity and Quality of the Analyst Workforce Need To Be Maintained.

Of importance to analytical methods research efforts is the availability of a high quality workforce. The pool of analytical chemists, however, is decreasing as fewer students are entering the field and many experienced chemists (especially at regulatory agencies) are approaching retirement (26). The concern about the potential shortage of chemists is growing and is shared by government agencies and the private sector alike (18).

Option 4.1: Federal agencies could revise their hiring practices and find ways to give laboratories increased flexibility in hiring new recruits.

Regulatory agencies are especially hard-pressed to attract high quality people because of low starting salaries compared with salaries offered

in the private sector. Some smaller State programs are severely affected by this problem. In addition, Federal hiring guidelines, encumbered by hiring freezes, short windows of hiring opportunity, and long hiring procedures, seem to make it more difficult to hire people when they are available **(29).** The Agricultural Research Service has partly avoided this problem by having a quick recruitment process for post-doctoral candidates (19).

To build up this workforce would probably require active promotion and incentives to enter the field of analytical chemistry. This problem is acute in the analytical chemistry specialty of pesticide residue analysis. Many academic institutions that once trained students in this specialty have left the field due to declines in the availability of research funds (much of which went to graduate student stipends) or because other areas, such as environmental toxicology or chemistry seemed to offer more opportunities for their students **(27).**

Some States (e.g., California and Florida) have already taken steps to attract future chemists by implementing programs for college students to work at or visit their regulatory laboratories. Private industry carries out similar programs. For example, Proctor & Gamble provides short courses to undergraduates on careers in analytical chemistry (5). Federal regulatory agencies have similar programs. For example, under an FDA program, undergraduate students split their year between attending university and working in a FDA laboratory (12). Federal agencies could benefit from taking a more active approach to recruit entry-level chemists.

Another way to attract students to the field would be the establishment of scholarships and fellowships for undergraduate and graduate education. To implement this last option would require additional funding.

Option 4.2: FDA and FSIS could increase continuing education and training programs for Federal analysts.

Concerns also exist about maintaining the quality of the regulatory workforce. Many analysts have been out of school for a number of years, may not be up-to-date on new developments, and may require some retraining (6). FSIS now holds an annual workshop on technology development, has a continuing education program and a competitive training program at the University of Georgia, and has training provided by contractors doing research (6). FDA has fewer external training connections (one exception is the Science Advisory Research Associate Program) and provides most of its training internally. A significant FDA forum is the annual pesticide workshop, which brings together pesticide analysts from the regulatory laboratories, research centers, and CFSAN. Overall, there seem to be additional opportunities for Federal agencies to make increased use of private sector and university expertise in staff training. For example, personnel exchanges with industry and universities could be supported.

Option 4.3: FDA and FSIS could sponsor analytical methods training workshops for State analysts.

Availability of training is even more important for State laboratory personnel, especially for individuals in small State laboratories (21). Analysts in many States do not have the opportunity to learn about the newest advances in pesticide use and analysis because of lack of time and funds to attend meetings.

One effective training program for State personnel, administrated by EPA, provides training in analytical methods, though not specifically applicable to pesticides in food. It seems to be popular and highly regarded by the States, and there is a waiting list for attendance. A similar program on pesticide residue methods could be modeled after EPA's program and implemented by FDA and FSIS. Currently, only State personnel near FDA laboratories have the opportunity to receive FDA training.

Some States also have set up their own training programs. For example, for the last 24 years, Florida has held a pesticide residue workshop at which State personnel learn of advances in the use of methods to detect pesticides in foods and the environment. Federal and foreign personnel also attend. California is considering

establishing a similar workshop for the western States in conjunction with the University of California.

Support for State analysts training would cost FDA and FSIS additional resources, but it would improve the overall regulation of pesticide residues in food while supporting closer Federal-State cooperation.

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