

**REPORT OF THE ORA SCIENCE PEER REVIEW
COMMITTEE**

on the

FDA PESTICIDES PROGRAM

October 12, 2004

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I. EXECUTIVE SUMMARY

ORA Pesticides and Chemical Contaminants Science Peer Review Process

In 2001, the former Acting Principal Deputy Commissioner, Bernard Schwetz, DVM, Ph.D., requested the Office of Regulatory Affairs (ORA) and the Centers to conduct a “Peer Review” of their program activities. Various approaches were used by the Centers for conducting their reviews. The Center for Devices and Radiological Health (CDRH) conducted their review by tracing a device from pre-approval to post-market, while the Center for Food Safety and Applied Nutrition (CFSAN) conducted an in-depth review of their research programs. ORA chose to conduct an internal Science Peer review of a single program area, in this case, Pesticides in the Food Supply.

An ORA Science Peer Review Committee (the Committee) was created to perform the internal review. The Committee consisted of ORA managers and staff who are knowledgeable over the breadth of ORA operations. The Committee members possessed significant knowledge of the cross-cutting program needs of other components. Their expertise covered domestic and import investigations, compliance, and laboratory science. Since June 2002, the Committee met bi-monthly, then via weekly conference calls, held face-to-face meetings, and made site visits to eight ORA district offices. The Committee focused on pesticides and chemical contaminants in food programs by examining a vertical cut of all operations within a program. The Peer Review was designed to be a scientific review covering implementation of national programs, not one focused on specific offices or laboratories within ORA.

Objectives

The major objectives encompassed a review of the effectiveness of major program activities surrounding ORA pesticide and chemical contaminants programs, such as:

- ?? Quality of Science across our organization in program planning, inspections, investigations, laboratory analysis, regulatory actions, quality management systems;
- ?? Adequacy of resources, skills and expertise, technologies, organizational structure;
- ?? Mission relevance; and,
- ?? Adequacy and currency of program guidance and policy.

The Committee concentrated on the underlying science used to make decisions, policies, guidance, and work associated with inspections, investigations, sample collections, laboratory analyses, import activities, and compliance decisions.

ORA's program responsibilities are extremely diverse and interdisciplinary. In order to approach the peer review process systematically, the Committee reviewed work in the Pesticide and Chemical Contaminants in Domestic and Imported Foods and Seafood Programs, the Dioxin and Furans in Food Assignment and the Total Diet

Study. Fiscal year 2001 was selected as the period of time for narrowing the document review for domestic programs. Due to rapid changes occurring in the import arena, current year 2004 was selected to assess the import operations. The program review focused on two very important questions. Did the decisions, policies, procedures, and program activities have the intended effect, impact or outcome? Did ORA consistently achieve the intended consumer protection outcomes as defined in the program or assignment?

ORA has a significant body of institutional memory in a variety of national policy, procedures, and guidance documents available to operational staff and management. These documents explain what we do, how we do it, and the expected impacts and outcomes. In addition, ORA district offices develop local guidance to further explain and define program execution. The Committee took all these documents under consideration while conducting reviews. Furthermore, the Committee developed a set of criteria to assess the work products.

Review Process

The Committee's review process consisted of three strategies:

1. On-site visits with interviews of key technical staff and managers;
2. Review of work products; and,
3. Input through questionnaires from district offices not visited.

The Committee issued a call to all district offices to gather specific documents associated with programs and assignments over a designated time period. The documents were identified using FDA's Field Accomplishment and Compliance Tracking System (FACTS). The Committee devised work product assessment criteria for each type of work, e.g. collection reports, analytical worksheets, establishment inspection reports, compliance recommendations and actions, and import entry reviews. Prior to the on-site visits, the Committee reviewed the assessment tools applied to a selection of work products to normalize the review process.

The Committee determined the numbers and kinds of program activities to assess. For example, the Committee decided to review all Laboratory Class 3 (violative) pesticide analytical packages for imported products in the eight site visits. The sample of laboratory packages reviewed needed to reflect a diversity of imported and domestic products. Similar decisions were made through various program areas, such as investigations of pesticide misuse, and chemical contaminations to assure a broad understanding of the application of the program across all products.

Database Development

A database to capture the assessment of the work products was developed by the Pacific Region Computer Center staff. The database facilitated the retrieval of data generated by the work product reviews and the ability to perform trend analysis. The Committee chose to review at least 10 work products per district office giving priority to regulatory packages. Three hundred and fifty-seven (357) work products were

reviewed from 15 ORA district offices and six ORA servicing laboratories using the work product assessment criteria.

Sites Visited and Site Teams

The Committee chose to physically visit a representative number of ORA districts and district servicing laboratories. Eight sites were chosen: Atlanta, GA; Seattle, WA; Los Angeles, CA; Kansas City, KS; Jefferson, AR; New York, NY; Philadelphia, PA; and Dallas, TX. Prior to each visit, the Committee sent a schedule with two questionnaires, one developed for managers and one for technical specialists. The questionnaires were the basis for the on-site interviews. Most of the on-site interviews were conducted in three days. The on-site team consisted of three to five Committee members from various technical backgrounds. Each visit included an initial briefing with management, interviews with key staff and review of the work products. Interview information was collected from on-site visits and other offices not visited.

This final report was developed from a review and analysis of all the data gathered from the site visits, questionnaires, and review of all policy and procedure documents by the Committee.

Brief Summary of Findings

It became clear during the course of the study, though robust in some aspects, the pesticides program has not evolved to take full advantage of current science and technology. Bringing current science into our laboratories and in support of our policies and procedures will substantially advance our ability to be more timely, efficient and effective in executing our program.

Through the years, the pesticides program has undergone studies to improve and focus the work we do. The program always has benefited from new ideas and a willingness to advance science and process. There are 39 recommendations from the identification of issues and findings as a result of the review. They cover a wide range of ideas from improvement of methods for testing products, management of the program, organizational changes and revision of policies. While modern technology can improve output in the laboratory, the science itself is more precise and reliable; also reducing the need for redundancy in analysis. In addition, ORA is certifying all labs under ISO 17025 standards, affording us a greater depth of reliance on the work produced in the laboratories. Procedural and policy changes aligned with the new science and technology will continue to support our programs and will help us achieve greater efficiency and impact with the resources available.

Can we now answer our initial broad questions: Did the decisions, policies, procedures, and program activities have the intended effect, impact or outcome? Did ORA consistently achieve the intended consumer protection outcomes as defined in the program or assignment? The answer would be yes, to a degree. The program has waned over the last several years in the shadow of other important programs. Although still effective in finding violations, intentional or unintentional, and clearly able to address them, some important aspects are not handled uniformly nor

efficiently completed. We have lost ground as the sheer volume of domestic and imported foods continues to expand. However, the recommended changes can improve our ability substantially to meet the challenges before us.

II. HISTORY

A. FDA PESTICIDE PROGRAM: BACKGROUND AND HISTORY

Pesticides thru the Years

The use of chemicals in the United States to control insect infestations can be traced to the mid-1860s. The predations of the Colorado Potato beetle forced farmers to consider the use of poison for insect control. The first chemical poison successfully used was Paris green (copper and arsenic) applied as a powder or water spray. Later, in the 1880s, London purple (arsenical) also became popular. By 1900, Lead arsenate replaced both Paris green and London purple as the insecticide of choice.

After World War II, the introduction of DDT into commercial use began the organic chemical revolution. Subsequently, organophosphorus pesticides, based on chemical warfare agents, came onto the scene. The 1980s saw the wide scale introduction of newer pesticides that do not bio-accumulate and are significantly less acutely toxic to humans and non-target species.

Regulation of Pesticides

In the late 1800s, discussions of arsenic toxicity began to appear in medical journals and other forums. The first known limits for pesticides were established in 1903, when the British established a tolerance for arsenic at 0.01 grains per pound.

Prior to the passage of the 1906 Food and Drug Act, there was no federal authority in the United States to regulate the use of chemical poisons on crops.

The 1906 Food and Drug Act authorized legal action if an added substance was injurious to health. The first federal seizure of a food contaminated with a pesticide chemical did not occur until 1925. During the late 1920s, FDA attempted to set arsenic tolerances for food; however, due to significant political opposition, was unable to do so. Finally, the 1938 Food, Drug, and Cosmetic Act granted the Agency authority to establish tolerances for added poisonous substances. In 1954, the Miller Pesticide Chemicals Amendment to FD&C Act authorized FDA to establish safe and legal pesticide tolerances for raw agricultural commodities.

In 1970, the Environmental Protection Agency (EPA) was established and the responsibility to establish pesticide tolerances was transferred to that Agency. FDA retained the responsibility to enforce EPA-established tolerances for animal feeds and human foods other than meats.

In August 1996, Congress passed and the President signed into law, the Food Quality Protection Act (FQPA). FQPA represented a major breakthrough in pesticide regulation and resolved many of the inconsistencies between the two major pesticide

statutes, Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Food, Drug, and Cosmetic Act (FD&C Act). FQPA amends FIFRA and FD&C Act to mandate a single, health based standard for all pesticides in foods, provide special protection for infants and children, expedite approval of safer pesticides, and require periodic re-evaluation of pesticide registrations and tolerances to ensure scientific data supporting pesticide registrations remain current.

FDA Pesticide Programs

The modern day FDA pesticide program can trace its roots to 1962 with the publication of Rachel Carson's *Silent Spring* and the enormous political turmoil which resulted. When *Silent Spring* was published, FDA was in the beginning of a technological revolution from "tumbling with benzene" to "blending with acetonitrile" for extraction and from "paper chromatography" to "gas chromatography" for detection. FDA now was capable of analyzing many more samples for many more residues. The program has evolved steadily over the intervening 42 years. Today's program is comprised of three major components: the Domestic and Import Pesticide Program, the Total Diet Study, and the Dioxin Sampling Program.

The last major critical review of FDA's pesticide programs occurred in 1978. The report from that review, "FDA Monitoring Programs For Pesticide and Industrial Chemical Residues in Food: Study Group on FDA Residue Programs", was published in 1979. The recommendations from the Study Group resulted in major changes to all facets of the program, many of which drive the programs today.

Domestic and Import Pesticide Programs

During the three-year period (1963-1966) after publication of *Silent Spring*, FDA analyzed over 54,000 food samples for pesticides. It is interesting to note that 49,356 of the 1963-66 samples were domestic and only 3,836 were imports. Through the 1970s and early 1980s, the number of samples remained reasonably constant at about 12,000 per year. The passage of the Pesticide Monitoring Improvements Act of 1988 resulted in a dramatic increase in the program to about 19,000 samples per year. A steady decline in the number of samples occurred from 1992 through 2001, when only 6,500 samples were analyzed. In 2004, the plan is for 8,000 samples, 2,700 domestic and 5,300 import foods.

Prior to 1980, domestic produce was collected in 12 sample surveys. The number of surveys and the identity of crops to be sampled were prescribed in the compliance programs. Samples were analyzed using only standard multiresidue methods. The FDA Study Group recognized the value of utilizing local knowledge of agricultural practices and growing conditions. As a result, the 12 sample surveys were eliminated and districts were given discretion on some of the crops to be sampled. There was still a core element to the program that included such items as eggs, milk/dairy products, fish, and grains.

Until the mid-1970s, sampling imported foods was a minor part of the pesticide program. FDA recognized the tremendous increase in foods being imported and

began shifting pesticide program emphasis from domestic to imported produce. Today, the Agency collects almost twice as many import food samples versus domestic food samples.

The Pesticide Monitoring Improvements Act of 1988 not only resulted in an increase in program size, but also changed program direction. Pesticide Coordination Teams (PCTs) consisting of analysts, investigators, and compliance officers were formed in each district to plan each year's program locally. Districts were given greater discretion on crops to analyze. A new component was added to the program, Incidence and Level Monitoring, to focus on generating extensive data on selected crops. The program flourished through the early 1990s.

Budget restraints and shifting priorities through the mid-1990s until today not only forced reductions in the size of the program but, more importantly, in scope. The large statistical surveys of the mid-1990s and the core elements of the program were eliminated. An attempt to resurrect the Incidence and Level Monitoring was made in 2001 and 2002 with the EPA 1000 Sample Survey. However, this segment again was dropped due to budget considerations. In most locations, the Pesticide Coordination Team concept fell into disuse concurrent with laboratory consolidation.

Total Diet Study

The Total Diet Study (TDS) was initiated in 1961 primarily to monitor possible contamination of foods by radionuclides resulting from atmospheric nuclear tests. These market baskets also were analyzed for pesticides. Rachel Carson's *Silent Spring* resulted in increased emphasis on the pesticide analyses in the TDS. From 1964 to 1975, 30 market basket samples representative of the diet of a 15-20 year old male were collected and analyzed per year. In 1975, the number of "adult baskets" analyzed was reduced to 20 and analyses of 10 "infant-toddler" baskets were added to the study.

Analyses are conducted using methods generally 10 times more sensitive than those used in the routine monitoring programs. Prior to 1970, the collecting district laboratory performed the analyses. In 1971, the analytical work was centralized at the Kansas City District laboratory. TDS is unique in that foods are prepared "table ready for consumption" prior to analysis. The prepared foods then were divided into food composite groups for analysis. Residue data from the study were used to calculate dietary intakes of pesticides and other analytes.

In 1982, TDS underwent a major revision. Analyses of composites were eliminated and analyses of individual food items were initiated. The number of food items was increased from 117 to 234, with each food item representing an aggregate of similar foods using food consumption data from the late 1970s. A subsequent revision was made in 1991, updating the food list based on consumption data from 1987-1988. The number of food items increased to 260 plus approximately 25 additional infant-toddler foods. Major changes to the analytical scheme also were implemented. The latest revision to the food list was made in 2003 and the number of food items analyzed has remained unchanged.

Dioxin Sampling Program

Analyses of foods for dioxins were first initiated in 1978 at the Dallas District laboratory and focused on octachloro-dibenzodioxin (OCDD). Selection of samples for analysis was based on the findings of elevated levels of Polychlorinated Biphenyls (PCBs). In 1980, Detroit District laboratory was added to the program for the analysis of tetrachloro-dibenzodioxin (TCDD). Samples of special concern were fish from the Great Lakes region, especially Saginaw Bay in Lake Huron.

In the mid-1980s, Chicago District laboratory was added to the program, initially for TCDD analysis. In 1987, Chicago was selected to be the primary dioxin laboratory and began analyses for 17 coplanar dioxin and furan congeners using high resolution-mass spectrometry (HR-MS). In 1998, this function was transferred to the new Arkansas Regional Laboratory.

Through the late 1990s, the program was quite small, at most, several hundred samples per year. Renewed concerns on dioxin toxicity changed the paradigm. In 1999, a decision was made to greatly increase the size of the program and total diet samples were analyzed for the first time. The number of samples has stabilized at about 1,500 per year. Although fish remains one of the primary commodities analyzed, others have been added to generate baseline data for dioxins in foods. Analyses of selected items from the TDS are included in the Dioxin Program.

III. PESTICIDE PROGRAM DESIGN

A. RESPONSIBLE FEDERAL ORGANIZATIONS

Three Federal government agencies share responsibility for the regulation of pesticides. EPA registers (i.e. approves) the use of pesticides and sets tolerances which are the maximum amounts of residues permitted in or on a food, if use of a particular pesticide may result in residues in or on food. Except for meat, poultry, and certain egg products, regulated by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), FDA is charged with enforcing tolerances in imported foods and in domestic foods shipped in interstate commerce. FDA also acquires incidence and level data on particular commodity and pesticide combinations and carries out its market basket survey, the TDS. Since 1991, USDA's Agricultural Marketing Service (AMS), through contracts with participating states, has carried out a residue testing program directed at raw agricultural products and various processed foods. FSIS reports results of pesticide findings through an annually published "Red Book". The AMS reports their pesticide residue data independently through a series of National Agricultural Statistics Service (NASS) reports.

B. PROGRAM DEVELOPMENT

FDA's pesticide compliance programs are designed through a cooperative effort with FDA's Center for Food Safety and Applied Nutrition (CFSAN), FDA's Center for Veterinary Medicine (CVM) and components of FDA's Office of Regulatory Affairs (ORA). CFSAN and CVM have the lead responsibility for program implementation

and monitoring. The flow of compliance program (CP) development is outlined in Figure 1.

Center Responsibilities

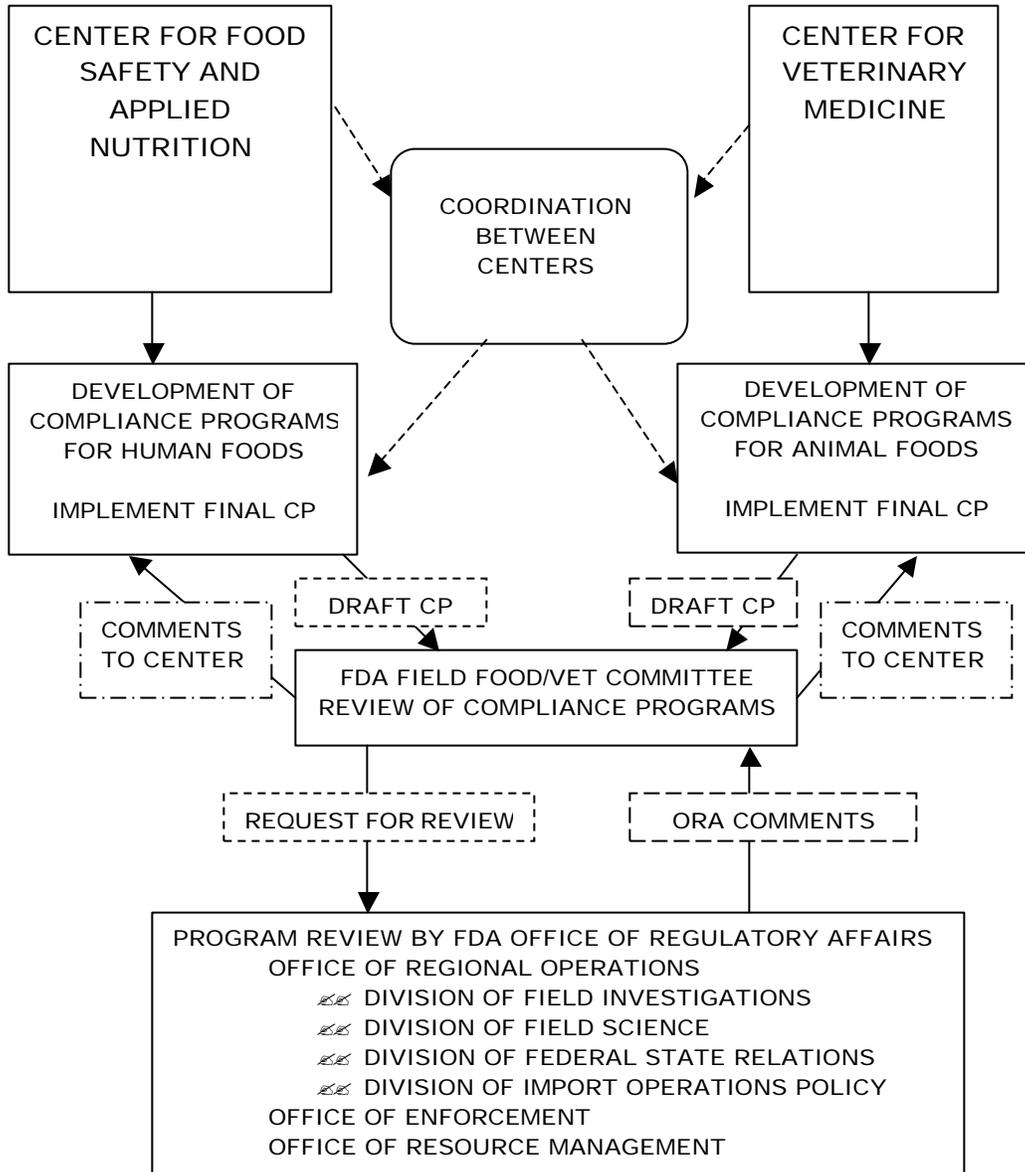
For domestic samples, CFSAN and CVM have designated individuals to coordinate exchange of residue data and other appropriate information, since residue findings in feeds and in foods derived from animals often are interrelated. Information developed through ORA inspections, investigations, and sampling activities is used to develop future sampling plans and to make changes in the compliance program.

For imported samples, CFSAN Director, Office of Plant, Dairy Foods and Beverages (OPDFB), in coordination with other appropriate staff, submits an annual evaluation of this program to the CFSAN Chief, Imports Branch, Division of Enforcement and Programs. Sampling plans subsequently are modified based on previous results and other pertinent intelligence.

OPDFB prepares an annual report for publication of the findings of the Total Diet program. Findings from current samples dictate changes in the direction of the compliance program.

CVM directs the Agency's monitoring of domestic and imported feeds through its Feed Contaminants compliance program. The CVM Program Manager works with the CFSAN Pesticides Program Manager to prepare an annual evaluation report of pesticides found in domestic and import programs.

Figure 1: COMPLIANCE PROGRAM DEVELOPMENT



C. PROGRAM IMPLEMENTATION

CP 7304.004-Pesticides and Industrial Chemicals in Domestic Foods and CP 7304.016-Pesticides and Industrial Chemicals in Imported Foods contain the major instructions, guidance and directions for use by the Agency, specifically ORA, to complete inspections, investigations, sample collections, laboratory analysis and compliance activities. On Dec. 4, 2000, an addendum was issued to the Pesticides and Industrial Chemicals in Domestic Foods compliance program involving special survey obligations for dioxins and furans in food. CP 7304.839-Total Diet Study is designed to study the levels of pesticide and industrial chemicals in the average American diet. This program is normally not regulatory in nature.

Additional information regarding inspections, investigations and sample collections can be found in FDA's Investigations Operations Manual (IOM). Additional information regarding laboratory analysis can be found in FDA's Pesticide Analytical Manuals (PAM) and Laboratory Information Bulletins (LIBs).

Other specialized compliance programs are directed toward specific commodities or specific goals. These compliance programs include: CP 7303.842-Domestic Fish and Fishery Products Inspection, CP 7303.803-Domestic Food Safety, CP 7371.003-Feed Contaminants, and CP 7304.019-Toxic Elements in Food and Foodware, Import and Domestic.

For the purpose of this report, the committee directed their review towards the major pesticide compliance programs dealing with human foods, CP 7304.004-Pesticides and Industrial Chemicals in Domestic Foods, CP 7304.016-Pesticides and Industrial Chemicals in Imported Foods, and CP 7304.839-Total Diet Study.

D. PROGRAM OBJECTIVES

FDA domestic and import pesticide programs are designed with similar objectives as follows:

1. To sample and analyze fresh and processed human and animal foods for pesticide residues and industrial chemicals, and to initiate enforcement action for shipments found to contain illegal residues.
2. To generate information on the incidence and levels of pesticide and industrial chemical residues in human and animal foods.

The scope of ORA's approach to these programs is designed to be regulatory in nature with emphasis on intelligence gathering, selective sampling, and aggressive compliance follow-ups. The residue monitoring data developed by these programs also are very important since they provide information on the overall incidence and level of pesticide and chemical residues in human and animal foods.

FDA's compliance programs direct ORA to maintain surveillance sampling of domestic and imported products to cover gaps in intelligence information. The

program emphasizes finding residues of regulatory significance and taking regulatory actions to control the immediate problems and deter future violations.

The Total Diet Study Program determines prevailing levels of contaminants rather than enforcement of tolerances or other regulatory limits. For this reason, the levels of the analytes that are measured in the Total Diet Study generally are much lower than those in FDA regulatory programs. These analytical data derived are used to calculate dietary intakes.

The objectives of the Dioxin Monitoring Program are to obtain data on background levels of dioxin in a wide variety of foods so the Agency can determine how to reduce dietary exposure to protect the public health and to improve exposure assessments of dioxin by providing better exposure data. The Dioxin Monitoring Program is used to gather surveillance information. Follow-up activity, if necessary, is determined after the Center reviews the analytical results. Products selected for surveillance sampling constantly are updated.

E. INSPECTIONS AND INVESTIGATIONS

Section 570 of the IOM provides guidance concerning domestic pesticide intelligence gathering operations, inspections and investigations.

The compliance programs direct district offices to form PCTs that consist of investigators, compliance officers and analysts, to manage the district's pesticide programs. Teams are instructed to coordinate the district's pesticide and other industrial chemical activities; plan and conduct sample collections and investigations; review laboratory reports; review data from sources other than FDA; gather intelligence on pesticide use; and, meet with state and local officials on local pesticide use. Further information on the purpose and responsibilities of the PCT are outlined in Field Management Directive (FMD) #134.

Inspections are not directed by the import pesticide program. The import pesticide compliance program recommends the district office utilize investigational time to develop, coordinate, and monitor regional import plans; develop intelligence concerning foreign pesticide use information; examine import records; investigate shipping, warehousing and handling practices to uncover potential routes of contamination; and, maintain contacts with Custom and Border Patrol agents, USDA/APHIS, commodity brokers, shippers, and importers and some of the important related activities.

Domestic Sample Collections

CP 7304.004-Pesticides and Industrial Chemicals in Domestic Foods provides specific directions for collection of samples. Samples may be surveillance (those collected to monitor pesticide use) or compliance (those collected when regulatory action is anticipated). Compliance samples are required for regulatory enforcement actions.

District offices are directed to develop pesticide sampling plans with specific criteria in mind. Special emphasis is placed on collection of food consumed by infants and children. Commodities of dietary importance are identified in an attachment to the program. Products, such as parsley and spices, which have little impact on total dietary intakes, are not sampled.

District offices collect surveillance samples of commodities found in their locality. Collection is based on past violative samples, current analytical findings, information obtained through intelligence gathering activities, and recent pesticide usage reports distributed by CFSAN or obtained locally. Coverage also includes the use of pesticides and fungicides on crops produced indoors, such as greenhouses, hydroponic facilities and mushroom beds. The district offices are advised not to collect surveillance samples at the retail level. Growers or packing sheds are the preferred sites for fruits and vegetables.

Guidelines for specific products or situations further enhance the planning direction for each district. The goal is to maximize use of data available while developing a comprehensive program, yet remain flexible when new information requires follow-up.

Import Sample Collections

CP 7304.016-Pesticides and Industrial Chemicals in Imported Foods Programs focuses sample collection on raw agricultural commodities of dietary significance although processed foods also can be considered. A list of commodities is provided.

For the fiscal year FY 2000-2002 and except when advised otherwise by CFSAN or CVM, FDA's sampling of imported foods for pesticide residues was on a surveillance basis to include only items selected from the following food commodities, in either raw or processed form (refer to the domestic sampling food list mentioned earlier). As with the domestic program, foods consumed by infants and children are represented well in the sampling scheme. Sampling of foods with problem residues in a past season are emphasized to assure the problem does not persist. When a new product and/or country combination is presented for entry, the product will be sampled to gather information.

Sample Size and Handling

The IOM Sample Schedule provides the sample size for the majority of fresh fruits and vegetables, generally at 20 lbs. Sample size and sampling method have been adjusted over the years to make the program more efficient while still meeting the objectives of isolating and identifying violative residues. District offices have the option to collect one intact shipping case or a total of 20 lbs. from one or more large containers of fresh produce from packing sheds or large produce warehouses.

For the TDS, there are usually four collections annually. Each is referred to as a "market basket", and consists of 261 foods and 25 additional infant and toddler foods. Each market basket collection represents one of four regions of the United States, e.g.

south, central, northeast, and west, and consists of three separate samplings of each food obtained simultaneously in the region.

F. LABORATORY ANALYSIS OF DOMESTIC AND IMPORTED FOODS

To analyze large numbers of samples, FDA uses analytical methods capable of simultaneously determining multiple pesticide residues. The multi-residue methods analyze about half of the approximately 400 pesticides with EPA tolerances and many other pesticides having no tolerances. The most commonly used multi-residue methods also can detect many metabolites, impurities, and alteration products of pesticides.

Single residue methods usually determine one pesticide, while selective methods measure a relatively small number of chemically-related pesticides. These methods usually are more resource-intensive per residue and, therefore, less cost effective than the multi-residue methods.

The lower limit of residue measurement in FDA's determination of a specific pesticide usually is well below tolerance levels, generally ranging from 0.1 to 50 parts per million (ppm). Residues present at 0.01 ppm and above usually are measurable; however, for individual pesticides, this limit may range from 0.005 to 1 ppm. For FDA, the term "trace" is used to indicate residues detected, but at levels below the limit of quantitation.

G. LABORATORY ANALYSIS IN THE TOTAL DIET STUDY

Selected TDS foods are analyzed for pesticide residues, PCBs, industrial chemicals, Folic Acid and mercury. All TDS foods are analyzed for toxic and nutritional elements. Foods from one market basket survey for each year are analyzed for radionuclides, Folic Acid and moisture. Additional infant and toddler foods are analyzed for pesticide residues and lead. Independent quality assurance analyses for selected elements and radionuclides are performed by CFSAN for a subset of TDS foods. Selected TDS foods are analyzed for dioxins under the Pesticides and Industrial Chemicals program, CP 7304.004.

H. DOMESTIC COMPLIANCE AND REGULATORY ACTIVITIES

FDA Compliance Policy Guide (CPG) 7141.01, Section 575.100, outlining FDA's enforcement policy for pesticides in food, coupled with the guidance found in CP 7304.004 – Pesticides and Industrial Chemicals in Domestic Foods and CP 7371.003 – Feed Contaminants, are used to ensure compliance with the provisions of the FD&C Act.

Domestic pesticide residue violations are considered adulterated under the FD&C Act. Pesticide residues in processed foods are subject to the same adulteration section as pesticide residues in raw agricultural commodities. Accordingly, when any food is found to contain an illegal pesticide residue as defined in the CPG, the district must

charge "it is adulterated under 402(a)(2)(B) in that it bears or contains a pesticide chemical residue that is unsafe within the meaning of Section 18 of FIFRA."

Seizure for domestic food, without prior consultation from CFSAN, is authorized under the strict conditions outlined in the compliance program. Each sample with a violative classification should result in a meeting with the grower/shipper to discuss corrective action, the issuance of a Warning Letter, or other corrective action unless the compliance unit determines the residue is of no regulatory significance.

The most effective way to remove food adulterated with pesticides from domestic channels has been through voluntary recalls. Where voluntary corrective actions are not effective, the district may seize the product, ask the state to place the product under embargo or request the firm to voluntarily hold the product. Because the time required to process an injunction usually exceeds the period of time where the food could be sold, it usually is not the action of choice. However, a firm with a large inventory of adulterated food for sale over a few months might be a candidate for this action.

When an FDA investigation or sample analysis reveals pesticide misuse, the district office will notify EPA. Procedures are outlined in FMD #129, "Interagency Pesticide Referrals between EPA and FDA" and based on a Memorandum of Understanding between FDA and EPA.

I. IMPORT COMPLIANCE

Actions taken against imported products with violative residues are different because they are carried out under Section 801(a) of the FD&C Act (the Act), which directs FDA to refuse admission of any article that appears to be in violation of the Act. FDA's CPG 7141.01, Section 575.100, outlines FDA's enforcement policy for pesticides in food and couples guidance found in CP 7304.016 –Pesticides and Industrial Chemicals in Imported Foods and CP 7371.003 – Feed Contaminants to ensure compliance with the provisions of the Act.

When a violative residue for which there is no established tolerance is encountered, a recommendation for detention without physical examination is forwarded to CFSAN's Office of Field Programs, Division of Enforcement and Programs, Import Branch and ORA's Division of Import Operations and Policy (DIOP). When the violation involves a product/residue combination for which there is a tolerance, the recommendation goes directly to DIOP. When the recommendation is accepted, an import alert is issued allowing detention of the same product from the same country without physically examining or testing the product. This action allows efficient use of FDA's limited resources as it places the burden of demonstrating the problem has been fixed on the importer. Individual growers can be eliminated from the Detention Without Physical Examination (DWPE) Import Alert if information is presented indicating they do not have the problem.

Import Perishable Product Policy

The Regulatory Procedures Manual (RPM) Chapter 9-73 dated 7/10/89, entitled “Perishable Foods Sampled by the Food and Drug Administration”, outlined a policy which required perishable imported foods be held while analysis was expedited, usually understood to be no more than 24 hours after sample collection. The 1997 and 2004 editions of the RPM do not contain this guidance, which has not been reissued by ORA; however, many district offices continue to operate under these or modified guidelines for perishable product analysis.

IV. PROGRAM MANAGEMENT

The Committee directed this review toward the major pesticide compliance programs dealing with human foods: 7304.004-Pesticides and Industrial Chemicals in Domestic Foods; 7304.016-Pesticides and Industrial Chemicals in Imported Foods; and 7304.839 Total Diet Study. The majority of the findings also may apply to those portions of other compliance programs which deal with pesticide and chemical contamination of human and animal foods, including: 7303.842-Domestic Fish and Fishery Products Inspection; 7303.803-Domestic Food Safety; 7371.003-Feed Contaminants; and 7304.019-Toxic Elements in Food and Foodware, Import and Domestic.

National management of FDA’s pesticide and related programs is formalized through a number of different documents and manuals, including the Compliance Programs Guidance Manual (CPGM), which contains the CPs; the PAM; CPGs; the IOM; the RPM; Import Alerts; FMDs; Special Assignments; and, the ORA Workplan.

Effective management of the pesticide program requires the cooperation and exchange of information among segments of CFSAN, CVM and ORA. Within ORA, several organizations are involved in management of the program including: the Office of Regional Operations (ORO); the Division of Field Investigations (DFI), Division of Field Science (DFS); the Division of Federal-State Relations (DFSR); the Division of Import Operations Policy (DIOP); the Office of Enforcement (OE) and the Office of Resource Management (ORM).

ORA uses a Field Food Committee (FFC) consisting of seven to nine ORA members from field and headquarters organizations to serve as the principal contact for ORA with CFSAN relating to program design, implementation, and compliance strategy. Similarly, there is a Veterinary Medicine Field Committee to coordinate ORA interactions with CVM.

A. COMPLIANCE PROGRAMS

Compliance programs are definitive written plans containing objectives, goals, guidance and instructions which direct the work to be done in the ORA field and headquarters and describe necessary Center support.

Compliance programs are written to:

- ?? Provide uniform guidance and specific instructions for gathering and presenting evidence necessary to support various Agency regulatory operations when noncompliance is encountered in industry and/or products;
- ?? Gather product or industry information within a specific timeframe to determine the existence or extent of a problem; and,
- ?? Accumulate data on a known problem to determine statistical long range trends.

The development and issuance of programs into the CPGM requires cooperation between the Centers, ORA and, where appropriate, other units, such as the Office of Chief Counsel. The responsible Center and ORA collaborate in developing and preparing the inspectional and analytical direction of a program with regard to program objectives, timetables and goals.

The guidance, procedures and policy contained in CPs must be consistent with other guidance documents, must be realistic in its expectations and must incorporate sound inspectional and analytical techniques. The Committee found this is not always true.

The Committee found an instance of contradictory policy statements in the CPs and the CPG. Specifically, when a field laboratory finds pesticides in raw agricultural commodities, the field may recommend the shipper or manufacturer, in the case of an import, be placed on import alert. Guidance on when the recommendation can be made on a direct reference basis, i.e. bypassing Center review, is found in both the CP and CPG. In cases where no tolerance has been established, the CP indicates a direct reference recommendation can be made if, among other things, the pesticide is found at a level greater than .05 ppm and the limit of quantitation has been exceeded by at least 15%. The CPG, in addition to the above, adds additional and significant criteria before direct reference is authorized. It requires the district to have had an enforcement action previously approved by the Center for the same pesticide in the same food. These criteria would apply equally to direct reference domestic seizure recommendations.

Further, in the absence of timely revisions, attempts to update guidance in the CPs frequently are made via memorandum. These may not be maintained as standard reference materials on FDA websites and frequently are lost and forgotten. For example, via an e-mail dated July 3, 2001, the Director of ORO issued a revision to the applicable criteria for analytical packages to support regulatory action on pesticide residues. The document was developed in conjunction with CFSAN management. The document outlined significant changes to the required analysis where there is no established tolerance for a pesticide/commodity combination. These include elimination of an independent quantitative check analysis and replacement with a qualitative confirmatory analysis. The requirement for a quantitative check analysis in situations involving no tolerance remains, in spite of this document, a major concern of field staff because it continues to be referenced in other formal guidance documents.

Recommendation:

1. Update and issue current guidance in both the CPs and applicable CPGs following the recommendations in this report.

There is a need to rapidly update and issue current guidance in both the CPs and applicable CPGs. The Committee recommends OE be charged to evaluate critically all regulatory and procedural guidance documents associated with the Pesticide and Chemical Contaminants programs to identify any and all instances of contradictory or outdated guidance. OE and CFSAN then would issue interim clarifying instructions to field offices and proceed, as needed, to rapidly update and reissue the guidance documents. While the interim clarifying instructions can take the form of a memo, experience has shown the instructions must be incorporated into the CP, CPGs and other guidance material in order to affect a systemic change.

The issues involving the dated analytical guidance in the CPs will be covered fully in another section of this report.

The organization of CPs is standardized into the following parts:

Part I is a Background section outlining the authority of the Agency and its experience with the issue addressed by the CP.

Part II is an Implementation section which outlines the objectives of the CP and indicates the Agency approach to its implementation. For example, it may stress the need for firm inspections or sampling of the impacted product(s). It may stress the need for cooperation and coordination with other Federal or State agencies.

Part III is Inspectional guidance. It instructs field Investigations units of their responsibilities to accomplish the intent of the CP. It will provide instructions, for example, on specific information to obtain or operations to investigate during inspections. It provides instructions on products to sample, the size of samples to collect, any special handling instructions, and other necessary guidance.

Part IV is Analytical guidance. It identifies the servicing laboratories and specifies the analysis necessary and methodology to support the CP.

Part V is the Regulatory/Administrative Strategy section. It identifies if the CP is compliance oriented or designed to gather data (surveillance) without anticipating regulatory action. It contains guidance on criteria to support compliance actions and which compliance actions to consider. Part V of Compliance Programs specifies the anticipated regulatory intent and strategy of the CP. For example, it is clear both the Domestic and Import Pesticide and Chemical Contaminant CPs are regulatory in nature and normal regulatory and administrative follow-up actions to violative findings are expected. However, the dioxin assignment is surveillance in nature. It is clear local district offices are not to initiate regulatory

or administrative action. Follow-up, if any, is directed by the program Center. In general, CPs and assignments specify the nature of the work (surveillance or regulatory). If regulatory, the anticipated follow-up actions are specified, along with the evidentiary requirements for initiating follow-up action. It also is anticipated work products would conform to Agency procedural guidance contained in documents such as the IOM, PAM, CPGs, etc.

Part VI outlines References, Attachments and Contacts pertinent to implementation of the CP.

Part VII is the Center Responsibilities section. It outlines how the responsible Center will use the information gathered from the implementation of the CP.

The committee found portions of the field staff either do not read or do not understand all the guidance contained in applicable Compliance Programs.

Interviews with field staff, particularly field chemists, indicated they were not aware of all guidance available in the compliance programs. For example, numerous chemists expressed frustration with the lack of regulatory follow-up by both CVM and CFSA on their dioxin findings. When it was pointed out the program for dioxins clearly is designed to gather exposure data and not regulatory in nature, the chemists were surprised. Further discussion indicated most staff only were aware of the portions of their program that applied to them (i.e. chemists only were aware of the Analytical section of the report). Some field staff interviewed were unaware that CPs were available to all staff on-line. Lack of understanding of the guidance in the CPs is a serious issue, both in terms of the field's ability to implement the compliance program and in avoiding unnecessary resentments between the field and Centers.

Recommendation :

- 2. The Committee recommends ORA's Division of Human Resource Development (DHRD) develop a training module for the on-line ORA University to explain the structure and function of Compliance Programs.**

Completion of this module will be made mandatory for all ORA field staff. Further, DHRD needs to incorporate a module on understanding Compliance Programs into the ORA New Hire Course Curriculum.

Pesticide and Industrial Chemicals in Domestic Foods

This CP, issued February 16, 2000, was intended to apply to fiscal years 2000, 2001 and 2002, but continues as the current operating instructions for this program.

The program has two objectives:

- ?? To sample, analyze and, when appropriate, initiate enforcement actions for fresh and processed domestic foods for pesticide and industrial chemicals; and,
- ?? To generate information on the incidence and levels of pesticide residues in domestic foods.

The CP gives management guidance in all pertinent areas: inspectional, analytical and compliance. In addition, to assure local information and experience is incorporated into the products selected for sampling, the program specifies the establishment in each district of PCTs, consisting of representatives of Investigations Branch, Compliance Branch and the Servicing Laboratories, to coordinate the district activities under the Pesticides and Chemical Contaminants program. This includes the evaluation of local pesticide usage data, review of previous violative findings and national trends and to plan and conduct sample collections and investigations. The CP gives the district offices wide latitude in selecting what products to sample while directing districts to specific focus areas (i.e. foods of dietary importance, foods consumed by infants and children).

The inspectional guidance in the CP, in addition to specifying the creation of PCTs and identifying focus areas, also emphasizes the selection of locally grown products for sampling and identifies 20 broad areas of raw and processed foods for sampling. It encourages the coordination of intelligence gathering activities and sampling with state and local counterparts.

Frequently, the pressure to accomplish the workplan results in collecting samples appearing to be either contrary to the directions of the CP for pesticides in raw agricultural products, or the instructions in the CP direct field resources to sample products that may not be the best risk-based candidates.

It was noted some districts select sampling sites which include very small growers selling produce from roadside stands. This may be done in part to meet program requirements for collection of locally grown produce. Violative sample results from such sources can result in significant resources spent on foods not shipped in interstate commerce and which represent a very small portion of the diet. Further, it was noted historically, a higher pesticide violation rate is found on imported raw produce when compared to domestically grown produce.

Recommendation:

3. The domestic CP should be revised to alter directions on sampling sites.

The Committee recommends necessary revision of the domestic CP to address this issue by: first, specifically excluding small roadside stands operating as retail entities as appropriate sampling sites; and, secondly, to direct sampling sites to include food found in retail grocery stores and distribution centers.

We believe, although these lots would not be sampled directly at the grower or

packing shed, they would be more representative of the normal food supply than samples collected from small lots, grown on small home farms and sold at roadside stands. Sampling at retail grocery and distribution centers would allow samples to be collected throughout the year at any location, providing a means to insure a more uniform sample flow to the laboratories. The trace back of lots of produce found to contain violative pesticide residue would be easier. Sampling at retail grocery and distribution centers also would result in sampling of additional foreign produce already in domestic distribution centers, thereby increasing the program focus at the demonstrably higher risk associated with foreign produce.

This change should be made concurrent with the recommended re-issuance of the domestic CP in March 2005. The Field Food Committee should be charged to engage with CFSAN to effect this change in program instructions.

The Regulatory/Administrative strategy guidance clearly reflects the program is regulatory in nature (as opposed to strictly data gathering). It instructs field offices that CPG 7141.01, section 575.100, which outlines FDA's policy for pesticides in food, is under revision to reflect amendments in the FQPA, which became law in August 1996. Until the CPG is revised, districts are instructed to use the current CPG coupled with guidance in the CP to ensure compliance with the Act. At publication of this report, it is noted the CPG has not been revised and its last revision appears to have been in 1995.

The compliance guidance in instances of violative findings calls for either a meeting with the grower/shipper to discuss corrective action, or the issuance of a Warning Letter or other corrective action, if appropriate. Also, it specifies districts immediately notify the regional EPA office when an investigation reveals possible misuse (unapproved pesticide or over tolerance) of pesticides.

Pesticides and Industrial Chemicals in Imported Foods

The CP for imports was issued June 14, 2000, and was intended to apply to fiscal years 2000, 2001 and 2002. It continues as the current operating instructions for the program.

The objectives of this program are the same as delineated in the domestic program, except they apply to imported foods. The inspectional, analytical and compliance guidance for this program essentially is similar to the domestic program. However, it clearly references the different administrative authority available to FDA involving food in import status (i.e. Detention, Detention Without Physical Examination, Refusal).

As in the domestic program, individual districts have wide latitude in selecting products for sampling and analysis. Indeed, the program states, "The program must be flexible in order that the emphasis of district import coverage can be

changed to cover, ideally, problems identified through the Import Alerts and monitoring results...”

The Committee believes the historically higher pesticide residue violation rate for imported raw agricultural commodities needs to be recognized further in the re-issuance of both the import and domestic CPs.

While we recognized, over the past few fiscal years, CFSAN has been diverting increasing resources from the domestic to the import portion of the Pesticide and Chemical Contaminants programs, the low rate of violative residue in domestic produce warrants a further diversion of resources. As stated above (Recommendation 3), allowing sampling of foreign sourced raw agricultural produce already in domestic distribution would be one way to affect this change.

Also, additional resources need to be diverted to sampling for pesticide along the Canadian border. The current CPG discourages the sampling of “Canadian Product”. Transshipments, the shipment of food from other countries through Canada to the U.S., have increased dramatically since the issuance of the CPG, necessitating an increase in the rate of sampling produce entered via Canada.

Recommendation:

- 4. The diversion of field resources from the domestic to the import program should be made concurrent with the recommended re-issuance of the Import compliance program in March 2005.**

The FFC should be charged to engage CFSAN to effect this change in program instructions.

The CP for Pesticide and Industrial Chemicals in Imported Foods indicates in order to achieve effective and systemic coverage, it is necessary, among other things, to review data on pesticide usage in foreign countries. While some districts attempt (generally with little success) to obtain this information, most did not. The Committee finds it unreasonable, duplicative and grossly inefficient for 20 districts to be charged, and expected, to perform this task separately.

Recommendation :

- 5. ORA HQ and CFSAN obtain, organize and disseminate pesticide use data to the field.**

The Committee recommends that the Pesticide Steering Committee (PSC), as proposed in the *Science Issues* section of this report, be responsible for providing this information to field districts and laboratories. Until such time as the PSC can be formed, DFS and DIOP, in consultation with CFSAN, will be responsible for obtaining, organizing into a useful format, and disseminating available pesticide use data. Procedural guidance for the

dissemination of foreign pesticide use data should be incorporated into the re-issuance of the Import Compliance Program scheduled for March 2005.

The Committee found there is an unnecessary lack of policy and, therefore, confusion on the part of FDA field staff and industry on how to handle imported food whose shelf life seriously will be impacted adversely during the time product is under analysis.

In the past, the Agency had published a Perishable Food Policy for pesticide analysis that assumed a one workday turn-around time in FDA laboratories to obtain an “in compliance” finding. Policy allowed for use of enforcement discretion in accessing Customs Bond penalties should an importer of perishable food being tested for pesticides distribute the entry prior to obtaining FDA release as long as it was held, and not distributed, under the control of the importer until 5 p.m. on the day following sample collection, and the importer made a reasonable attempt to retrieve the product from commerce if it was found to contain unapproved or above tolerance levels of pesticides. The purpose of the policy was to ensure imported perishable food tested for attributes that did not pose immediate public health hazards (e.g. policy would not apply to testing for microbiological pathogens) and involved analysis the Agency could normally complete within one work day, would not deteriorate and become unmarketable while being tested by FDA.

This policy was not included as part of the revised RPM in 1997 or 2004 and since has not reappeared. It has not been replaced by any other policy or procedural statement on the part of the Agency. Currently, there is much confusion by the field offices concerning whether or not the “Perishable Policy” was still current. Most reported their import industry believed it was, and local Agency management continued, in most cases, to follow the old “Perishable Policy.”

In reality, the basis of the old “Perishable Policy” is no longer operative. Due to ORA’s laboratory consolidation project and the frequent need to ship samples long distance to servicing laboratories, the necessary turn-around time for pesticide analysis envisioned in the Policy may not be achievable.

Recommendation:

6. OE and DIOP initiate a review of the need for a Perishable Policy and establish it, as warranted.

The Committee recommends OE as lead, and DIOP, engage CFSAN in reviewing the need for a Perishable Policy and establishing that policy, if needed. The Committee urges a policy is necessary to avoid adversely affecting perishable product while, at the same time, affording necessary consumer protection.

One suggestion is to revise current regulations to require imported product be held and not distributed pending completion of FDA examination (21 CFR 1.90) by allowing release of certain classes of food pending completion of analysis when the examination is strictly surveillance in nature. Any violative findings would result in holding future shipments of the same product from the same source under a program of DWPE based on the previous violative finding.

Dioxin Program

On Dec. 4, 2000, an addendum was issued to the Pesticides and Industrial Chemicals in Domestic Foods CP involving special survey obligations for dioxins and furans in food. The objective of the dioxin monitoring program was to obtain data on background levels of dioxin in a wide variety of foods so the Agency can determine how to reduce dietary exposure and improve exposure assessments of dioxin by providing better exposure data. The addendum gives management guidance in all pertinent areas: inspectional, analytical and compliance.

The inspectional guidance for this addendum is specific and allows little latitude to district offices. Each district is specified a number of samples and products to collect. The analytical guidance specifies the analytical methodology and procedural guidance to be followed. It also identifies the laboratories that will perform analysis under the assignment.

The assignment for dioxin was, and remains, surveillance in nature and no regulatory action was anticipated based on the assignment. However, it is anticipated if any follow-up activity is deemed necessary, its nature would be determined after Center review of the analytical results.

The structure and guidance of the dioxin program has not changed substantially since the issuance of this assignment. However, products selected for surveillance sampling are updated constantly.

It is noted the dioxin portion of the CP will soon have been gathering background data for four years. It appears necessary, at this point, for the responsible Center to evaluate the data to determine if it is yet appropriate or feasible to establish action levels for dioxin in specified food products.

Total Diet Study

The TDS CP was last updated October 8, 2003, and contains the current operating instructions for this program.

The objectives of the TDS are:

- ?? Determine the levels of pesticides, industrial chemicals, toxic and nutritional elements, select radionuclides, and folate in foods as consumed.

- ?? Calculate daily dietary intakes of all TDS analytes for 14 age and sex groups.
- ?? Identify trends and compare levels in foods and dietary intakes of TDS analytes with acceptable levels and recommended intakes established by FDA, Food Agriculture Organization (FAO) and World Health Organization (WHO), the National Academy of Sciences, and other agencies and scientific bodies.

The TDS is a very structured and prescriptive program. Collections are scheduled four times per year, with each consisting of simultaneous collections in three cities in a specific geographic area. All collections are sent to the Kansas City District laboratory where foods are prepared as consumed. Analyses are performed at the Kansas City laboratory with the exceptions of folate (sent to Atlanta Center for Nutrient Analysis) and radionuclides (sent to Winchester Engineering and Analytical Center).

B. POLICY AND PROCEDURE MANUALS

Pesticide Analytical Manual

The PAM is published by FDA and is the official repository [40CFR180.101(c)] of analytical methods used in FDA laboratories to examine food for pesticide residue for regulatory purposes.

While the PAM is formally a manual published by CFSAN, updating to assure referenced analytical methods reflect current, standardized and validated science is a joint responsibility of CFSAN and ORA. In the past, this was accomplished by appointing a co-editor from each organization and through joint discussions regarding method needs between ORA (field and DFS) and CFSAN. This resulted in assignments to develop and validate analytical methods for inclusion in the PAM.

Because the pesticide programs, both import and domestic, are regulatory in nature and presume possible regulatory and administrative actions by the FDA when violations are noted, the use of standardized and validated analytical methodology is critical. It is necessary each FDA laboratory use validated methodology to assure reproducible results that can withstand scrutiny by the courts.

In addition, it is critical that analytical packages to support violative samples meet the criteria outlined under Procedural Requirements in the CPs. The analytical packages will include the results obtained, reference the methodologies and equipment employed, as well as document the quality assurance procedures followed to assure the accuracy of the results and establish the chain of custody of the sample while under analysis.

The Committee determined that PAM Volumes I and II need to be updated to reflect current technology in use in FDA laboratories and to include currently

available state-of-the-art technology. A full discussion of the PAM is included under the *Science Issues* section of this report.

Compliance Policy Guides

CPGs are developed to provide guidance to the Agency's compliance staff and field investigators on Agency policy on regulatory issues related to FDA laws and regulations. As guidance, a CPG represents the Agency's current thinking on specific regulatory issues. The CPG manual is a repository for all Agency compliance policy. CPGs are prepared from many sources. These include: statements or correspondence by headquarters offices or Centers; precedent-setting court decisions; multi-center agreements regarding jurisdiction over FDA-regulated products; preambles to proposed or final regulations or other Federal Register documents; and, approved regulatory actions.

As regards the pesticide program, the most pertinent CPG is 7141.01, Pesticide Residue in Food and Feed Enforcement Criteria. This guidance contains the criteria for initiating an enforcement action. It provides the necessary legal charges for an enforcement or administrative action; specifies enforcement levels for pesticides for which there is no tolerance and for instances where established tolerances are exceeded; and, lists action levels for unavoidable pesticide levels in food and feed commodities.

The Committee's review determined the CPG needs updating. The current CPG conflicts in at least one instance with a CP (see Recommendation 1). Further, the CPG does not recognize differences in regulatory standards between domestic and import products. Specifically, the CPGs and CPs need to:

- ?? Recognize the "appearance of a violation" is a regulatory standard that can be applied to import food products when entry decisions are made.
- ?? Evaluate the need for quantitation in no tolerance situations and the need for quantitative check analysis for imports.

The Committee determined that guidance in both the CPs and CPGs does not recognize adequately the difference in evidentiary standards between a domestic legal action (i.e. seizure) and an import related administrative action (i.e. refusal). This results in laboratory resources being devoted to potentially unnecessary check analysis. This time could be better used in testing additional lots of produce, thereby increasing our surveillance rate.

An "appearance of a violation" is the standard in the Act that is applied to administrative refusal of imported product, as well as to the preliminary step of detention which is designed to allow for submission of information to "overcome" the appearance of a violation. However, rather than use this standard of proof, recognized in the Act, the current policy outlined in guidance documents calls for both quantitation of the pesticide when no tolerance exists, plus performing a quantitative check analysis for both "no tolerance" and "exceeds tolerance" findings for each pesticide violation found. This practice not only diverts limited

laboratory resources from testing additional lots, it delays administrative action against shipments of the same product from the same grower, which are likely to exhibit the same pesticide violation.

Recommendation:

7. Develop a regulatory structure for imports to take advantage of the resource saving achieved using the “appearance of a violation” standard in Section 801 of the FD&C Act.

The Committee recommends OE as lead, with the participation of DIOP, be charged immediately to engage CFSAN and CVM in development of a regulatory structure for imports that takes advantage of the resource saving that can be achieved using the “appearance of a violation” standard. New procedural guidance is to be incorporated into the re-issuance of the CPs scheduled for March 2005.

Investigations Operations Manual

The IOM is the primary source of guidance regarding Agency policy and procedures for field investigators and inspectors. It directs the conduct of all fundamental investigational field activities. Adherence to guidance in the IOM is necessary to assure quality, consistency, and efficiency in field operations.

There are many sections of the IOM that impact the pesticide program, e.g. sampling schedules and procedures to insure the proper collection, storage and transport of samples and maintaining sample integrity.

The Committee observed the IOM is currently up to date. Hardcopy IOMs contain current information when printed; however, ORA/DFI procedures allow for updating the IOM on-line when changes are needed. This on-line manual is available through FDA websites to all FDA personnel.

Regulatory Procedures Manual

The RPM primarily is a manual on “how to” proceed in regulatory matters, both domestic and imports. It contains procedural guidance on the preparation of legal and administrative documents to Agency personnel. It also contains a summary of the various laws FDA administers.

In terms of the Pesticide and Chemical Contaminants program, it contains guidance for criteria and preparation of both domestic legal actions and import administrative actions.

In 1989, the Agency published a Perishable Food Policy (one day laboratory turn-around) in the RPM. The purpose of this policy was to insure that imported perishable products would not deteriorate and become non-marketable while laboratory samples were analyzed. This policy was not included as part of the

revised RPM in 1997 or 2004. However, local management, in many cases, continues to follow this policy and many importers presume the policy remains in effect and demand to be informed of results within those time frames. Those time frames may no longer be realistic due to the distance of servicing labs, delivery time to the lab, and lab work schedules (see Recommendation 6).

Import Alerts

Import Alerts, along with Import Bulletins, are used to identify and disseminate import information (problems, violative trends, etc.) and to aid in providing effective import coverage.

Import Alerts identify problem commodities, shippers, or importers and provide guidance for import coverage. They also identify those products or shippers that have met the criteria for DWPE based on the information available to the Agency (i.e. results of laboratory examination, foreign inspection findings, epidemiological association with food borne illnesses, information from other domestic or foreign government agencies), or which may require increased sampling. Import Alerts significantly improve the uniformity of enforcement in import problem areas.

Import Bulletins generally are informational only. They are used to share information between field offices regarding findings that do not meet the level of an Import Alert, but which field offices may wish to use to focus their import coverage.

The Committee found an unacceptable time-lag in issuing new or updating existing Import Alerts when pesticide violations are found. Delays frequently are several months in length. The consequent inability to apply a timely policy of DWPE on subsequent entries of the same product from the same source diverts limited investigational and laboratory resources continually to sample and test these subsequent entries.

Import Alerts are issued when evidence is found of a violation of an imported product and it is likely subsequent entries would exhibit the same violation. They are used to communicate instances where an “appearance of a violation” has been established and future entries may, based on an evaluation of the background, be detained without laboratory analysis. Examples are subsequent shipments of the same product from the same grower when a violative pesticide residue is found; another example would be the presence of an unapproved food additive in a processed food.

Above and beyond the extensive analysis expected to document a pesticide tolerance violation for an imported product, recommendations from field offices to place product/grower combinations on Import Alerts reportedly take an inordinate amount of time to process through DIOP and CFSAN.

Recommendations:

- 8. OE and DIOP coordinate a review of current policy and procedures for placing imported produce, found violative for unapproved pesticide residues, onto Import Alerts.**
- 9. OE and DIOP review the utility of the “pesticide specific” charge currently used on Import Alerts.**

Considering the following points, the review, to be made in consultation with CFSAN, is to determine:

- ?? If improvements in science make extensive headquarters reviews unnecessary;
- ?? The possible effect of laboratory accreditation on the need for headquarters reviews; and,
- ?? The effect of the nature of the “appearance of a violation” requirements of Chapter 801 of the Act.

OE and DIOP also are to be charged to review the utility of the “pesticide specific” charge currently used on Import Alerts. The effect of the current policy is future shipments need only present evidence of the lack of a specific pesticide to overcome the “appearance of a violation”. Evidence is not required to demonstrate the product was tested using the same multi-residue methods used in FDA laboratories and, therefore, is free of additional residues identifiable through the methodology.

Field Management Directives

The FMD manual is an additional mechanism for distributing procedural information and policy on the management of ORA field activities. The manual is intended as internal guidance directed to field managers.

Some FMDs are directly related to the Pesticide and Chemical Contaminant Program, including:

- ?? FMD #134, Pesticide Coordination Teams;
- ?? FMD #129, Interagency Pesticide Referrals between EPA and FDA; and,
- ?? FMD #77, Abbreviated Analytical Reporting.

FMD #'s 134 and 129 cover important aspects of the overall pesticide strategy within FDA. Field offices' compliance with FMD #134, on the functioning of PCTs and FMD #129, on interagency referrals concerning pesticide violations between FDA and EPA, was clearly the exception rather than the rule.

Functioning PCTs are a valuable tool to focus FDA's surveillance sampling for pesticides on properly risk-based, targeted product. They also, via

improved advance communication with servicing laboratories, would help to eliminate laboratory backlogs that unnecessarily delay the analysis of produce. PCTs would be charged to assure that the Agency's overall pesticide surveillance program is implemented in a thoughtful, risk-focused manner. The PCTs in each district would insure program requirements, including surveillance activities, non-redundant reports to national program management, selection of sampling sites and compliance activities (including referrals to EPA and state counterparts), are initiated and properly monitored.

The Committee realizes the previous model for PCTs will need to be revised for the current environment. Clearly, reporting to national program managers by 20 districts on information readily obtainable on a national basis through existing databases requires a re-evaluation of what reports are needed. Also, the ORA laboratory consolidation program has resulted in servicing laboratories that are distant from the districts and which frequently analyze samples from multiple districts. Mechanisms will have to be found to assure districts can collect needed samples to accomplish their workplan, do this in coordination with other districts serviced by the same laboratory, and coordinate this work to avoid seasonal backlogs in the laboratories.

Recommendations:

- 10. The Committee recommends that the Deputy ACRA, as soon as possible, issue a memo to all field offices regarding the need to comply with FMD #129 and share violative pesticide residue data with EPA.**
- 11. ORO develop an outline of functions for field PCTs in the current environment of national databases and distant servicing laboratories for field offices to follow.**
- 12. PCTs performing newly established functions be established in each district by FY-06.**

Special Assignments

Occasionally, in response to specific concerns or documented problems, the responsible Center (i.e. CFSAN or CVM) with the concurrence of ORA, or ORA on its own, will issue special assignments to the field to respond to the problem or gather information to better evaluate an emerging concern.

CFSAN, CVM, or ORA special assignments can have a significant impact on accomplishment of the workplan for Pesticides and Chemical Contaminants in Foods. A recent example under the Pesticides and Chemical Contaminants program was the series of assignments to collect and analyze Ginseng and Ginseng-containing products for pesticide contamination.

Field offices expressed concern with the amount of time some special projects required and the impact of this work on their regulatory activities. Uniformly,

the analyzing laboratories indicated the required analyses were complex and took significantly more time to perform than the normal pesticide screenings. The time to perform the requested analyses was resourced insufficiently and, therefore, adversely affected other activities in the program.

The Committee noted frequently, Centers in their Special Assignments mandate special reporting requirements beyond ORA's FACTS or OASIS systems. Normally, these requirements involve information not available in FACTS or OASIS, but appear to be designed to allow Centers to obtain data in a manner with which they are most familiar. This practice is not exclusively a problem with Special Assignments.

Dual reporting requirements are time consuming and redundant.

Recommendations:

13. The Committee recommends the FFC, CVM Committee and ORO critically evaluate all requests for data reporting outside of the FACTS or OASIS systems.

14. DHRD should offer additional training on the FACTS and OASIS systems so CFSAN and CVM can access needed data from the systems and avoid duplication of data reporting by field offices.

ORA Workplan

Annually, in cooperation with program Centers, ORM issues a workplan that allocates responsibilities to assure accomplishment of planned work. The workplan will assign specific numbers of investigations, inspections and sample collections to field offices and sample analysis responsibilities to field laboratories. The workplan also allocates resources to field offices, via average time modules for work products, to assure field offices and laboratories are staffed to accomplish the assigned work.

Upon receipt of the national workplan, field offices and laboratories are expected to develop a local workplan to assure accomplishment of assigned work during the fiscal year.

C. DISTRICT AND LABORATORY MANAGEMENT

Local district and laboratory management are expected to have policies and procedures in place to assure:

- ?? Local workplanning is accomplished to implement work assigned under the national Workplan;
- ?? Work accomplishments conform with Agency policy and procedures and are appropriate for use to accomplish the intent of the CP and, when appropriate, to allow follow-up regulatory and administrative actions;

- ?? When there is a need for regulatory and administrative action, the need is recognized and appropriate follow-up is initiated; and,
- ?? Work is accomplished in an efficient manner recognizing the programmatic needs of others in the Agency.

The Peer Review Committee observed the current domestic and import compliance programs provide district and laboratory management with guidance, although dated, for program implementation. However, it was noted district and laboratory management procedures and requirements often deviated from the compliance program. For example, formation of a PCT, development of local surveillance data on pesticide usage, and submission of a yearly pesticide program report to CFSAN, seldom were followed.

Several districts indicated restrictions on sampling (i.e. focus of foods consumed by infants, collection directly from growers, special assignments, collection during certain times of the year, etc.) prevented an even flow of samples to the laboratories. It should be noted the domestic pesticide compliance program does suggest 50% of samples should be directed towards foods consumed by infants and children. Although the program lists a number of products, local discretion can be used to select additional foods which would be consumed by infants and children. Local management is afforded wide flexibility in deciding which products to sample based on knowledge of local produce and growing conditions. It appears local management may not understand fully the latitude in sampling decisions afforded to them by the CP.

The majority of districts stated they believed PCTs needed to be reestablished everywhere. In those districts where PCTs are in place or where management used a similar team approach, the district appeared to have better control over implementation of the pesticide program, including a more controlled flow of samples to laboratories.

The committee determined the majority of districts refer violative domestic sample results to state regulatory authorities for follow up action. Results of state regulatory actions seldom are documented. Districts do not appear to follow program guidance which calls for meetings with growers and the issuance of Warning Letters for Class 3 violations. The majority of districts contacted routinely did not notify the Federal or State EPA when sample analysis indicated possible misuse of pesticides.

The Committee determined there is notable and distressing lack of real time evaluation and feedback on findings of the Pesticide and Chemical Contaminants CPs.

This issue involves the need for local district offices, in order to meet the expectations of the CP, to incorporate information of pesticide usage, both domestic and foreign, in their local sampling program. One of the most important sources of such information is the FDA monitoring program. The most current report on the Agency pesticide program involves FY-01 findings. Interviews with

field staff, including managers, indicated few field staff are aware of the CFSAN Annual Pesticide Report. Further discussions indicate there are available mechanisms to share real time pesticide violation data, including regular field laboratory pesticide calls to share violation information, and a report, issued regularly by DIOP, which delineates all import Class 3 laboratory findings.

Recommendations:

15. ORO work with CFSAN to assure timely issuance of an annual pesticide report to be used by field staff to direct sampling of agricultural products for pesticide use.

16. ORO organize and disseminate all ORA-generated information on pesticide violations to assure staff have the information necessary to direct local sampling plans.

The Committee found there is no single point of contact for ORA field units to obtain guidance on current policy interpretation. All field units interviewed expressed frustration with their ability to obtain timely guidance on investigational, regulatory and compliance issues involving the Pesticide and Chemical Contaminants programs and to coordinate regulatory response and develop policy, when necessary. Field offices indicated it was difficult to get guidance from either ORA or Centers on new or unusual issues.

Recommendation:

17. A specific individual in OE become ORA's clearinghouse for all policy and regulatory issues involving the Pesticide and Chemical Contaminants program.

This person would be expected, through in-depth knowledge and consultation with other Agency units, to supply authoritative answers for all field questions in a timely manner.

Committee requests for complete inspectional/laboratory/compliance packages for review, dating from FY-01, clearly showed an inability on the part of many districts to retrieve the packages. The Committee suspects this problem is not limited to the Pesticide and Chemical Contaminants programs. In addition, even when packages were available, the level of documentation maintained varied significantly between districts.

In the *Science Issues* section of this report, the Committee will recommend field laboratories, in anticipation of the requirements for laboratory accreditation, be designated the official repository of all original laboratory records. However, the problems encountered of varying degrees of documentation being maintained, or perhaps retrievable, by different districts clearly indicates a need to establish standards of what must be maintained by FDA districts to document compliance activities and consultations and what

must be maintained to document in-compliance situations. The need for review of this is especially acute in this era of increased field automation (FACTS, OASIS, TURBO) with retrievable databases. There is need to establish definitively which items to maintain in either paper or electronic format, and which organizations are responsible for assuring their maintenance.

Recommendation:

18. The Deputy ACRA create a multi-disciplinary task force, including a Quality Management Systems representative, to review and establish standards to document and maintain records for in-compliance situations.

This task group will make specific recommendations to the ACRA. Those portions of their recommendations approved by the ACRA will be issued as guidance to field offices.

V. SCIENCE ISSUES

A. DIRECTION AND LEADERSHIP

Historically, FDA has been recognized for its pesticide program leadership role in the areas of method development research, instrumentation, program oversight, and technical expertise. This leadership resided primarily in CFSAN. With time, many of the influential scientists in CFSAN retired, program emphasis shifted, and scientific leadership emerged from ORA scientists located in the field. Innovations from the field laboratories are exemplified by the Luke methods developed in the Los Angeles District laboratory. ORA now is experiencing a similar succession challenge with the retirement of several of its top pesticide program scientists.

As the Committee conducted site visits and interviewed pesticide technical experts and managers throughout the field, it became clear, despite the loss of many key scientists, expertise and program leadership potential exists in the new generation of analysts in ORA laboratories. The development of the mass-selective detection (MSD) procedures and miniaturized extraction methods are examples of this expertise. To date, such advances have occurred on an individual analyst basis, with little formal organizational attention or structure. Analysts have been appreciated for their technical capability, but their depth of knowledge in the purposes and directions of the program itself has not been significantly utilized. This became clear to the Committee during interviews with scientists and managers in field laboratories. Senior analysts in several laboratories, for example, expressed the need for new directions in method development and validation, standardization of procedures among servicing laboratories, and new procedures for technical review of analytical packages.

Recommendations:

- 1. Establish a PSC to address national program issues.**
- 2. Create a National Pesticide Expert within ORA.**

The Committee recommends ORA establish a formal mechanism to retain and fully develop scientific leadership in the program, and incorporate this group into the program planning and implementation process. Establishment of a PSC would accomplish the goal. The PSC would consist of four to six technical specialists and two managers from field pesticide laboratories, one DFS representative and representatives from CFSAN and CVM. The PSC would be responsible for nationwide program issues, including standardizing procedures among pesticide servicing laboratories, specifying uniform use of equipment configurations, and addressing method validation issues. Scientists on the PSC would possess sufficient expertise to assist in policy development, serve as a pool of expert witnesses, and perform regulatory package scientific review functions, when appropriate.

Another frequently expressed theme heard by the Committee was the need for directed research in pesticide analysis. At one point, this was performed by Pesticide and Industrial Chemicals Research Center (PICRC). Located in Detroit, PICRC consisted of five research scientists tasked with development and validation of methods to be used by ORA laboratories. At the time of laboratory consolidation, the function moved to the laboratory in Kansas City; however, as resources have been reduced, little capability exists today. The Committee recommends this function be served by a single person, serving as a focal point for scientific leadership in this program. This role has been assumed unofficially and informally for a number of years by a senior scientist in a FDA laboratory, who soon will retire. Several other ORA scientists have the knowledge, interest, and leadership potential to assume this role, but under current pressure to generate high sample output, they may not have the time flexibility to devote their efforts in this manner.

The Committee recommends the creation of a National Pesticide Expert position within ORA with the following features and duties:

- ?? GS-13 position with potential for advancement to GS-14 or higher through the Regulatory Scientist Peer Review process.
- ?? Reports to DFS but located in an ORA laboratory.
- ?? Conducts research and coordinates other pesticide research and related activities throughout the field.
- ?? Coordinates the validation of proposed regulatory methods to facilitate their incorporation into regulatory programs.
- ?? Actively is involved in policy setting and procedure development as a member (and perhaps Chair) of the PSC.

This position should be developed, advertised, and filled as soon as possible to strengthen the leadership of this program. It may be a model for other Science National Expert positions in other program areas.

B. METHODS

The latest scientific techniques, such as mass spectrometry (MS), bring new opportunities for time saving and accuracy in pesticide analysis. Because of budget constraints and program priority shifts, FDA has been slow to bring these new techniques into our field laboratories. As a result, we have fallen behind many other world leaders in pesticide science. Although the shift is occurring in ORA laboratories, the official methods remain the multiple column/detector systems. To maximize the advantage of technical upgrades, we need to move away from the antiquated methods developed over twenty years ago.

We are limited by our regulatory policies, which prescribe old, less efficient methods. The specificity of the newer MS technique is sufficient to be considered the primary residue identity technique. Therefore, use of time consuming, multiple column/multiple detector systems currently required by policy is unnecessary. This is particularly important as we test time-sensitive perishable products streaming through the borders.

Recommendation:

3. The PSC facilitate continued incorporation of state-of-the-art pesticide methodology into official regulatory procedures.

The Committee recognized that other advances in pesticide methodology, developed in recent years, should be incorporated into national procedures. Examples are the “QuEChERS” miniaturized extraction and cleanup procedure and the new miniaturized salt-out procedures based on LIBs 4110, “Multiresidue Method for the Analysis of Polar and Nonpolar Pesticides in Fatty Products” and 4178, “A Multiresidue Analytical Method Using Solid Phase Extraction Without Methylene Chloride.” These provide similar recoveries to traditional methods while minimizing solvent use, eliminating the use of methylene chloride and separatory funnels, and saving time. Hazardous waste management is an acute concern in our laboratories, as well as the reduction of costs commensurate with less need for expensive solvents. Priority should be given to validation and adoption of these methods.

Many of the new pesticides being introduced, including the so-called “third-generation” pesticides, such as imidazolenones, are not amenable to detection using current methods. These pesticides require use of more sophisticated techniques, such as liquid chromatography-mass spectrometry (LC-MS), a technique not currently used in FDA’s pesticide programs. As resources permit, LC-MS needs to be incorporated into routine screening procedures. This equipment is expensive, but FDA needs to make this commitment to state-of-the-art science.

The PSC would monitor development of new techniques in the five field laboratories and in coordination with CFSAN and CVM. Through timely introduction of new applications and coordinated validation of methods, FDA would continue to have state-of-the-art methods required to carry out its regulatory mission.

C. POLICY

While interviewing ORA laboratory scientists and compliance officials, the Committee identified instances where regulatory policy appears to stifle execution of the program. These policy issues included those related to evidence required for a regulatory action and records retention.

As scientific methods, information technology applications and instrumentation advance, and FDA shifts to an ISO-17025 environment, policy changes are appropriate. One necessary change involves retention of analytical records. Current policy requires records be sent to the home-district Compliance Branch, where either the domestic manufacturer is located or the import entry is made. ISO-17025 requires such records be available to auditors without delay. There is no ISO-17025 housing location requirement for records of import samples or non-actionable domestic samples; only that they are retrievable.

Recommendation:

4. Retain analytical records in the analyzing laboratory; establish the FACTS sample summary as the official regulatory analytical record.

In conducting district audits, teams from the Committee often found records incomplete and, in many cases, missing altogether. Where laboratories and district offices were co-located, this seldom was a problem. With the consolidation of laboratories, movement of records became more confusing. Since laboratories now service multiple home districts, a single, useful records retention procedure would best serve ORA. Several district Compliance Branches use electronic copies or photocopies of records, while others require the original worksheet package for final regulatory decisions. The process for communicating analytical results to a home district needs to be quick, efficient and reliable. Original records should be retained by the analyzing laboratory, thus preventing loss and facilitating retrieval. FACTS sample summaries can communicate reviewed analytical results for any appropriate regulatory action or release of product. This already is the practice in several ORA laboratories and district offices; the Committee recommends this to be the standard procedure.

Recommendation:

5. Review requirements in the CPG for check analyses for samples containing pesticides with tolerances and with no tolerances as part of the review and revision recommended in Program Management (section IV).

A second major consideration for change in policy is interpretation of analytical results and the degree of quantitative evidence necessary to take regulatory action. Current policy for samples containing “No-Tolerance” residues (pesticides not permitted at any level in a commodity) is to quantitate the level of each residue identified and perform an independent, qualitative, confirmatory analysis. The policy for samples containing residues that exceed a tolerance requires quantitative original and check analyses, including spike recovery and reagent blank determinations. Spike recoveries (fortification of product known standard and recovery using methods for isolation and identification of the pesticide) and blank injections can increase analysis time ten-fold when multiple residues are encountered. Proving a recovered residue is greater than the limit of quantitation (LOQ) is sufficient quantitative evidence, in addition to identity confirmation for regulatory action when no tolerance has been established. Similar logic should be applied when a residue is encountered that exceeds a tolerance.

D. DOMESTIC AND IMPORT SAMPLE ANALYSIS

Under current programs, import pesticide samples are analyzed by five ORA regional laboratories; domestic samples are analyzed by the same five laboratories, plus Kansas City District laboratory. The number of samples collected under the pesticide programs declined considerably through the 1990s. Over the last several years, the number has stabilized to around 8000 samples per year (5300 import and 2700 domestic). During this time period, the domestic program was cut disproportionately compared to the import program, from a 1:1 ratio to the current 2:1 ratio.

These resource reductions have impacted the program in several ways. Required core sampling for staple commodities, such as milk, dairy products, and eggs, was eliminated. The “Statistical Sampling Assignments” and “Special Emphasis Surveys” were eliminated. The statistical sampling assignments were designed to collect statistically significant numbers of a targeted commodity and analyze a targeted group of pesticides, including as many pesticides with tolerances as practical. All samples were analyzed by a single laboratory to enable economies of scale. The special emphasis surveys were intended to provide limited coverage for pesticides not determined by commonly-used multiresidue methods.

Recommendations:

- 6. Consolidate all domestic pesticide analyses within two laboratories: Arkansas Regional Laboratory (food) and Kansas City District laboratory (feed).**
- 7. Consolidate all import pesticide analyses in four laboratories: Northeast Regional Lab (NRL), Southeast Regional Lab (SRL), Pacific Regional Lab Southwest (PRL-SW), and Pacific Regional Lab Northwest (PRL-NW). Shift existing import workload from ARL to PRL-SW.**
- 8. Develop a national sampling plan for domestic produce targeting specific commodities for coverage each year and focusing collections to a limited time period.**

9. Reinitiate statistical sampling surveys to include import products collected in domestic commerce.

10. Focus the program in consultation with EPA to provide risk analysis data needed for tolerance reassessment.

During the course of this Peer Review, the Committee found virtually unanimous response from district offices and laboratories that resources of the domestic program could be better utilized for greater regulatory impact. Several respondents recommended terminating the domestic program. As was evidenced in the work product review, domestic samples are given low priority for collection and analysis, and laboratories often choose to apply only a basic pesticide screen and do not perform analyses for additional classes of pesticides. Additionally, large numbers of samples are sometimes collected at one time, straining laboratory capacity and resulting in lengthy delays in completion of analyses.

Based on these findings, the Committee concluded a major redesign and restructuring of the domestic program is necessary. Terminating the program is not considered a viable option as under International Trade Treaties; imported and domestic products must be treated similarly. Thus, a domestic program must be maintained to complement the import program. Several assumptions were used in the deliberations: the available resources for collection and analysis are constant, the total number of samples will not decrease, net shift of resources among laboratories must be minimized, and the net result must enhance program coverage. The best solution appeared to be consolidating the domestic program analyses into one or two laboratories and to focus on specific commodities to be sampled each year. Other laboratories would do only import program analyses.

This solution offers the following benefits:

- ?? Enhanced productivity by batching similar samples.
- ?? Expanded analytical coverage by freeing resources for using single residue methods.
- ?? Eliminating the “summer rush” of domestic pesticide analyses.
- ?? Allowing improved coordination with EPA to fulfill their residue data needs. The selection of commodities to be sampled would be developed in conjunction with EPA data needs for risk assessments.
- ?? Reducing analytical turn-around time in laboratories having an import focus.

E. INSTRUMENTATION

Traditionally, lab instrumentation has been funded centrally, but specified locally. Each lab determined the appropriate configuration and vendor for its individual operation. The result is a myriad of different instrument configurations in the various pesticide laboratories.

The initial major purchase of MSD systems established a new paradigm for instrument acquisition in ORA. This occurred in 2000, when money originally allocated for tobacco enforcement became available for new technology acquisition. Recognizing the need to incorporate mass spectrometry into pesticide screening protocols, DFS, in conjunction with several senior analysts, agreed upon a single configuration from a specific vendor and purchased seven instruments for field use. This has proven beneficial in several ways, some unforeseen at the time the decision was made. ORA was able to negotiate a significant discount on the per-unit price and obtain a commitment from the vendor to include analyst training which otherwise would have been an additional cost. The similarity of configuration has allowed the various labs to assist each other in training, data interpretation and troubleshooting, and the familiarity of labs with the equipment has helped to direct subsequent purchases to a similar configuration.

These multiple benefits have proven the need to continue this approach. As further equipment is needed in the pesticide labs, the configuration for such equipment will be defined by recommendations from the PSC and anticipated program needs. Purchases will continue to be funded by the existing central process, although savings from larger group instrument purchases can be expected.

Recommendations:

- 11. PSC determine configurations of equipment to be used in all pesticide labs utilizing group purchases, whenever appropriate.**
- 12. Negotiate and fund service contracts for complex instrumentation.**
- 13. The PSC, in development of national protocols, should maximize automation capabilities of instrumentation.**

The Committee reported interviews with laboratory personnel identified another major issue: service contracts for new equipment. Historically, with simpler equipment, maintenance was performed by experienced analysts. With today's instrumentation, basic maintenance and troubleshooting can still be performed by experienced analysts. However, the complexity of the instrumentation requires serious instrument malfunctions be diagnosed and repaired by qualified service engineers. Combined with the high cost of replacement parts, there is now a need for service contracts. Two potential approaches are to buy contracts annually or to negotiate extended warranty service into the purchase.

Consideration also needs to be given to efficiency in purchase and use of instrumentation. Automation needs to be used to its fullest possible extent. Autoinjectors are now standard equipment on chromatographs of all types. The Peer Review Committee observed this capability as underutilized in our labs. Protocols need to be established to maximize this capability. For example, calibration runs (to conform to ISO 17025 standards) could be performed in the early morning while samples are being extracted. Sample analysis could proceed throughout the day using instrument automation features and throughout the night on an unattended basis, if necessary. Data processing also could be automated

once Laboratory Automation Management Systems (LAMS) are incorporated. The PSC should work toward establishing uniform protocols to accomplish these efficiency gains.

F. PESTICIDE ANALYTICAL MANUAL

The PAM is referenced in 40 CFR180.101xx as the repository of methods used by FDA for enforcing tolerances for pesticide residues in foods. Currently, the PAM consists of two volumes. PAM Volume I consists of multiresidue methods. PAM Volume II contains methods for individual pesticides submitted by registrants as part of the registration process. Both volumes are outdated, as PAM I was last revised in 2000 and PAM II in 1989.

Recommendations:

- 14. Initiate a fast-track process for updating PAM I with methods and techniques currently used in FDA laboratories.**
- 15. Refocus PAM I as a methods manual, eliminating textbook chapters on general technologies.**
- 16. Establish critical limits for adjusting operating parameters when focusing on individual pesticides.**
- 17. Establish a schedule for routine updates of both PAM volumes.**

PAM I

Although the methods in PAM I are scientifically sound and validated, they are, generally, resource intensive and specify the use of obsolete technology and techniques. Existing methods are written in very prescriptive terms. While this is necessary for multi-residue screening, provision is necessary to allow minor adjustments or changes when the analysis is focused on a specific pesticide. For example, a specific temperature program must be used for initial analysis, but a modified program may be necessary to resolve a residue of interest for a co-extractive interference or another pesticide that co-elutes under the prescribed conditions.

PAM I also contains chapters on general techniques, such as gas chromatography (Chapter 5) and liquid chromatography (Chapter 6). These “text book” chapters require considerable effort to write. While these were relevant when written, they now are outdated. Up-to-date textbooks on general techniques are available commercially to fulfill this need. In today’s environment of limited resources, our efforts would be better spent exclusively on methods issues.

New methods have been developed that are much more rapid, use significantly less solvents, generate ten times less hazardous waste, and are significantly more efficient. Additionally, instrument technology has advanced well beyond that which is included in PAM methods. This new technology, for example, gas chromatography-mass

spectrometry (GC-MS) and liquid chromatograph-mass spectrometry (LC-MS), is used routinely in FDA laboratories in the pesticide monitoring programs.

The fact these new methods and technologies are not included in PAM I creates problems when these methods are used in regulatory analyses. This has led to unnecessary complications in compliance situations. Other issues regarding PAM I the Committee identified follow:

- ?? Requirements for adding new methods to PAM I specifically are not defined.
- ?? No schedule exists for routine updating of PAM I.

The process to update PAM I was initiated in March 2004. A new group of PAM technical advisors was identified. A conference call, including the new technical advisors, DFS and CFSAN, was held to discuss and prioritize new additions to PAM I. Assignments were made for drafting updates to include several new methods.

PAM II

The issue with updating PAM II is not as critical. The last full update was issued in 1989, however, an updated index of pesticides and methods was issued in 1999. The newer registrant methods are available from CFSAN. An updated index is needed on a regular basis along with a specific contact point for FDA and other regulatory (State) laboratories to obtain the methods.

G. DIOXINS PROGRAM

The primary dioxin analytical laboratory for FDA is the Arkansas Regional Laboratory (ARL). This is a full capability, high capacity lab with state-of-the-art high resolution gas chromatography-mass spectrometry (HR-GC-MS) and automated extraction apparatus. ARL has capability for using the CALUX, a biological screening method for dioxins and furans. A second dioxin lab was established in the Kansas City District laboratory (KAN) in 2002. KAN has limited capacity and capability. It does not have high resolution GC-MS or automated extraction systems.

Recommendations:

- 18. Establish a research effort for dioxin method development at ARL.**
- 19. Reaffirm the need for a second dioxin analytical lab at KAN and equip the laboratory appropriately with state-of-the-art technology.**

The Committee reported ARL currently is the only FDA laboratory with both the HR-GC-MS and automated extraction capabilities. The methods developed at CFSAN use manual techniques for extraction and isolation of analytes. Thus, the new methods and modifications of existing methods to expand capability to additional compounds, such as PCB congeners, require significant adaptation for use at ARL. The automated extraction system has untapped capabilities that

should be exploited. Other rapid screening methods for dioxins are appearing in the literature. The potential applications of these techniques for foods and feeds must be investigated. Thus, a research effort at ARL focusing on dioxins is warranted.

Limited capability at KAN has become an issue because it limits the types of samples it can analyze. For example, lack of HR-GC-MS precludes the analysis of TDS samples for dioxins at KAN. These samples must be shipped to ARL for analysis. A majority of samples analyzed requires HR-GC-MS to achieve the necessary sensitivity levels required for risk assessment. Since dioxins are a significant issue, the Agency must address, in the foreseeable future, the necessity of a second full capability lab to provide required capacity and redundant capability.

H. TOTAL DIET STUDY

Analytical efforts for the TDS are centered at KAN and include analyses for pesticides, toxic elements, and nutritional elements. Other TDS analyses are conducted at Southeast Regional Laboratory (folic acid), Arkansas Regional Laboratory (dioxins), and Winchester Engineering and Analytical Center (radionuclides). Only the pesticide and dioxins components of the TDS were included in this review.

Recommendation:

20. Implement the GC-MSD method in the TDS.

The TDS program has been ongoing for over 40 years and is well managed and conducted. Only minor issues arose during this review. The primary issue identified was the ongoing review of methods and analytes included in the TDS. Some methods included in the current TDS have resulted in very few findings. New technology, such as the GC-MS methods used in the regular pesticide program, could replace some existing methods and expand coverage to new pesticides.

I. SCIENCE DISPUTE RESOLUTION

FDA defines and uses ad-hoc committees to resolve issues for which Agency precedent is lacking on matters involving complex and difficult enforcement issues, as described in RPM Chapter 10. Traditionally, ad-hoc committees were convened to expedite processing of injunctions, planning regulatory procedures, and committing responsible units to an action plan. These ad-hocs were convened for the regulatory issues, not technical laboratory issues.

If a recommended regulatory action is overruled by CFSAN or CVM based on a technical issue, the ORA laboratories have no recourse on the decision. Implementation of a Science Dispute Resolution Ad-Hoc committee will address the handling of disputes over technical science issues. For example, if CFSAN or CVM

turns down a recommendation based on the use of a modification of a PAM method, there is no recourse. Under the new model, an ad-hoc is convened to resolve the dispute between the Center and the district/laboratory.

Recommendation:

21. Create and utilize Science Dispute Resolution process based on the ad-hoc procedures described in RPM Chapter 10.

The Committee recommends this very highly. The Science Dispute Resolution will follow the RPM procedures, with the director of the committee appointed by the ACRA. The ad-hoc will consist of the Regional Food and Drug Director (RFDD), the Director for Compliance, CFSAN/CVM, appropriate CFSAN/CVM program office directors or designees, and appropriate laboratory and district office representatives.

As described in RPM Chapter 10, all decisions of the ad-hoc committee, including any necessary follow-up actions, will be recorded and disseminated by an assigned person on the ad-hoc committee.

VI. SUMMARY/CONCLUSIONS

A. SUMMARY

The newly designed internal review process afforded the Committee a comprehensive review of the Pesticide & Industrial Chemical Program for FY 2001 and subsequent years. From the review, 39 recommendations were identified and are presented in this report for management consideration. The report identified 18 recommendations in Program Management and 21 recommendations in Science.

The recommendations target one or more of the Committee's review objectives outlined in the process:

- ?? Quality of Science across our organization in program planning, inspections, investigations, laboratory analysis, regulatory actions, and quality management systems;
- ?? Adequacy of resources, skills & expertise, technologies, and organizational structure;
- ?? Mission relevance; and,
- ?? Adequacy and currency of program guidance and policy.

A number of recommendations from the Program Management and Science reviews overlap or affect multiple objectives. For example, the recommendation to revive the Pesticide Coordination Team would have major impacts on all four objectives. It provides leadership and direction, enhances and fortifies communications between field offices, and provides a means to introduce enhanced procedures, new technologies and new science through updated methods.

Quality of Science

More than half the recommendations (21/39) focus on the quality of science. Opportunities to improve the science, take advantage of emerging laboratory technologies, as well as evaluate data reporting and dissemination of policies and procedures to drive consistency were identified. These factors provided a foundation for the pesticide program and proved to be a success as the program evolved during the 1980s, culminating in the Pesticide Monitoring Improvement Act in 1988. Our previous successes have waned, with our attention being drawn to other priorities in the recent past. Quality Management Systems and ISO 17025 Accreditation, on the rise in ORA, are systems that foster consistency and allow for continuous improvement and feedback. ORA's commitment to these efforts through the implementation of the recommendations will provide a solid foundation and use best practices in advancing our science.

Adequacy of Resources, Skills and Expertise, Technologies, and Organizational Structure

Sixteen of the recommendations focus on enhancements or better utilization of resources currently available in field laboratories. As with other programs in FDA, the Pesticide & Industrial Chemical Programs have cycled through abundant and lean years of resources. Succession planning was always a part of the FDA culture as the next generation was planted and grown in field organizations. In the early development of the program, most of the technical expertise and research took place in the Centers, then was communicated to field laboratories. With the turnover in personnel and as programs decline, much of the expertise and program knowledge now resides in the field organizations. With a well coordinated and thought out program designed to bring new science into our field laboratories, expertise will be developed and enhanced. Work planning to execute compliance programs effectively through targeted and timed sampling programs allowing for batching samples and maximizing laboratory automation was a recurrent theme throughout the process.

Mission Relevance

A smaller number of recommendations focus on mission relevance. Many were tied to assuring program policy and guidance are current. Main themes included sharing all pesticide-use information, fostering communications with EPA and others, to provide improved consumer protection strategies, establishing a Pesticide Steering Committee to address national program issues, and creating a National Pesticide Expert position within ORA.

Adequacy and Currency of Program Guidance and Policy

One quarter of the recommendations addressed this objective, but also included items that fell into one or more objectives mentioned above. The most prevalent and compelling theme in this objective was revising the Compliance Program, Compliance Policy Guides, development of a regulatory structure for imports to take advantage of saving resources by using the "appearance of a violation" standard, and clarification of the "Perishable Policy" for Imports.

Based on the Committee's internal review of the Pesticide & Industrial Chemical Program, 39 recommendations have been identified and are presented for ORA management to evaluate and implement.

B. CONCLUSION

The Peer Review Process

During the course of this first ORA Peer Review study, the Committee developed several approaches to evaluate the success and identify the flaws in one of ORA's major programs. Initially, using a "fitness for use" strategy, we examined the data bank of work products available for review. Realizing a review of paper and data did not tell the whole story behind successes and failures over the years, the Committee delved more deeply into the history and evolution of the program. Most revealing were the initial discussions with those implementing the program. The Committee felt it was important to not just look at what we had done, but gain a greater understanding of what field offices understood they were expected to do and what they thought would improve mission accomplishment, and public health. The Committee developed a series of questions based on roles in the program. The combination of work product review and interviews garnered many ideas and revelations we feel are useful to ORA's desire to improve our ability to carry out our mission of consumer protection. The process developed in the last two years was very successful. It will be a useful process for future peer review studies.

When considering the pesticide program from a broad perspective, the Committee wanted to answer these questions: Did decisions, policies, procedures, and program activities have the intended effect, impact or outcome? Did ORA consistently achieve intended consumer protection outcomes as defined in the program or assignment? As previously mentioned, the answer is yes, to a degree. Although the program has diminished over the last several years in the shadow of other important programs, it is still effective in finding violations, intentional or unintentional, and clearly able to address them. However, some important aspects are not handled uniformly nor efficiently completed. We have lost ground as the sheer volume of domestic and imported foods continues to expand. However, the recommended changes can improve our ability substantially to meet the challenges before us.

VII. SUMMARY CHART

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#1	There is a serious need to update Compliance Programs (CPs) and Compliance Policy Guides (CPGs).	The last CPG was issued in 1995. At least one contradiction was found between the CP and the CPG. CP was last issued in 2000. Significant procedural changes have been made by memo, but not incorporated into the document.	Update and issue current guidance in both the CPs and applicable CPGs following the recommendations in this report.	M		OE, CFSAN, CVM
#2	Field staff is not always aware of contents of the CPs.	In several site visits, field personnel expressed frustration at the lack of compliance follow-up guidance for the dioxin program. The CP clearly states the program is surveillance only, with no regulatory enforcement.	The Committee recommends ORA's Division of Human Resource Development (DHRD) develop a training module for the on-line ORA University to explain structure and function of CPs.	M		CFSAN
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#3	Sampling instructions in CP may not appropriately direct field staff to sample highest risk produce or to sampling sites with highest impact.	Sampling small growers and roadside stands has little impact, and may not support I.S. commerce. Sampling retail groceries and distribution centers would allow sample collections throughout the year at any location and provide means to ensure more uniform sample flow to laboratories.	The domestic CP should be revised to alter directions on sampling sites. In addition, it should allow sampling of imported produce already in domestic commerce which, historically, have a higher violation rate.	M		CFSAN
#4	The import CP should be updated to include all policy and procedural changes. The CP should increase the number of import sample collections.	The current import CP is outdated and still being used. The CP needs to further reflect the higher violation rate associated with imported produce through transfer of sampling/analytical resources from the domestic program.	The diversion of field resources from the domestic to the import program should be made concurrent with the recommended re-issuance of the import CP.	M		DFS, DIOP
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#5	Currently, there is no dissemination of pesticide usage data in foreign countries to laboratories performing pesticide analysis.	Field offices need data on pesticide usage in foreign countries for effective and systemic pesticide coverage.	ORA HQ and CFSAN obtain, organize, and disseminate pesticide use data to the field.	M		DFS, CFSAN
#6	The basis for the former “Perishable Policy” is no longer operative.	There is much confusion in field offices concerning the “Perishable Policy.” Some field offices still refer to this policy, while others do not. It has not been included in the revised RPM in either 1997 or 2004.	OE and DIOP should review the need for a Perishable Policy and establish it, as warranted.	M		OE, DIOP
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues					TARGET DATE	LEAD OFFICE
(Cross reference recommendations within Program Management or Science Sections)						
No.	Issue	Finding	Recommendation	M or S		
#7	An “appearance of a violation” is the standard in the Act applied to administrative refusal of imported product.	Current policy outlined in guidance documents calls for both quantitation of the pesticide when no tolerance exists, plus performing a quantitative check analysis for both “no tolerance” and “exceeds tolerance” findings for each pesticide violation found. This practice not only diverts limited laboratory resources from testing additional lots, it delays administrative action against future shipments of the same product from the same grower, which is likely to exhibit the same pesticide violation.	Develop a regulatory structure for imports to take advantage of resource savings achieved using the “appearance of a violation” standard in Section 801 of the Federal Food, Drug, and Cosmetic Act.	M		OE, DIOP
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#8	There is unacceptable lag time in issuance of new or updating existing Import Alerts for pesticide violations.	Delays to apply timely policy of Detention without Physical Examination (DWPE) on subsequent import entries of the same product from the same source divert limited inspectional and laboratory resources to continually sample and test products from subsequent entries.	OE and DIOP coordinate review of current policy and procedures for placing imported produce found violative for unapproved pesticide residues onto Import Alerts.	M		OE, DIOP
#9	Import Alerts employ a “pesticide specific” violation charge.	To overcome an “appearance of a violation” on future shipments, it is only necessary to test for presence of the specific pesticide for which product previously was found violative. The use of multi-residue methods normally employed in FDA surveillance is not required.	OE and DIOP review utility of the “pesticide specific” charge currently being used on Import Alerts.	M		OE, DIOP, CFSAN

M = Management; S = Science

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#10	FMD #129 directs FDA to share violative pesticide residue data with EPA.	<p>With the decline in Pesticide Compliance Teams (PCTs) in each District, FMD #129 seldom is followed.</p> <p>The majority of Districts contacted routinely did not notify the Federal or State EPA when sample analysis indicated possible misuse of pesticides.</p>	The Committee recommends the Deputy ACRA, as soon as possible, issue a memo to all field offices regarding the need to comply with FMD #129 and share violative pesticide residue data with EPA.	M		Deputy ACRA
#11	Functioning PCTs are a valuable tool to focus FDA's surveillance sampling for pesticides on properly risk-based, targeted product. They also, via improved advance communication with servicing laboratories, would aid in eliminating laboratory backlogs that unnecessarily delay analysis of produce.	PCTs no longer are present in most District offices. Many disbanded when FDA's laboratories consolidated.	ORO develop an outline of functions for field PCTs to follow with respect to the current environment of national databases and distant servicing laboratories.	M		ORO
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#12	Same as #11.	Same as #11.	PCTs performing newly established functions be established in each District by FY-06.	M		ORO, District Offices
#13	Dual reporting requirements are time consuming, redundant, and add no value.	Frequently, Centers mandate special reporting requirements beyond ORA FACTS or OASIS systems in the Special Assignments. These requirements ask for information found in FACTS or OASIS, and appear to be designed to allow Centers to obtain data in a manner with which they are most familiar. This practice is not an exclusive problem with special assignments.	The Committee recommends FFC, CVM Committee, and ORO critically evaluate all requests for data reporting outside of the FACTS or OASIS systems.	M		FFC, CVM Committee, ORO

M = Management; S = Science

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#14	Same as for #13.	Same as for #13.	DHRD should offer additional training on the FACTS and OASIS systems so CFSAN and CVM can access needed data from the systems and avoid duplication of data reporting by field offices.	M		DHRD, CFSAN, CVM
#15	There is a notable and distressing lack of real time evaluation and feedback on findings of the Pesticide and Chemical Contaminants CPs.	There is a need for local District offices, in order to meet the expectations of the CP, to incorporate information of pesticide usage, both domestic and foreign, in their local sampling programs. One of the most important sources of such information is the FDA monitoring program. The most current report on the Agency Pesticide Program includes FY-01 findings.	ORO work with CFSAN to assure timely issuance of an annual pesticide report for use by field staff to direct sampling of agricultural products for pesticide use.	M		ORO, CFSAN
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#16	Same as #15.	Same as #15.	ORO organize and disseminate all ORA-generated information on pesticide violations to assure staff have the information necessary to direct local sampling plans.	M		ORO
#17	There is no single point of contact for ORA field offices to obtain guidance on current policy interpretation.	All field offices interviewed expressed frustration with their ability to obtain timely guidance on investigational, regulatory, and compliance issues involving Pesticide and Chemical Contaminants Programs and to coordinate regulatory response and develop policy, when necessary. Field offices indicated difficulty in obtaining guidance from either ORA or Centers on new or unusual issues.	Designate specific individual in OE as ORA's clearinghouse for all policy and regulatory issues involving the Pesticide and Chemical Contaminants Program.	M		ORA/OE
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues					TARGET DATE	LEAD OFFICE
(Cross reference recommendations within Program Management or Science Sections)						
No.	Issue	Finding	Recommendation	M or S		
#18	Standards of which records to maintain to document compliance actions, out of compliance situations, etc., are unclear. The need to establish such standards is especially acute in this era of increased field automation and retrievable databases.	The Committee found problems retrieving records to review. Varying degrees of documentation are maintained by different Districts, indicating a need to establish minimum standards FDA Districts must maintain in either paper format or electronically.	The Deputy ACRA create a multi-disciplinary task force, including a Quality Management Systems representative, to review and establish standards to document and maintain records for in-compliance situations.	M		Deputy ACRA
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues					TARGET DATE	LEAD OFFICE
(Cross reference recommendations within Program Management or Science Sections)						
No.	Issue	Finding	Recommendation	M or S		
#1	ORA needs to fully utilize the knowledge and experience of its field analysts when national program issues are under discussion.	There is loss of leadership in the pesticide area due to retirement of top pesticide program specialists, and the shift in program priorities. Yet, considerable expertise still exists, which should be utilized in a more formal manner.	Establish a Pesticide Steering Committee (PSC) to address national program issues.	S		DFS, District Offices
#2	Function of the former Pesticide Research Center no longer exists in a formal manner.	A need exists for a research scientist to conduct research, direct other research, coordinate validation of methods, and provide program input and guidance.	Create a National Pesticide Expert within ORA.	S		DFS
#3	Rapid advances are being made in pesticide extraction and detection methods. These methods generally are incorporated into official regulatory procedures.	ORA laboratories are incorporating modern techniques into their procedures, and submitting them in analytical packages.	The PSC must facilitate continued incorporation of state-of-the-art pesticide methodology into official regulatory procedures.	S		DFS, Field Laboratories (PSC)
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#4	ISO 17025 requires analytical records be readily retrievable; questions exist as to whether the analytical worksheet or the FACTS record is considered the official regulatory analytical record.	Analytical records requested by the Committee for review often were incomplete or missing in field offices. Record retention and analytical results communication procedures were inconsistent among field laboratories and offices.	Establish procedures for retention of analytical records in the analyzing laboratory; establish FACTS sample summary as the official regulatory analytical record.	S		DFS/OE
#5	Current policies requiring original and check analyses, plus extensive quantitation on “no-tolerance” pesticides result in excessive delays.	There can be ten-fold increase in analytical time for samples containing “no tolerance” residues, due to current policies requiring extensive quantitative determination plus check analysis. Identity confirmation is the critical issue; quantitation for “no tolerance” pesticides should be limited to determination of presence above the Limit of Quantitation (LOQ).	Review requirements in the CPG for quantitation requirements and check analyses for samples containing “no tolerance” pesticides, as well as pesticides with a tolerance. This would be part of the review and revision recommended in Section IV of Program Management.	S		DFS/OE

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Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#6	Domestic pesticide samples, currently done in all laboratories, no longer receive priority focus as compared to import samples, yet are still important for various reasons.	Domestic pesticide samples are given low priority for collection and analysis, compared to import samples, and often are not screened for all classes of pesticides due to resource issues.	Consolidate all domestic pesticide analyses in two laboratories: Arkansas Regional Laboratory (ARL) for food samples and Kansas City District Laboratory (KAN) for feed samples.	S		DFS, DPEM
#7	Consolidation of import sample analysis and batching samples could lead to increased efficiency and reductions in sample turnaround time.	All pesticide labs, except KAN, have an import pesticide workplan, as well as a domestic workplan. Sample output often suffers.	Consolidate all import pesticide analyses in four laboratories: Northeast Regional Lab (NRL), Southeast Regional Lab (SRL), Pacific Regional Lab Southwest (PRL-SW), and Pacific Regional Lab Northwest (PRL-NW). Shift existing import workload from ARL to PRL-SW.	S		DFS, DPEM
#8	Domestic “Statistical Sampling Assignments” and “Special Emphasis Surveys” have been eliminated.	The domestic pesticide produce sampling plan is not flexible and promotes sampling low risk commodities.	Develop a national sampling plan for domestic produce targeting specific commodities for coverage each year and focus collections on a limited time period.	S		CFSAN

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Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
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#9	The domestic pesticide program does not include collection of import products in domestic commerce.	Import food products in domestic commerce may contain pesticides. However, the domestic pesticide program does not allow for collection of import produce in domestic commerce.	Reinitiate statistical sampling surveys to include import products collected in domestic commerce.	S		CFSAN
#10	FDA needs to improve coordination with EPA in sharing residue data.	FDA should refocus the pesticide program to utilize EPA risk analysis data for selection of commodities to be sampled.	Focus the program in consultation with EPA to provide risk analysis data necessary for tolerance reassessment.	S		DFS/OE/CF SAN
#11	Traditional instrument acquisition procedures have resulted in a wide variety of instrument configurations in various laboratories.	In 2000, FDA established a new paradigm for instrument acquisition, in which DFS and senior analysts agreed upon a single configuration from a single vendor. This resulted in a significant cost savings, plus benefits from consolidated training and sharing of experiences among analysts.	PSC should determine configurations of equipment to be used in all pesticide laboratories, utilizing group purchases, whenever possible.	S		DFS/Field Laboratories (PSC)

M = Management; S = Science

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#12	Service contracts rarely are purchased for instrumentation in ORA laboratories. Service expenses are funded from laboratory operating budgets.	The most complex modern instrumentation is very costly to maintain and repair, causing a major strain on laboratory operating budgets.	Negotiate and fund service contracts for complex instrumentation.	S		DFS
#13	Full utilization of automation can offer major benefits, including 24-hour processing of sample extracts. Enhanced efficiency should result.	Autoinjectors are now standard equipment on chromatographs of all types. The Committee observed this capability is underutilized in some field laboratories.	The PSC, in development of national protocols, should maximize automation capabilities of instrumentation.	S		DFS/Field Laboratories (PSC)
#14	The Pesticide Analytical Manual (PAM) is referenced in the CFR as an official source of regulatory pesticides. PAM I, which contains the multi-residue methods, is outdated.	Laboratories, typically, now use methods incorporating more modern extraction and determinative techniques to improve efficiency and increase coverage of additional classes of pesticides.	Initiate fast-track process for updating PAM I with methods and techniques currently used in FDA laboratories.	S		DFS
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#15	PAM I includes chapters on general techniques, such as “Gas Chromotagraphy.” Up-to-date textbooks on such general techniques are available commercially and available to analysts, when needed.	General chapters in the PAM are not up-to-date, and even if up-to-date, are not considered valuable.	Refocus PAM I as a methods manual, eliminating textbook chapters on general technologies.	S		CFSAN, DFS
#16	PAM I methods do not allow adjustment of instrument parameters, as can be required in certain specific instances.	Issues can occur with specific samples, such as co-eluting pesticide or matrix interferences. These problems often can be readily resolved by adjustment of instrument operating parameters.	Establish critical limits for adjusting operating parameters when focusing on individual pesticides.	S		CFSAN, DFS
#17	PAMs I and II are not updated on a scheduled basis.	PAMs I and II need scheduled annual updates, similar to updates to the Investigations Operations Manual (IOM) or RPM.	Establish schedule for routine updates of both PAM volumes.	S		CFSAN, DFS

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Pesticide and Industrial Chemical Program Management and Science Issues (Cross reference recommendations within Program Management or Science Sections)					TARGET DATE	LEAD OFFICE
No.	Issue	Finding	Recommendation	M or S		
#18	The ORA dioxin laboratories (ARL and KAN) do not perform research function in this area.	Dioxin methods provided to the two ORA dioxin laboratories often require extensive modification before they can be used. Opportunities exist for additional research and method evaluation to approve efficiency, as well as coverage of additional compounds.	Establish a research effort for dioxin method development at ARL.	S		DFS, ARL
#19	The decision to establish a back-up laboratory for dioxin analysis was made several years ago. Due to funding issues, this laboratory was not fully equipped with state-of-the-art instrumentation for this program	Due to its lack of a high-resolution mass spectrometer, KAN must ship many of its samples to ARL to achieve the needed sensitivity provided by this instrument.	Reaffirm need for a second dioxin analytical laboratory at KAN, and equip the laboratory appropriately with state-of-the-art technology.	S		DFS
#20	Total Diet Study (TDS) is well-run and managed, but some methods could be updated to include additional classes of compounds.	GC-MSD methods are not incorporated into TDS procedures.	Implement the GC-MSD method in the TDS.	S		
M = Management; S = Science						

Pesticide and Industrial Chemical Program Management and Science Issues					TARGET DATE	LEAD OFFICE
(Cross reference recommendations within Program Management or Science Sections)						
No.	Issue	Finding	Recommendation	M or S		
#21	If a recommended regulatory action is overruled by CFSAN or CVM, ORA has no recourse on the decision.	Currently, there is no formal mechanism to resolve conflicts on laboratory issues between ORA and CVM or CFSAN.	Create and utilize a Science Dispute Resolution process based on the Ad-Hoc procedures described in RPM Chapter 10.	S		DFS, OE, CFSAN, CVM
M = Management; S = Science						

VIII. ATTACHMENTS

(This page still under construction)

CONCUR _____ NONCONCUR _____ DATE _____

John M. Taylor, III
Associate Commissioner for Regulatory Affairs