

PN-ADC-654

**Supporting
Egypt's
Processed
Foods
Export
Industry**

**Pesticide
Safeguards on
Foods Imported
into the USA**

**Action Levels for
Poisonous or
Deleterious
Substances in
Food, Including a
Private Laboratory
Procedure Manual**

**Annexure to a set of
XII Volumes**

**Prepared By
Agriculture-Led
Export Businesses
(ALEB)**

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Copies of the Compliance Policy Guides (CPG) referenced in the action level list may be purchased from:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161
Telephone (703) 605-6000
Order number: PB97 915 400

FDA's Compliance Policy Guides are accessible via the Internet:

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Substance

Aflatoxin
Aldrin & Dieldrin
Benzene Hexachloride
Cadmium
Chlordane
Chlordecone (Kepone)
Dicofol (Kelthane)
DDT, DDE, TDE
Dimethylnitrosamine (Nitrosodimethylamine)
Ethylene Dibromide (EDB)
Heptachlor & Heptachlor Epoxide
Lead
Lindane
Mercury
Methyl Alcohol
Mirex
N-Nitrosamines
Paralytic Shellfish Toxin
Polychlorinated Biphenyls (PCBs)

ALDRIN & DIELDRIN

Commodity^a	Action Level (ppm)	Reference
Alfalfa	0.03	CPG 575.100
Animal feed, processed	0.03	CPG 575.100
Artichokes	0.05	CPG 575.100
Asparagus	0.03	CPG 575.100
Bananas	0.02	CPG 575.100
Beets (garden and sugar)	0.1	CPG 575.100
Beet tops (garden and sugar)	0.05	CPG 575.100
Broccoli	0.03	CPG 575.100
Brussel sprouts	0.03	CPG 575.100
Bulb vegetables	0.1	CPG 575.100
Cabbage	0.03	CPG 575.100
Carrots	0.1	CPG 575.100
Cauliflower	0.03	CPG 575.100
Cereal grains (except buckwheat, millet, teosinte, and wild rice)	0.02	CPG 575.100
Celery	0.03	CPG 575.100
Clover	0.03	CPG 575.100
Collards	0.05	CPG 575.100
Cowpea hay	0.03	CPG 575.100
Cucumbers	0.1	CPG 575.100
Eggplant	0.05	CPG 575.100
Eggs	0.03	CPG 575.100
Endive (escarole)	0.05	CPG 575.100
Fats and oils (animal feed)	0.3	CPG 575.100

ALDRIN & DIELDRIN, Cont'd.

Commodity^a	Action Level (ppm)	Reference
Peanuts	0.05	CPG 575.100
Peanut hay	0.03	CPG 575.100
Peppers	0.05	CPG 575.100
Pimentos	0.05	CPG 575.100
Pineapple	0.03	CPG 575.100
Pome fruits (except crabapples and loquats)	0.03	CPG 575.100
Potatoes	0.1	CPG 575.100
Radishes	0.1	CPG 575.100
Radish tops	0.03	CPG 575.100
Rutabagas	0.1	CPG 575.100
Salsify roots	0.1	CPG 575.100
Salsify tops	0.05	CPG 575.100
Small fruits and berries	0.05	CPG 575.100
Soybean hay	0.03	CPG 575.100
Spinach	0.05	CPG 575.100
Squash	0.1	CPG 575.100
Stone fruits (except Chickasaw, Damson, Japanese plums, and peaches)	0.03	CPG 575.100
Sugarbeet pulp (animal feed)	0.1	CPG 575.100
Sweet potatoes	0.1	CPG 575.100
Swiss chard	0.05	CPG 575.100
Tangerines	0.02	CPG 575.100
Tomatoes	0.05	CPG 575.100
Turnips	0.1	CPG 575.100

BENZENE HEXACHLORIDE (BHC)

Commodity^a	Action Level (ppm)	Reference
Animal feed, processed	0.05	CPG 575.100
Apples	0.05	CPG 575.100
Asparagus	0.05	CPG 575.100
Avocados	0.05	CPG 575.100
Beans	0.05	CPG 575.100
<i>Brassica</i> (cole) leafy vegetables (except broccoli raab, and rape greens)	0.05	CPG 575.100
Celery	0.05	CPG 575.100
Carrots	0.3	CPG 575.100
Cereal grains (except buckwheat, millet, popcorn, teosinte, and wild rice)	0.05	CPG 575.100
Citrus fruits	0.05	CPG 575.100
Cocoa beans	0.5	CPG 575.100
Cucurbit vegetables (except Balsam pears, Chinese wax gourds, gherkins, and gourds)	0.05	CPG 575.100
Eggplant	0.05	CPG 575.100
Eggs	0.05	CPG 575.100
Endive	0.05	CPG 575.100
Figs	0.05	CPG 575.100
Frog legs (edible portion)	0.3	CPG 575.100
Guavas	0.05	CPG 575.100
Hays (animal feed)	0.05	CPG 575.100
Lettuce	0.05	CPG 575.100
Mangoes	0.05	CPG 575.100

CADMIUM

Commodity	Action Level ($\mu\text{g}/\text{mL}$ leaching solution)	Reference
Pottery (ceramics)		
Flatware (average of 6 units)	0.5	CPG 545.400
Small hollowware (any 1 of 6 units)	0.5	CPG 545.400
Large hollowware (any 1 of 6 units)	0.25	CPG 545.400

CHLORDANE

Commodity ^a	Action Level (ppm)	Reference
Animal fat, rendered	0.3	CPG 575.100
Animal feed, processed	0.1	CPG 575.100
Asparagus	0.1	CPG 575.100
Bananas	0.1	CPG 575.100
Beans	0.1	CPG 575.100
Beets (with or without tops)	0.1	CPG 575.100
Beet greens	0.1	CPG 575.100
<i>Brassica</i> (cole) leafy vegetables (except broccoli raab, Chinese mustard cabbage, and rape greens)	0.1	CPG 575.100
Carrots	0.1	CPG 575.100
Celery	0.1	CPG 575.100
Citrus fruits	0.1	CPG 575.100
Corn	0.1	CPG 575.100
Cucumbers	0.1	CPG 575.100
Eggplant	0.1	CPG 575.100
Fish	0.3 (edible portion)	CPG 575.100
Lettuce	0.1	CPG 575.100
Melons	0.1	CPG 575.100
Okra	0.1	CPG 575.100
Onions	0.1	CPG 575.100
Papayas	0.1	CPG 575.100
Parsnips	0.1	CPG 575.100
Peanuts	0.1	CPG 575.100

CHLORDANE, Cont'd.

Commodity ^a	Action Level (ppm)	Reference
Peas	0.1	CPG 575.100
Peppers	0.1	CPG 575.100
Pineapple	0.1	CPG 575.100
Pome fruits (except crabapples and loquats)	0.1	CPG 575.100
Potatoes	0.1	CPG 575.100
Radishes (with or without tops)	0.1	CPG 575.100
Radish tops	0.1	CPG 575.100
Rutabagas (with or without tops)	0.1	CPG 575.100
Rutabaga tops	0.1	CPG 575.100
Small fruits and berries (except cranberries, currants, elderberries, gooseberries, and olallie berries)	0.1	CPG 575.100
Spinach	0.1	CPG 575.100
Squash	0.1	CPG 575.100
Stone fruits (except Chicasaw, Damson, and Japanese plums)	0.1	CPG 575.100
Sweet potatoes	0.1	CPG 575.100
Swiss chard	0.1	CPG 575.100
Tomatoes	0.1	CPG 575.100
Turnips (with or without tops)	0.1	CPG 575.100
Turnip greens	0.1	CPG 575.100

The listed action levels are for residues of chlordane, including *cis*- and *trans*-chlordane, *cis*- and *trans*-nonachlor, oxychlordane, alpha-, beta-, and gamma-chlordene, and chlordene. Levels of individual components must be quantitated at 0.02 ppm or above and confirmed in order to be added into the "chlordane" total value.

The GLC pattern of the residue determines which reference standard(s) will be used for quantitation. If the residue pattern matches that of technical chlordane, quantitate against a technical chlordane reference standard. If the residue consists of identifiable individual

components (i.e., *cis*- and *trans*-chlordane, *cis*- and *trans*-nonachlor, oxychlordane, alpha-, beta-, and gamma-chlordene, and chlordene), quantitate individual components against their respective standards. Sum individual values to obtain the total "chlordane" level. Do not include levels of heptachlor epoxide in the summation.

(*) Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f), unless an exception is noted.

CHLORDECONE

(Decachlorooctahydro-1,3,4-methano-2H-cyclobuta(cd)pentale~~n~~-2-one)
 (Previously listed as "Kepone," the trade name for chlordec one)

Commodity	Action Level (ppm)	Reference
Crabmeat	0.4 (edible portion)	CPG 575.100
Fish and shellfish	0.3 (edible portion)	CPG 575.100

DICOFOL

(1,1-Bis(p-chlorophenyl)-2,2,2,-trichloroethanol)
 (Previously listed as "Kelthane," the trade name for dicofol)

Commodity	Action Level (ppm)	Reference
Animal feed, processed	0.5	CPG 575.100

DDT, DDE, & TDE

Commodity^a	Action Level (ppm)	Reference
Animal feed, processed	0.5	CPG 575.100
Artichokes	0.5	CPG 575.100
Asparagus	0.5	CPG 575.100
Avocados	0.2	CPG 575.100
Beets (roots and tops)	0.2	CPG 575.100
<i>Brassica</i> (cole) leafy vegetables (except broccoli raab, Chinese mustard cabbage, and rape greens)	0.5	CPG 575.100
Carrots	3	CPG 575.100
Cereal grains (except buckwheat, fresh sweetcorn, millet, popcorn, teosinte, and wild rice)	0.5	CPG 575.100
Celery	0.5	CPG 575.100
Citrus fruits	0.1	CPG 575.100
Cocoa beans	1	CPG 575.100
Corn, fresh sweet	0.1	CPG 575.100
Cottonseed	0.1	CPG 575.100
Cucumbers	0.1	CPG 575.100
Eggplant	0.1	CPG 575.100
Eggs	0.5	CPG 575.100
Endive (escarole)	0.5	CPG 575.100
Fish	5 (edible portion)	CPG 575.100
Grapes	0.05	CPG 575.100
Guavas	0.2	CPG 575.100
Hay	0.5	CPG 575.100
Hops	0.1	CPG 575.100

DDT, DDE, & TDE, Cont'd.

Commodity^a	Action Level (ppm)	Reference
Legume vegetables (except guar, jackbeans, lablab beans, and lentils)	0.2	CPG 575.100
Lettuce	0.5	CPG 575.100
Mangoes	0.2	CPG 575.100
Melons	0.1	CPG 575.100
Milk	1.25 (fat basis)	CPG 575.100
Mushrooms	0.5	CPG 575.100
Okra	0.2	CPG 575.100
Onions (dry bulb)	0.2	CPG 575.100
Papayas	0.2	CPG 575.100
Parsnips (roots and tops)	0.2	CPG 575.100
Peanuts	0.2	CPG 575.100
Peppermint hay	0.5	CPG 575.100
Peppermint oil	1	CPG 575.100
Peppers	0.1	CPG 575.100
Pineapples	0.2	CPG 575.100
Pome fruits (except crabapples and loquats)	0.1	CPG 575.100
Potatoes	1	CPG 575.100
Radishes (roots and tops)	0.2	CPG 575.100
Rutabagas (roots and tops)	0.2	CPG 575.100
Small fruits and berries (except elderberries, grapes and olallie berries)	0.1	CPG 575.100
Soybean oil (crude)	1	CPG 575.100
Spearmint hay	0.5	CPG 575.100

DDT, DDE, & TDE, Cont'd.

Commodity^a	Action Level (ppm)	Reference
Spearmint oil	1	CPG 575.100
Spinach	0.5	CPG 575.100
Squash	0.1	CPG 575.100
Stone fruits (except Chickasaw, Damson, and Japanese plums)	0.2	CPG 575.100
Sweet potatoes	1	CPG 575.100
Swiss chard	0.5	CPG 575.100
Tomatoes	0.05	CPG 575.100
Tomato pomace	0.5	CPG 575.100
Turnips (roots and tops)	0.2	CPG 575.100

The listed action levels are for residues of the above pesticides individually, or in combination. However, in adding amounts of DDT, DDE and TDE, do not count any of the three found below 0.02 ppm for non-fatty food, and 0.2 ppm for fish, eggs, and grains.

(^a) Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f), unless an exception is noted.

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DIMETHYLNITROSAMINE (NITROSODIMETHYLAMINE)

Commodity	Action Level (ppb)	Reference
Barley malt	10	CPG 578.500
Malt beverages	5	CPG 510.600

ETHYLENE DIBROMIDE (EDB)

Commodity^a	Action Level (ppb)	Reference
Grain products, intermediate (milled), must be cooked prior to consumption	150	CPG 575.100
Grain products, ready-to-eat (cooked), require no cooking prior to consumption	30	CPG 575.100
Honey, ready-to-eat (will not undergo further processing prior to consumption)	30	CPG 575.100
Fish	0.3 (edible portion)	CPG 575.100
Fruiting vegetables	0.01	CPG 575.100
Grass forage, fodder, and hay	0.01	CPG 575.100
Leafy vegetables (except <i>Brassica</i>)	0.01	CPG 575.100
Legume vegetables	0.01	CPG 575.100
Milk	0.1 (fat basis)	CPG 575.100
Nongrass animal feeds	0.01	CPG 575.100
Peanuts	0.01	CPG 575.100
Pineapple	0.02	CPG 575.100

(^a) Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f).

HEPTACHLOR AND HEPTACHLOR EPOXIDE

Commodity ^a	Action Level (ppm)	Reference
Animal feed, processed	0.01	CPG 575.100
Artichokes	0.01	CPG 575.100
Asparagus	0.01	CPG 575.100
<i>Brassica</i> (cole) leafy vegetables	0.01	CPG 575.100
Bulb vegetables	0.01	CPG 575.100
Cereal grains	0.01	CPG 575.100
Citrus fruits	0.01	CPG 575.100
Cottonseed	0.02	CPG 575.100
Cucurbit vegetables	0.02	CPG 575.100
Eggs	0.01	CPG 575.100
Figs	0.01	CPG 575.100
Fish	0.3 (edible portion)	CPG 575.100
Fruiting vegetables	0.01	CPG 575.100
Grass forage, fodder, and hay	0.01	CPG 575.100
Leafy vegetables (except <i>Brassica</i>)	0.01	CPG 575.100
Legume vegetables	0.01	CPG 575.100
Milk	0.1 (fat basis)	CPG 575.100
Nongrass animal feeds	0.01	CPG 575.100
Peanuts	0.01	CPG 575.100
Pineapple	0.02	CPG 575.100
Pome fruits	0.01	CPG 575.100
Rabbit	0.2 (fat basis) ^b	CPG 575.100
Root and tuber vegetables	0.01	CPG 575.100
Salsify tops	0.01	CPG 575.100

HEPTACHLOR AND HEPTACHLOR EPOXIDE, Cont'd.

Commodity^a	Action Level (ppm)	Reference
Small fruits and berries	0.01	CPG 575.100
Stone fruits	0.01	CPG 575.100
Sugarcane	0.01	CPG 575.100

The listed figures are for residues of the pesticide and its metabolite individually or in combination. However, do not count heptachlor or heptachlor epoxide found at a level below 0.1 ppm for fish, 0.05 ppm (fat basis) for milk, and 0.01 ppm for nonfatty foods.

(^a) Action levels for crop groups cover all commodities specified in 40 CFR 180.34(f).

(^b) For rabbits that contain insufficient fat to conduct an analysis on a fat basis, analyze the rabbits on a whole product basis (edible portion) and, assuming 10 percent fat content, use 0.02 ppm as the action level.

LEAD

Commodity	Action Level ($\mu\text{g/ml}$ leaching solution)	Reference
Ceramicware		
Flatware (average of 6 units)	3.0	CPG 545.450
Small hollowware (other than cups and mugs) (any 1 of 6 units)	2.0	CPG 545.450
Large hollowware (other than pitchers) (any 1 of 6 units)	1.0	CPG 545.450
Cups and mugs (any 1 of 6 units)	0.5	CPG 545.450
Pitchers (any 1 of 6 units)	0.5	CPG 545.450
Silver-plated hollowware		
Product intended for use by adults (average of 6 units)	7	CPG 545.500
Product intended for use by infants and children (any 1 of 6 units)	0.5	CPG 545.500

LINDANE

Commodity	Action Level (ppm)	Reference
Animal feed, processed	0.1	CPG 575.100
Artichokes	0.5	CPG 575.100
Barley	0.1	CPG 575.100
Beans	0.5	CPG 575.100
Citrus fruit(a)	0.5	CPG 575.100
Cocoa beans, whole raw bean	0.5	CPG 575.100
Corn, fresh sweet	0.5	CPG 575.100
Corn	0.1	CPG 575.100
Eggs	0.5	CPG 575.100
Endive	0.5	CPG 575.100
Figs	0.5	CPG 575.100
Hay	0.1	CPG 575.100
Milk	0.3 (fat basis)	CPG 575.100
Oats	0.1	CPG 575.100
Peas	0.5	CPG 575.100
Rice	0.1	CPG 575.100
Root vegetables ^{a,b}	0.5	CPG 575.100
Rye	0.1	CPG 575.100
Small fruits ^{a,b}	0.5	CPG 575.100
Sorghum (milo)	0.1	CPG 575.100
Turnip greens	0.5	CPG 575.100
Wheat	0.1	CPG 575.100

(^a) Refer to 40 CFR 180.34(f) for commodities covered by this food group.

(^b) Other than those commodities specified in 40 CFR 180.133.

MERCURY

Commodity	Action Level	Reference
Fish, shellfish, crustaceans, other aquatic animals (fresh, frozen or processed)	1 ppm methyl mercury in edible portion	CPG 540.600
Wheat (pink kernels only)	1 ppm on pink kernels and an average of 10 or more pink kernels/500 g	CPG 578.400

METHYL ALCOHOL

Commodity	Action Level (%)	Reference
Imported brandy	0.35	CPG 510.200

MIREX

Commodity	Action Level (ppm)	Reference
Fish	0.1 (edible portion)	CPG 575.100

N-NITROSAMINES

Commodity	Action Level (ppb)	Reference
Rubber baby bottle nipples	10	CPG 500.450

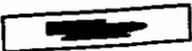
PARALYTIC SHELLFISH TOXIN

Commodity	Action Level	Reference
Clams, mussels, oysters (fresh, frozen, and canned)	80 µg/100 g meat	CPG 540.250

POLYCHLORINATED BIPHENYLS (PCB'S)

Commodity	Action Level (ppm)	Reference
Red meat	3 (fat basis)	CPG 565.200

Industry Activities Staff Booklet: March 1998



Hypertext updated by j3b/dms/rwk/ear 1998-AUG-10

15. Mycotoxin Analysis Training

16. Drug Analysis Training

17. Pesticide Residue Analysis Training

18. Entomologist Training

19. Microbiologist Training

20. Engineer Training

21. Private Laboratories

22. Courtroom Testimony

CHAPTER 21

GUIDANCE ON THE REVIEW OF ANALYTICAL DATA GENERATED BY PRIVATE LABORATORIES

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21.6	<u>REPORTING TO HOME DISTRICT</u>
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	<u>EXHIBIT 21-B ANALYSIS REPORT FORMAT</u>

21.1 Objective

To establish a uniform, systematic, and effective approach to assure that private laboratories conducting analyses on U.S. Food and Drug Administration (FDA) regulated commodities submit scientifically sound data. Although FDA has no legislative authority to directly regulate these private laboratories, this guidance is provided to ensure the scientific credibility of data submitted to the Agency.

21.2 Introduction

For many years, FDA has recognized the role of private testing laboratories in evaluating the quality and safety of FDA regulated commodities, both domestic and imported. Domestic firms whose product(s) is (are) under seizure by FDA may choose to file claim to their product and enter into a Consent Decree of Condemnation, with the goal of bringing their product(s) into compliance. The firm may contract the services of a private laboratory to assess the reconditioning of the product. Likewise, to resume operations, domestic firms under injunction may choose to use a private laboratory to evaluate and bring their product(s) into compliance. Increased scrutiny of import commodities and limitations on Agency resources are likely; therefore, enforcement efforts will be expedited by the use of scientifically sound data provided by private laboratories to determine if products should be allowed entry. Programs such as automatic detention have increased the use of private laboratories by importers/brokers. Under such programs, commodities are not permitted entry into the United States without scientific analytical data demonstrating compliance with U.S. federal laws and regulations. While in some instances this has alleviated the analytical workload on FDA district laboratories, review of data packages from private laboratories for scientific integrity continues to require increased resources, including audit analysis by FDA.

It is estimated that over 100 private laboratories are currently being used by importers/brokers to generate data for submission to FDA, with many doing work for more than one district. While this guidance is written in reference to private laboratories, it is really

the user of the private laboratory, the importer/broker or domestic firm, who is ultimately responsible for the commodities compliance with FDA laws and regulations. If a private laboratory does not provide acceptable evidence or documentation to support the credibility of its analyses, the importer/broker, individual, partnership, corporation, firm, etc. bears the responsibility and consequences of the inadequacy. Reliance on analytical data provided by private laboratories necessitates a uniform, systematic, and effective approach. FDA must be assured that scientific analytical data supplied by private laboratories is technically valid, has been obtained using sound methods of sampling and analysis, and has had recognized quality assurance and quality control activities applied that are acceptable to the Agency.

21.3 General Guidance

There are a number of steps that the district offices can take to facilitate assuring the credibility, accuracy, validity, and reliability of scientific analytical data from private laboratories.

For the sake of efficiency and historical perspective, the district offices may want to insure that it has certain information on file on each private laboratory that submits analytical packages to FDA. The information may come from visits to the private laboratory, brochures distributed by the laboratory describing its capabilities, or quality assurance manuals. Some examples of useful information to be gathered and retained follow:

--Types of analyses performed by the private laboratory on Fee regulated imported commodities. Such a list indicates the scope of their business and may assist in developing criteria to assess the laboratory's performance.

--Information concerning the background and training of the analysts in the laboratory. This information is helpful in assessing the capabilities of laboratory personnel.

--Equipment available for conducting the analyses. This aids in determining whether appropriate facilities and apparatus are available to perform the required methods.

--Information on the laboratory's internal quality control (QC) program (i.e., maintenance and calibration of equipment, standardization of solutions, etc.) and quality assurance (QA) programs (i.e. record keeping, audits, etc.). This information aids in evaluating the validity of analytical data generated by the laboratory.

--Information on a private laboratory's level of commitment and adherence to its written QA/QC programs. This would be demonstrated by existence of a written program and by the extent to which the staff effectively uses the program.

--Reports of FDA site visits. These reports are valuable to assess the level of consistency in performance by the private laboratory and to document observations that could not be made without a site visit.

If the district office cannot obtain the information it needs to appropriately review the scientific analytical data generated by the private laboratory, either directly from the laboratory or through the importer/broker or domestic firm, the analytical package will be considered incomplete. Without credible information, there is no way of assuring the scientific integrity of the data being submitted.

21.4 Sampling and Analytical Requirements

Samples for analysis must be collected to appropriately represent the lot. Ideally, sampling should be performed by a disinterested, objective, third party. If, in the judgment of the reviewing district office, the method of collection does not result in a representative sample, the analytical package would be rejected.

The importer/broker or domestic firm must submit an analytical package that contains documentation of the sampling scheme, method of collection and preservation (including storage conditions), analytical method(s), data generation, and certification (signatures and dates) of the procedures.

The district office should encourage the private laboratory to discuss with the appropriate district office staff the documentation format and any other information that, when submitted for review, would ensure the adequacy and validity of the data.

The analytical package will be reviewed by staff from the servicing science and compliance branches of the district office and headquarters office, as necessary to determine the validity of the reported analytical results. Analytical results will not be accepted if technically significant deficiencies exist. In some cases, the package may be returned to the private laboratory through the importer/broker or domestic firm for additional information before a final determination is made to accept or reject it.

21.5 Audit Samples, Site Visits, and Consultations

The district office may determine that an in-depth assessment is necessary to evaluate the capability and/or capacity of the laboratory to satisfactorily perform certain analyses. For example, the district office may wish (1) to observe that equipment to conduct the proposed analyses is available and in good operating order, (2) to review the adequacy of the laboratory's quality assurance and record-keeping programs, or (3) to observe the techniques and practices of the scientists and technicians during actual analysis. These information gathering activities provide a picture of the laboratory's capabilities. One way this can be accomplished is by conducting periodic audits of the analytical results through FDA sampling and analysis. District offices may base the frequency of audits on the following:

--History of prior audit checks of and contacts with the laboratory, including previous submissions to FDA.

--Experience of the laboratory and analysts in a particular technical area requiring special skills, such as organoleptic screening for decomposition of foods

--Comparison of the laboratory's reported results for a commodity with findings by FDA or other laboratories.

FDA laboratory and investigational workload should be considered in committing FDA resources to resolve issues with a private laboratory. While FDA should be helpful in providing guidance and advice, it is the responsibility of the importer/broker or domestic firm and the private laboratory to provide FDA with the documentation and assurance that is needed for regulatory decision-making.

Site visits should ideally occur when the analyses at issue can be observed, and should be

scheduled in advance with the private laboratory through the importer/broker or domestic firm whose shipment or lot is under review. While these visits are best accomplished through a team approach involving district or regional laboratory personnel, investigators and/or inspectors, the on-site visit can be conducted by experienced FDA laboratory personnel alone. In this case, the laboratory personnel should discuss the procedures with investigations and compliance branch staff prior to the visit.

Inviting the private laboratory's management to meet and discuss the issues or problems may facilitate their resolution. These contacts should be scheduled to ensure that effective decision-making is not delayed and resources are not overly taxed. The responsible broker/importer or domestic firm management should be notified and invited to such discussions as appropriate. The district office staff should provide the firms with clearly defined reasons why the analytical results are not acceptable and with the criteria that must be met for acceptance.

If the private laboratory either fails to provide documentation demonstrating the capability to produce technically sound data or declines to make it available, the district office should advise the private laboratory, as well as the importer/broker or domestic firm using its services, that its analytical data will not be accepted until the matter is satisfactorily resolved. When a specific analysis or all analyses from a laboratory are found to be deficient, the Division of Field Science (DFS), HFC-140, must be promptly notified in writing via EMS/FAX to allow notification of other district offices and headquarters. The DFS staff is available to provide guidance in resolving technical or other issues involving private laboratories and can assist in coordinating with other components of the Agency or FDA offices.

21.6 Reporting to Home District

When private laboratories do business or have facilities in several districts, it should be recognized that all sites may not have full service capabilities or equal performance. If a district office determines that a private laboratory does not produce consistently valid data, it is necessary to notify all district offices in which the laboratory operates, as well as the home district office, and the Division of Field Science. Records of significant Agency decisions relating to performance of a private laboratory must be sent to the home district office to keep them informed regarding the status of private laboratories in their jurisdiction. District offices should contact the home district office for information on a laboratory's capabilities. In addition, all formal dealings with a private laboratory should be coordinated through the home district office.

21.7 Reporting to Headquarters

The Division of Field Science will maintain and disseminate information on the acceptability of private laboratory analyses of FDA regulated commodities. Prior to determining that a laboratory's analytical data will not be accepted for certain analyses, the district office is encouraged to consult with DFS and other FDA offices. When a district office has determined that certain analyses performed by a private laboratory are unacceptable, the district office will promptly provide DFS with the following information:

--Name and address of the private laboratory, including all locations pertinent to the issue in question.

--Listing of each type of analysis of FDA regulated commodities performed by the laboratory for which FDA will not accept scientific analytical data.

--For rejected analytical packages, a listing of the methodology, date on which the rejection was communicated by FDA to the private laboratory, reason(s) for the rejection, analysts' names if appropriate, and any other relevant information.

The importer/broker or domestic firm should be kept informed by the district office of any direct contact between FDA and the private laboratory, particularly when deficiencies in analytical packages occur. Whenever analytical data from a specific analysis, or all analyses, performed by a particular private laboratory are not acceptable to a district office, that district office must notify DFS. Should the cause(s) of non-acceptance of certain private laboratory analytical packages be satisfactorily resolved, the private laboratory, importer/broker or domestic firm, and DFS must be notified.

DFS will communicate appropriate information to district offices and Headquarters regarding the acceptability status of private laboratories.

21.8 Review of Foreign Laboratories

When evaluating scientific data generated by a foreign private laboratory and submitted by an importer or broker, the same criteria as for domestic private laboratories should be used--sound scientific validity of the sampling and the subsequent analytical data generated. When a Memorandum of Understanding (MOU) or other formal agreement exists with a foreign country, review of their certificates of analysis for products should be in accord with the MOU, as well as with the principles of good science.

If the district office has information (such as audit sample results) demonstrating that the products are violative, the entry in question should be detained, despite certification, and the appropriate offices, such as the Division of Import Operations and Policy (DIOP), HFC-170, and DFS should be notified.

DIOP and DFS will work with the International Affairs Staff and the appropriate Center offices to resolve the problem.

21.9 Providing Guidelines to Private Laboratories

To facilitate complete, systematic, and consistent submissions of analytical packages, district offices may provide guidelines to brokers, importers, domestic firms, and private laboratories. It should be recognized that these are only guidelines and that the information requested must be based on sound regulatory science. There are numerous ways to get information needed for regulatory decision making, i.e., audit samples, site visits, consultations, etc. If appropriate information is not made available to FDA, consideration of the data cannot proceed, thus invoking the next level of administrative action.

Whenever guidelines are provided, copies of the procedures should be sent to the DFS and to DIOP. To facilitate communications and retain consistency with other district offices, they should be informed of the procedures.

Any questions regarding appropriate methodology should be addressed to the Division of Field Science, HFC-140, FTS (301) 443-3320, after discussion with the servicing laboratory.

The intent of providing private laboratory guidelines is to enable the Agency to have effective and efficient interactions with all responsible parties, to disseminate these recommendations, and to establish an effective dialogue among all involved.

The following information serves as guidance to brokers, importers, or domestic firms who employ private laboratories or others for sample collection, analysis, and reporting on commodities for review by FDA.

21.9.1 Sample Collection

The following sample information should accompany the analytical package to adequately describe the validity of the sampling procedure(s).

- Lot size and identification number.
- Sample size, method of collection, storage, and preservation (if appropriate).
- Identity of the sample collector and description of collection data, including the chain of custody of the sample.
- Statement from the sample collector describing any unusual observations about the lot, container(s), etc., relating to the integrity of the sample collected.

21.9.2 Analytical Package

The analytical package and reported results will not be considered acceptable if good scientific principles and validated methods are not followed. When there are questions on acceptability of a method of collection or analysis, assistance may be obtained from the compliance branch of the home district office. It is recommended that such advice be sought before sampling and analyses are undertaken.

The following documentation should be provided in writing and verified (signed and dated) for each analytical package to be submitted to FDA. Such information demonstrates that valid analytical techniques and quality assurance/quality control practices were used.

- Identity of the analyst(s), appropriate signature(s), and date(s) on which the work was performed.
- Specific analytical method(s) used, appropriate references, and any modifications and in-house validations of the method(s).
- Signed worksheets containing the analytical data, instrument calibration data, calculations, chromatograms (of samples, standards, and blanks), etc.
- Source and procedure for preparation of reference standard(s), and data to establish purity.
- Other pertinent analytical documentation, i.e., photographs of thin layer chromatography plates, which may be necessary to determine the technical validity of the package.

21.9.3 Reporting

All reports submitted to FDA should adequately document the identity of the lot sampled, the sampling procedure used, the identity and integrity of the portions collected (handling, storage and documentation), the analytical procedure or method, and the results.

As a guide, two report formats are provided as exhibits. They are not all inclusive and should be tailored to each situation. A copy or facsimile of the label from the immediate container and any additional labeling needed to evaluate the product should be attached to the analytical report.

Exhibit 21-A is a collection reporting format. There are sections for the sample collector and receiving analyst to complete. The condition of the lot from which the samples are collected should be documented. The lot sampled should be described in detail sufficient enough to relate it to invoice and entry documents. The containers from which the samples were taken should be identified in detail sufficient enough to allow the collection of an audit (duplicate) sample, if required.

Exhibit 21-B is an analysis reporting format. For clarity, separate reports should be completed for each individual analysis. The report should be detailed enough to allow the reviewer to follow the analysis step by step and to understand and check all data and calculations. A complete description of the method, sample analyzed, and findings facilitates review of the report by FDA, thus expediting movement of acceptable imports into domestic commerce.

In general, the analysis report should contain the method, weighings, volumes, dilutions, instrument readings and conditions, matrix clean-up procedures, chromatograms, charts, graphs, observations, and calculations of results, including those for reference standards. The dates and methods by which standards were prepared should be reported. In addition, good quality assurance and quality control principles dictate that blanks and fortified samples be analyzed and that their chromatograms, etc., be included in reports of such analyses.

EXHIBIT 21-A

SAMPLE COLLECTION REPORT FORM

Broker's Reference No. _____
Port of Entry _____ Truck License No. _____
Importer/Broker of Record _____
(Name, Address, Phone) _____

Grower _____ Shipper _____

Address _____

Description of Product _____

Description of Container _____

Brand Name _____
Label Size _____ Product _____
Code _____ Invoiced Quantity _____

Actual Quantity _____

~~Copy of Invoice Attached? YES/NO Package Label Attached? YES/NO~~

Carton Label Attached? YES/NO Bulk Label Attached? YES/NO

Warehouse/Freezer Lot No. _____

Address Where Sampled _____

Method of Collection _____
No. of Cartons/Drums Opened _____
No. of Packages/Portions From Each _____

Weight/Volume of Portion Collected _____
Identified by Collector on Each Portion As _____
Method of Sealing _____

Date of Collection _____

Signature _____
Collector's Name _____

Collector's Employer _____

Supervising Federal Representative (if any) _____

Date _____
Agency _____
Signature _____

EXHIBIT -21-B

ANALYSIS REPORT FORMAT

Description of Product _____
Broker's Reference No. _____
FDA Sample No. _____
Lab Sample No. _____
Date Received _____ Seal Intact? YES/NO
Condition of Sample: _____ Frozen _____
Refrigerated _____ Ambient _____
Sample Description (Size, No. of Portions) _____

Container Code, if Present _____

Portions Identified by Collector as _____
Portions Agree with Description? YES/NO
Date Analysis Begins _____ Date Analysis
Completed _____
Method Used (Reference(s) and Any Modifications) _____

Analyst(s) _____
Number of Subsamples _____ Amount Analyzed per Sub _____
Total Amount Analyzed _____ Sample composited? YES/NO

How Composited

NOTE: Clearly indicate on each analytical worksheet who did what part of the analysis, with signature(s) and date(s). **Results:** For example, in pesticides, report residues found in the sample. Report the values for the fortified crop, unfortified crop and blank. **Equipment Used:** Identify equipment(and parameters) used to weigh and process samples, analyze extracts, etc.

Laboratory Director's statement: Review of records indicate that the product and lot referred to in this report have _____ have not _____ been subject to prior analysis by this laboratory. If the lot has been subject to prior analysis by this laboratory, copies of the final results are hereto attached. The prior analysis was conducted on the following date(s) and covered by the following lab report number(s): _____

Signed _____ Date _____
Importer's statement: The analytical results submitted with this report include all analytical work related to this sample performed by this laboratory and all other laboratories that may have conducted the analyses.

Signed _____ Date _____
NOTICE: The knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to the provisions of Title 18 of the U. S. Code, Section 1001.