United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-K-94-001
June 1994

EPA

Pesticide Reregistration Rejection Rate Analysis Residue Chemistry

Follow-up Guidance for:

- Updated Livestock Feeds Tables
- Aspirated Grain Fractions (Grain Dust): A Tolerance Perspective
- Calculating Livestock Dietary Exposure
- Number and Location of Domestic Crop Field Trials

Table of Contents

Updated Livestock Feeds Table for Subdivision O

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 2 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Updated Livestock Feeds Table for Subdivision O (Residue Chemistry) of the Pesticide Assessment Guidelines

FROM: Esther Saito, Chief Esther Saito
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

and

Ed Zager, Chief Edward Zager
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: Peter Caulkins, Deputy Director
Special Review and Reregistration Division (7508W)

and

Steven L. Johnson, Acting Director
Registration Division (7505C)

THRU: Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division (7509C) Penelope A Fenner-Crisp 6/2/94

In April 1994, the Chemistry Branches provided for internal review an updated version of Table II of the Pesticide Assessment Guidelines, Subdivision-O, Residue Chemistry. The attached June 1994 Update to Table II is provided to you for release to all interested parties via SRRD's Rejection Rate Project follow-up document publication mechanism. This June 1994 issue of TABLE II will also be provided immediately to scientists in both Chemistry Branches and will be utilized in future Residue Chemistry reviews. Therefore we recommend that this document be provided to all interested parties in a timely manner.

A Notice of Availability will be published in the Federal Register within the next two weeks. A 75-day comment period will be allowed. The Notice will state that public comments on the new table and our plan for implementation will be accepted and considered.

The Chemistry Branches, HED, will work with the Field Operations Division to develop a communication strategy that includes the States, USDA, Canada, grower organizations, NACA, feed industry groups, livestock producer organizations, consumer groups, and environmental groups.

After comments are received, they will be reviewed and the document revised and reissued, if necessary.

Attachment: PESTICIDE ASSESSMENT GUIDELINES, SUBDIVISION O, RESIDUE CHEMISTRY, TABLE II UPDATE (JUNE 1994): THE RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS.

cc: RBP, Margie Feherenbach (FOD)

PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION O

RESIDUE CHEMISTRY

TABLE II UPDATE (JUNE 1994)

RAW AGRICULTURAL AND PROCESSED COMMODITIES

AND

LIVESTOCK FEEDS DERIVED FROM FIELD CROPS

INTRODUCTION

TABLE II UPDATE (JUNE 1994): RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS.

As a culmination of a long-term project to update the "Guide For Estimating Toxic Residues in Animal Feeds or Diets" (authored by Dr. L. Harris in 1975, and commonly known as the "Harris Guide") and as part of the Rejection Rate Project, the Chemistry Branches in OPP's Health Effects Division have updated Table II of the Pesticide Assessment Guidelines, Subdivision-O, Residue Chemistry. Table II provides a listing of all significant food and feed commodities, both raw and processed, for which residue data are collected and tolerances are set. In addition, for feed commodities, the table provides **1)** the maximum percent of the diet for beef and dairy cattle, poultry and swine, and **2)** guidance on the acceptability of label restrictions prohibiting use as a feed. This update of the table was deemed appropriate because there have been significant changes in agricultural, processing and feeding practices in the past decade. The attached document is intended to update Table II to reflect these changes. Information regarding feed items (raw agricultural or processed commodities), feeding levels and % in the diet on a "dry weight" or "as fed" basis was obtained from the contract reports by Animal Nutrition Inc. (EPA contract #68-DO-0107) and the National Food Processors Association (EPA contract #68-02-4263). Animal Nutrition Inc. provided the major updated data on what is currently fed to livestock, including the update of the percents of various feedstuffs in livestock diets. The National Food Processors Association provided data which is based on a national survey of food processors of what byproducts from agricultural crops, and how much, could be diverted to animal feeds. These data in combination with other data on crops, raw agricultural commodities (racs) and differences in cultivars and/or species of plants obtained from Chemistry Branch files, the Census of Agriculture, scientific literature, various USDA crop specialists and other individuals in academia or industry throughout the United States were evaluated to develop the attached updated Table II. Copies of the above reports are available from National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, order #'s PB94-107877 and PB94-107885, respectively. Additional information on other data used can be obtained from the Chemistry Branches in the Health Effects Division (7509C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. This document (Table II Update) will be available <u>via</u> Internet and NTIS in the near future.

A team was formed that included scientists from the two Chemistry Branches within the Health Effects Division, OPP, EPA. The team devised criteria to **1)** include or exclude feed items from Table II and **2)** assess the practicality of label restrictions prohibiting the use (or sale) of a potential feed commodity as a feed item. In addition, the team made many improvements in the table by providing **1)** clarifications and definitions of terminology used, **2)** dry matter content of each feed item (important in calculating livestock dietary burdens) and **3)** updated information on the maximum percent of a given feed in the livestock diet.

As the report from Animal Nutrition Inc. revealed, most plant commodities (e.g., acorns, duckweed and lettuce) can, and are, fed to livestock. However, for regulatory purposes, the Agency requires residue data only and livestock metabolism and feeding studies for only those feed items considered to be "significant".

The criteria developed by the team to decide what feed items are considered "significant" are:

1. The US annual production of the crop (raw agricultural commodity) is $\geq$500 million pounds.

   and

   The maximum amount in the livestock diet is $\geq$10 percent.

or

2. The commodity is grown mainly as a livestock feed.

In some cases, the criteria in #1 were also applied to byproducts of food processing to determine if there were "significant" feed items produced and fed to livestock.

Historically, a label restriction has precluded the need for residue data, tolerances or consideration of selected commodities in the livestock diet. In reviewing the data collected on animal feeds EPA also reevaluated the policy of allowing as a substitute for data, a label restriction prohibiting the use (or sale) of a commodity for livestock feed purposes. EPA derived three criteria which would be weighed in determining whether to permit label restrictions in lieu of data in the future.

Criteria developed by the team to determine whether a restriction of a commodity from use as a livestock feed could be allowed are:

1. The feed item must be under the control of the grower (For example, byproducts of processing would usually **not** be under the control of the grower.).

and

2. The crop must not be grown primarily as a livestock feed.

and

3. A label restriction should cause no economic hardship.

Generally, the Agency does not consider it good public policy to regulate pesticides in such a way that growers/farmers using a registered product must then destroy an economically and nutritionally valuable portion of the treated crop. EPA's preliminary view is that there are only four cases where a label restriction should be allowed: safflower forage, buckwheat forage, lentil forage, and sunflower forage. EPA will reevaluate the appropriateness of label restrictions on a commodity by commodity basis in future registration and tolerance actions. Comments are specifically requested on the Agency's label restriction policy. Other comments on the updated Table II will also be evaluated.

Commodities which EPA believes will not meet the three criteria necessary to allow a label restriction are as follows:

Alfalfa: forage
Barley: forage and straw
Bean: forage and straw/hay
Buckwheat: hay and straw
Corn, pop: fodder (stover)
Flax: straw
Oats: forage and straw
Pea: vines and hay
Peanut: hay
Rye: forage and straw
Sorghum: (grain) forage, fodder (stover), and hay
Soybean: forage and hay
Turnip: root and tops (varieties grown for livestock feed only)
Wheat: forage

Additional changes involve 1) the removals and additions of crops, and 2) the redefinition and reclassification of raw agricultural and processed commodities, and livestock feeds, and these are listed below. However, not listed here individually are name changes that were made in the updated table to other commodities, [e.g. (new name {old name}), fruit {fresh}, flower head {fresh}, tops (leaves and stems) {hay}, leaf stalk {fresh}, petioles {fresh}, etc.] to more accurately define the commodities for a variety of crops. Likewise, the various percentage changes for feedstuffs in livestock diets are not listed here individually.

Crops removed:
Crenshaw (a variety of melon)
Damsons (a variety of plum)
Guar
Mint (note: Peppermint and Spearmint are still in updated table)

Crops added:
Canola
Crown vetch
Herbs
Mangel beets
Sorghum forages (sudangrass)
Yam

Rac's removed:
Cabbage: fresh (w/o wrapper leaves)
Cotton: forage
Corn, field: silage
Corn, pop: forage
Guar: seed and forage
Lentil: (fresh) and hay
Lettuce: fresh (w/o wrapper leaves)
Mint: hay

Pea: straw
Peanut: vines
Pineapple: forage
Peppermint: hay
Sorghum (grain): hay and silage
Sorghum (sweet): seed, forage, and fodder
Spearmint: hay
Sugarcane: forage

Rac's added:

Alfalfa: seed screenings
Barley: hay
Canola: seed
Corn, sweet: grain
Corn, sweet: fodder (stover)
Cotton: gin byproducts
Crown vetch: forage and hay
Grass: seed screenings
Herbs: fresh
Lentil: seed
Lupine: seed and straw
Mangel beet: root and tops (leaves)
Millet: forage, hay, and straw
Mung bean: bean sprouts
Oats: hay
Pea: hay
Rape: forage
Safflower: forage
Sorghum (sweet): stalk
Wheat: hay
Yam: tuber

Processed commodities removed:

Alfalfa: meal
Apple: pomace, dry
Barley: grain dust
Bean: cannery waste
Buckwheat: grain dust
Corn, field: grain dust (renamed "aspirated grain fractions" and redefined as a rac)
Corn, sweet: cannery waste
Cotton: soapstock
Guar: meal and gum
Hops: dried (renamed "cones, dried" and redefined as a rac)
Millet: grain dust
Mint: spent hay and oil
Mung bean: bean sprouts (redefined as a rac)
Oats: grain dust

Peanut: soapstock
Pineapple: bran
Rice: grain dust
Sorghum (grain): starch
Sorghum (grain): grain dust (renamed "aspirated grain fractions" and redefined as a rac)
Soybean: grain dust (renamed "aspirated grain fractions" and redefined as a rac)
Soybean: soapstock
Tomato: catsup
Wheat: grain dust (renamed "aspirated grain fractions" and redefined as a rac)

Processed commodities added:

Beet, sugar: pulp, wet
Canola: meal and oil (both crude and refined)
Citrus: pulp, wet
Flax: linseed oil, crude
Herbs: dried
Pineapple: process residue
Potato: flakes
Rye: hulls
Sesame: meal and oil
Tea: instant
Tomato: paste
Wheat: germ

Feeds removed:

Apple: pomace, dry
Barley: grain dust
Bean: cannery waste
Buckwheat: grain dust
Corn, field: silage
Corn, pop: forage
Coconut: copra meal
Cotton: forage and soapstock
Guar: seed, forage, and meal
Lentil: hay
Millet: grain dust
Mint: spent hay
Mustard: seeds
Oats: hulls
Oats: grain dust
Parsnip: roots
Peanut: vines and soapstock
Peppermint: spent hay
Pineapple: bran and forage
Rice: milled byproducts and grain dust
Rye: grain dust

Sorghum (grain): silage and hay
Sorghum (sweet): forage and fodder
Soybean: soapstock
Spearmint: spent hay
Sugarcane: bagasse and forage

Feeds added:

Alfalfa: seed screenings and silage
Apple: pomace, wet
Barley: hay and flour
Bean: straw/hay
Beet, sugar: pulp, wet
Buckwheat: flour
Canola: meal
Carrot: culls
Clover: silage
Corn, pop: grain
Corn, sweet: grain and fodder (stover)
Cotton: gin byproducts
Crown vetch: forage and hay
Grapes: raisin culls
Grass: silage and seed screenings
Lentil: seed
Lespedeza: meal
Lupine: seed and straw
Mangel beet: root and tops (leaves)
Millet: forage, hay, and straw
Oats: hay
Pea: silage
Pineapple: process residue
Rape: forage
Rice: hulls
Safflower: forage
Sorghum (grain): forage
Sunflower: seed
Turnip: root and tops (leaves) (livestock varieties only)
Wheat: hay

A Notice of Availability will be published in the Federal Register. The Notice will request public comments on the new table for a 75-day comment period. After comments are received, they will be reviewed and the document revised and reissued, if necessary.

In the interim, the updated table has been provided to scientists in both Chemistry Branches and will be utilized as guidance in future Residue Chemistry reviews for the evaluation of pesticide registrations and tolerances. EPA realizes that in some instances where studies have already begun or are scheduled to begin in the near future, data may not be able to be collected on the commodities that have been added to Table II. EPA believes that six months should be sufficient time for registrants to familiarize themselves

with the changes in Table II. For studies begun either prior to the publication of this notice or in the next six months, EPA will be flexible regarding whether studies which do not supply data on the new commodities in Table II are adequate for registration and tolerance purposes and when additional data, if any, will be required to be submitted under EPA's data call-in authority.

Attachment: TABLE II UPDATE (JUNE 1994): THE RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS.

Table II Update (June 1994)

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Alfalfa	forage seed[4] seed screenings[4] hay		forage	35	50	70	NU[6]	60	NU
			seed[4]	88	25	25	20	35	30
			seed screenings[4]	88	25	30	NU	NU	NU
			hay	89	25	70	NU	20	NU
			meal[6]	89	25	50	10	20	10
			silage[7]	40	60	75	NU	50	NU
Almond	nutmeat hulls		hulls	90	25	15	NU	10	NU
Apple	fruit	pomace, wet[8] juice	pomace, wet[8]	40	40	20	NU	25	NU
Apricot	fruit								
Artichoke, Globe	flower head								
Asparagus	spears (stems)								
Avocado	fruit								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Banana[9]	fruit								
Barley[10]	grain[11] forage hay straw	hulls bran flour pearled barley	grain[11]	88	80	60	75	85	80
			bran	88	50	20	10	25	15
			forage	30	30	75	NU	20	NU
			hay	88	25	60	NU	10	NU
			straw	89	15	10	NU	NU	NU
			flour	88	20	20	20	20	20
Bean[12]	bean, succulent seed forage straw/hay[13]		seed	88	15	15	10	25	15
			forage	35	30	60	NU	NU	NU
			straw/hay[13]	89	15	10	NU	NU	NU
Beet, garden	root tops (leaves)								

Table II Update (June 1994)

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Beet, sugar	root tops (leaves)	sugar, refined molasses pulp, wet pulp, dried	tops (leaves)	23	20	10	NU	NU	NU
			molasses	25	10	10	NU	NU	NU
			pulp, wet	30	35	35	NU	25	NU
			pulp, dried	88	20	25	NU	15	NU
Blackberry	berry								
Blueberry	berry								
Boysenberry	berry								
Broccoli	flower head and stem								
Brussels sprouts	leaf sprouts								
Buckwheat[14] (continued)	grain[15] forage hay straw	hulls middlings flour	grain[15]	87	50	60	70	80	80
			forage (R)[16]	30	25	60	NU	10	NU
			hay	83	25	60	NU	10	NU

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Buckwheat			straw	88	20	10	NU	NU	NU
			milled bypdts[17]	89	25	25	25	30	50
			flour	89	25	25	20	NU	NU
Cabbage	fresh, w/wrapper leaves[18]								
Cacao bean	bean	roasted bean cocoa powder chocolate							
Canola	seed	meal oil, crude[19] oil, refined	meal	88	NU	15	25	15	15
Cantaloupe	fruit								
Carob bean	bean								
Carrot	root		culls[20]	12	40	25	NU	20	10
Casaba	fruit								

Table II Update (June 1994)

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Cauliflower	flower head and stem								
Celery	leaf stalk (petiole)								
Cherry, sweet	fruit								
Cherry, sour	fruit								
Chicory	root								
	tops (leaves)								
Citrus	fruit, whole	pulp, wet pulp, dried molasses oil juice	pulp, wet	21	40	30	NU	15	NU
			pulp, dried	91	25	20	NU	10	NU
			molasses	68	10	15	NU	NU	NU
Clover[21]	forage hay		forage	30	30	70	NU	10	NU
			hay	89	20	60	NU	NU	NU
			silage[22]	30	30	60	NU	10	NU

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Coconut	coconut (meat and liquid combined)	copra (dried meat) oil meal[19]							
Coffee	bean, green	bean, roasted instant							
Collards	greens								
Corn, field	grain forage[23] fodder (stover)[24] aspirated grain fractions[25]	wet milling: starch oil, crude[19] oil, refined dry milling: grits meal flour oil, crude[19] oil, refined	grain	88	80	60	80	80	90
			forage[23]	40	40	90	NU	15	NU
			fodder (stover)[24]	83	25	15	NU	NU	NU
			milled bypdts[26]	85	50	25	60	90	75
			aspirated grain fractions[25]	85	20	20	NU	20	20

Table II Update (June 1994)

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Corn, pop	grain fodder (stover)[24]		grain	88	75	60	60	75	85
			fodder (stover)[24]	85	25	15	NU	NU	NU
Corn, sweet	sweet corn (K + CWHR)[27] forage[28] grain[29] fodder (stover)[24]		forage[28]	48	40	50	NU	15	NU
			cannery waste[30]	30	35	20	NU	NU	NU
			grain[29]	88	70	60	NU	75	80
			fodder (stover)[24]	83	25	15	NU	NU	NU
Cotton	undelinted seed cotton gin bypdts[31]	meal hulls oil, crude[19] oil, refined	meal	89	10	15	20	15	15
			undelinted seed	88	25	25	NU	NU	NU
			hulls	90	20	15	NU	NU	NU
			cotton gin bypdts[31]	90	30	20	NU	NU	NU

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Cowpea[32]	seed		seed	88	50	25	10	30	50
	hay		hay	86	20	40	NU	NU	NU
	forage		forage	30	40	60	NU	15	15
Crabapple	fruit								
Cranberry	berry								
Crown vetch[33]	forage		forage	30	25	70	NU	10	NU
	hay		hay	90	20	60	NU	10	NU
Cucumber	fruit								
Currant	fruit								
Date	fruit	dried							
Dewberry	berry								
Eggplant	fruit								
Elderberry	berry								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Endive/Escarole	leaves								
Fig	fruit	dried							
Flax	seed straw[34]	meal linseed oil, crude[19]	meal	88	10	15	30	20	15
			straw[34]	89	10	10	NU	NU	NU
			seed	88	10	20	20	20	10
Garlic	bulb								
Gooseberry	berry								
Grape	fruit	raisin pomace, wet pomace,dried raisin waste juice	raisin, culls	85	25	20	NU	20	NU
			pomace, wet	15	20	NU	NU	NU	NU
			pomace, dried	89	20	NU	NU	NU	NU
			raisin waste	79	25	10	NU	NU	NU

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Grass (pasture & rangeland)[35]	forage hay seed screenings[36]		forage (fresh)	25	60	70	NU	NU	NU
			hay	88	25	50	NU	NU	NU
			silage[37]	40	30	60	NU	NU	NU
			seed screenings[38]	88	25	30	NU	NU	NU
Herbs[38]	fresh	dried							
Hops	hops cones, dried[39]	spent hops[40]	spent hops[40]	86	20	10	NU	NU	NU
Horseradish	root								
Huckleberry	berry								
Jerusalem artichoke	tuber								
Kale	leaves								
Kiwifruit	fruit								
Kohlrabi	bulbous stem								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Kumquat	fruit								
Leek	whole plant								
Lentil	seed		seed	88	10	25	NU	20	20
	forage		forage (R)[16]	85	30	20	NU	NU	NU
Lespedeza[41]	forage		forage	22	50	60	NU	15	NU
	hay		hay	88	20	50	NU	10	NU
			meal[42]	89	10	25	10	20	20
Lettuce	fresh, w/wrapper leaves[43]								
Loganberry	berry								
Lupine[44] (continued)	seed		seed	88	15	20	15	15	20
	forage		forage	30	25	60	NU	20	NU
	hay		hay	85	25	50	NU	NU	NU
	straw								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Lupine			straw	90	15	15	NU	NU	NU
Mangel beet	root		root	11	50	20	NU	25	10
	tops (leaves)		tops (leaves)	23	20	40	NU	NU	NU
Mango	fruit								
Melon	fruit								
Millet[45,46]	forage	hulls[19]	forage	30	35	60	NU	15	NU
	grain[47]	flour	grain[47]	88	75	50	70	85	75
	hay	meal[19]	hay	85	20	50	NU	NU	NU
	straw[48]		straw[48]	90	20	10	NU	NU	NU
Mung bean	bean sprouts[49]								
Mushroom	cap and stem								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Mustard	greens seed								
Nectarine	fruit								
Nuts[50]	nutmeat								
Oats[51]	grain[11] forage hay straw	hulls[19] flour groats/rolled oats	grain[11]	89	80	50	80	80	80
			forage	30	35	60	NU	NU	NU
			hay	90	20	50	NU	10	NU
			straw	90	20	10	NU	NU	NU
Okra	fruit (pods)								
Olives	fruit	oil							
Onion, bulb	bulb								
Onion, green	whole plant								
Papaya	fruit								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM[3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Parsley	leaves								
Parsnip	root								
Passion fruit	fruit								
Pawpaw	fruit								
Pea[62]	pea, succulent		seed	90	65	50	60	50	60
	seed		vines	25	35	50	NU	20	NU
	vines[63]		hay	88	25	60	NU	10	NU
	hay[63]		silage[54]	40	25	60	NU	20	NU
Peach	fruit								
Peanut	nutmeat	meal	meal	85	15	20	25	20	15
	hay[65]	oil, crude[19]	hay	85	25	60	NU	10	NU
	hulls (shells)	oil, refined	hulls (shells)	95	15	NU	NU	NU	NU
Pear	fruit								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Peppermint	tops (leaves and stems)	oil spent hay[19,56]							
Pepper	fruit								
Pimento[57]	fruit								
Pineapple	fruit	process residue[58] juice	process residue[58]	25	30	20	NU	20	NU
Pistachio	nutmeat								
Plantain	whole fruit								
Plum	fruit	prune							
Potato	tuber	granules/flakes chips peel, wet peel, dried	culls	20	75	50	NU	50	50
			processed potato waste[59]	12	75	50	NU	25	NU
Pumpkin	fruit								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Quince	fruit								
Radish	root tops (leaves)								
Rape	greens[60] seed forage	meal oil, crude[19] oil, refined	meal	88	15	20	20	20	15
			forage	30	30	50	NU	15	NU
Raspberry	berry								
Rhubarb	petioles								
Rice	grain[11] straw[61]	polished rice hulls bran[19]	grain[11]	88	60	50	60	60	65
			hulls	90	10	10	15	10	NU
			straw	90	10	10	NU	NU	NU
Rutabaga	root								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Rye[62]	grain[63] forage straw	flour milled bypdts[64] hulls	grain[63]	88	75	50	50	80	70
			forage	30	30	75	NU	15	NU
			straw	88	10	10	NU	NU	NU
			hulls	88	20	10	NU	NU	NU
			milled bypdts[64]	85	35	50	50	50	50
Safflower	seed forage[65]	meal oil, crude[19] oil, refined	seed	94	10	25	NU	20	20
			forage (R)[16]	23	25	33	NU	NU	NU
			meal	91	10	15	25	25	25
Sainfoin[66]	forage hay		forage	30	30	75	NU	10	NU
			hay	89	25	60	NU	10	NU
Salsify	root tops (leaves)								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Sesame	seed	oil meal[19]							
Shallot	bulb								
Sorghum,grain	grain forage[23] fodder (stover) aspirated grain fractions[25]	flour[67]	grain	86	80	60	80	80	90
			forage[23]	35	90	75	NU	NU	NU
			fodder (stover)	88	20	10	NU	NU	NU
			aspirated grain fractions[25]	85	20	20	NU	20	20
Sorghum, sweet[68]	stalk	syrup							
Sorghum forages, sudangrass (See Grass)									

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Soybean[69]	seed forage hay aspirated grain fractions[25]	meal hulls oil, crude[19] oil, refined	seed	89	15	20	20	25	25
			meal	92	15	20	40	20	25
			hulls	90	20	20	20	10	NU
			forage	35	35	70	NU	10	NU
			hay	85	20	60	NU	10	NU
			silage[70]	30	50	60	NU	20	NU
			aspirated grain fractions[25]	85	20	20	NU	20	20
Spearmint	tops (leaves and stems)	spent hay[19,66] oil							
Spices[71]	fresh	dried							
Spinach	leaves								
Squash	fruit								
Strawberry	berry								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Sugarbeet (see Beet, sugar)									
Sugarcane	cane	molasses bagasse[72] sugar, refined	molasses	75	10	10	NU	NU	NU
Sunflower	seed forage[73]	meal hulls oil, crude[19] oil, refined	meal	92	10	20	30	10	20
			hulls	89	20	10	10	NU	NU
			seed	90	10	20	NU	NU	10
			forage (R)[16]	23	35	50	NU	NU	NU
Sweet potato	root		root	32	60	25	NU	60	25
Swiss chard	petioles								
Taro	corm foliage								
Tea	leaves[74]	dried instant							

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Tomato	fruit	pomace, wet pomace, dried puree[75] paste[76] juice	pomace, wet	15	30	20	NU	NU	NU
			pomace, dried	92	25	10	10	10	10
Trefoil[77]	forage hay		forage	30	35	70	NU	15	10
			hay	85	25	60	NU	NU	NU
Turnip	root tops (leaves)		root[78]	15	75	20	NU	40	40
			tops (leaves)[78]	30	50	30	NU	10	NU
Vetch[78,80]	forage hay		forage	30	35	60	NU	15	NU
			hay	85	20	60	NU	NU	NU
Watercress	leaves and stems								
Watermelon	fruit								

RAW AGRICULTURAL AND PROCESSED COMMODITIES AND LIVESTOCK FEEDS DERIVED FROM FIELD CROPS									
CROP	RAC	PROCESSED COMMODITY	FEED		PERCENT OF LIVESTOCK DIET[1,2]				
			FEEDSTUFF	% DM [3]	BEEF CATTLE	DAIRY CATTLE	POULTRY	BREEDING SWINE	FINISHING SWINE
Wheat[81,82]	grain[63] forage hay straw aspirated grain fractions[25]	bran flour middlings shorts germ	grain[63]	89	60	50	82	80	80
			forage	25	30	65	NU	15	NU
			hay	88	25	60	NU	NU	NU
			straw	88	15	10	NU	NU	NU
			milled bypdts[83]	88	63	50	50	70	50
			aspirated grain fractions[25]	88	20	20	NU	20	20
Yam	tuber								
Youngberry	berry								

(See Attached Footnotes 1 through 83)

Table II Update (June 1994)

1. Percentages of feedstuffs in livestock diets other than those listed here can be found in the complete contract (#68-DO-0107) report dated May 17, 1993 that was prepared by Animal Nutrition, Inc., Breese, IL, under the technical guidance of the Chemistry Branch/Tolerance Support, HED, OPP, OPPTS. A copy of this report is available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (#PB-94-107877).

2. Maximum percent of diet on a "dry weight" basis for finishing beef and lactating dairy cattle, and on an "as-fed" basis for poultry and swine (hogs). Poultry percentages are the higher of the values for broilers and laying hens as listed in the report cited in footnote #1.

3. % DM: percent dry matter.

4. Alfalfa seed: For registered uses on alfalfa grown for seed, residue data should be provided on seed, seed screenings, forage, and hay; for all other uses data should only be provided on forage and hay.

5. NU: Not used or a minor livestock feed. Therefore, no residue data are needed at this time. Items considered to be livestock feeds have greater than 500,000,000 lb available for use as a feedstuff and the maximum daily amount in a livestock diet is greater than 10%.

6. Residue data are not needed for meal, however, the meal should be included in the livestock diet using the hay tolerance level. Hay should have a moisture content of 15 to 20%.

7. Residue data on silage are optional. Alfalfa silage: Harvest sample at late bud to early bloom stage (first cut), and/or at early bloom stage (later cuts). In the absence of silage data, residues in forage will be used for silage.

8. Wet apple pomace is approximately 60% moisture.

9. Field residue data on both bagged and unbagged bananas should be provided.

10. Barley forage: Harvest sample between tillering to joint stage; Barley hay: Cut when the grain is in the milk to soft dough stage; Barley straw: Plant residue (dried stalks or stems with leaves) left after the grain has been (threshed) harvested.

11. Barley grain, oat grain, or rice grain: Kernel (caryopsis) plus hull (lemma and palea).

12. Bean seed: Dried seed for uses on dried shelled beans; succulent seed without pod for uses on succulent shelled beans (e.g., lima beans); succulent seed with pod for edible-podded beans (e.g., snap beans); Bean forage: Whole green plant; Bean hay: Succulent plant, cut and dried, with or without pods, prior to bean harvest; Bean straw: Dried plant, material remaining after bean harvest.

13. Bean straw/hay: Data on bean straw should be provided for: Phaseolus spp. (including kidney beans, lima beans, mung beans, navy beans, pinto beans, snap beans, and waxbeans) and Cicer arietinum (chick peas, garbanzo beans); data on bean hay are required for: cowpeas and lupines. (See individual table entries for cowpea and lupine hays for percentages of the livestock diet in exposure calculations).

14. Buckwheat forage: Harvest sample (leaf plus stems) at 6 inch to bloom initiation stage at approximately 30 % DM; Buckwheat hay: Cut before seeds are fully developed; Buckwheat straw: Stubble (basal portion of the stems) left standing after harvesting the grain.

15. Buckwheat grain: Seed (achene) plus hull.

16. (R): Label restrictions against feeding may be allowed, e.g., "Do not feed green immature growing plants to livestock", or "Do not harvest for livestock feed."

17. Milled byproducts: Use residue data for buckwheat hulls or middlings, whichever has the higher residues.

18. Cabbage fresh, w/wrapper leaves: Entire cabbage head with obviously decomposed leaves removed. Residue data on cabbage head, w/o wrapper leaves, is desirable particularly when a more accurate assessment of exposure is necessary.

19. Data are needed for mass balance purposes only. A tolerance will not be set on this commodity at this time.

20. Carrot culls: Data for rac will cover residues on culls.

21. Clover forage: Harvest sample at the 4 to 8 inch stage to prebloom with approximately 30% DM; Clover hay: Cut at early to full bloom stage. Residue data for clover seeds are not needed.

22. Residue data on silage are optional. Clover silage: Harvest sample at late bud to early bloom stage (first cut), and/or at early bloom stage (later cuts). In the absence of silage data, residues in forage will be used for silage.

23. Field corn or sorghum forage: Harvest sample (whole aerial portion of the plant) at late dough/early dent stage (black ring stage for corn only). Forage samples should be analyzed immediately after collection, or may be analyzed after ensiling for 3-weeks <u>maximum</u>, and reaching a pH of 5.0 or less.

24. Corn fodder (stover): Mature dried stalk from which the grain (ear) is removed; contains 80 to 85% DM.

25. Aspirated grain fractions (previously called "grain dust") collected at elevators for environmental and safety reasons. Residue data should be provided only when finite surface residues are expected on the grain.

26. Corn milled byproducts: Use residue data for corn processed commodities having the highest residues, excluding oils.

27. Sweet corn (K+CWHR): Kernel plus cob with husks removed.

28. Sweet corn forage samples should be taken when sweet corn is normally harvested for fresh market, and may or may not include the ears. The petitioner may analyze the freshly cut sample, or may analyze the ensiled sample, as described in footnote #23 for field corn.

29. Field corn grain tolerance covers residues in sweet corn grain (dry), providing the use patterns are the same.

30. Sweet corn cannery waste includes husks, leaves, cobs, and kernels. Use forage residue data.

31. Cotton gin byproducts (commonly called gin trash) include the plant residues from ginning cotton, and consist of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. Cotton must be harvested by commercial equipment (or a small scale simulation thereof) to provide an adequate representation of plant residue for the ginning process.

32. Cowpea forage: Harvest sample at 6 inch to prebloom stage with approximately 30% DM; Cowpea hay: Cut when pods are 1/2 to fully matured.

33. Crown vetch forage: Harvest sample at 6 inch to prebloom stage with approximately 30% DM; Crown vetch hay: Cut at full bloom stage.

34. Flax straw: Stubble (basal portion of the stems) left standing after harvesting the grain.

35. Zero day crop field residue data for grasses should be provided unless it is not feasible, e.g., preplant/premergent pesticide uses. Grass forage: Harvest sample at 6 to 8 inches high to boot stage with approximately 25% DM; Grass hay: Cut in boot to early head stage. For example, grasses include barnyardgrass, bentgrass, bermudagrass, Kentucky bluegrass, big bluestem, smooth bromegrass, buffalograss, reed canarygrass, crabgrass, cupgrass, dallisgrass, sand dropseed, meadow foxtail, eastern gramagrass, side-oats grama, guineagrass, Indiangrass, johnsongrass, lovegrass, napiergrass, oatgrass, orchardgrass, pangolagrass, redtop, Italian ryegrass, sprangletop, squirreltailgrass, stargrass, switchgrass, Timothy, crested wheatgrass, and wildryegrass. Also included are sorghum, sudangrass and sorghum forages and their hybrids.

36. Grass seed screenings: Residue data should be provided for uses on grass grown for seed only.

37. Residue data on silage are optional. Grass silage: Harvest sample at boot to early head stage wilted to 55 to 65% moisture. In the absence of silage data, residues in forage will be used for silage.

38. Herbs consist primarily of leaves, stems, and flowers and are marketed fresh (succulent) or dried.

39. According to PR Notice 93-12 (12/23/93), for regulatory purposes hops will be considered as a raw agricultural commodity in both the fresh (green) and dried forms.

40. Spent hops are defined only as the plant material which remains after dried hops are extracted to produce a hop extract, and not spent hops that are filtered after they have been brewed in beer making. Residue data on dried hops can be used for spent hops.

41. Lespedeza forage: Harvest sample at 4 to 6 inches to prebloom with 20 to 25% DM; Lespedeza hay: annual/Korean: Cut at early blossom to full bloom; Sericea: Cut when 12 to 15 inches tall.

42. Use lespedeza hay residue data for meal. Hay should have a moisture content of 15 to 20%.

43. Lettuce fresh, w/wrapper leaves: Entire lettuce head with obviously decomposed leaves removed. Residue data on lettuce head, w/o wrapper leaves, is desirable particularly when more accurate assessment of exposure is necessary.

44. Lupine forage: Harvest sample at 6 to 8 inches tall to pod formation with 30% DM; Lupine hay: Cut at early to full bloom; Lupine straw: Stubble (basal portion of the stems) left standing after harvesting the seed.

45. Millet forage: Harvest sample at 10 inches to early boot stage with approximately 30% DM; Millet hay: Cut at early boot stage or approximately 40 inches tall, whichever is reached first.

46. Millet includes pearl millet.

47. Millet grain: Kernel plus hull (lemma and palea); Pearl millet grain: Kernel with hull (lemma and palea) removed.

48. Millet straw data are required for proso millet only. Proso millet straw:

49. Data on mung bean covers sprouts except when pesticide is used on the sprouts per se.

50. See almonds: Almond hulls are considered a feed item. Hulls from other tree nuts are not considered feed items at this time.

51. Oats forage: Harvest sample between tillering to joint stage; Oats hay: Cut at early flower to soft dough stage; Oats straw: Plant residue (dried stalks or stems with leaves) left after the grain has been (threshed) harvested.

52. Succulent pea seed: Dried seed for uses on dried shelled peas; succulent seed without pod for uses on succulent shelled peas (e.g., English peas); succulent seed with pod for edible-podded peas (e.g., sugar peas); Pea vines: Whole green plant: Pea hay: Succulent plant, cut and dried.

53. Pea vines: Harvest sample for forage anytime after pods begin to form with approximately 25% DM; Pea hay: Cut in full bloom to when most of the pods are formed.

54. Use pea vine residue data for pea silage.

55. Peanut hay: Peanut hay consists of the dried vines and leaves left after combining of the peanuts from the vines that are sun-dried to a moisture content of 15 to 20%.

56. Spent hay: Material remaining after the oil is distilled from the fresh mint.

57. Pimento is the official name adopted by the Georgia Pimento Growers Association.

58. Pineapple process residue: A wet waste byproduct from the fresh-cut product line, and usually contains pineapple bran.

59. Feed additive tolerances for processed potato waste should be based on the maximum concentration factor observed for residues in/on wet peel.

60. Rape greens are a commodity listed in the Brassica Leafy Vegetable Group (40 CFR 180.34).

61. Rice straw: Stubble (basal portion of the stems) left standing after harvesting the grain.

62. Rye forage: Harvest sample at 6 to 8 inch stage to boot stage with approximately 30% DM; Rye straw: Plant residue (dried stalks or stems with leaves) left after the grain has been (threshed) harvested.

63. Rye grain or wheat grain: Kernel (caryopsis) with hull (lemma and palea) removed.

64. Milled byproducts: Mix of rye bran, red dog flour, and rye middlings.

65. Safflower forage: Harvest sample from 6 inches to early bloom with 20 to 25% DM.

66. Sainfoin forage: Harvest sample at 6 to 8 inches tall to pod formation with 30% DM; Sainfoin hay: Cut at early bloom stage.

67. Sorghum flour: Residue data are not needed at this time since sorghum flour is used exclusively in the US as a component for drywall, and not as either a human or animal feed item. However, because 50% of the worldwide sorghum production goes toward human consumption, data may be needed at a later date.

68. Sweet sorghum seed will be covered by the sorghum grain tolerance.

69. Soybean forage: Harvest samples at 6 to 8 inches tall to pod formation with approximately 35% DM; Soybean hay: Cut at mid-to-full bloom and before bottom leaves begin to fall or when pods are approximately 50% developed.

70. Residue data on silage are optional. Soybean silage: Harvested sample when pods are one-half to fully matured. In the absence of silage data, residues in forage will be used for silage.

71. Spices include aromatic seeds, buds, bark, berries, pods, and roots consumed and marketed primarily in their dried form. Note postharvest treatments may also be applied to dried spices.

72. Information indicates that sugarcane bagasse is mainly used for fuel. Residue data will not be needed at this time, but may be needed at a later date.

73. Sunflower forage: Harvest sample up to approximately 25% bloom with 20 to 25% DM.

74. Tolerances are not required for "leaves"; tea leaves are shipped/imported in processed form, thus only food additive tolerances are required.

lower to ower vested.

animal feeds. However, recently because of dumping restrictions in many communities, disposal via animal feeds is much more widely used.

The grain and the animal feed industries commonly refer to this material as "aspirated grain fractions" and this is the preferred term when discussing elevator grain dust.

Various pesticides are applied either preharvest to growing grains (and oil seeds) or postharvest to stored grains (and oil seeds), and the harvested/stored grains (oil seeds) could potentially have high surface residues of pesticides that could concentrate in the aspirated dust due to the large absorbent-surface areas of the dust particles. Thus incorporation of this aspirated dust into animal feeds can cause increased exposure of pesticide residues to animals, and possibly result in the transfer of pesticide residues into the human food chain through meat, milk, and eggs.

The incorporation of "aspirated grain fractions" into animal feeds falls under the auspices of the Federal Food, Drugs, and Cosmetic Act (Amended January 1980), and a tolerance is needed to cover any pesticide residues in cereal grains and oil seeds. A discussion of this feed use for "aspirated grain fractions" from a tolerance perspective follows in the attached report and includes a summary of the total volume of aspirated dust that might be available from export elevators for animal feeds, a discussion how the aspirated dust is used in animal feeds and to what the extent in the livestock meat-producing industries, and guidance in regards to residue chemistry data requirements for this aspirated dust in registration and tolerance actions of pesticides used on cereal grains and oil seeds.

Attachment: ASPIRATED GRAIN FRACTIONS (GRAIN DUST): A TOLERANCE PERSPECTIVE (JUNE 1194)

cc: RBP, Margie Feherenbach (FOD)

ASPIRATED GRAIN FRACTIONS (GRAIN DUST):

A TOLERANCE PERSPECTIVE

(JUNE 1994)

ASPIRATED GRAIN FRACTIONS (GRAIN DUST):

A TOLERANCE PERSPECTIVE

BACKGROUND

Every time cereal grains or oilseeds (e.g., corn, wheat, sorghum, barley, oats, rye, and rice, and soybeans) are moved into, transferred within, or shipped from US grain handling facilities, dust is generated as the grain moves through a transfer point, e.g., bucket elevator, one belt to another, etc.. This dust escapes as an air pollutant and is potentially damaging to workers if inhaled, and because of its flammability when it becomes airborne, it is also a highly explosive dust which creates a hazardous work environment. The Occupational Safety and Health Administration (OSHA, US Department of Labor) regulations require dust control systems in grain elevators to remove this dust both for environmental and safety reasons. The grain elevator industry has designed dust control systems to capture dust at each of these transfer points in compliance with OSHA standards. OSHA commonly refers to the elevator dust as "fugitive dust", and defines this dust as combustible particles $\leq$425 microns (μm) which escape in the handling of grain. Particles sizes $<$425 μm are a factor in worker inhalation, while from an explosion safety point, dust particles below 100 μm cause the major explosion hazard; even larger particles 250 to 500 μm can also be made to explode in sufficient concentrations. OSHA standards also require that grain elevators implement a housekeeping program to reduce accumulations of "fugitive dust" on ledges, floors, equipment, and other exposed surfaces. Thus, the elevator dust is collected by the dust control system solely to achieve worker safety and to produce good air quality at the elevator facilities, and not for grain cleaning. Of course, some cleaning of the grain is accomplished in the process. The grain elevator industry refer to this elevator dust as **"grain dust"**. However, the livestock feed manufactures for aesthetical reasons commonly refer to this material as **"aspirated grain fractions"**. Since our interest is related to livestock feeding **"aspirated grain fractions"** is the preferred term in this discussion of elevator **"grain dust"**.

Dust captured by above systems is divided into three types: I) dust removed from the grain stream and collected into dust bins, 2) dust sweepings gathered from the elevator floors, equipment and other elevator areas, and 3) dust removed from grain stream by a dust recirculation/recombination (R/R) system. Many facilities disposed of this aspirated dust either by recombining with the grain as it is moved through the elevators, or by dumping into landfills or the waterways, or by processing into animal feeds. Since many landfills or waterways will no longer accept aspirated dust, other disposal methods have been investigated, i.e., burning at elevator sites to provide heat energy, using in building materials and roadways, etc., but not with great success. Thus disposal via animal feeds may become more important since it is a nutritious livestock feed somewhat comparable to the whole grain, and therefore an acceptable disposal method.

Changes in the grain standards by the Grain Quality Improvement Act of 1986 (GQIA) prohibit the recombination or addition of previously collected **"aspirated grain fractions"** once it has been removed at the **export** facilities and have consequently increased the volume of **"aspirated grain fractions"** available for disposal. This includes all three types of dust that are

generated at elevators: bin dust, dust sweepings, and recirculation/ recombination dust. The Federal Grain Inspection Service (FGIS), after public comments on the GQIA, adopted the final rules (Federal Register, Vol. 52, No. 125, June 30, 1987, pp. 24414-24441)that prohibit the addition of dust from bins and sweepings to grain at export facilities. However, based on public comments, FGIS has not yet implemented the prohibition of recombining recirculation (R/R) dust to the grain stream, and has deleted this proposal from the final rule-making until additional data are gathered for the recirculation/recombination dust. In addition, although not prohibited by law, FGIS has recommended that operators of non-export elevators (i.e., country and inland terminals) refrain from the recombination or addition practices of bin dust and dust sweepings, but not including the R/R dust. If the addition of R/R dust back into grain is also prohibited, then the volume of dust that must be disposed will increase, and more dust will possibly be available for use in animal feeds. The current market value of **"aspirated grain fractions"** averages $20/ton, while in some cases, in busy seasons, operators of the export elevators will even pay the shipping freight for disposal of the dust.

Since various pesticides are applied either preharvest to growing grains or postharvest to stored grains, the harvested/stored grains could have pesticide surface residues which could concentrate in the aspirated dust. This concentration occurs from postharvest treatment because pesticide residues are absorbed onto the large surface areas of the dust particles on the grain. The particle sizes of the dust can range from $< 1\ \mu m$ to $2500\ \mu m$, with a much as 50% being $< 100\ \mu m$. Incorporation of this fine dust into animal feeds can cause increased exposure of pesticide residues to animals, and these residues could be transferred into the human food chain through livestock meat, milk, or eggs. Concentration of residues in aspirated dust can also potentially occur if measurable surface residues of pesticides are found on harvested grain/oilseeds even from preharvest treatment.

The incorporation of **"aspirated grain fractions"** into animal feeds would fall under the auspices of the Federal Food, Drugs, and Cosmetic Act (Amended January 1980) if a tolerance for pesticide residues is needed as a result of moving cereal grains and oil seeds through commerce. A discussion of this feed use for **"aspirated grain fractions"** from a tolerance perspective follows in this report. Included is a summary of the estimated total volume of aspirated dust that might be available yearly from export elevators for animal feeds. Since these estimates are based upon the total US grain export volumes, the R/R dust would also be included in the estimated dust volumes and these estimated volumes will not be affected even if the FGIS prohibits the recombination of the recirculation dust. Also included is a discussion how the aspirated dust is used in animal feeds, the extent of its use in the cattle, swine, and poultry producing industries, and conclusions about residue data needs for this aspirated dust.

DEFINITIONS/CHARACTERISTICS

The 1993 Official Publication of the Association of American Feed Control Officials (AAFCO) defines **"grain dust"** (Section 60.43) as **"aspirated grain fractions"**. [(IFN 4-12-208) Cereals-oil seeds grain and seed fractions aspirated.]: **"'Aspirated grain fractions'** are obtained during the normal aspiration of cereal grains and/or oil seeds for the purpose of environmental control and safety within a grain handling facility. It shall consist primarily of seed parts and may not contain more than 15% ash. It shall not contain aspirations from medicated feeds." (Note:

Medicated feeds refer to those treated with animal drugs; Ash is defined as the mineral residue remaining after combustion in air.). [International Feed Numbers and Names (IFN) were developed and provided by the Feed Composition Data Bank, USDA National Agricultural Library, Beltsville, MD.].

A related grain byproduct is called **"chaff and/or dust"**. This material is collected in grain processing plants solely to clean the grain, whereas **"aspirated grain fractions"** are collected at grain elevators for environmental and safety reasons. The AAFCO defines **"chaff and/or dust"** [IFN 4-02-149 Cereals-legumes chaff and/or dust (Section 81.3, Screenings)] as follows: **"Chaff and/or dust** is material that is separated from grains or seeds in the usual commercial cleaning processes. It may include hulls, joints, straw, mill or elevator dust, sweepings, sand, dirt, grains, seeds. It must be labelled, 'chaff and/or dust'. If it contains more than 15% ash the words 'sand' and 'dirt' must appear on the label." **"Chaff and/or dust"** is normally recombined with unprocessed broken grain pieces and/or bran before being used in animal feeds. Any pesticide residues in regard to tolerance needs would be considered in grain byproducts from the grain processing.

Therefore, only the residue data requirements of the tolerance setting process for **"aspirated grain fractions"** will be considered in this discussion.

Although **"aspirated grain fractions"** can be defined in general by IFN 4-12-208, more specific characteristics for this dust are not as easily defined. First, the dust collection systems are designed to achieve safety and air quality, and not to isolate the dust by particle size or content, i.e., dust, and/or chaff, bran, other light materials. There are no specific guidelines or industrial standards of dust collection equipment for grain handling facilities. Second, the large variability of the dust composition is governed by the location, time of year, and crop condition at harvest, as most elevators handle grains on a seasonal basis, e.g., wheat in the summer, and corn, sorghum, and soybeans in early fall. Third, the dust is not normally segregated by an individual grain or seed commodity as it is collected, but is trapped in a common container or bin. Normally this dust will be recombined with other transient grain at the elevator site. Thus, a composite of this aspirated dust will probably be found at inland and export terminal elevators. In general, aspirated dust from one commodity will only be found at country elevators.

Various physical properties, e.g., particle size, density, and surface area, are basic parameters that can be measured aspirated dust. Figures 1 through 5 (Appendix A) show the dry-sieved fractions of corn, rice, soybean, wheat, and wheat-sorghum dust, respectively, from terminal elevators located along the Gulf coast. These samples were analyzed for the purposes of elevator explosion studies, and showed that all five dusts had the greatest mass percentage in the 45 to 106 μm range. The level of large particles greater than 1000 μm varied from 25% for both wheat and wheat/sorghum samples to only 1% for rice. Wet-sieved measurements in Figure 6 (Appendix A) shows a similar pattern, i.e., greater mass percentage below 400 μm. Figure 7 (Appendix A) reveals large differences between the dry- and wet-sieved measurement methods for the 100 μm particle size, but these differences are explained by entrapment of the irregularly shaped particles on the top of the filter media in wet sieving, while the mechanical shaking in the dry sieving causes the particles to reorient so these pass through the sieve openings. Dry sieving may also cause addition mechanical breakdown of the dust

and subsequent generation of smaller size dust particles. In either case, results show that the dust consists of very fine particles, particles which probably contain highly absorbent surface areas.

Other workers have investigated particle size distribution and found similar results. These samples, however, were analyzed only for the purposes of investigating dust explosions (dust particles below 100 μm): wet sieving of the soybean, rice, corn, wheat, and sorghum dusts showed 51%, 44%, 54%, 34%, and 34% (% by wgt), respectively, of dust particles below 100 μm.

Additional particle size data were reported for wheat and wheat/oats aspirated dust samples that were collected from three Texas Gulf export terminals in the Houston/Corpus Christi area. These samples were dry-sieved through the following four screen sizes: 2030, 1190, 841, and 420 μm. The size distribution patterns are shown in Figures 8 through 10 (Appendix A). The two wheat samples showed approximately 79% and 68% (% by wgt) of the particles <420 μm. The remaining 11% and 5% (% by wgt) of the particles were greater than 1190 μm, and ca. 21% and 32 % of the particles greater than 420 μm, respectively. In comparison, the wheat sample in Figure 4 (Appendix A) showed ca. 25% of the particles greater than 1000 μm, and 34% greater than 500 μm, thus underlining the point about the variability of particle size distribution based on the factor discussed above. However, the data indicate that a large portion of the **"aspirated grain fractions"** can be defined as very small particle sizes, usually <420 μm, and a very useful characteristic to more adequately define the elevator aspirated dust.

The ash content of samples in Figures 1 through 5 (Appendix A) showed considerable variation. The corn dust sample was the lowest in ash with only 1.8%, the wheat and wheat/sorghum samples had 12% and 7.7%, respectively. Rice showed 32%, and soybeans showed 33% ash. The high ash content in rice is a result of soil particles and husk parts which concentrate in the aspirated dust. The high ash content in soybeans is a consequence of soil contamination in the harvested soybeans which eventually concentrates in the aspirated dust. As stated above the ash content of **"aspirated grains fractions"** is defined at less than 15%. Ash content, of course, based on seasonal and harvesting differences can also vary, and is probably a more general term to be used in defining **"aspirated grain fractions"**.

VOLUMES OF EXPORTED GRAINS AND ESTIMATED VOLUMES OF ASPIRATED GRAIN FRACTIONS.

In order to estimate the volume of **"aspirated grain fractions"** produced annually in the US, and the subsequent incorporation into animal feeds, the US volumes of grains harvested and moved into and out of grain elevators must be considered.

Based on Agricultural Statistics (1992), the US has produced up to 347 million metric tons of grains/oilseeds (i.e., corn, wheat, soybeans, grain sorghum, barley, oats, rye, and rice) in one year. The percentage breakdown for the specific grains are corn, 40%, wheat, 28%, soybeans, 14%, grain sorghum, 6%, barley, 4%, oats, 4%, and other (including rye and rice), ca. 4%.

Based upon FGIS grain export data, an average of 4.1 billion bushels (Bbu) of inspected U.S. grains/oilseeds (i.e., corn, wheat, soybeans, sorghum, oats, barley, and rye) have been exported each year from 1987 to 1992. FGIS no longer measures rice exports because of minute volumes. Exported grains may pass through three types of elevators, i.e., country, inland, and export terminals. There are over 7000 country elevators in the U.S., approximately 400 inland terminals, and 63 export facilities (Grain Guide, 1990) which handle US grain storage/commerce. Aspirated dust is handled at each type of elevator, but several factors must be considered in the estimation of the volumes of this aspirated dust produced in the US per year. These factors are: 1) according to a grain industry representative, grain can be moved up to 10 times before it is exported or processed; 2) dependent on the grain harvest, the US can export as much as 1/3 of the total harvested and stored grain in a year; 3) every time grain is moved in an elevator, the amount of dust collected can reportedly range from 0.06 % to 0.7% of the total weight of grain moved; the best industrial estimation, to include all grains, since some are dustier that others, is 0.2%; 4) since the country and inland elevators normally recombine the collected dust to the transient grain, then presently the disposal of dust is only a problem at the export facilities; less dust from the grain may be available at the country elevator since this is normally the first storage location after harvest where most of the grain drying occurs; 5) in addition, at no point in the movement of grain from the farm to the export terminal is there any economic incentive to separate the aspirated dust from grain; the economic incentive is to transport all grain products (including the dust) forward from the country elevator to the inland terminal, and subsequently to the export terminal; any products that are separated and not returned to the grain stream are losses referred to as "shrinkage", and mean a financial difference in the total payment for the grain with the dust vs. without the dust.

If the problem of estimation is approached in consideration of these factors, then any best estimate of the total volume of **"aspirated grain fractions"** available for livestock feeds should be based upon the U.S. export grain/oilseed volumes, and not the U.S. yearly production volumes. Corn averages 46%, wheat, 30%, soybeans, 16%, and sorghum, 6% of this 4.1 Bbu export volume and these crops make up 98% of the total U.S. grain exports each year. Oats, barley and rye make up the remaining 2% of the total exports. FGIS no longer records rice exports.

Table 1 (Appendix B) gives FGIS data for grain volumes shipped from U.S. export elevators for corn, wheat, sorghum, soybeans, barley, oats, and rye.

Based upon the grain volumes listed in Table 1, and using the industry estimate of 0.2 % for **"aspirated grain fractions"** usually collected from transient grain, Table 2 (Appendix B) gives estimations of the total volumes of **"aspirated grain fractions"** that could be available at export terminals, **per move**, within a storage/export facility.

Recently in a report prepared for FGIS by Texas A & M researchers volumes of bin dust collected by aspiration were reported from seven US export facilities (See Table A).

TABLE A. Volumes of Grain Handled Yearly and Amounts of Bin Dust Generated at Seven Export Elevators.

Elevator	Million Bu/Yr Grain	Amount of Bin Dust (tons/yr)	Pounds of Bin Dust/ton of Grain	Average % of Bin Dust in Grain
1	360	5000	1.0	0.05
2	129	7150	3.9	0.2
3	400	0	0	0
4	430	12,600	2.1	0.1
5	40	1300	2.3	0.11
6	100	1300	0.75	0.04
7	470	13,000	2.0	0.1

The volumes of grain handled per year for the seven facilities ranged from 40 Mbu to 470 Mbu. These seven elevators not only span the range from the small public elevator to the large corporate elevator, but also accounted for 47% of the U.S. annual average grain exports of 4.1 billion bushels.

The above table also gives the amount of dust collected per ton of grain handled by the bin dust systems in operation at seven export elevators and the average weight percentage of bin dust collected vs. grain weight. If these elevators handle 47% of the total US grain exports, then a rough estimate of the total bin dust collected at the 63 export terminals is 86,000 tons/yr (1.7 million lb./yr). This of course does not include the R/R dust which at the present time is added back to the grain stream. If FGIS decides that R/R dust must be collected and not returned to the grain stream, then the volume of dust could double, i.e., 172,000 tons/yr (3.4 million lb./yr). Table A also shows the large variability between elevators of the amounts of dust produced because of the varying degrees of moisture in the transient grains/oil seeds, differences in the aspiration equipment at the elevator sites, and the type of grain/oil seed passing through a facility. This 172,000 tons/yr value is approximately 2/3's the total estimated in Table 2 using the 0.2% (by weight) value for the amount of dust generated each time the grain is moved. Judging from this fact, it appears that the 0.2% value will provide a good estimate of the total amount of **"aspirated grain fractions"** that could be available in one year for inclusion in animal feeds.

According to the authors of the above report, the data presented in Table A are affected by the following: Elevator 2 collected more dust per ton of grain than the others because approximately 85% of this elevator's dust control systems were the bin dust type. Elevator 3 uses 100% recirculation/recombination systems, therefore it had 0% bin dust. All the other elevator's dust control systems were approximately 50% bin dust except elevator 5. A high percentage of elevator 5's export was sorghum, and since sorghum tends to have higher dust

levels than corn or soybeans, this elevator uses mineral oil for dust suppression. Elevator 1 had a pelleting system for their dust and data on the amount of dust collected per year was not as reliable as some other elevators. Elevator 6 exported predominantly hard wheat which tends to contain significantly less dust than corn or soybeans.

However, even with these variations between elevators, the 172,000 tons/year value is still a good estimation of the total volume of **"aspirated grain fractions"** that can be funneled into the US animal feedstuff market on an annual basis.

UTILIZATION IN ANIMAL FEEDSTUFFS

"Grain dust appears to be a suitable feedstuff for swine and poultry, replacing part of the grain in the ration. Use in feeds could provide a market for dust, making efficient dust collection more feasible, improving elevator safety and providing cleaner commodities." (Behnke, Clark, and Helman, 1979). (Note: As explained below, "aspirated grain fractions" is **not being fed** to poultry.)

"Our preliminary studies indicate that cereal grain dust has nutritive values similar to the grain itself. If we can process it on site (in elevators and mills), it will be much more readily acceptable for use in the feed industries."...." In studies conducted with cattle, crumblized dust replaced 70 percent of the cereal grain fraction of the ration with no apparent rejection or reluctance to consume demonstrated by the animals." (Behnke, 1978)

These comments of fifteen years ago, still hold today.

The feed industry has always been an outlet or dumping ground for waste materials or byproducts from other industries. A high percentage of the modern feeds are composed of materials which were formally considered waste, e.g., byproducts from the cereal milling, meat packing waste, vegetable and fruit processing waste, brewers' and distillers' grains, and livestock waste. These materials have high feed value in today's feedstuff market.

Studies have indicated that **"aspirated grain fractions"** from cereal grains and soybeans have nutritive values similar to the grain or seed itself. The technology to remove the dust from grain has been available for almost 50 years, thus **"aspirated grain fractions"** is not a recent or new feedstuff, but has been an acceptable ingredient in feed for years. However, government regulations and potential environmental hazards from the presence of pesticides, have narrowed the avenues for disposal of this aspirated dust. There is an economic resistance to removing this material because removing it is expensive, i.e., the dust is paid for at the price of the grain. When it is removed, it reduces the weight of the grain and the profits from the grain, and the dust is worth a lot less in this form. Therefore, the animal feedstuffs market is a viable alternative for disposal of **"aspirated grain fractions"**.

However, several factors affect the **"aspirated grain fractions"** composition: 1) type of dust collecting system, 2) type of grain, 3) season of the year, and 4) supply point in the grain handling system. The closer a grain facility is to the point of harvest, the greater the effect of seasonal harvest on the **"aspirated grain fractions"** quality. A port terminal sees little difference in product mix throughout the market year; consequently, the dust would be quite similar in mix throughout the year. A country elevator in western Kansas in June would

expect to handle very little grain sorghum, while an eastern Kansas elevator in November would likely handle mostly corn, sorghum, soybeans, and some wheat. In addition, inland and country elevators also show variability during the year, i.e., dust from a country elevator would be expected to be somewhat lower in quality than dust from a port or large inland terminal due to soil contamination from the harvest. Then as grain is handled at each subsequent location, the proportion of fines generated from the moving grain would increase relative to the dirt from the harvest.

Several problems face the feed industry in utilizing **"aspirated grain fractions"**: 1) the product is hazardous to handle in its normal state, both from a human risk exposure and from a potential explosive nature, 2) the quality is somewhat variable and the supply is sometimes erratic, and 3) the dust provides an ideal growth media for germination of mold spores if the moisture content is high enough. However, one restriction placed on the utilization of **"aspirated grain fractions"** is simply its name "dust". To overcome this problem, the grain and animal feed industry commonly refer to this dust product as **"aspirated grain fractions"**.

Based upon the feed industry uses of **"aspirated grain fractions"**, the initial estimate of 20% of the diet was used for all livestock, although some research had shown that the dust can be fed up to 50% to cattle and swine. **"Aspirated grain fractions"** is normally mixed with other feedstuffs (e.g., molasses as a binding agent), or it can be pelleted by mixing with alfalfa meal at 50% to produce "range cubes" which are fed possibly at 20-30% in addition to other feedstuffs, e.g., grasses, hay, etc. Dairy farmers and processors of dairy feeds also tend not to use **"aspirated grain fractions"** in feeds because of the possibility of pesticide contamination of milk. Leading US poultry producers have stated that the current poultry production practices prevent the use of **"aspirated grain fractions"** in their feed mixes because of the possible presence of high pesticide concentrations in the feed which can result in a lower weight gain for broiler and/or a drop in egg production with laying hens. Thus, the inclusion of **"aspirated grain fractions"** in poultry diets should not be considered. It also appears that much more of the dust may be used for beef cattle, than for other livestock.

SIGNIFICANCE OF ASPIRATED GRAIN FRACTIONS TO RESIDUE CHEMISTRY DATA REQUIREMENTS. QUESTION and ANSWERS.

Should "aspirated grain fractions" be considered an animal feedstuff?

"Aspirated grain fractions" is used in animal feeds, although it appears that this feed may be restricted largely to the beef producing industry. Data to support that **"aspirated grain fractions"** are not being fed to dairy cattle are not presently available, and thus, it must be considered a feed item for both beef and dairy cattle. **"Aspirated grain fractions"** should also be considered a feedstuff for swine. However, comments from the leading poultry producers clearly show that **"aspirated grain fractions"** are not used in the poultry industry, and should not be considered a poultry feed item. **"Aspirated grain fractions"** should not be considered for the remaining livestock, i.e., horses, sheep, and goats, or for catfish.

What are the maximum levels of "aspirated grain fractions" that could be in animal diets?

Based upon available data, a maximum anticipated use level of 20% in animal feeds, to include poultry had previously been established. Currently, data in this report still support this 20% value, thus the use of this level in cattle and swine diets only should be considered.

What grains/oil seeds should be considered contributors to the "aspirated grain fractions" used in animal feeds?

Based upon the US export volumes it appears that corn, wheat, sorghum, and soybeans are the major grains/oil seed that will generate the estimated elevator dust volumes shown in the above tables. Barley, oats, rye, and rice are either exported at very low volumes or not at all, and any dust collected from these grains would make up a very small percentage (<2%) of the total **"aspirated grain fractions"** available for animal feeds. In addition, rice grain dust is not used in animal feeds because of a high silica content of >30%.

Can the "aspirated grain fractions" residue data from one crop be translated to support the required residue data on one of the other three grains?

Because of different growing patterns, i.e., difference in the grain exposure because of protective glumes around the kernels in several crops, and possibly different application patterns of the pesticide, individual data will be required for corn, wheat, sorghum, and soybeans, and should not be translated from one to the other to support a proposed or registered use.

Should "aspirated grain fractions" be considered a rac or a processed commodity?

Presently the grains of corn, wheat, and sorghum, and the seed of soybeans are considered rac's. When the grain is harvested and stored some dust is present on the grain. **"Aspirated grain fractions"** from these crops are removed by aspiration methods for environmental and safety reasons as the grain and seed are moved through commerce. This dust is normally added back to the whole grain/seed as it travels through country and inland elevators, with final removal, in many cases, occurring at the export elevators. Removal and/or addition of this aspirated dust does not change the rac. There is no processing **per se** involved in its removal or its addition. Therefore, for consistency, **"aspirated grain fractions"**, which is only a portion of the whole grain or seed at harvest and storage, should also be considered a rac.

Should tolerances be established for each of the four crops listed above?

According to the grain elevator industry, **"aspirated grain fractions"** is normally a composite of more than one grain. The collected dust from the grain being moved through the elevator is added to a common dust bin, meaning that the dust from corn can be added to dust from wheat, the dust from sorghum can be added to corn, etc. Therefore, a tolerance for **"aspirated grain fractions"** should be established for the pesticide, and this tolerance should consider the use of a pesticide on corn, wheat, sorghum, and/or soybeans. For example, if the pesticide is used only on one grain/oil seed, then the tolerance should be established assuming this crop will represent 100% of the dust. If the pesticide is used on several crops, then the rac with the highest residues in the dust will be used to establish the tolerance.

Are residue data needed for both preharvest and postharvest uses?

Presently residues data for **"aspirated grain fractions"** are required for all postharvest applications of pesticides for corn, wheat, sorghum, soybeans, barley, oats, rye, and rice, and on some preharvest applications for these crops with a zero day or short PHI whose seed heads are formed at the time of application. **However, based upon the above discussion, "aspirated grain fractions" data is needed only for corn, wheat, sorghum, and soybeans.**

Residue data should be submitted in support of all postharvest uses. Data needs for a preharvest use follow the discussions on postharvest uses.

How are residue data for "aspirated grain fractions" to be collected for a postharvest use?

For a postharvest use the following can be used as a reference to help design a laboratory experiment to measure residue levels in **"aspirated grain fractions"** from transient grains in elevator operations.

If the pesticide is currently registered for a postharvest use, then treated grain from a commercial operation can be used. The treated grain should be analyzed for residues of the pesticide under investigation, then cleaned by an aspirated method identical or similar to a commercial elevator operation to trap the dust. For each 100 lb of grain, the amount of dust should be approximately 200 g. Depending upon the pesticide residue levels, this may or may not be a sufficient amount for fractionation and analyses; larger quantities of grain may be utilized. Next, the cleaned grain and the dust should be analyzed for the pesticide residues, and the level of pesticide residue concentration determined. However, before analysis of the dust, it should be fractionated into 4 or 5 different ranges, e.g, under 400 μm, 400 to 800 μm, 800 to 1200 μm, 1200 to 2000 μm, and 2000 to 2500 μm, or any other similar sieve sizes to determine the particle size distribution. The purpose of this distribution data is to show that the aspirated dust sample typifies a sample of commercial elevator **"aspirated grain fractions"**; normally, at least 50% of the elevator **"aspirated grain fractions"** have a particle size of <400 μm. But, for purposes of residue analysis, the pesticide treated dust should be recombined since this reconstituted dust sample would be more representative of **"aspirated grain fractions"** used in commercial feed production and/or feeding practices. In addition, since **"aspirated grain fractions"** are defined according to the American Feed Control Association to contain ash at less than 15%, the ash content of the combined dust fractions should also be determined. The elevator dust sample should be analyzed using methodology for the pesticide under investigation which does not exhibit interference problems from residues of other registered cereal/oilseed pesticides that might be present from prior applications. It is recommended that triplicate samples be taken. Duplicate analyses of pesticide residue levels should be performed on all samples.

An alternative procedure for either a currently registered postharvest pesticide, or a proposed registration of a newly developed postharvest pesticide could be as follows.

First, **"aspirated grain fractions"** that has been collected by a commercial elevator aspiration system should be acquired. A particle size distribution of the aspirated dust should be measured from 2500 (or 2000) μm to under 400 μm (using 4 or 5 sieve sizes to cover this range as described above), and the ash content determined. Analysis of the untreated dust

as the control will indicate any problems if other pesticides are present from prior applications. A sample of the grain should be cleaned by aspiration, using a method identical or similar to commercial operations. Next, using the unfractionated aspirated dust sample that was acquired as described above from a commercial grain elevator, apply the dust to the cleaned grain at a rate of 0.2% (by weight), and mix to distribute the dust evenly over the grain. Apply the pesticide at its maximum allowable label rate, and after the solvent has dried, a portion of the grain, which is now covered with the aspirated dust and the pesticide, should be sampled for analysis. Remove the treated dust from the grain by an aspirated method, and analyze this cleaned grain and the treated dust for pesticide residues. It is recommended that triplicate samples be taken. Duplicate analyses of pesticide residue levels should also be performed on all samples. The level of concentration should be determined for the pesticide using average results.

Will separate storage stability data be required for "aspirated grain fractions"?

Storage stability data on the whole grain will adequately support storage of **"aspirated grain fractions".**

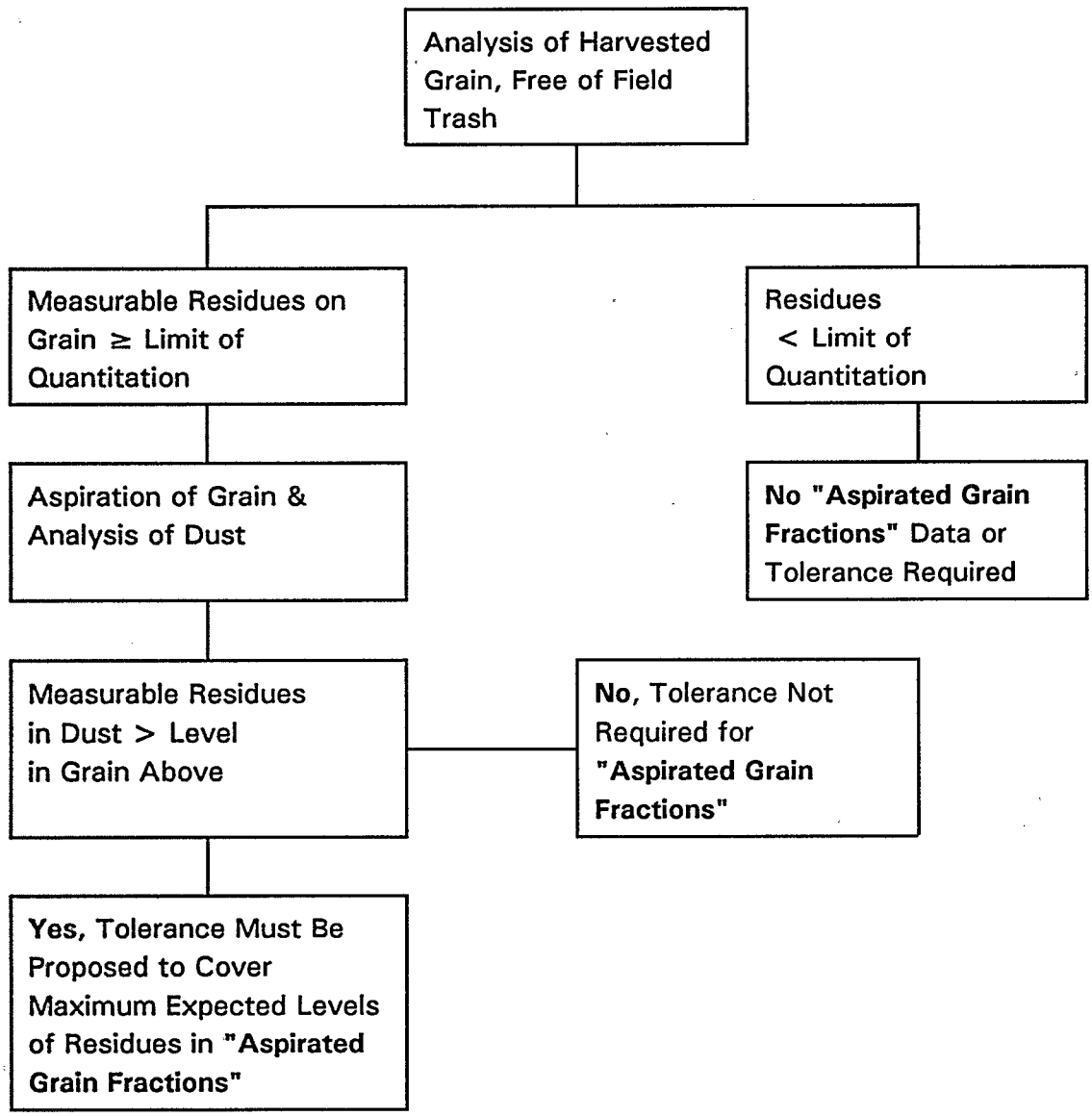
Are any additional data needed for postharvest pesticides normally used on stored grains?

According to an industry representative, in commercial practices, grain can be moved as many as 10 times before utilized, processed, or exported. However, a new pesticide application may not always accompany the grain transport every time. Previously, however, for the purposes of residue studies, in regard to possible multiple postharvest applications of some grain pesticides, CBTS required "grain dust" data to reflect a minimum of four applications over a minimum one-year period, with the collection, particle size distribution, and residue analysis of the treated grain and the dust only at the end of the one-year trial.

However, on reconsideration of these four applications due to, 1) vast variability of the **"aspirated grain fractions"** composition (composite mixture in grain dust collection bins), 2) variability of volume of **"aspirated grain fractions"** collected from transient grains (0.05 to 0.7 % by weight), 3) possible partial removal of pesticide residues when the aspirated dust is collected from transient grain, and 4) residue data showing low levels of pesticide residues in support of the several postharvest pesticide from samplings of commercial elevator **"aspirated grain fractions"**, it appears that four application are not needed. **Therefore, one application at the maximum allowable label rate**, followed by the collection and the analysis of the **"aspirated grain fractions"** for the pesticide immediately after application, should provide sufficient data to adequately determine the expected level of a pesticide in commercial elevator **"aspirated grain fractions"**. The collection and analysis of this dust should follow the above suggestions for the gathering of **"aspirated grain fractions"** data from a postharvest pesticide use. The Agency reserves the right to change this data requirement if actual commercial practices change to require additional applications.

When and how are residue data for "aspirated grain fractions" to be collected for a preharvest use?

For a **preharvest use**, residue data for **"aspirated grain fractions"** will not normally be needed if the pesticide is applied during the vegetative stage and before the reproduction stage begins and seed heads are formed, unless the plant metabolism and /or processing study shows a concentration of residues of regulatory concern in outer seed coat. If there are higher pesticide residues in the outer seed coat, data needs for preharvest uses are determined according to the following flowchart:



Note: Additional guidance for data requirements for aspirated grain fractions can be obtained from the Chemistry Branches, HED, OPP, OPPTS, EPA.

REFERENCES

American Feed Control Officials, Inc. Official Publication 1993.

Anderson, S. L. and Foley, K. M. Current Utilization of Grain Dust. National Grain & Feed Assoc. Research Report. March 13, 1981.

Behnke, K. C., Grain Dust May Be a Quality Ingredient. Feed Industry Review, 54 (20): 20-21. 1978.

Behnke, K. C. Grain Dust Utilization, A Literature Survey. National Grain & Feed Assoc. Research Report. December, 1979.

Behnke, K. C., Clark, III, H. M., and Helman, L. Grain Dust Utilization in Animal Feeds. FEEDSTUFFS, 51 (11): 31-32. March 12, 1979.

Clark, III, H. M. The Incorporation of Grain Dust in Livestock Diets. M. S. Thesis. Kansas State University. Manhattan, KS. 1979.

Gerngross, M. Food Protein and Development Center, Texas A & M University. Letter to the author, July 5, 1990.

Grain Guide/North American Grain Yearbook. Milling & Baking News (Pub.), Shawnee, KS. 1990.

Martin, C. R. Characterization of Grain Dust Properties. Transactions of the ASAE, 24 (3): 738-742. 1981.

Miller, B. S. and Pomeranz, Y. Proceedings of the International Symposium on Grain Dust. pp 219-240. October 1979.

Parnell, Jr. C. B., Jones, D. D., Rutherford, R. D., and Goforth, K. J. Physical Properties of Five Grain Dust Types. Environmental Health Perspectives, 66: 183-188. 1986.

Parnell, Jr., C. B., Spillman, D. D., and Whitelock, D. P. Impact Study of Prohibiting Recombining Recirculation Dust At Export Elevators. Contract report from Texas A & M University to FGIS, USDA. February 1992.

OSHA. Grain Handling Facilities: Final Rule. Federal Register, Vol. 52, No. 251, December 31, 1987, pp. 49624-49631.

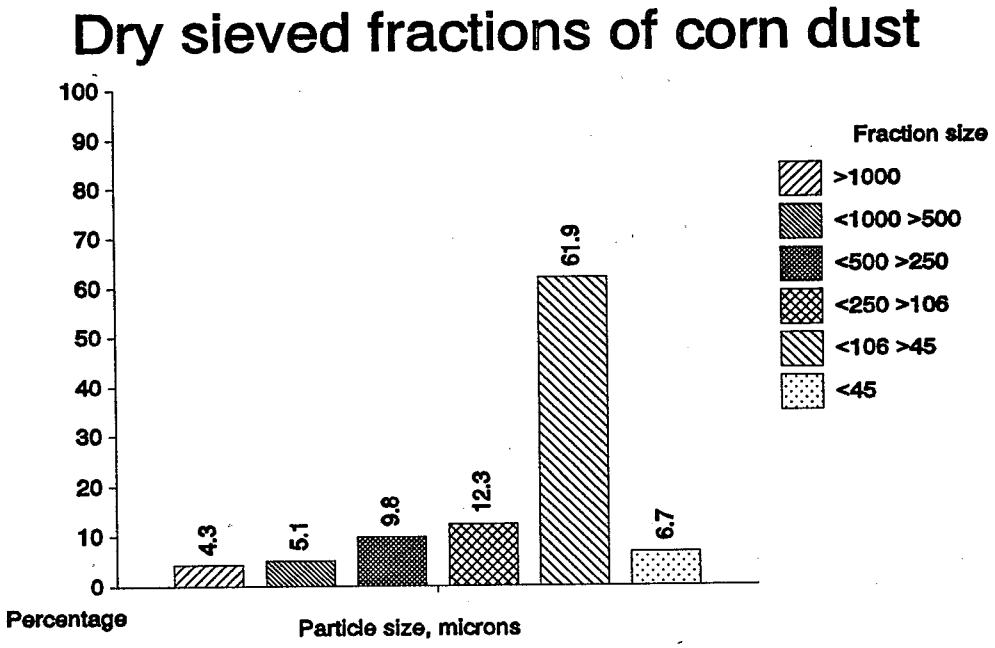
Schnake, L. D. Grain Dust: Problem and Utilization. USDA, ESS-6, April 1981.

USDA. Agricultural Statistics 1993. U. S. GPO. Washington, D. C. 1993.

USDA. Grain Standards: Official U. S. Standards, Handling Practices and Insect Infestation: Final Rules. Federal Register, Vol. 52, No. 125, June 30, 1987, pp. 24414-24441.

USDA. Task Force Report: Prevention of Dust Explosions In Grain Elevators - An Achievable Goal. U. S. GPO, 0-310-945/FGIS-24. 1980.

APPENDIX A



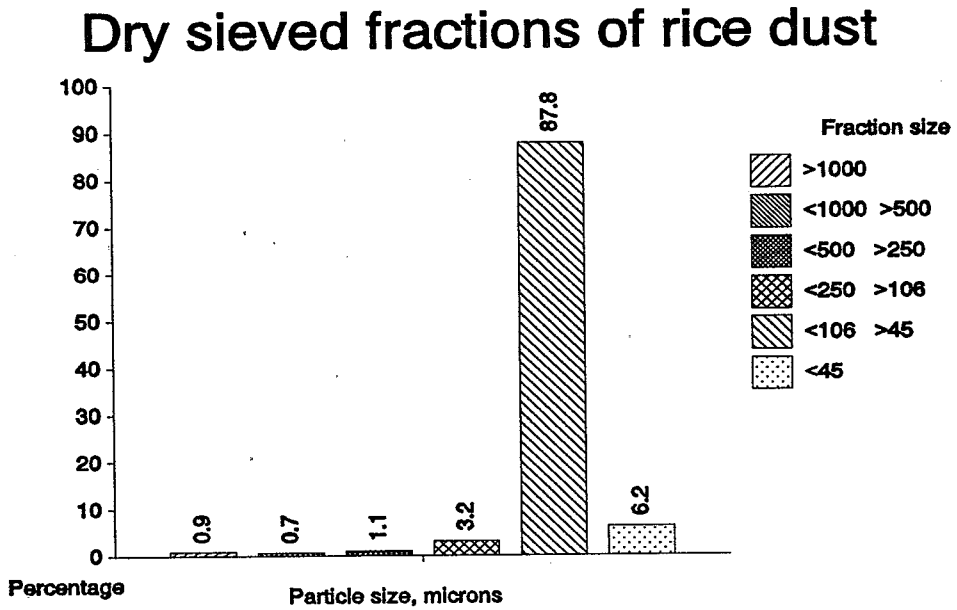
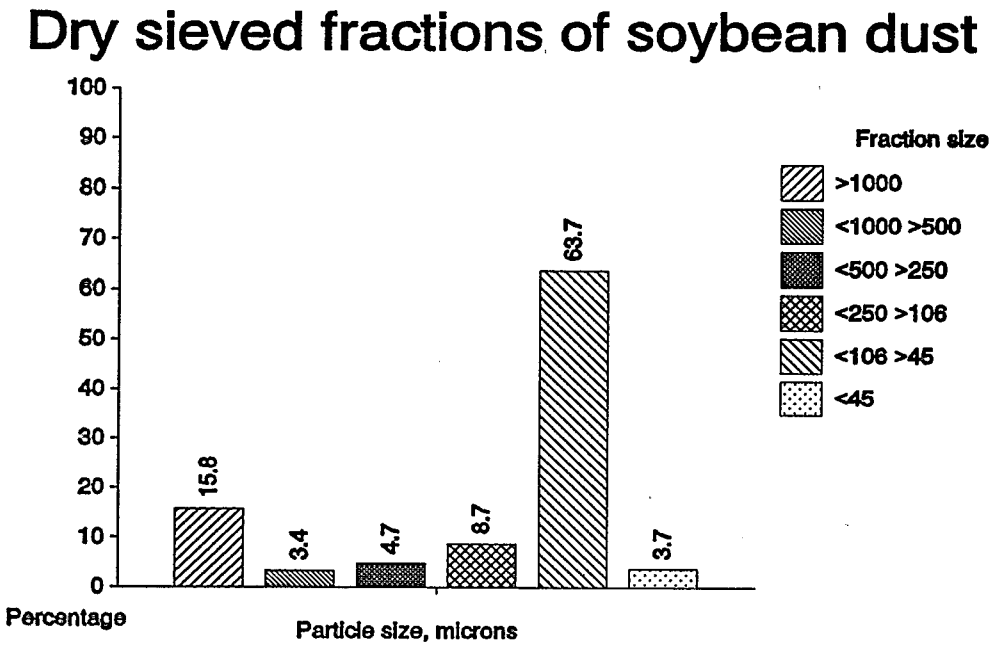


Figure 1. (top) and Figure 2. (bottom)



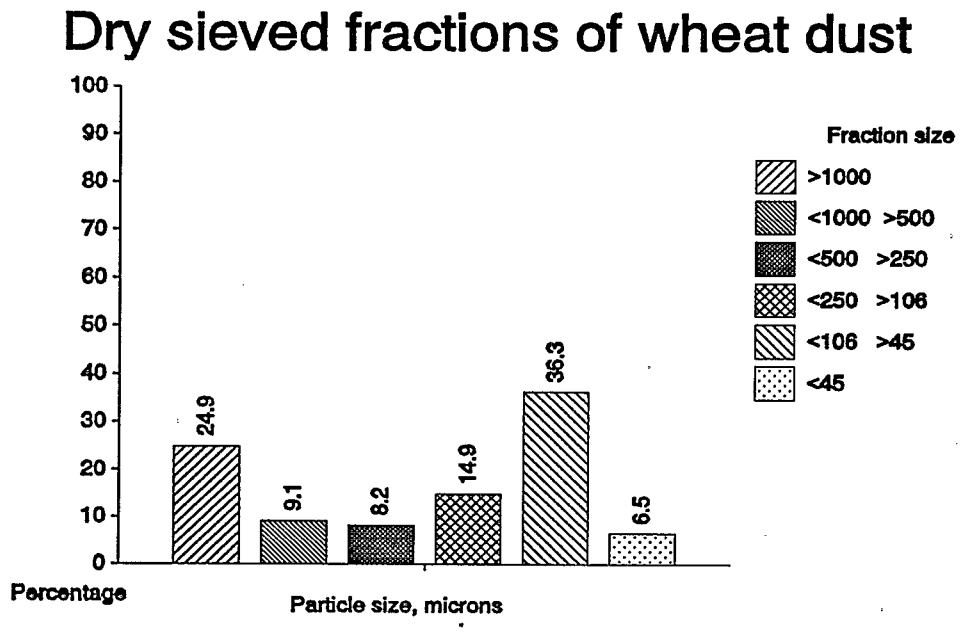
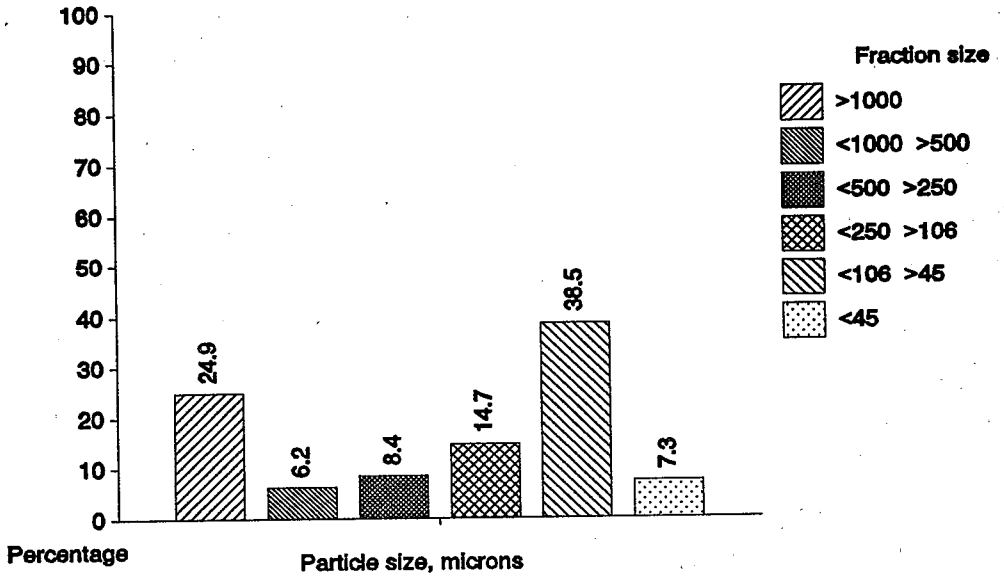


Figure 3. (top) and Figure 4. (bottom)

Dry sieved fractions of wheat/sorghum dust



Wet sieve analyses of five grain dusts

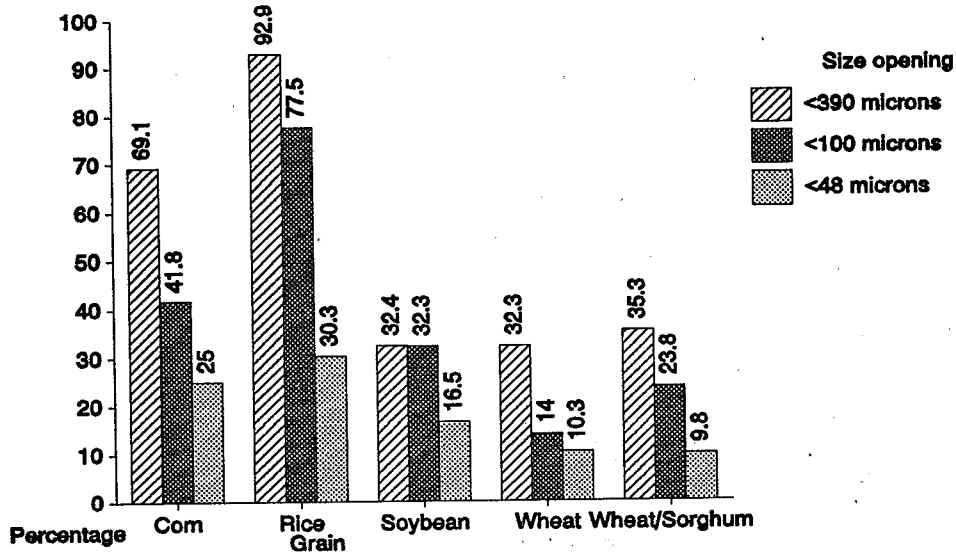


Figure 5. (top) and Figure 6. (bottom)

Comparison of wet and dry sieving methods

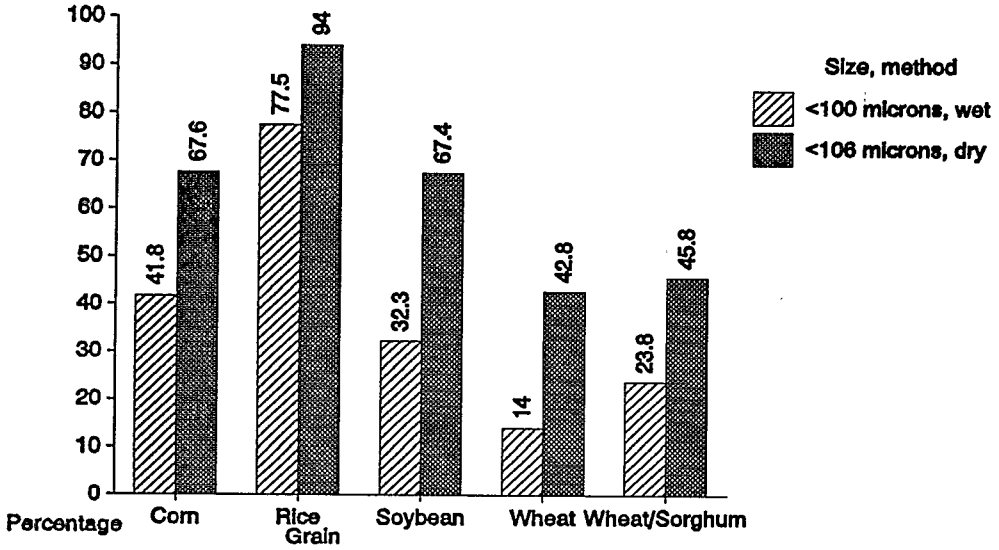
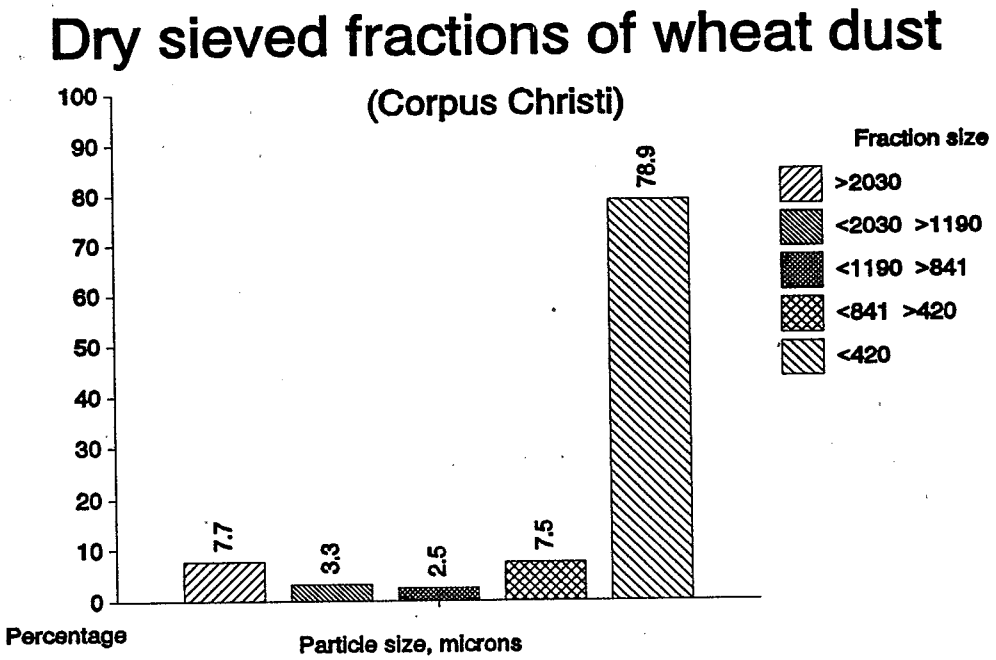


Figure 7.



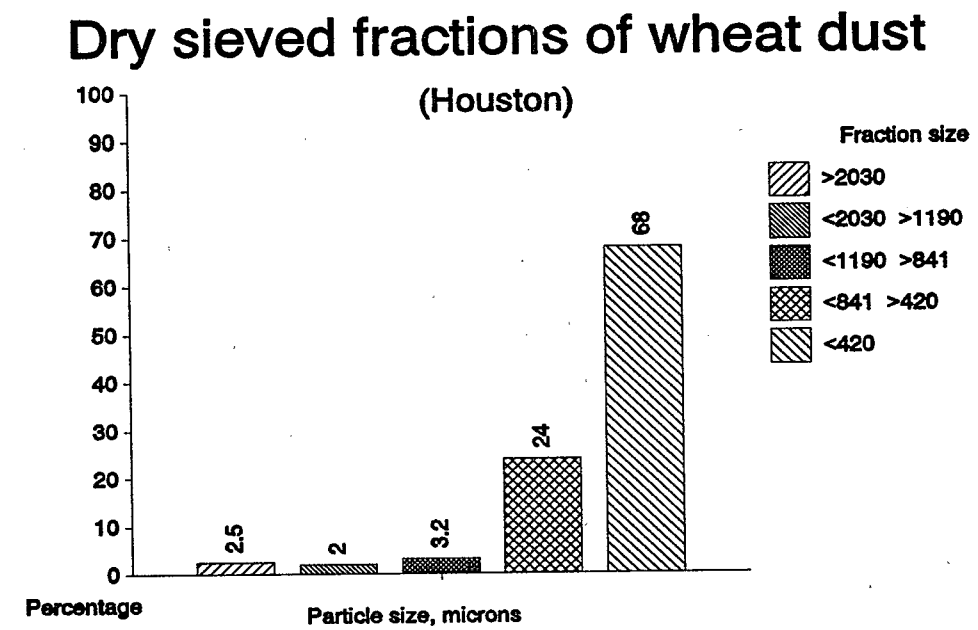


Figure 8. (top) and Figure 9. (bottom)

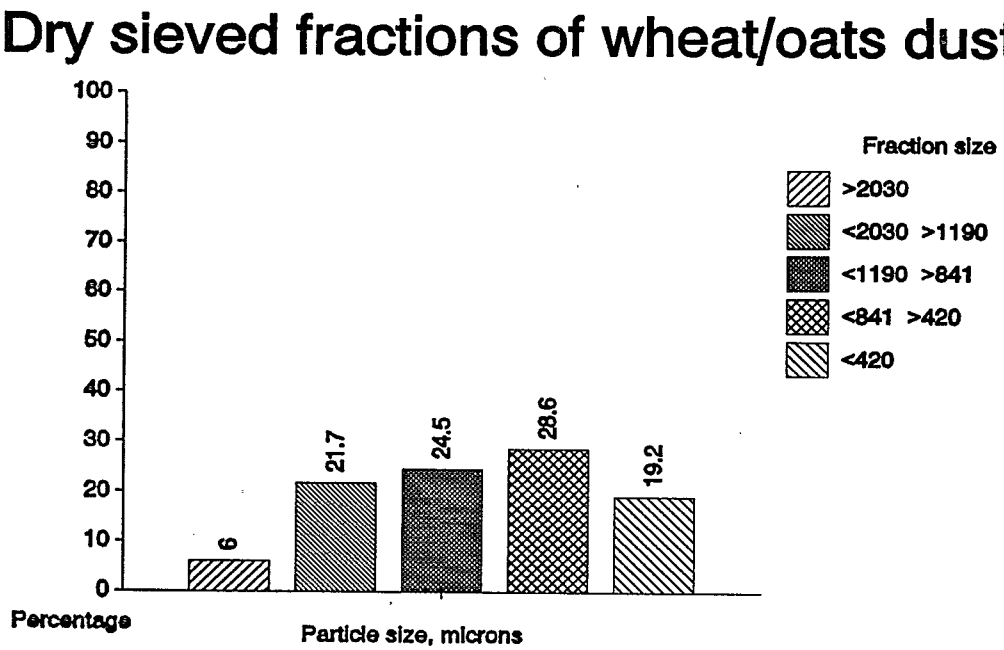

Dry sieved fractions of wheat/oats dust
100
90
80
70
60
50
40
30
20
10
0
Percentage
6
21.7
24.5
28.6
19.2
Particle size, microns
Fraction size
>2030
<2030 >1190
<1190 >841
<841 >420
<420

Figure 10.

APPENDIX B

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Corn	Atlantic...						
	N. Atlantic	4,139	9,688	3,737	10,622	1,260	3,306
	S. Atlantic	17,854	55,250	83,479	84,857	66,227	80,701
	Gulf...						
	East Gulf	11,783	1,557	5,153	9,334	10,307	42,207
	Miss. R.	1,349,075	1,313,191	1,440,406	1,438,511	1,207,641	1,125,394
	N. Texas	11,184	5,702	22,301	41,079	15,658	10,401
	S. Texas	4,733	3,587	5,184	7,142	6,436	5,962
	Interior	8,530	8,988	8,921	22,127	42,572	36,644
	Lakes...						
	Chicago	10,115	12,284	14,610	24,775	32,487	26,002
	Duluth-Sup.	4,953	3,851	6,912	11,362	32,252	1,300
	Saginaw	-	-	-	475	-	-
	Toledo	34,390	23,827	27,261	52,376	29,565	43,843
	Pacific...						
	California	-	-	-	737	-	-
	Columbia R.	142,681	162,225	245,687	246,969	208,914	158,126
	Puget Sound	116,171	157,777	194,710	267,858	203,219	99,246
	SUBTOTAL	1,715,608	1,757,927	2,058,361	2,218,224	1,856,538	1,633,132

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Wheat	Atlantic...						
	N. Atlantic	-	2,415	-	1,115	637	-
	S. Atlantic	25,828	23,621	26,156	87,521	42,193	23,441
	Gulf...						
	East Gulf	2,441	9,609	8,007	10,726	7,936	5,916
	Miss. R.	405,243	317,088	300,122	406,129	266,653	182,923
	N. Texas	323,462	346,141	237,265	389,784	590,666	479,120
	S. Texas	8,574	13,190	15,991	6,823	29,441	16,442
	Interior	5,227	2,511	284	2,278	7,243	2,482
	Lakes...						
	Chicago	-	-	-	767	-	1,367
	Duluth-Sup.	52,594	46,727	57,651	70,555	59,651	58,451
	Saginaw	-	-	-	8	-	-
	Toledo	6,099	437	1,378	7,714	4,453	768
	Pacific...						
	California	14,407	4,294	10,985	19,251	19,184	14,292
	Columbia R.	417,669	404,892	387,011	376,841	498,847	346,981
	Puget Sound	5,302	5,599	1,667	11,414	15,139	8,734
	SUBTOTAL	1,266,846	1,176,524	1,046,517	1,390,926	1,542,043	1,140,917

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Sorghum	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	443	477	1,130	134	12,174
	Miss. R.	111,239	85,086	99,929	95,996	104,188	83,500
	N. Texas	63,095	67,549	61,687	97,369	71,701	51,276
	S. Texas	14,780	11,647	15,339	24,300	31,034	20,191
	Interior	48,392	27,169	23,044	27,488	24,267	12,262
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	-	21	-	-
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	13,158	6,920	21,827	15,227	8,016	9,919
	Puget Sound	3,064	5,874	13,637	39,251	6,138	308
	SUBTOTAL	253,728	204,688	235,940	300,782	245,478	189,630

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Soybeans	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	52,541	37,471	47,452	41,746	28,660	22,375
	Gulf...						
	East Gulf	2,378	2,410	5,866	12,132	12,500	43,462
	Miss. R.	575,950	509,367	428,227	413,709	524,347	633,283
	N. Texas	2,367	2,906	15,844	9,326	10,773	12,009
	S. Texas	-	-	-	-	-	10
	Interior	44,221	34,521	20,025	22,160	31,707	24,269
	Lakes...						
	Chicago	11,324	-	-	4,965	-	10,483
	Duluth-Sup.	3,746	5,352	4,492	7,219	23,171	9,421
	Saginaw	-	-	-	-	-	434
	Toledo	19,461	8,075	7,804	13,188	2,666	22,204
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	8,617	2,471	3,623	7,673	11,871	12,606
	Puget Sound	36,564	36,198	34,885	33,950	21,077	9,562
	SUBTOTAL	757,169	638,771	568,218	566,068	666,772	800,118

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Barley	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	5,640	6,969	3,472	3,692	2,310	2,869
	Gulf...						
	East Gulf	-	-	-	-	1,054	-
	Miss. R.	10,141	5,860	357	-	3,443	2,913
	N. Texas	-	802	6,426	1,045	19,850	1,097
	S. Texas	-	-	-	-	-	-
	Interior	210	278	505	48	-	-
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	48,313	27,279	49,683	43,775	33,745	23,224
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	16,773	25,477	31,467	23,627	35,499	72,250
	Puget Sound	-	-	-	-	1,474	34,207
	SUBTOTAL	85,550	66,665	91,910	72,187	97,375	136,560

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Oats	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	-	-	-	-	-
	Miss. R.	-	-	-	-	-	-
	N. Texas	2,231	74	17	-	-	127
	S. Texas	-	-	-	-	-	-
	Interior	96	-	-	67	-	130
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	-	-	-	-
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	-	-	-	-	-	-
	Puget Sound	-	-	-	-	-	-
	SUBTOTAL	2327	74	17	67	-	257

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas

		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Rye	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	-	-	-	-	-
	Miss. R.	-	-	-	155	-	-
	N. Texas	-	-	-	-	-	-
	S. Texas	-	-	-	-	-	-
	Interior	-	-	-	-	-	-
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	1	303	410	205
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	-	-	-	-	-	-
	Puget Sound	-	-	-	-	-	-
	SUBTOTAL	-	-	1	458	410	205

TABLE 1. Yearly Volumes of Inspected Grain/Oil Seed Shipped From US Export Areas							
		Volumes of Grain/Oil Seed (1000 bu)					
Grain	Export Area	1992	1991	1990	1989	1988	1987
	ROUNDED TOTAL FOR ALL CROPS	4,100,000	3,800,000	4,000,000	4,500,000	4,400,000	3,900,000

TABLE 2. Estimated **"aspirated grain fractions"** Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Corn	Atlantic...						
	N. Atlantic	230	540	210	600	70	180
	S. Atlantic	1,000	3,100	4,700	4,800	3700	4,600
	Gulf...						
	East Gulf	660	90	300	520	580	2,400
	Miss. R.	76,000	74,000	81,000	81,000	68,000	63,000
	N. Texas	630	320	1,200	2,300	880	580
	S. Texas	270	200	290	4,000	360	330
	Interior	480	500	500	1,200	2,400	2,100
	Lakes...						
	Chicago	560	690	820	1,400	2,000	1,500
	Duluth-Sup.	280	220	390	640	1,800	70
	Saginaw	-	-	-	30	-	-
	Toledo	1930	1,300	1,500	2,900	1,700	2,500
	Pacific...						
	California	-	-	-	40	-	-
	Columbia R.	8,000	9,100	14,000	14,000	12,000	8,700
	Puget Sound	6,500	8,800	11,000	15,000	11,000	5,600
	SUBTOTAL	96,540	98,860	115,910	128,430	104,490	91,560

TABLE 2. Estimated "aspirated grain fractions" Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Wheat	Atlantic...						
	N. Atlantic	-	140	-	70	40	-
	S. Atlantic	1,600	1,400	1,600	5,300	2,500	1,400
	Gulf...						
	East Gulf	150	580	480	640	480	360
	Miss. R.	24,000	19,000	18,000	24,000	16,000	11,000
	N. Texas	19,000	21,000	14,000	23,000	35,000	29,000
	S. Texas	310	800	960	410	1,800	990
	Interior	510	150	20	140	430	150
	Lakes...						
	Chicago	-	-	-	50	-	80
	Duluth-Sup.	3,200	2,800	3,500	4,200	3,600	3,500
	Saginaw	-	-	-	1	-	-
	Toledo	370	30	80	460	270	50
	Pacific...						
	California	860	260	660	1,200	1,200	900
	Columbia R.	25,000	24,000	23,000	23,000	30,000	21,000
	Puget Sound	320	340	100	680	910	520
	SUBTOTAL	75,320	70,500	62,400	83,000	92,220	68,760

TABLE 2. Estimated **"aspirated grain fractions"** Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Sorghum	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	-	-	60	8	680
	Miss. R.	6,200	4,800	5,600	5,400	5,800	4,700
	N. Texas	3,500	3,800	3,500	5,400	4,000	2,900
	S. Texas	830	650	860	1,400	1,900	1,100
	Interior	2700	1,500	1,300	1,500	1,400	690
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	-	1	-	-
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	740	390	1200	850	450	560
	Puget Sound	170	330	760	2,200	340	20
	SUBTOTAL	14,140	11,490	13,240	16,800	13,900	10,600

TABLE 2. Estimated "aspirated grain fractions" Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Soybeans	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	3,200	2,200	2,800	2,500	1,700	1,300
	Gulf...						
	East Gulf	140	140	350	730	750	2,600
	Miss. R.	35,000	31,000	26,000	25,000	31,000	38,000
	N. Texas	140	170	950	560	650	720
	S. Texas	-	-	-	-	-	1
	Interior	2,700	2,100	1,200	1,300	1,900	1,500
	Lakes...						
	Chicago	680	-	-	300	-	630
	Duluth-Sup.	220	320	270	430	1,400	570
	Saginaw	-	-	-	-	-	30
	Toledo	1,200	480	470	790	160	1,300
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	520	150	220	460	710	760
	Puget Sound	2,200	2,200	210	2,000	1,300	570
	SUBTOTAL	45,860	38,760	32,470	34,070	39,590	47,890

TABLE 2. Estimated **"aspirated grain fractions"** Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Barley	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	270	330	170	180	110	140
	Gulf...						
	East Gulf	-	-	-	-	50	-
	Miss. R.	490	280	20	-	170	140
	N. Texas	-	40	310	50	950	50
	S. Texas	-	-	-	-	-	-
	Interior	10	10	20	2	-	-
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	2,300	1,300	2,400	210	1,600	1,100
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	800	1200	1500	1,100	1,700	3,500
	Puget Sound	-	-	-	-	70	1,600
	SUBTOTAL	3,870	3,160	4,420	1,542	4,650	6,530

TABLE 2. Estimated "**aspirated grain fractions**" Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Oats	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	-	-	-	-	-
	Miss. R.	-	-	-	-	-	-
	N. Texas	70	2	1	-	-	4
	S. Texas	-	-	-	-	-	-
	Interior	3	-	-	2	-	4
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	-	-	-	-
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	-	-	-	-	-	-
	Puget Sound	-	-	-	-	-	-
	SUBTOTAL	73	2	1	2	-	8

TABLE 2. Estimated **"aspirated grain fractions"** Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported

		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
Rye	Atlantic...						
	N. Atlantic	-	-	-	-	-	-
	S. Atlantic	-	-	-	-	-	-
	Gulf...						
	East Gulf	-	-	-	-	-	-
	Miss. R.	-	-	-	9	-	-
	N. Texas	-	-	-	-	-	-
	S. Texas	-	-	-	-	-	-
	Interior	-	-	-	-	-	-
	Lakes...						
	Chicago	-	-	-	-	-	-
	Duluth-Sup.	-	-	1	17	23	12
	Saginaw	-	-	-	-	-	-
	Toledo	-	-	-	-	-	-
	Pacific...						
	California	-	-	-	-	-	-
	Columbia R.	-	-	-	-	-	-
	Puget Sound	-	-	-	-	-	-
	SUBTOTAL	-	-	1	26	23	12

TABLE 2. Estimated "aspirated grain fractions" Weight Based Upon Yearly US Grain/Oil Seed Volumes Exported							
		Yearly Tonnage					
Grain	Export Area	1992	1991	1990	1989	1988	1987
	ROUNDED TOTAL FOR ALL CROPS	236,000	213,000	227,000	264,000	256,000	227,000

Guidance Procedures for Calculating Livestock Dietary Exposure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 2 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Guidance Procedure for Calculating Livestock Dietary Exposure

FROM: Esther Saito, Chief
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

and

Ed Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: Peter Caulkins, Deputy Director
Special Review and Reregistration Division (7508W)

and

Steven L. Johnson, Acting Director
Registration Division (7505C)

THRU: Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division (7509C)

As an additional guidance to registrants and petitioners the Chemistry Branches, HED, OPP, have outlined a procedure for correcting for feed moisture in calculating livestock dietary burdens for pesticide residues in the attached document. This document and the discussion therein does not represent any change from normal past procedure.

Chemistry reviewers routinely utilize this correction procedure in their reviews. We recommend that this document be provided to all interested parties via SRRD's Rejection Rate Project follow-up document publication mechanism.

Attachment: GUIDANCE PROCEDURE FOR CALCULATING LIVESTOCK DIETARY EXPOSURE

cc: RBP, Margie Feherenbach (FOD)

GUIDANCE PROCEDURE

FOR CALCULATING

LIVESTOCK DIETARY EXPOSURE

(JUNE 1994)

Guidance Procedure for Calculating Livestock Dietary Exposure

As a guidance to registrants and petitioners the Chemistry Branches have outlined a procedure for the correction of feed moisture in the calculation of livestock pesticide dietary burdens. The discussion herein does not represent any change from normal past procedure. The updated Table II (June 1994) of the Residue Chemistry Guidelines is currently being used by reviewers of the Chemistry Branches as the source of percentage dry matter and percentage of the diet for such calculations.

The feed percentages listed for ruminants (i.e., beef and dairy cattle) in the updated Table II are on a dry matter basis, while tolerances for these feed items are established on an as-fed basis. Percentages for ruminants in the "Guide For Estimating Toxic Residues in Animal Feeds or Diets" (authored by Dr. L. Harris, 1975, and commonly known as the Harris Guide), and the "Update of Livestock Feed Consumption" [Animal Nutrition, Inc., 1993, referred to in this document as the ANI Report) are also listed on a dry matter basis. Therefore, the correct calculation of ruminant dietary burden includes the conversion of the feed to a dry-matter basis in the diet.

Percentages of the diet for poultry and swine feeds in the Harris Guide and the previous Table II are also on a dry matter basis. However, poultry and swine listings in the updated Table II and the ANI Report are on an as-fed basis since almost all feeds for poultry and swine are in the dry category. Therefore, the dietary burden calculation for poultry and swine using the updated Table II does not require conversion of the feed to a dry-matter basis.

The dietary burden calculation must also handle the situation that arises when the feed item(s) on which there is (are) tolerance(s) for a given chemical do not comprise a complete diet for the animal. For example, at the time of this document, hexazinone has tolerances on alfalfa forage (50% of beef cattle diet) and alfalfa hay (25%), but on no other feed items. In this case, there is no information on the feed item(s) which would be used to round out the animal's diet. If those additional feed items are wet, the residues on an as-fed basis will be diluted more than they would be if the feed items were dry. Errors in the estimate of the dietary burden to the animal could result.

These problems can be avoided, however, if the burden is calculated in terms of the weight (as opposed to concentration) of the pesticide consumed by the animal, and that amount compared with a standard amount of feed consumed by the animal. Thus using this approach an equation is derived for such calculations and the derivation scheme of such an equation, Equation A, is discussed in Appendix A.

For ruminants, where feed percentages are expressed on a dry matter basis, equation A should be used.

$$\left(\begin{matrix}dietary\\burden\end{matrix}\ [DM]\right)(ppm) = \sum_i \frac{(\%diet\ [DM])_i}{(\%DM)_i} \times (tolerance)_i \left(\frac{mg}{kg}\right) \qquad \textbf{(A)}$$

(dietary burden [DM]) (ppm) = estimation of total exposure of a pesticide through feeds on a dry-matter basis, expressed in ppm (mg pesticide per kg feed)

$(\%diet\ [DM])_i$ = percentage in the animal diet of commodity i expressed on a dry-matter basis

$(\%[DM])_i$ = dry-matter percentage in feed commodity i

$(tolerance)_i$ (mg/kg) = proposed or existing tolerance expressed in mg/kg (i.e., parts per million, ppm)

The burden thus calculated is on a dry-matter basis. Therefore, ruminant feeding and metabolism studies submitted to the Agency must have their feeding levels calculated on a dry-matter basis. For feeding studies in which the pesticide has been introduced via capsule, the petitioner should report the feed items and intake of each animal so that dietary burden can be calculated on a dry-matter basis.

Also note that Equation A could have been used for poultry and swine in the previous Table II. However, as noted above the feed percentages for poultry and swine in the updated Table II are on an as-fed basis. In that case, no correction will have to be made for percent moisture; the dietary burden will be simply calculated by Equation B as follows:

$$\left(\begin{matrix}dietary\\burden\end{matrix}\right)(ppm) = \sum_i (\%diet)_i \times (tolerance)_i \left(\frac{mg}{kg}\right) \qquad \textbf{(B)}$$

The dietary burden in this case will be on an as-fed basis.

The following sample calculations using both Equations A and B show how dry matter correction(s) can alter the estimated dietary burden.

Scenario I. All feed items in the selected diet have proposed or established tolerances, and all feed items have low moisture content.

For example, consider the burden for beef cattle to chlorpyrifos fed the following diet (Updated Table II percentages). The dietary burdens are calculated with and without correcting for moisture content using the feed items chosen for the animal's diet which have relatively low moisture contents.

corn grain	80% of diet	88% DM	0.1 ppm tolerance
corn fodder	20% of diet	83% DM	10.0 ppm tolerance

Calculation of the burden by Equation B (i.e., without conversion to a dry matter basis) would give the following:

$$(0.80)\ x\ (0.1\ ppm) \ + \ (0.20)\ x\ (10.0\ ppm) = 2.1\ ppm$$

When the adjustment for moisture content is made, a difference of 0.4 ppm is observed using Equation A:

$$\frac{(0.80)}{(0.88)}\ x\ (0.1\ ppm) \ + \ \frac{(0.20)}{(0.83)}\ x\ (10.0\ ppm) = 2.5\ ppm$$

Scenario 2. All feed items in the selected diet have established tolerances, and some, or all feed items have a high moisture content.

If wet items are included in the diet (e.g., forages), substantial errors in the estimated ruminant dietary burden could result if the calculations are not corrected for the moisture content. For example, if corn fodder in the above diet is replaced with corn forage,

corn forage	20% of diet	25% DM	10.0 ppm tolerance

without correcting for moisture, the same 2.1 ppm burden would be calculated by Equation B. However, correcting for moisture, the burden calculated by Equation A

would be:

$$\frac{(0.80)}{(0.88)} \times (0.1\ ppm) + \frac{(.20)}{(0.25)} \times (10.0\ ppm) = 8.1\ ppm$$

Thus, using only Equation B, the dietary burden for beef cattle would be seriously underestimated.

Scenario 3. Not all feed items in the selected diet have established tolerances.

Similar underestimation of an animal's dietary burden can occur if the available feed items do not comprise a complete diet. Using the above example of hexazinone for beef cattle,

alfalfa forage	50% of diet	35% DM	2.0 ppm tolerance
alfalfa hay	25% of diet	89% DM	8.0 ppm tolerance

the dietary burden, if calculated using Equation B without conversion to a dry matter basis, follows:

$$(0.50) \times (2.0\ ppm) + (0.25) \times (8.0\ ppm) = 3.0\ ppm$$

Using Equation A, the dietary burden is calculated as follows:

$$\frac{(0.50)}{(0.35)} \times (2.0\ ppm) + \frac{(0.25)}{(0.89)} X (8.0\ ppm) = 5.1\ ppm$$

This latter number represents a worst-case scenario; thus, the burden cannot be more than 5.1 ppm.

NOTE: Dry-matter percentages for feed items in the updated Table II are listed in Appendix B. For unlisted feed items, consult the above ANI Report, or contact the Chemistry Branches, HED, OPP, OPPTS, EPA.

Appendix A: Derivation of Equations A and B

Appendix A

Based on the principles discussed in the preceeding text, i.e., if the burden is calculated in terms of the weight as opposed to concentration of the pesticide consumed by the animal, and that amount compared with a standard amount of feed consumed by the animal, Equations A and B are derived.

First, imagine a diet comprised of a number of feed items where *i* represents each individual feed item. For each ingredient *i*, the amount of that item consumed by the animal can be calculated from the assumed total weight of the animal's daily intake expressed on a dry-matter basis, as indicated by the symbol "[DM]"):

$$(\%diet\ [DM])_i \times \left(\begin{matrix}total\\consumed\end{matrix}\ [DM]\right)(kg) = \left(\begin{matrix}amount\\consumed\end{matrix}\ [DM]\right)_i (kg) \qquad (1)$$

Note that both (% diet [DM]); and (% dry matter) in Equations 1 and 2 should be expressed as fractions, e.g. 87% = 0.87. The amount of each ingredient is still expressed on a dry-matter basis at this point. In order to convert this value to an as-fed basis, one corrects for the amount of moisture in the item:

$$\frac{(amount\ consumed\ [DM])_i\ (kg)}{(\%DM)_i} = \left(\begin{matrix}amount\\consumed\end{matrix}\ [as\text{-}fed]\right)_i (kg) \qquad (2)$$

If the amount of feedstuff and the tolerance are expressed on the same basis (i.e. as-fed), the amount of pesticide contributed from each feed item can be calculated:

$$\left(\begin{matrix}pesticide\\consumed\end{matrix}\right)_i (mg) = \left(\begin{matrix}amount\\consumed\end{matrix}\ [as\text{-}fed]\right)_i (kg) \times (tolerance)_i \left(\frac{mg}{kg}\right) \qquad (3)$$

After substituting Equations 1 and 2 into Equation 3, the total pesticide burden in mg is found by adding up the contributions of each feed item.

$$\begin{matrix}total\ (mg)\\pesticide\\consumed\end{matrix} = \sum_i \frac{(\%diet\ [DM])_i}{(\%DM)_i} \times (tolerance)_i \left(\frac{mg}{kg}\right) \times \left(\begin{matrix}total\\consumed\end{matrix}\ [DM]\right)(kg)$$

(4)

The burden can be calculated in terms of a concentration by dividing the sum total of pesticide consumed by the total amount of feed consumed by the animal. If the total amount consumed is expressed on a dry-matter basis, the result is Equation 5:

$$\left(\begin{matrix}dietary\\burden\end{matrix}\right)(ppm) = \frac{\sum_i \frac{(\%diet\ [DM])_i}{(\%DM)_i} \times (tolerance)_i \left(\frac{mg}{kg}\right) \times \left(\begin{matrix}total\\consumed\end{matrix}\ [DM]\right)(kg)}{\left(\begin{matrix}total\\consumed\end{matrix}\ [DM]\right)(kg)}$$

(5)

Since the total amount is expressed on a dry-matter basis for this to occur, the total amount consumed by the animal divides out in this equation. Therefore, it is not necessary to make any assumptions about the total amount of feed that the animal eats. Equation 5 thus simplifies to the final Equation A, and Equation A is used in the dietary burden calculations for ruminants (i.e., beef and dairy cattle in the updated TAble II):

$$\left(\begin{matrix}\text{dietary}\\ \text{burden}\end{matrix}\ [DM]\right)(ppm) = \sum_i \frac{(\%\,\text{diet}\ [DM])_i}{(\%\,DM)_i} \times (\text{tolerance})_i \left(\frac{mg}{kg}\right) \qquad \text{(A)}$$

In the case that no correction will have to be made for percent moisture (i.e., poultry and swine), the dietary burden will be simply calculated by Equation B.

$$\left(\begin{matrix}\text{dietary}\\ \text{burden}\end{matrix}\right)(ppm) = \sum_i (\%\,\text{diet})_i \times (\text{tolerance})_i \left(\frac{mg}{kg}\right) \qquad \text{(B)}$$

Appendix B: %DM for Feedstuffs in Table II Update (June 1994)

Appendix B

CROP	FEEDSTUFF	% DM
Alfalfa	forage	35
	seed	88
	seed screenings	88
	hay	89
	meal	89
	silage	40
Almond	hulls	90
Apple	pomace, wet	40
Barley	grain	88
	bran	88
	forage	30
	hay	88
	straw	89
	flour	88
Bean	seed	30
	forage	35
	straw/hay	89
Beet, sugar	tops (leaves)	23
	molasses	25
	pulp, wet	30
	pulp, dried	88
Buckwheat	grain	87
	forage	30
	hay	83
	straw	88
	milled bypdts	89
	flour	89
Canola	meal	88
Carrot	culls	12
Citrus	pulp, wet	21
	pulp, dried	91
	molasses	68
Clover	forage	30
	hay	89
	silage	30
Corn, field	grain	88
	forage	40
	fodder (stover)	83
	milled bypdts	85
	aspirated grain fractions	85
Corn, pop	grain	88
	fodder (stover)	85
Corn, sweet	forage	48
	cannery waste	30
	grain	88
	fodder (stover)	83

CROP	FEEDSTUFF	% DM
Cotton	meal	89
	undelinted seed	88
	hulls	90
	cotton gin bypdts	90
Cowpea	seed	88
	hay	86
	forage	30
Crown vetch	forage	30
	hay	90
Flax	meal	88
	straw	89
	seed	88
Grape	raisin, culls	85
	pomace, wet	15
	pomace, dried	89
	raisin waste	79
Grass (pasture & rangeland)	forage (fresh)	25
	hay	88
	silage	40
	seed screenings	88
Hops	spent hops	86
Lentil	seed	88
	forage	85
Lespedeza	forage	22
	hay	88
	meal	89
Lupine	seed	88
	forage	30
	hay	85
	straw	90
Mangel beet	root	11
	tops (leaves)	23
Millet	forage	30
	grain	88
	hay	85
	straw	90
Oats	grain	89
	forage	30
	hay	90
	straw	90
Pea	seed	90
	vines	25
	hay	88
	silage	40
Peanut	meal	85
	hay	85
	hulls (shells)	95
Pineapple	process residue	25

Appendix B

CROP	FEEDSTUFF	% DM
Potato	culls	20
	processed potato waste	12
Rape	meal	88
	forage	30
Rice	grain	88
	hulls	90
	straw	90
Rye	grain	88
	forage	30
	straw	88
	hulls	88
	milled bypdts	85
Safflower	seed	94
	forage	23
	meal	91
Sainfoin	forage	30
	hay	89
Sorghum,grain	grain	86
	forage	35
	fodder (stover)	88
	aspirated grain fractions	85
Sorghum forages, sudangrass (See Grass)		
Soybean	seed	89
	meal	92
	hulls	90
	forage	35
	hay	85
	silage	30
	aspirated grain fractions	85
Sugarcane	molasses	75
Sunflower	meal	92
	hulls	89
	seed	90
	forage	23
Sweet potato	root	32
Tomato	pomace, wet	15
	pomace, dried	92
Trefoil	forage	30
	hay	85
Turnip	root	15
	tops (leaves)	30
Vetch	forage	30
	hay	85
Wheat	grain	89
	forage	25
	hay	88
	straw	88
	milled bypdts	88
	aspirated grain fractions	88

EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 2 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances

FROM: Esther Saito, Chief
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

and

Ed Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: Peter Caulkins, Deputy Director
Special Review and Reregistration Division (7508W)

and

Steven L. Johnson, Acting Director
Registration Division (7505C)

THRU: Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division (7509C)

As part of the Rejection Rate Project, the Chemistry Branches in the Health Effects Division have prepared the attached guidance document on crop field trials. The document was prepared by the Senior Scientists Advisory Council (SSAC) of the Chemistry Branches following submission of a proposal by NACA, IR-4, and USDA. That proposal proved to be a useful starting point, but the SSAC concluded that additional field trials would be needed for many fruits and vegetables. Therefore, a scheme was developed whereby the number of trials required for a crop takes into account not only its production acreage, but also its dietary significance. The senior scientists also believed the proposal needed to be expanded to address collection of samples and other considerations such as formulations.

As stated in the document, we expect crop field trial programs initiated in 1995 or later to adhere to this guidance. For studies initiated prior to 1995, implementation of this guidance will be handled as follows:

Registration: Issuance of this document should not impede registration actions in which crop field trials are initiated prior to 1995. We will be flexible regarding whether such studies which do not meet the guidance in this document are adequate to support tolerances and whether additional data will be required to be submitted under our data call-in authority.

Reregistration: Issuance of this document should also not impede Reregistration Eligibility Decision (RED) schedules. In those cases where the registrant will not initiate required crop field trials until 1995, the new guidance can be referred to and will provide assurance that the trials will be acceptable in terms of number of sites, site locations, etc. For field trials initiated prior to 1995, we will be flexible as noted above as to whether additional data will need to be called in when the RED is issued. [For those uses registered after 1984 (i.e., those not subject to the present reregistration process), the need for additional studies will be determined when the Agency reexamines those uses in future reregistration assessments (e.g., as planned in the pending legislation).]

The attached guidance document will be provided to scientists in both Chemistry Branches and will be utilized in future Residue Chemistry reviews. Therefore we recommend that this document be provided as soon as feasible to all interested parties via SRRD's Rejection Rate Project follow-up document publication mechanism.

Finally, it should be noted that the Office of Pesticide Programs is currently exploring more rigorous statistical approaches to collecting and analyzing residue data used to establish pesticide tolerances. As a result, additional guidance may be issued in the future on how and where to conduct crop field trials.

Attachment: EPA GUIDANCE ON NUMBER AND LOCATION OF DOMESTIC CROP FIELD TRIALS FOR ESTABLISHMENT OF PESTICIDE RESIDUE TOLERANCES

cc: D. Barolo (7501C), A. Lindsay (7501C), R. Schmitt (7509C), D. Edwards (7509C)

EPA GUIDANCE ON NUMBER AND LOCATION OF DOMESTIC CROP FIELD TRIALS FOR ESTABLISHMENT OF PESTICIDE RESIDUE TOLERANCES

Senior Scientists Advisory Council
Chemistry Branches
Health Effects Division

June 1994

TABLE OF CONTENTS

JUNE 1994

EPA GUIDANCE ON NUMBER AND LOCATION OF DOMESTIC CROP FIELD TRIALS FOR ESTABLISHMENT OF PESTICIDE RESIDUE TOLERANCES

Summary

As a follow-up to the Rejection Rate Analysis of residue chemistry studies, the Agency has developed more specific guidance on the number and location of crop field trials. All trials initiated in 1995 or later should adhere to this guidance, which is a modification of a proposal submitted by NACA and IR-4 in Sept. 1992. That proposal served as a useful starting point, but the Agency concluded that dietary significance of crops needed to be factored in to a greater extent, especially for crops having <300,000 acres. In addition, the NACA/IR-4 proposal did not address how crop samples should be collected and the number of samples per site.

It should be emphasized that the Agency believes this guidance formalizes the current requirements for crop field trials. Results of FDA monitoring showing ≤1% violation rates over the last five years is one indication that adequate data are currently being submitted to establish tolerances. Therefore, significant changes in the number of field trials typically required are not considered to be necessary.

Definitions for the terms "pesticide field trial site", "pesticide field trial", and "sample" were developed in the process of generating this document (see page 7).

The actual **numbers of field trials** that will be required for a large number of crops are shown in Table 1 or Attachment 7 ("REQ #FT" column). The required numbers of trials range from 1 to 20. Crops having large acreage and high consumption for the general population or infants will need up to 20 trials, whereas crops of <200 total U.S. acres will need only one trial. In each case these represent the number of acceptable trials reflecting the label use pattern (maximum rate, etc.) producing the highest residue. Trials which reflect other use patterns or which for some reason do not generate viable samples (e.g., crop failure) will not be counted. For the purposes of standardizing the number of field trials, it should be emphasized that in most cases (see next paragraph) these numbers represent the minimum that will be accepted to establish a tolerance (with the exception of crop group tolerances or uses resulting in no quantifiable residues). Additional trials are always welcome and even encouraged by the Agency.

EPA has taken into consideration several major factors to determine the necessary numbers of trials and believes these numbers will be applicable in most cases. However, in limited circumstances the Agency may require additional trials or accept

fewer trials than specified in Table 1. Any petitioner believing that fewer trials are adequate for a given crop will need to provide a convincing rationale. In such cases the Agency strongly advises petitioners to submit a protocol and rationale before initiating such trials. Likewise, any residue chemistry reviews requesting additional trials will include a justification as to the need for such data.

This document also gives more specific guidance for current residue decline requirements. **Residue decline** data will be required for uses where: (1) the pesticide is applied when the edible portion of the crop has formed or (2) it is clear that residues may occur on the food or feed commodities at, or close to, the earliest harvest time. The number of decline studies needed is one for crops requiring 5-12 total trials and two for crops requiring 16-20 total trials. These studies are included in the 5-12 or 16-20 total trials (i.e., not "in addition to" these numbers of trials). For a given pesticide additional decline studies will not be required crop by crop if studies on representative crops (tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable) indicate residues do not increase with longer preharvest intervals.

Two independently composited **samples** of treated commodity should be collected and separately analyzed in each field trial. These two samples may be taken from the same plot. An exception to these guidelines is crops requiring only 1-2 trials; for these crops four samples (one each from four separate plots (2 at 1x rate, 2 at 2x rate)) will be needed for each trial. In all cases Codex guidelines on minimum sample sizes should be followed (Attachment 8). A control crop sample should also be collected from each crop field trial site for analysis.

The numbers of trials in Table 1 or Attachment 7 are based upon each crop being the only one within its crop group for which a tolerance is requested. In the case of **crop group tolerances** for which there are at least two representative crops, the number of trials can be reduced by 25% for those representative commodities that need ≥8 trials when requested individually (i.e., 20 → 15, 16 → 12, 12 → 9, 8 → 6). Table 2 shows the resulting numbers of trials needed for all crop groups in 40 CFR 180.34(f).

Since the Agency has recently proposed creation of **subgroups** within the existing crop grouping scheme, guidance on the number of field trials needed for the representative commodities in these subgroups is also provided in Table 3. These numbers of trials were determined on a case-by-case basis looking at the acreages and consumption of the representative commodities and of the whole subgroup. Similar principles were applied to crop "groups" established in 40 CFR 180.1(h) as specified in Table 4.

Provided metabolism data (on the crops of interest or related crops) or field trial data on related crops indicate quantifiable residues are not likely, a petitioner may elect to conduct 25% fewer trials for crops normally requiring ≥8 trials. However, if all of these trials do not show **residues below the method's limit of quantitation (LOQ)**, additional trials will normally be required to bring the total number conducted up to the standard requirement. In addition to residues being below the LOQ, the following two conditions must be met for 25% fewer trials to be accepted: (1) the method has a sufficiently low LOQ (usually ≤0.01-0.05 ppm) and (2) the trials still represent all significant regions of production.

The application of both 25% reductions discussed above (crop group and residues <LOQ) to a given crop will not be acceptable. In addition, neither 25% reduction will be applied to crops requiring ≤5 trials.

The numbers of trials in Table 1 or Attachment 7 are also predicated upon only **one formulation** type being requested for use on each crop. If additional types of formulation are desired, additional data such as side-by-side bridging studies may be needed as discussed in the Formulations section of this document.

Some special considerations are also provided in this document for **early season uses on annual crops** and **spray volumes--ground versus aerial equipment.**

For **amended registrations** that involve significant changes in application rate or preharvest interval, the number of field trials required will normally be 25% less than that needed to establish an original tolerance, provided that the tolerance level is shown by the reduced number of trials to be adequate to cover the new use. However, if the reduced number of trials indicates that the original tolerance is inadequate, or if the original number of trials was ≤5 or already included a 25% reduction (crop group or <LOQ), the number of trials needed for an amended registration will be the same as that for the original tolerance. On a case-by-case basis the Agency may require less additional data than described above for an amended registration.

With regard to the **location of trials**, the Agency agrees with the division of the country into 13 **regions** as proposed by NACA/IR-4 (see Attachments 9-10). This will allow greater flexibility in data collection for minor uses. For crops requiring >3 total trials, Table 5 shows suggested distributions of trials among these 13 regions. These distributions were developed using the concept that the number of trials per region should generally correlate with the percentage of the crop grown in that region. However, where possible, at least one trial should be included in each region having ≥2% of the national production.

The distributions of trials in Table 5 are not intended to be absolute requirements. Petitioners may wish to contact EPA regarding the suitability of alternative distributions of trials. To aid petitioners in determining distribution of trials, the production of numerous crops by region is specified in Table 6.

For crops requiring ≤3 trials, the data should represent to the extent possible a balance of the highest production areas, different geographic/climatic conditions, and/or major differences in varieties of the crop. At least one trial should be conducted in the region of highest production.

With respect to the distribution of multiple trials <u>within</u> a region, this should generally follow the relative production in the individual growing areas (states or counties as appropriate) of the region. However, the sites should also be sufficiently separated to reflect the diversity of the growing region.

To aid the Agency's review process, petitioners are requested to include a copy of the map in Attachment 9 showing the locations of all sites of acceptable trials in the volume of field trial reports for each crop.

Finally, separate guidance has been provided in Attachment 11 to address requirements for tolerances with **geographically restricted registrations** and for **24(c) registrations.**

DETAILED DISCUSSION

Background

In 1992 EPA conducted an analysis of residue chemistry studies that had been submitted in support of the reregistration of pesticides to determine the factors that led to rejection of certain studies (i.e., classified as unacceptable). This analysis included active participation by representatives of the pesticide industry (National Agricultural Chemicals Association or NACA) and the IR-4 program, the two major groups which generate residue chemistry data. The results of this analysis were published in a June 1992 document entitled "Pesticide Reregistration Rejection Rate Analysis Residue Chemistry".

For crop field trials a frequent reason for rejection was insufficient geographical representation. This could be due to either an insufficient number of trials being conducted or to the trials not being conducted in all areas of significant production for a given crop. NACA stated that Agency guidance in this area is vague and proposed that an EPA, USDA, IR-4, and industry workgroup address this topic to resolve ambiguities for both petitioners (usually pesticide companies/registrants or IR-4) and reviewers. EPA suggested that industry and IR-4 prepare a package for Agency review that addresses the definition of a site, the number of sites needed for various crops, the states in which trials should be conducted, and the percent of national production to be accounted for. (See pages 37-39 of the "Rejection Rate" document.) EPA also noted (page 46 of same document) that industry could address the issue of number of samples per site in its proposal.

The document entitled "NACA Recommendations for Residue Site Selection and Number of Field Trials" (hereafter referred to as the "NACA proposal") was prepared by members of NACA, USDA and IR-4 and submitted to EPA in September 1992.

Summary of NACA Proposal

NACA/IR-4/USDA proposed dividing crops into 3 groups (based on total acres) for purposes of defining the number and location of crop field trials:

Major crops - >2 million acres
Major-Minor crops - >300,000 acres but <2 million acres
Minor crops - ≤300,000 acres

The **number of trials** suggested for major crops (20 trials) and minor crops (3-6 trials) did not take into account factors such as dietary significance or the geographical distribution of production. Such factors were considered for the major-minor crops (8-12 trials). If the data indicate residues below the level of quantitation (LOQ), the proposed number of trials was

reduced significantly for the major and major-minor crops. No such reduction was proposed for minor crops. It was also proposed that the number of trials needed for label expansions (new formulations, use rate increases, decreases in PHI) be 10 for major crops and 6-8 for the major-minor crops (i.e., same # of trials as proposed for establishing the initial tolerance when residues are below LOQ). The NACA proposal did not address the number of samples per site with the exception of minor crops for which it was specified that a control, 1x and 2x use samples will be taken from each site.

With regard to **location of trials** the NACA proposal divided the country into 13 regions based on natural geography and climatic boundaries for the major and major-minor crops. For minor crops the same basic regions are used, although four are subdivided. For distribution of trials for major and major-minor crops it was stated that "The number of trials per region should generally correlate with the percent of the crop grown in that area. In order to ensure geographic diversity, however, at least one trial should be included for each region with 2% or more crop production." Multiple test sites within a region should be spread over the region as much as possible. "However, running the residue trial in typical growing regions should take precedent."

For the minor crops it was ambiguous as to how the distribution of trials is to be determined. Regions were listed for each crop in Attachment 6 of the proposal and the Overview stated that there should be at least one trial in each region. However, there are about 20 crops for which there were more regions listed than number of sites (e.g., mustard greens--4 regions, but only 3 sites proposed). Attachment 6 also had the following guidelines based on production:

"≥90% in 1 state- all sites in the major producing state
≥75% in 2-3 states- all sites in the major producing states with regional representation.
All others- Obtain sites in regions with the regional production accumulating to about 75% of the total production for the crop."

EPA Analysis of NACA Proposal

A team of EPA senior scientists reviewed the NACA proposal in detail and concluded it was a useful starting point. However, there were two major concerns. First, there was no consideration of the dietary significance of the crops that NACA had placed in the "minor" crop category (3-6 trials). The Agency scientists concluded that more trials were necessary for a significant number of the fruits and vegetables categorized as minor crops. On the other hand, fewer trials were considered necessary for those minor crops with very low dietary intake. The second major concern was that the NACA proposal did not address the definition

of a site, how samples should be collected, and the number of samples per site. The proposal was revised to take into account the above concerns.

Each of the topics such as definitions of site, numbers of trials, sampling, and distribution of trials is discussed in more detail below. Tables are also included to specify the numbers of trials for many crops, crop groups, and crop subgroups; the percentages of crop production by region; and suggested distribution of trials in each region for numerous crops.

It should be emphasized that the Agency believes this guidance formalizes the current requirements for crop field trials. Results of FDA monitoring showing ≤1% violation rates over the last five years is one indication that adequate field trial data are currently being submitted to establish tolerances. If insufficient data were being received such that tolerances are being set too low, the violation rate should be considerably higher than 1%. Therefore, significant changes in the number of field trials typically required are not considered to be necessary.

Definitions

A **"pesticide field trial site"** is a geographically defined address/location within a country/region/state of a field, space, water body or other area in or on which a pesticide field trial is conducted. (In most cases this definition boils down to a site being one farm.) A site typically consists of several **plots** (areas of ground with defined boundaries on which a crop is grown), each of which receives a specified pesticide application regimen.

A **"pesticide field trial"** entails one or more applications per growing season of a formulated pesticide product to a specified crop (or the soil) at one site following actual or simulated cultural practices. Such applications are usually in accordance with registered or proposed uses (or a fraction or multiple thereof in some cases) to provide treated commodity samples for estimating pesticide tolerances and/or dietary exposure to pesticides.

"Sample" is a defined amount of individual agricultural commodity units (e.g., specific number of fruits or tubers; a set weight of grain; etc.) randomly selected from a plot which may be composited for pesticide analysis. [NOTE: As discussed in the next section, tolerances will continue to be based on analyses of composite samples. In the future EPA may also require analyses of individual servings (e.g., one apple, one potato) to assess the dietary risk from acutely toxic pesticides. This possible requirement will not be discussed further in the present document.]

[The Agency will not address **plot size** in this document. NACA is encouraged to submit a proposal on this issue at a later time.]

Sampling Requirements

With respect to how samples should be collected, the Agency will continue to base tolerances on composite samples. As to the number or weight of agricultural commodity that should be collected for each composite sample, petitioners should follow the Codex "Guidelines on Minimum Sample Sizes for Agricultural Commodities from Supervised Field Trials for Residue Analysis", ALINORM 87/24A (1987)(Attachment 8). In each field trial report the petitioner should indicate whether or not these guidelines were followed. If they were not, an explanation should be provided along with details of how the sampling deviated from the Codex recommendations. Petitioners should also include in the field trial report the number of agricultural commodity units making a composite as well as the weight of the composite sample.

With regard to the **number of samples** per site, the Agency has decided that more than one treated sample is needed to provide some estimate of variability, but that three or more samples are unlikely to result in much additional information since compositing will tend to mask much of the variability. Therefore, the Agency has concluded that two independently composited samples should be collected at each site (i.e., for each field trial--with the exception of crops needing only 1-2 trials as described later in this section). The treated samples may be taken from two separate plots or from the same plot. In addition, at least one control (untreated) sample should be collected and analyzed at each site.

In those cases where the two treated samples are obtained from the same plot, it needs to be emphasized that the samples be collected by two separate runs through the plot following the aforementioned Codex guidelines. Splitting one sample from a plot or conducting two analyses on one sample will not be an acceptable alternative to separately collecting and analyzing two samples. In other words, **multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point**. (However, as explained below, if such multiple analyses are conducted, each value should be reported and clearly indicated as to which sample it represents.)

For crops which require only 1 or 2 field trials (≤200 and >200-2000 acres, respectively), at least one composite sample should be collected from each of the four separate treated plots (plus the control plot) at each site. It is strongly suggested that more than one sample be collected from each plot. Two plots should be treated at the proposed or registered application rate (1x) and two plots at a 2x rate. Furthermore, each plot should

receive independently prepared applications of the pesticide. In other words, the same tank mixture should not be used to treat more than one plot. This will allow some assessment of variability due to factors such as preparation of the tank mix. [NOTE: As discussed in the next section of this document, petitioners always have the option of conducting three or more field trials at the 1x rate (with two treated samples per trial) instead of the one or two trials with at least four treated samples per trial and plots reflecting both 1x and 2x rates.]

With regard to the handling of samples at the residue analysis stage, petitioners should follow the guidance in Section 142 of FDA's Pesticide Analytical Manual (PAM), Volume I on sample compositing and comminuting. Multiple analyses of a sample are not required, but are advised as a check in those cases where the residue values from the two composite samples are significantly different.

In all field trial reports petitioners need to indicate clearly whether each reported residue refers to a separate sample or a second analysis of the same sample. In either case, all analyses should be reported--petitioners should not average multiple analyses of a single sample or the results of multiple samples in a trial. The January 1993 EPA document entitled "Guidance on Submission of Raw Data" should be consulted concerning this point.

Number of Trials for Individual Crops

The required number of trials for a crop can be found in either Table 1 or Attachment 7 (column "REQ FT"). Table 1 is an alphabetical list of crops with the minimum number of trials and treated samples. Attachment 7 lists the crops in order of number of required field trials, but does not specify numbers of samples. However, Attachment 7 does include the acreages and consumptions of crops that were used to determine the number of trials as discussed below. Although the list of crops is not all inclusive, an attempt was made to include all crops for which acreage and/or consumption information was available. With regard to names for crops, the Index to Commodities as published in the proposed "Pesticide Tolerances; Revision of Crop Groups" rule (8/25/93) was used.

As discussed above, the Agency believed that dietary significance needed to be a greater factor in determining the amount of residue data required for each crop. First, criteria were developed to assign a base number of field trials dependent solely on total U.S. acreage of the crop. Acreage was used instead of production by weight since the former is more consistent from year to year. The primary sources used for acreage information were USDA's Agricultural Statistics (1991) and the 1987 Census of Agriculture (Dept. of Commerce). IR-4

also provided information on some low acreage crops that are not included in the aforementioned publications. When acreage figures varied between sources, the highest figure was used. Acreage from Puerto Rico was included for coffee and bananas since such production was greater than or comparable to that in the fifty states. The base numbers of field trials as a function of acreage are delineated in Attachment 7. For simplicity the base numbers of trials are limited to 16, 12, 8, 5, 3, 2 and 1.

Next, criteria were developed to adjust the number of trials based on dietary importance of the commodity. The figures contained in the Agency's Dietary Risk Evaluation System (DRES) for the general population were used to make a first cut. The diets of non-nursing infants and children aged 1-6 were then examined to adjust upward the number of trials on any commodities that had significantly higher consumption by these groups than by the general population. The consumption percentages used are those of the whole diet (i.e., food plus water consumption) and are shown along with the acreages of crops in Attachment 7.

For crops having 8-16 base trials (>300,000 acres), it was decided that the number of trials could be increased or decreased based on human consumption. Crops which comprise >0.4% of the general population diet had the number of trials increased by one level (e.g., 8 → 12, 12 → 16). For those crops having 16 base trials, the number of trials was increased to 20 if they comprise >0.4% of the diet. In addition, any crop with >300,000 acres and comprising >1.0% of general population consumption requires at least 16 field trials. This particular criterion results in an increased number of trials for apples, oranges, and tomatoes. On the other hand, crops with >300,000 acres accounting for <0.1% of consumption had their number of trials decreased by one level. The crops affected by this criterion are primarily or exclusively animal feeds: alfalfa, clover, cotton, grasses, and sorghum.

For crops ≤300,000 acres the Agency has concluded that due to the small number of base trials (≤5) for such crops, it would not be appropriate to decrease the number of trials based on low consumption. However, any such crops comprising ≥0.02% of the general population diet had their number of trials increased by one level (e.g., 3 → 5, 5 → 8). This criterion affected a significant number of fruits and vegetables such as broccoli, carrots, grapefruit, lettuce, peaches, pears, and snap beans.

As noted above and addressing concerns raised in the recent NAS report entitled "Pesticides in the Diets of Infants and Children", the Agency also looked at the contribution of crops to the diets of **non-nursing infants and children** 1-6 years of age. In most cases, crops that are significant in these diets are also important in the diet of the general population. However, **rice** and **oats** were found to exceed the 0.4% of the diet criterion for large acreage crops using the infant diet, but not when using the

diet of the general population. Therefore, the number of trials for these two crops was increased from 12 to 16. In addition, **peaches** comprise a much higher percentage (1.12%) of the non-nursing infant diet than of the general population diet (0.366%). Therefore, the number of trials required for peaches was increased from 8 (number based on general population) to 12. [Based on the relatively low acreage of peaches, it was decided not to increase the number of peach trials to 16, the number of trials required for crops having >300,000 acres and comprising >1.0% of the diet.]

For a number of crops no information could be located as to total acreage. The acreage for such crops is "0.00" in Table 7. While most of these are almost certainly very minor crops, for such crops a minimum of three field trials will be required unless documentation of national acreage can be provided to show fewer trials are an acceptable number.

In addition to total acreage and percentage of the diet, one other factor was considered in determining the number of trials for crops. The Agency believes that the number of trials can be reduced if most of a crop is grown in one region. Therefore, for most crops which have ≥90% of their production in one region the number of trials has been reduced one level (e.g., 8 → 5, 5 → 3). Crops subject to this reduction include avocadoes, olives, and pistachios. It should be noted, however, that for some crops having >90% of production in one region the number of trials was not reduced due to the dietary significance of these commodities. In the case of crops which only require 3 trials based on total acreage but have ≥90% of production in one region, petitioners will have the option of conducting 3 trials with 2 treated samples per trial <u>or</u> 2 trials with 4 treated samples each (4 plots per trial--two at 1x rate and two at 2x rate as described above). Some of the crops having this option include globe artichokes, brussels sprouts, figs, mangoes and parsley. For crops which require ≤2 trials based on total acreage, there will be no reduction based on production being primarily in one region.

The effect of the 90% production being in one region can be ascertained by comparing the "REQ #FT W/O 90%" AND "REQ #FT" columns in Table 7. Those crops which have a smaller number of trials in the "REQ #FT" have received a reduction due to ≥90% of production being in one region. The "REQ #FT" column agrees with the "Minimum No. of Trials" column in Table 1.

For the purposes of standardizing the number of required field trials, it should be emphasized that in most cases (see next paragraph) the number of trials based on the above criteria and listed in Table 1 or Attachment 7 (REQ #FT) represent the **<u>minimum</u>** number of trials that will be accepted (with the exception of crop group tolerances or uses resulting in no

quantifiable residues as described later in this document). Additional trials are always welcome and, in fact, encouraged in the sense that more data points provide greater certainty of expected residue levels.

As discussed above, EPA has taken into consideration several major factors to determine the necessary numbers of trials and believes these numbers will be applicable in most cases. However, in limited circumstances the Agency may require additional trials or accept fewer trials than specified in Table 1. Any petitioner believing that fewer trials are adequate for a given crop will need to provide a convincing rationale. In such cases the Agency strongly advises petitioners to submit a protocol (outlining number and locations of trials) and rationale before initiating such trials. Likewise, any residue chemistry reviews requesting additional trials will include a justification as to the need for such data.

The numbers of trials in Table 1 or Attachment 7 represent how many acceptable trials are required reflecting the label use pattern producing the highest residue. In most cases such trials include the maximum rate per application and per season, the minimum intervals between applications, and the minimum preharvest interval. Trials which reflect other use patterns will not be counted unless the difference in use is insignificant (e.g., application rate 5% higher; PHI of 23 days versus 21 days). In those cases where multiple use patterns are desired and it is not clear which would result in the highest residue (e.g., different PHI's as a function of application rate), the full number of trials will be needed for each use unless side-by-side studies consistently show higher residues from one use pattern. [Additional guidance on this subject for early season uses appears in a later section of this document.] Petitioners should also be aware that trials which for some other reason do not generate viable samples reflecting the proposed use will not be counted. Possible causes of the absence of such samples are crop failure, mislabelling of samples, contamination, and insufficient documentation of sample integrity from collection to analysis. For these reasons it would be prudent for petitioners to conduct at least the field portions of a greater number of trials than the minimum listed in Table 1.

Although the NACA proposal included three trials as a minimum for any crop, the Agency believes that one or two trials are adequate for very low acreage crops (≤200 and >200-≤2000 acres, respectively). A greater uncertainty in residue levels is tolerable for these crops based on their extremely low contribution to the diet. However, if considerable variability is encountered between plots or between trials for such crops, the Agency may set the tolerance noticeably higher than the highest observed residue. In such scenarios petitioners have the option of conducting additional field trials to attempt to show

that a lower tolerance level would suffice. In fact, petitioners always have the option of conducting three or more field trials at the 1x rate (with two treated samples per trial) instead of the one or two trials with at least four treated samples per trial and plots reflecting both 1x and 2x rates.

Additional points need to be made with regard to the numbers of trials listed in Table 1 or Attachment 7:

1. Residue decline studies are included for many uses on crops needing ≥5 trials. Refer to the next section of this document for details.
2. These numbers are based upon each crop being the only one within its crop group for which a tolerance is requested. Refer to the Crop Group Tolerances section for how many trials are needed for uses on crop groups.
3. Fewer trials may be accepted for uses that do not yield quantifiable residues. Refer to the appropriate section later in this document for details.
4. The numbers are also predicated upon only one formulation type being requested for use on each crop. Refer to the Formulations section for data requirements for additional types of formulations.
5. The spray volumes specified for certain uses, especially ultra-low volume (ULV) and orchard uses, can affect the number of required trials. This is discussed in more detail later in this document.
6. Fewer trials will be needed for an amended registration provided the existing tolerance is shown to be adequate. Refer to the appropriate section later in this document for more details.
7. Table 1 addresses only **national registration** of terrestrial uses on **domestic** crops. Import tolerances are not covered. Refer to Attachment 11 for guidance on crop field trials to support regional and 24(c) registrations.
8. The numbers represent trials required for **permanent** tolerances. With the exception of the small acreage crops, fewer trials will normally be accepted for temporary tolerances (experimental use permits).
9. Validated analytical methodology, appropriate storage stability data, and documentation on sample handling, shipping, and storage intervals and conditions from sampling to analysis are needed to support all field trials.
10. Sampling and analysis of **treated and control samples** for **each raw agricultural commodity** of a crop as specified in Table II of the Residue Chemistry Guidelines (e.g., corn grain, forage and fodder) should be included in all field trials unless a practical livestock feeding restriction is placed on the pesticide label for a commodity.
11. Commercially important **varieties** of a crop as well as **seasonal variations** (e.g., winter wheat vs. spring wheat) should be covered by the field trials. Data on different varieties are especially important if there are significant differences in size

and/or length of growing season. Residue data from **more than one year** are desirable, but not required for national registration. [NOTE: Data from more than one year will be required for regional registration of crops which require ≥8 trials for national registration as detailed in Attachment 11.]

12. The numbers of trials are intended to cover terrestrial food uses on growing crops. They do not address **postharvest** applications to commodities such as fruit or stored grain. These will continue to be handled on a case-by-case basis.

13. Unless radiolabeled data show a seed treatment to be a non-food use, it will not be treated differently than any other food use. However, in many cases such uses may be eligible for the 25% reduction in the number of trials due to residues being below the method's LOQ.

Residue Decline Studies

Residue decline studies are required by the Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry). Such data will be needed for uses where (1) the pesticide is applied when the edible portion of the crop has formed or (2) it is clear that quantifiable residues may occur on the food or feed commodities at, or close to, the earliest harvest time. The primary purpose of these studies is to determine if residues are higher at longer preharvest intervals than requested and the approximate half-life of the residues. In addition, such studies are frequently of great value for determining an appropriate tolerance when a use pattern is changed. The number of decline studies needed is one for crops requiring 5-12 total trials and two for crops requiring 16-20 total trials. These studies are included in the 5-12 or 16-20 trials (i.e., not "in addition to" these numbers of trials). Decline studies will not be required for crops needing ≤3 total trials.

The design of the decline studies should include 3-5 sampling times in addition to the requested preharvest interval (PHI). The sampling times should all fall within the crop stage when harvesting could reasonably be expected to occur. The time points should be approximately equally spaced and, where possible, represent both shorter and longer PHI's than that requested. Of course, shorter PHI's can not be examined in the case of a use with a zero day PHI. In addition, for an at-plant/pre-plant use, the PHI is usually predetermined by the length of the growing season of the crop. Therefore, for such uses that result in quantifiable residues, petitioners should attempt to stretch the harvest period by sampling immature fruit, tubers, etc. if necessary.

Only one composite sample will be required for each time point in a decline study. However, petitioners are advised to take two or more samples to prevent method and sampling variability from masking or appearing to create residue changes

with time.

For most pesticides it is anticipated that residue decline studies will not be necessary for all crops. For a given pesticide additional decline studies will not be required if studies on representative crops indicate residues do not increase with longer preharvest intervals. This will provide some assurance that the tolerances represent the maximum residues that will occur from proposed or registered uses of a pesticide. The representative crop approach to be used is similar to that described in the January 1993 document "Guidance on Generating Storage Stability Data in Support of Pesticide Residue Chemistry Studies". If a pesticide is to be applied to all types of crops, it is recommended that decline data be obtained on the following five representative commodities: a tree fruit, root crop, leafy vegetable, grain, and fruiting vegetable. Some flexibility in the choice of crops will be permitted. For example, a legume vegetable could be substituted for the fruiting vegetable.

Crop Group Tolerances

As mentioned above, the numbers of trials in Table 1 are based upon each crop being the only one within its crop group for which a tolerance is requested. In the case of **crop group tolerances** for which there is more than one representative crop, the number of trials can be reduced based on the reasonable assumption that residues in the representative commodities should reflect residues on all crops in the group. The reduction in the number of trials is 25% (i.e., 20 → 15, 16 → 12, 12 → 9, 8 → 6) for those representative commodities that need ≥8 trials when requested individually. Crops which require ≤5 field trials will not receive any reduction when used as a representative commodity. Table 2 shows the resulting numbers of trials needed for all crop groups in 40 CFR 180.34(f).

As stated in 180.34(f)(5), if maximum residues for the representative crops vary by more than a factor of 5 from the maximum value observed for any crop in the group, a group tolerance will ordinarily not be established. In this case individual crop tolerances will normally be established and the 25% reduction in the number of trials will not apply. Petitioners should keep this in mind when planning crop field trials for crop group tolerances.

It should be noted that a similar 25% reduction in the number of trials may be applied to uses that do not yield quantifiable residues (see next section of this document). However, both of these 25% reductions may not be applied to the same crop. In other words, the number of trials can not be reduced 50% for a representative commodity that does not contain quantifiable residues.

Since the Agency has recently proposed creation of **subgroups** within the existing crop grouping scheme ("Pesticide Tolerances; Revision of Crop Groups", Federal Register Vol. 58, No. 163, pp. 44990-45006, 8/25/93), guidance on the number of field trials needed for the representative commodities in these subgroups is also provided in Table 3. These numbers of trials were determined on a case-by-case basis looking at the acreages and consumption of the representative commodities and the whole subgroup. Refer to the footnotes of Table 3 for more details. It should be noted that these subgroups are only proposed at this time and can not be used for establishment of tolerances until a final rule is published.

In effect, some crop groups have been established in 40 CFR 180.1(h). For example, a tolerance on "onions" applies to "dry bulb onions, green onions, and garlic". To determine the number of trials required for the "groups" in 180.1(h) refer to Table 4.

Uses Resulting in No Quantifiable Residues

Provided metabolism data or field trial data on related crops indicate quantifiable residues are not likely, a petitioner may elect to conduct 25% fewer trials for crops normally requiring ≥8 trials. However, if all of these trials do not show **residues below the method's limit of quantitation (LOQ)**, additional trials will normally be required to bring the total number conducted up to the standard requirement. Thus, the petitioner could risk a delay in obtaining a tolerance if this option is chosen. In addition to residues being below the LOQ, two other conditions must be met for the 25% fewer trials to be acceptable. First, the method must have a sufficiently low LOQ both from an analytical chemistry standpoint and for risk assessment purposes. This means the LOQ will need to be in the ≤0.01-0.05 ppm range in most cases. Second, the trials still need to represent all significant regions of production. Distribution of trials across regions is discussed in more detail in a later section of this document.

As explained earlier in this document, the 25% reduction in the number of field trials for residues below the LOQ can not be applied to representative commodities being used to establish crop group tolerances. The reduction is also not applicable to crops that require ≤5 field trials.

For crops which have more than one raw agricultural commodity, the 25% reduction for residues below the LOQ may be applied to one commodity even if the others have quantifiable residues. For example, if a pesticide is applied to an early stage of corn, it is possible residues are found on forage and fodder, but not in the grain. In this case, 16 trials may be acceptable for grain, even though 20 are needed for the forage and fodder. This is not meant to imply that separate trials are

to be conducted for different crop parts. In other words, corn grain, forage and fodder should be collected from each trial site. If no residues are found on grain from a minimum of 16 geographically representative sites, the grain collected at other sites need not be analyzed.

To take advantage of this option, petitioners should be certain to submit adequate recovery data and chromatograms establishing the limit of quantitation of the method. If the method ends up being validated in Agency laboratories, the LOQ will be included in the fortification levels that are tested. For a definition of LOQ the Agency suggests the article "Principles of Environmental Analysis", Analytical Chemistry, **1983**, 55, 2210-2218 (L.H. Keith, et al).

Additional Considerations for Early Season Uses on Annual Crops

For pesticide applications made prior to crop emergence, many labels give options such as allowing the use to be pre-plant, at-plant, or pre-emergence. The Agency has concluded that these three types of application can be grouped for the purposes of determining the total number of field trials. In other words, the trials for a specific crop can be divided among these three applications at the petitioner's discretion. For example, the twelve trials for a particular pesticide on cotton could consist of 3 pre-plant, 3 at-plant, and 6 pre-emergence applications (plus the maximum rate and number of any proposed post-emergence applications--see last paragraph of this section).

If the label gives a choice for surface application versus incorporation into the soil, data reflecting both of these modes of application will be required. There are two options as to how to conduct and determine the number of trials in this instance. The preferred option is for each trial to include both the surface and incorporated applications on side-by-side plots. Only one composite treated sample would be required for each plot. The minimum number of trials should be as designated in Table 1. This means that the total number of samples would be equivalent to that required for most other uses on the same crop. Using cotton again as the example, at least twelve trials would be needed with each having two samples (one for surface applied and one for soil incorporated). As described in the previous paragraph, the 12 trials can be divided among pre-plant, at-plant and pre-emergence applications if all these appear on the label.

The alternative option is to divide the total number of trials in Table 1 (but note caveat below) roughly equally between those having only the surface treatment and those reflecting only soil incorporation. Two composite treated samples will be needed in each trial. Since the trials for each mode of application will need to have adequate geographic representation, this option may result in a greater number of trials for those crops which

have a region(s) normally needing only one trial. Using the cotton example, the result would be at least two additional trials (14 total) since regions 6 and 2 (representing 10% and 8% of production, respectively) would each need to have two trials (one for surface and one for incorporation). If the side-by-side option above were chosen, only one trial would be required in each of those regions.

Particularly in the case of herbicides, the label may permit pre- and/or post-emergence applications. If both are allowed, all field trials should include both applications. If the choice is limited to one or the other, the full number of trials as specified in Table 1 should be conducted for each type of application. However, fewer total trials will be accepted if some side-by-side studies show a consistent pattern between the residues from the pre- and post-emergence uses. In this instance the full number of trials will be needed only for the mode of application consistently resulting in higher residues. [NOTE: The discussion in this paragraph refers to before or after the emergence of the food/feed crop. Occasionally, labels specify application timing in terms of before or after weeds emerge. The critical factor for purposes of this discussion is whether or not the food/feed crop has emerged.]

Formulations

In the "Number of Trials for Individual Crops" section of this document it is stated that the numbers are based upon only one formulation type being requested for use on each crop. The number of trials needed to register additional formulation types or classes will be addressed on a case-by-case basis. In some instances the full number of trials will also be needed for a new type of formulation, whereas other formulation classes may be registered with a few bridging studies or perhaps no field trials at all. The decision depends upon how similar the formulations are in composition and physical form, the mode of application, and the timing of the application. More details are provided below.

One type of formulation which will normally require a full set of field trials is the microencapsulated or controlled release formulation. Since these are designed to control the release rate of the active ingredient, the same number of field trials is needed as to obtain an original tolerance regardless of the timing and mode of its application and the amount of data available on other formulations classes.

Most of the remaining types of formulations can be divided into two groups: those which are diluted with water prior to application and those which are applied intact. Granules and dusts are the most common examples of the latter. Granular formulations will generally require the full number of field

trials regardless of what data are already available for other formulation classes. This is based on several observed cases of residue uptake being quite different for granules versus other types of formulations of the same active ingredient. No residue data will be required for dusts if data are available at the same application rate and preharvest interval for a formulation applied as a wetting spray (e.g., EC, WP).

The most common formulation types which are diluted in water prior to application include emulsifiable concentrates (EC), wettable powders (WP), water dispersible granules (WDG; WG) or dry flowables (DF), flowable concentrates (FlC), and soluble concentrates (liquid or solid)(SC; SL). Residue data may be translated among these classes of formulations for applications that are made prior to crop emergence (i.e., pre-plant, at-plant, and pre-emergence applications) or just after crop emergence. Data may also be translated among these formulation classes for applications directed to the soil (as opposed to foliar treatments).

For mid- to late season foliar applications of formulation types listed in the previous paragraph, two options are available. The new type of formulation could be treated similarly to an amended registration (see later section): 25% fewer trials would be required than were required for the formulation class used to obtain the original tolerance. Alternatively, side-by-side studies (often referred to as bridging data) could be conducted. These involve applications of the registered formulation (the type used to obtain the tolerance) and the new type of formulation to side-by-side plots using the same rates and pre-harvest intervals. If residues from the new formulation are comparable to or less than those from the registered formulation, the new formulation can be registered. However, if residues are higher from the new formulation in the side-by-side comparison, the full number of trials specified in Table 1 will be required for that formulation to determine the higher tolerance level needed to cover its registration.

The exact number of side-by-side studies required will be decided on a case-by-case basis. A "representative crops" approach may be used if the new formulation is requested for use on numerous crops. Submission of protocols outlining the crops and sites to be used in these bridging studies is encouraged. The most common questions from petitioners in this area have involved use of EC data to support registrations of wettable powders. It is EPA's understanding that NACA is compiling data from its members that compare residues from EC's and WP's. If a sufficient number of such studies are available, it is possible a conclusion could be made in the future that no additional crop field trials are required to register a WP if data for an EC reflecting the same use pattern are available.

The previous two paragraphs address the data requirements for a new type of formulation when a registered one already exists. If a petitioner wishes to register two or more formulation classes when obtaining the initial tolerance and registration, the same basic concepts would apply. That is, a complete set of trials as specified in Table 1 should be conducted on one type of formulation and the additional formulation classes handled like an amended registration (25% fewer trials than the primary formulation) or compared to the primary type of formulation using side-by-side studies.

A few other statements can be made concerning data requirements for formulations. Dry flowable or water dispersible granular formulations are sufficiently similar to wettable powders to allow translation of residue data between them. Placing a formulation (typically WP) in a water soluble bag does not require additional residue data provided adequate data are available for the unbagged product.

Some pesticides (e.g., phenoxy herbicides) can be applied as one or more **salts** and/or **esters**. Generally, different salts or esters of an active ingredient can be treated as new formulations of that active ingredient for purposes of determining the number of crop field trials. Thus, a new salt could be treated like an amended registration (25% fewer trials than the original salt or form of the active ingredient) or compared to the registered form of the active ingredient using side-by-side studies.

Spray Volumes--Ground versus Aerial Equipment

The subjects of spray volumes and aerial versus ground equipment are often interconnected and were addressed in PR Notice 93-2 (Feb. 11, 1993). This notice stated the following: "Provided that the pesticide product label specifies that aerial applications are to be made in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree or orchard crops), crop field trials reflecting aerial application will be waived in those cases where adequate data are available from use of ground equipment reflecting the same application rate, number of applications, and preharvest interval. This data waiver does not apply to aerial applications using diluents other than water (e.g., vegetable oils). In addition, the Agency reserves the right to require aerial data if special circumstances warrant it."

Based on the above, there are only a few instances where the number of field trials will be affected by the spray volumes or type of equipment (at least for aerial versus ground) specified on the label. However, the following two exceptions should be kept in mind:

(1) Ultra-low volume uses (<2 gallons spray per acre; <10 gallons per acre for orchards) in mid- to late season will be

treated as separate use patterns regardless of the nature of the diluent (water, vegetable oil, etc.). If the ULV application is the first use on the crop (i.e., no tolerance established), the minimum number of field trials specified in Table 1 or Attachment 7 is required. If data are already available reflecting higher spray volumes, the ULV application can be handled similarly to an amended registration (i.e., 25% fewer trials than specified in Table 1 providing these trials show the existing tolerance is adequate--see Amended Registrations below). Alternatively, it would acceptable for petitioners to demonstrate using side-by-side studies that residues from the ULV applications are comparable to or lower than those from higher spray volumes. However, if residues are higher from the ULV application in these side-by-side studies, the full number of trials specified in Table 1 will be required for this use.

(2) For treatment of orchards, dilute sprays (typically 100-400 gallons per acre) and concentrate sprays (typically 20-100 GPA) will be treated as separate uses. The number of trials will depend upon which of two options is chosen, analogous to the discussion earlier in this document for surface applied versus soil incorporation (see Additional Considerations for Early Season Uses on Annual Crops). If side-by-side plots (dilute vs. concentrate) are included at all sites (the preferred option), the numbers of trials in Table 1 will apply and one treated sample from each plot (instead of the normally required two) will be acceptable. Alternatively, the trials could be divided roughly equally between dilute and concentrate sprays with adequate geographic representation required for each type of spray. In this case, two treated samples are needed at each site and the total number of required trials may exceed that in Table 1 if one or more regions require only one study. Refer to the example for cotton in the section on Early Season Uses.

If either dilute or concentrate sprays are already approved for use on an orchard crop, the request to add the other type of spray to the label will be treated as an amended registration requiring 25% fewer trials than specified in Table 1 (see Amended Registrations below) or a number of side-by-side studies establishing that residues from the requested type of spray are not higher than those from the registered one. The exact number of side-by-side studies required will be determined on a case-by-case basis. Submission of protocols outlining the locations and numbers of sites is encouraged.

One final comment on spray volumes concerns chemigation--the application of pesticides by injection into irrigation water. The Agency views this as a type of ground application using very large spray volumes. Provided that data are available for typical ground spray volumes, data reflecting chemigation are not required.

Amended Registrations

For amended registration requests that involve a significant change in application rate (either individual or seasonal), interval between applications, or preharvest interval, the number of field trials required will normally be 25% less than that needed to establish an original tolerance, provided that the latter is shown by the reduced number of trials to be adequate to cover the new use. However, if the reduced number of trials indicates that the original tolerance is inadequate, or if the original number of trials was ≤5 or already included a 25% reduction (crop group or residues <LOQ), the number of trials for an amended registration is the same as that for the original tolerance. On a case-by-case basis the Agency may require less additional data than described above for an amended registration. This could be particularly true when residue decline studies are available reflecting a proposed change in a preharvest interval. In some instances, no additional data may be necessary. An example would be a request to reduce the application rate for a use that already does not produce quantifiable residues.

Location of Trials

The NACA/IR-4 report proposed dividing the United States into 13 regions based on growing conditions (see map in Attachment 9). The dividing lines reflect natural geography or climatic boundaries and, therefore, in many cases do not coincide with state lines. The exact definitions of the regions are specified by states, counties, highways, or mountain ranges in Attachment 10. Further subdivision of Regions 2, 3, 5 and 10 was proposed by NACA for crops having <300,000 acres.

EPA agrees with the regional approach as proposed by NACA. This will allow greater flexibility in data collection for minor uses in that a cooperator in another state within a region can be used in cases where one can not be found in the state of highest production. However, the Agency concludes that the further subdivision of Regions 2, 3, 5 and 10 is not necessary for the purpose of distributing trials for low acreage crops. The Agency also notes that Puerto Rico was assigned to Region 13 on NACA's map for "major and major-minor crops", but to Region 3A on the map for "minor crops". EPA has concluded that Puerto Rico is more similar to Hawaii (Region 13) than Florida (Region 3) in terms of climate and geography. Therefore, Puerto Rico should be considered to be combined with Hawaii to form Region 13. The production figures in Table 6 and distributions of trials in Table 5 have been developed on this basis.

Using crop production figures the Agency has developed suggested distributions of trials among the 13 regions for crops requiring >3 trials. These distributions are delineated in Table 5 and were developed using the following general criteria

proposed by NACA. The number of trials per region should generally correlate with the percentage of the crop grown in that region. However, where possible, at least one trial should be included in each region having ≥2% of the national production. The latter criterion can be met in most, if not all, cases for crops requiring ≥12 trials. However, for some crops needing 5-8 trials, trying to satisfy this criterion would result in regions with a high percentage of the production having too few trials. For example, in the case of sweet cherries the Agency has not suggested that trials be conducted in Regions 1 and 9 (3% each of national production) since this would leave too few trials in the major regions of production (5, 10, 11).

The distributions of trials in Table 5 are not intended to be absolute requirements, but "suggested" designs for these studies. There are likely to be several acceptable alternatives for most crops. Petitioners may wish to contact EPA regarding the suitability of alternative distributions of trials.

For crops requiring ≤3 trials, it is more difficult to develop guidance on distribution of trials since the number of growing regions is often comparable to or even greater than the total number of trials. In these cases the data should represent to the extent possible a balance of the highest production areas, different geographic/climatic conditions, and/or major differences in varieties of the crop. At least one trial should be conducted in the region of highest production.

To aid petitioners in determining distribution of trials for crops not listed in Table 5 or alternative distributions of trials for crops that are in that table, the production of numerous crops by region is specified in Table 6. Most of these figures were provided by NACA (crops >300,000 acres) and IR-4 (crops <300,000 acres) using acreage information from USDA's Agricultural Statistics (1991) and the 1987 Census of Agriculture (Dept. of Commerce). These publications list production by state instead of region. Since numerous states fall into more than one region, NACA/IR-4 had to estimate the distribution of acreage within these states to calculate regional production. Numerous crops (primarily minor crops such as spices, herbs, and unusual berries) are not listed at all in this table since the IR-4 report contained no regional production figures for them. As can also be seen in Table 6, the total accountability of production is <100% for a considerable number of crops. However, the Agency believes sufficient percentages of production (most are >85%) are accounted for to determine the distribution of trials.

A special comment needs to be made concerning distribution of trials for crop group or (proposed) crop subgroup tolerances for legume vegetables. The regulation and proposed rule specify that the representative commodities include one variety of succulent bean, one variety of dried bean, one variety of dried

pea, etc. depending upon the crop group or subgroup. If possible, the variety chosen should be one that is grown in all significant areas of production for that class of bean or pea. If this can not be done, then a combination of varieties may be used to encompass all regions of production. As an example, it will not be acceptable to provide data from only one region for a certain variety of dried bean even if that dried bean is grown only in that region. The data need to reflect all significant regions of production for all dried beans if a crop group or subgroup tolerance is desired.

The above discussion focuses on the distribution of trials among regions. With respect to the distribution of multiple trials within a region, this should generally follow the relative production in the individual growing areas (states or counties as appropriate) of the region. However, the sites should also be sufficiently separated to reflect the diversity of the growing region including soil types. In other words, if production is scattered throughout much of a region, the trials should not be clustered in one small portion of that region.

To aid the Agency's review process with regard to the distribution of trials among and within regions, petitioners are requested to include a copy of the map in Attachment 9 showing the locations of all sites of acceptable trials (i.e., those reflecting the proposed use and generating viable samples) in the volume of field trial reports for each crop.

Requirements for Tolerances with Geographically Restricted Registrations and for 24(c) Registrations

The preceding discussion in this document on determining the number of crop field trials addresses national registration of pesticides. Since regional registration is accepted by the Agency under certain circumstances, separate guidance has been developed as detailed in Attachment 11. This attachment also addresses field trial requirements for 24(c) or Special Local Needs registrations. In summary, the basic concept described in Attachment 11 is that the number of trials for a regional registration should be determined by multiplying the number of field trials required for national registration by the proportion of the crop (on an acreage basis) grown in the region in which registration is sought.

List of Attachments/Tables

TABLE 1: MINIMUM NUMBERS OF CROP FIELD TRIALS AND TREATED SAMPLES FOR TOLERANCES ON INDIVIDUAL CROPS

Following the procedure explained in the body of this document and in Attachment 7, this table specifies the minimum numbers of field trials and treated samples required to obtain tolerances on individual crops. For those crops requiring ≥8 trials in this table, a 25% reduction in the number of trials is acceptable for uses resulting in no quantifiable residues providing certain criteria are met (see document for details). The same reduction is acceptable for representative commodities that are being used to obtain crop group tolerances (see Table 2) and some crop subgroup tolerances (see Table 3). [NOTE: Application of both 25% reductions (residues <LOQ and crop group) to a given crop will not be acceptable.]

The numbers in this table represent the minimum number of acceptable trials reflecting the label use pattern producing the highest residue. Trials reflecting other use patterns or which for some reason do not generate viable samples will not be counted. In addition, these numbers of trials are predicated upon only **one formulation** type being requested for use on the crop. If additional types of formulations are desired, additional data may be needed as discussed in the Formulations section of this document.

A minimum of **two treated samples** is required from each field trial for crops requiring ≥3 trials. For crops requiring <3 trials, a minimum of four treated samples from four independently treated plots is required for each trial - two samples reflecting the maximum proposed application rate (1x) and two reflecting a 2x rate. As discussed in the Sampling Requirements section of this document, each composite sample should be collected by a separate run through a treated plot. Splitting one sample from a plot or conducting two analyses on one sample will not be an acceptable alternative to separately collecting and analyzing two samples. **Multiple analyses of a single sample or of subsamples constitute the equivalent of only one data point.**

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops

Crop	Minimum No. of Trials	Minimum No. of Treated Samples
Acerola	1	4
Alfalfa	12	24

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Almonds	5	10
Apple, Sugar	2	8
Apples	16	32
Apricots	5	10
Arracacha	2	8
Artichokes, Globe	3 or 2*	6 or 8*
Artichokes, Jerusalem	3	6
Asparagus	8	16
Atemoya	1	4
Avocado	5	10
Bananas	5	10
Barley	12	24
Beans, Dried[1]	12	24
Beans, Edible Podded[1]	8	16
Beans, Lima, Dried	3	6
Beans, Lima, Succulent	8	16
Beans, Mung	3 or 2*	6 or 8*
Beans, Snap	8	16
Beans, Succulent Shelled[1]	8	16
Beets, Garden	5	10
Blackberries	3[2]	6[2]
Blueberries	8	16
Bok choi	2	8
Boysenberries	2	8
Broccoli	8	16
Broccoli, Chinese (gai lon)	2	8

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Brussels Sprouts	3 or 2*	6 or 8*
Buckwheat	5	10
Cabbage	8	16
Cabbage, Chinese	3	6
Cacao Bean (cocoa)	3	6
Calabaza	2	8
Calamondin	1	4
Canola	8	16
Cantaloupe	8	16
Carambola	2	8
Carob	3	6
Carrots	8	16
Cassava, bitter or sweet	2	8
Cauliflower	8	16
Celery	8	16
Cherries, Sour	8	16
Cherries, Sweet	8	16
Chestnuts	3	6
Chickpea (garbanzo bean)	3	6
Chicory	2	8
Clover	12	24
Coconut	5	10
Coffee	5	10
Collards	5	10
Corn, Field	20	40
Corn, Pop	3	6
Corn, Sweet	12	24

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Cotton	12	24
Crabapples	3	6
Cranberries	5	10
Cress, Upland	1	4
Cucumbers	8	16
Currants	2	8
Dandelion	1	4
Dates	3 or 2*	6 or 8*
Dill (dill seed, dillweed)	2	8
Eggplant	3	6
Elderberries	3	6
Endive (escarole)	3	6
Figs	3 or 2*	6 or 8*
Filberts (hazelnuts)	3 or 2*	6 or 8*
Flax	5	10
Garlic	3	6
Genip	1	4
Ginger	2	8
Ginseng	1	4
Gooseberries	3	6
Grapefruit	8	16
Grapes	12	24
Grasses (crop group) (also see Table 2)	12	24
Guar	3 or 2*	6 or 8*
Guava	2	8
Hops	3	6

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Horseradish	3	6
Huckleberries	3	6
Kale	3	6
Kiwi fruits	3 or 2*	6 or 8*
Kohlrabi	3	6
Kumquats	1	4
Leeks	3	6
Lemons	5	10
Lentils	3	6
Lettuce, Head	8	16
Lettuce, Leaf	8	16
Limes	3	6
Loganberries	2	8
Longan Fruit	1	4
Lotus Root	1	4
Lychee	1	4
Macadamia Nuts	3 or 2*	6 or 8*
Mamey Sapote	2	8
Mandarins (tangerines)	5	10
Mangoes	3 or 2*	6 or 8*
Melons, Casaba	3	6
Melons, Crenshaw	3	6
Melons, Honeydew	5	10
Millet, Proso	5	10
Mint[3]	5	10
Mulberry	3	6
Mushrooms	3	6

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Muskmelons[4]	8	16
Mustard, Chinese	2	8
Mustard Greens	5[5]	10[5]
Nectarines	8	16
Oats	16	32
Okra	5	10
Olives	3	6
Onions, Dry Bulb	8	16
Onions, Green	3	6
Oranges, Sour and Sweet	16	32
Papaya	3 or 2*	6 or 8*
Parsley	3	6
Parsnips	3	6
Passion Fruit	2	8
Pawpaws	3 or 2*	6 or 8*
Peaches	12	24
Peanuts	12	24
Peanuts, Perennial	3	6
Pears	8	16
Peas, Austrian Winter	3	6
Peas, Chinese	1	4
Peas, Dried[1]	5	10
Peas, Edible Podded[1]	3	6
Peas, Garden, Dried	3	6
Peas, Garden, Succulent	8	16
Peas, Succulent Shelled[1]	8	16
Pecans	5	10

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Peppers, Bell	8	16
Peppers, Non-bell	3	6
Persimmons	3 or 2*	6 or 8*
Pimentos	2	8
Pineapples	8	16
Pistachios	3	6
Plantains	3 or 2*	6 or 8*
Plums	8	16
Pomegranates	3 or 2*	6 or 8*
Potatoes	16	32
Pumpkins	5	10
Quinces	3 or 2*	6 or 8*
Radish, Japanese (daikon)	2	8
Radishes	5	10
Raspberries, Black and Red	3^2	6^2
Rhubarb	2	8
Rice	16	32
Rice, Wild	5	10
Rutabagas	3	6
Rye	5	10
Safflower	5	10
Sainfoin	3	6
Salsify	3	6
Sesame	3	6
Shallots	1	4
Sorghum, Grain (milo)	12	24

Table 1: Minimum Numbers of Crop Field Trials and Treated Samples for Tolerances on Individual Crops		
Crop	**Minimum No. of Trials**	**Minimum No. of Treated Samples**
Soybeans (dried)	20	40
Spinach	8	16
Squash, Summer	5	10
Squash, Winter	5	10
Strawberries	8	16
Sugar Beets	12	24
Sugarcane	8	16
Sunflowers	8	16
Sweet Potatoes	8	16
Swiss Chard	3	6
Tangelos	3	6
Tanier	2	8
Taro (dasheen)	2	8
Tobacco	3	6
Tomatoes	16	32
Turnip roots	5	10
Turnip tops	5	10
Walnuts, Black and English	3	6
Watercress	2	8
Watermelons	8	16
Wheat	20	40
Yam, True	3	6

* For these crops petitioners have the option of doing 3 trials with two treated samples (1x rate) per trial or 2 trials with four treated samples (two at 1x rate, two at 2x rate) per trial.

1. These bean/pea commodities include more than one type of bean/pea. The specific commodities included in each of these

groups are shown below. The specific representative commodity for which field trials should be run in each case are those representative commodities provided in the proposed crop subgroup Federal Register notice.

beans, dried: include those commodities listed in the proposed crop subgroup 6-C as Lupinus spp., Phaseolus spp., Vigna spp., guar and lablab beans.

peas, dried: include those commodities listed in the proposed crop subgroup 6-C as Pisum spp., lentils and pigeon peas.

beans, edible podded: include those commodities listed in the proposed crop subgroup 6-A as Phaseolus spp., Vigna spp., jackbeans, soybeans (immature seed) and sword beans.

peas, edible podded: include those commodities listed in the proposed crop subgroup 6-A as Pisum spp. and pigeon peas.

beans, succulent shelled: include those commodities listed in the proposed crop subgroup 6-B as Phaseolus spp., Vigna spp. and broad beans.

peas, succulent shelled: include those commodities listed in the proposed crop subgroup 6-B as Pisum spp.

2. A minimum of five trials (and 10 samples) is required on any one blackberry or any one raspberry if a tolerance is sought on "caneberries" (see Table 3 or Table 4). A minimum of three trials (and six samples) is required if a tolerance is sought only on blackberries or only on raspberries.

3. A tolerance for mint may be obtained using residue data for spearmint and/or peppermint. If a tolerance is sought for either spearmint or peppermint separately, five trials are still required.

4. A tolerance for muskmelons may be obtained using residue data for cantaloupes.

5. A minimum of eight trials (and 16 samples) is required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens (see Table 3).

TABLE 2: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP GROUPS [180.34(f)]

Crop Group	Representative Commodities	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for a Commodity as Part of Crop Group
1) Root and Tuber Vegetables.	carrot	8	6
	potato	16	12
	radish	5	5
	sugar beet	12	9
			Total = 32
2) Leaves of Root and Tuber Vegetables (Human Food or Animal Feed)	turnip	5	5
	sugar beet[1]	12	9
			Total = 14
3) Bulb Vegetables (Allium spp.)	green onion	3	3
	bulb onion	8	6
	one other commodity in group[2]	3	3
			Total = 12
4) Leafy Vegetables (Except Brassica Vegetables)	leaf lettuce	8	6
	head lettuce	8	6
	celery	8	6
	spinach	8	6
			Total = 24
5) Brassica (Cole) Leafy Vegetables	broccoli[3]	8	6
	cabbage	8	6
	mustard greens	5	5
			Total = 17
6) Legume Vegetables (Succulent or Dried)	bean (Phaseolus spp.), succulent	NA	12[4]
	bean (Phaseolus spp.), dried	12	9
	pea (Pisum spp.), succulent	NA	9[5]

TABLE 2: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP GROUPS [180.34(f)]

Crop Group	Representative Commodities	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for a Commodity as Part of Crop Group
	pea (Pisum spp.), dried	5	5
	soybean	20	15
			Total = 50
7) Foliage of Legume Vegetables	bean (any variety)	8	6
	field pea[9]	5	5
	soybean	20	15
			Total = 26
8) Fruiting Vegetables (Except Cucurbits)	tomato	16	12
	pepper	8	6
			Total = 18
9) Cucurbit Vegetables	cucumber	8	6
	melon (cantaloupe or muskmelon)	8	6
	summer squash	5	5
			Total = 17
10) Citrus Fruits (Citrus spp., Fortunella spp.)	orange, sweet	16	12
	lemon	5	5
	grapefruit	8	6
			Total = 23
11) Pome Fruits	apple	16	12
	pear	8	6
			Total = 18
12) Stone Fruits	sweet or sour cherry	8	6
	peach	12	9
	plum (or fresh prune)	8	6
			Total = 21

TABLE 2: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP GROUPS [180.34(f)]

Crop Group	Representative Commodities	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for a Commodity as Part of Crop Group
13) Small Fruits and Berries	blackberry (or raspberry)	3	3
	blueberry, highbush	8	6
	cranberry[6]	5	5
	grape[6]	12	9
	strawberry[6]	8	6
			Total = 29
14) Tree Nuts	almond	5	5
	pecan	5	5
	English walnut[7]	3	3
			Total = 13
15) Cereal Grains	sweet corn	12	9
	field corn	20	15
	rice	16	12
	sorghum	12	9
	wheat	20	15
			Total = 60
16) Forage, Fodder and Straw of Cereal Grains	corn	20	15
	wheat	20	15
	any other cereal grain	16	12
			Total = 42
17) Grass Forage, Fodder, and Hay	Bermuda grass, bluegrass, and bromegrass or fescue	12 (4 trials for each variety)	Total = 12
18) Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay)	alfalfa	12	9
	clover	12	9
			Total = 18

TABLE 2: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP GROUPS [180.34(f)]

Crop Group	Representative Commodities	Number of Field Trials for Commodity if Not Part of Crop Group	Number of Field Trials for a Commodity as Part of Crop Group
19) Herbs and Spices[8]	basil	3	3
	chive	3	3
	dill	2	3
	marjoram (or other Origanum spp.)	3	3
	sage	3	3
			Total = 15

1. The Proposed Revision of Crop Groups (OPP-300269; FRL-4170-6; published 8/25/93) allows a choice between sugar beet or garden beet as a representative commodity. The same number of field trials would be required for each.
2. The Proposed Revision of Crop Groups includes only green and bulb onions as representative commodities for this crop group.
3. The Proposed Revision of Crop Groups allows a choice between broccoli or cauliflower as a representative commodity. The same number of field trials would be required for each.
4. Twelve total field trials are required, 6 for an edible podded bean, and 6 for a succulent shelled bean.
5. Nine total field trials are required, 3 for an edible podded pea, and 6 for a succulent shelled pea.
6. The Proposed Revision of Crop Groups includes "blueberry and any one blackberry or any one raspberry" as representative commodities for the crop group "berries". Cranberries, grapes, and strawberries will no longer be included in any crop group.
7. The Proposed Revision of Crop Groups includes only almonds and pecans as representative commodities for this crop group.
8. The Proposed Revision of Crop Groups (a) deletes marjoram and sage, (b) changes "dill" to "dill seed", (c) provides an option to obtain data on celery seed or dill seed, (d) adds black pepper as a representative commodity, and (e) specifies that data are required on both fresh and dried basil. Since a minimum of 3 field trials is required for any representative commodity, each of the above will require 3 field trials for a crop group tolerance.
9. The required number of field trials for field peas takes into account the total acreage of various types of peas and lentils.

TABLE 3: REQUIRED NUMBERS OF FIELD TRIALS FOR PROPOSED CROP SUBGROUPS [180.34(f)]

The number of field trials required for crop groups is provided in Table 2. For crop groups, the required number of field trials shown in Table 1 should be done for each representative commodity, except that 25% fewer trials are required for representative commodities normally requiring 8 or more trials. This procedure does not necessarily apply to the proposed crop subgroups shown in the Table below since there are fewer representative commodities in many cases (see Pesticide Tolerances; Revision of Crop Groups; OPP-300269; FRL-4170-6, published 8/25/93). The table below and the corresponding footnotes describe the required numbers of field trials for crop subgroups.

Crop Group	Representative Commodities	Other Commodities[1]	Production Acres[8] (x1000)	% Consumption	# Field Trials[2]
1A. Root Vegetables[3]	carrot		98	0.322	6
	radish		46	0.003	5
	sugarbeet		1350	0.617	9
		Total	1494	0.942	20
1B. Root Vegetables Except Sugar Beets[3]	carrot		98	0.322	6
	radish		46	0.003	5
		beet, garden	13	0.042	
		turnip	20	0.043	
		Total	177	0.410	11
1C. Tuberous and Corm Vegetables[4]	potato		1310	2.091	16
		sweet potato[8]	90.5	0.072	
		Total	1400	2.163	16
1D. Tuberous and Corm Vegetables Except Potato[4]	sweet potato[8]		90.5	0.072	8
4A. Leafy Greens[3]	lettuce, head		240	0.394	6
	lettuce, leaf		51	0.025	6
	spinach		36	0.081	6
		Total	327	0.500	18

TABLE 3: REQUIRED NUMBERS OF FIELD TRIALS FOR PROPOSED CROP SUBGROUPS [180.34(f)]

Crop Group	Representative Commodities	Other Commodities[1]	Production Acres[6] (x1000)	% Consumption	# Field Trials[2]
4B. Leaf Petioles[4]	celery[8]		36	0.114	8
5A. Head and Stem[3] Brassica	cabbage[8]		98.7	0.182	6
	cauliflower (or broccoli)		65 (115)	0.029 (0.091)	6
		Total	278.7	0.302	12
5B. Leafy Brassica Greens[7]	mustard greens		9.7	0.027	5[7]
		cabbage, Chinese (napa)	8.7	0.007	
		collards	15	0.035	
		kale	6.2	0.003	
		Total	39.6	0.072	8[7]
6A. Edible Podded Legume Vegetables[3]	one bean		289	0.372	6
	one pea		unknown	unknown	3
		Total	289	0.372	9
6B. Succulent, Shelled Pea and Bean[3]	one bean		51	0.048	6
	one pea		314	0.319	6
		Total	365	0.367	12
6C. Dried, Shelled Pea and Bean, Except Soybean[3]	one bean		1750	0.267	9
	one pea		395	0.005	5
		Total	2145	0.272	14
7A. Foliage of Legume Vegetables Except Soybeans[3]	one bean		2090	0	6
	field pea		709	0	5
		Total	2799	0	11
9A. Melons[4]	cantaloupe		130	0.083	8
		watermelon	193	0.142	
		melon, honeydew	29	0.034	

TABLE 3: REQUIRED NUMBERS OF FIELD TRIALS FOR PROPOSED CROP SUBGROUPS [180.34(f)]

Crop Group	Representative Commodities	Other Commodities[1]	Production Acres[8] (x1000)	% Consumption	# Field Trials[2]
		Total	352	0.259	8
9B. Squash / Cucumber[3]	one variety summer squash		29	0.059	5
	cucumber		130	0.134	6
		pumpkin	41	0.008	
		winter squash	29	0.060	
		Total	229	0.261	11
13A. Caneberry (Blackberry and Raspberry)[5]	any one blackberry[8] (or raspberry)		7.9 (15)	0.018 (0.006)	3 (3)
		Total	22.9	0.024	5
13B. Bushberry[4]	blueberry, high bush		59	0.017 (consumption for non-nursing infants = 0.043%)	8
19A. Herbs[6]	basil, fresh and dried				3
	chive				3
		Total	2.75	0.014	6
19B. Spices[6]	black pepper				3
	celery or dill seed				3
		Total	2.75	0.014	6

1. The column "other commodities" only includes commodities which account for ≥5% of the acreage estimates for the representative commodities.
2. A minimum of 3 field trials is required for any representative commodity.
3. The number of required field trials for these crops was determined in the same manner as for crop groups.
4. For each of these crop subgroups, the normal number of field trials required for the representative commodity is required for the crop subgroup.
5. The required number (five) of field trials for Caneberries was determined using the total acreage and consumption estimates for blackberries and raspberries, and then applying the same criteria as used for determining the

number of required field trials for individual commodities. A minimum of three field trials is required if a tolerance is sought for either blackberries or raspberries separately.

6. For the subgroups "Herbs" and "Spices", the minimum number of required field trials (3) was required for each representative commodity.

7. The required number of field trials for Leafy Brassica Greens was determined using the total acreage and consumption estimates for the major commodities in the subgroup (since mustard greens represents a relatively small fraction of this total), and then applying the same criteria as used for determining the number of required field trials for individual commodities. Therefore, a minimum of eight trials is required if a tolerance is sought on Leafy Brassica Greens. If a tolerance on only "mustard greens" is desired, a minimum of five trials is required (see Table 1).

8. Acreage information (given in thousands of acres) and consumption for the following commodities include values for both the commodity itself, and the acreages and consumptions of other commodities for which the tolerance would apply as defined in 40 CFR 180.1(h):

blackberries:	blackberries (6.7), boysenberries (1.2)
cabbage:	cabbage (90), Chinese cabbage (napa) (8.7)
celery:	celery (36), fennel (only consumption data available)
sweet potatoes:	sweet potatoes (87), yams (3.5)

TABLE 4: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP "GROUPS" IN 180.1(h)

The Code of Federal Regulations (40 CFR 180.1(h)) states the following:

> "Tolerances and exemptions established for pesticide chemicals in or on the general category of raw agricultural commodities listed in column A apply to the corresponding specific raw agricultural commodities listed in column B. However, a tolerance or exemption for a specific commodity in column B does not apply to the general category in Column A."

This section of the CFR addresses two distinct situations. In the first situation, a specific commodity is included in both columns A and B. Residue data for that commodity support a registration or tolerance for itself as well as for the additional items listed in column B. These include the following column A commodities: alfalfa, bananas, blackberries, broccoli, cabbage, celery, endive, lettuce (head), lettuce (leaf), marjoram, muskmelons, onions (dry bulb only), onions (green), peaches, sugar apple, summer squash, sweet potatoes, tangerines, tomatoes, turnip tops or turnip greens, and wheat. The required number and distribution of field trials for items in column A support items in column B for this situation. The minimum numbers of field trials for these commodities are specified in Table 1 or Attachment 7. [Note: Although "muskmelons" and "summer squash" do not appear by name in column B next to their entry in column A, for practical purposes these entries are treated as falling under the situation described above with the numbers of field trials specified in Table 1.]

The second situation occurs in cases where the item in column A is a term identifying a group of commodities in column B. These include the following column A commodities: beans, beans (dry), beans (succulent), caneberries, cherries, citrus fruits, lettuce, melons, onions, peas, peas (dry), peas (succulent), peppers, and squash. Since these column A commodities are in essence crop "groups", the number of field trials required for these "commodities" will be determined in a similar manner as for crop subgroups (or crop groups in the case of citrus). Listed in Table 4 below are the field trial requirements to support a tolerance for these column A commodities. In each case, one or more representative commodities from column B are shown for which field trial data are required to support the "commodity" in column A. The required number of field trials for each representative commodity is also provided. Since these are treated similar to crop groups and/or subgroups, a 25% reduction in the required number of field trials for commodities typically requiring 8 or more field trials was employed in those cases where there is more than one representative commodity.

TABLE 4: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP "GROUPS" IN 180.1(h)

Column A Commodities	Representative Column B Commodities	Acres (x1000)	% Consumption	Number of Field Trials if Not in Crop Group	Number of Field Trials if Part of Crop "Group" in Column A	Total Number of Required Field Trials for Tolerance on Crop "Group" in Column A
Beans	one edible podded bean	289	0.372	8	6	
	one succulent shelled bean	51	0.048	8	6	
	one dried shelled bean	1750	0.267	12	9	
						21
Beans, dry	one dried shelled bean	1750	0.267	12	12	12
Beans, succulent	one succulent edible podded bean	289	0.372	8	6	
	one succulent shelled bean	51	0.048	8	6	
						12
Caneberries	any one blackberry or raspberry	23	0.024	3	5	5
Cherries	sour cherries	68.4	0.035	8	6	
	sweet cherries	60.5	0.031	8	6	
						12
Citrus fruits	See Table 2					23
Lettuce	lettuce, head	240	0.394	8	6	
	lettuce, leaf	51	0.025	8	6	
						12
Melons	cantaloupe	130	0.083	8	8	8
Onions	dry bulb onions	246	0.199	8	6	
	green onions	18.1	0.004	3	3	
						9

TABLE 4: REQUIRED NUMBERS OF FIELD TRIALS FOR CROP "GROUPS" IN 180.1(h)

Column A Commodities	Representative Column B Commodities	Acres (x1000)	% Consumption	Number of Field Trials if Not in Crop Group	Number of Field Trials if Part of Crop "Group" in Column A	Total Number of Required Field Trials for Tolerance on Crop "Group" in Column A
Peas	one edible podded pea	unknown	unknown	3	3	
	one succulent shelled pea	314	0.319	8	6	
	one dried shelled pea	395	0.005	5	5	
						14
Peas (dry)	one dried shelled pea	395	0.005	5	5	5
Peas (succulent)	one edible podded pea	unknown	unknown	3	3	
	one succulent shelled pea	314	0.319	8	6	
						9
Peppers	peppers, bell	70.6	0.040	8	6	
	peppers, non-bell	27.7	0.016	3	3	
						9
Squash[1]	one variety summer squash	29.0	0.055	5	8	8

1. To be consistent with the proposed squash/cucumber subgroup (see Table 3), one variety of summer squash was chosen as representative of all squash and pumpkins. However, since the combined acreage and consumption for all these commodities far exceeds that for the representative commodity, summer squash (combined acreage = 99,000 including 58,000 for summer and winter squash, and 41,000 for pumpkins; combined consumptions are 0.118% and 0.2% for the general population and non-nursing infants, respectively), the required number of field trials for the latter was increased one level from 5 to 8. Alternatively, five trials each could be conducted on summer squash and winter squash to obtain a tolerance on "squash".

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Alfalfa	12	1	1			6		1		1	1	1		
	9	1				4		1		1	1	1		
Almonds	5										5			
Apples	16	4	2			3				1	1	5		
	12	3	1			2				1	1	4		
Apricots	5										4	1		
Asparagus	8		1			2					3	2		
	6		1			2					2	1		
Avocados	5			1							4			
Bananas	5			1										4
Barley	12	1[2]				3		4		1	1	2		
	9	1[2]				2		3		1	1	1		
Beans, Dried	12	1				5		2	1	1	1	1		
	9					4		1	1	1	1	1		
Beans, Lima, Succulent	8		4			1					2	1		
	6		3			1					1	1		
Beans, Snap	8	1	1	1		3					1	1		
	6	1	1	1		2						1		
Beets, Garden	5	1				2	1						1	
Blackberries[3]	5		1				1						3	

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Blueberries	8	1	3			3							1	
	6	1	2			2							1	
Broccoli	8						1				6		1	
	6						1				4		1	
Buckwheat	5	1				1		3						
Cabbage	8	2	1	1		1	1		1		1			
	6	1	1	1		1	1				1			
Canola	8		1			2		2				3		
	6		1			2		1				2		
Cantaloupes	8		1			1	2				4			
	6		1			1	1				3			
Carrots	8			1		1	1				4	1		
	6			1		1	1				3			
Cauliflower	8	1				1					5		1	
	6	1				1					3		1	
Celery	8			2		1					5			
	6			1		1					4			
Cherries, Sour	8	1				5				1		1[2]		
	6	1				4				1				
Cherries, Sweet	8					2					2	3	1	
	6					2					2	2		
Clover	12	1	1		1	3	1	1	1	1	1	1		

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
	9	1	1		1	2	1	1	1		1[2]			
Coconut	5													5
Coffee	5													5
Collards	5		2	1			1				1			
Corn, Field	20	1	1			17	1							
	15	1	1			12	1							
Corn, Sweet	12	2	1	1		5					1	1	1	
	9	1	1	1		3					1	1	1	
Cotton	12		1		3		1		4		3			
	9		1		2		1		3		2			
Cranberries	5	2				2							1	
Cucumbers	8		3	1		2	1				1			
	6		2	1		2	1							
Flax	5					2		3						
Grapefruit	8			5			1				2			
	6			3			1				2			
Grapes	12	2									8	2		
	9	2									5	2		
Grasses	12/9	All Areas Across the Country												
Lemons	5			1							4			
Lettuce, Head	8	1[2]		1							6			
	6	1[2]		1							4			

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Lettuce, Leaf	8	1[2]		1							6			
	6	1[2]		1							4			
Mandarins (tangerines)	5			3							2			
Melons, Honeydew	5						1				4			
Millet, Proso	5					1		2	2					
Mint	5					2						3		
Mustard Greens[4]	8		2	1	1	1	1				2			
	5		1		1	1	1				1			
Nectarines	8	1	1								5	1		
	6	1[2]									4	1		
Oats	16	1	1			9	1	3	1					
	12	1	1			6	1	2	1					
Okra	5		1	1	1		2							
Onions, Dry Bulb	8	1				1	1		1		2	1	1	
	6	1					1		1		2	1		
Oranges, Sour and Sweet	16			11			1				4			
	12			8			1				3			
Peaches	12	1	4		1	1	1				4			
	9	1	3			1	1				3			
Peanuts	12		8	1			2		1					
	9		5	1			2		1					

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Pears	8	1									3	4		
	6	1									2	3		
Peas, Garden, Succulent	8	1[2]				4						2	1	
	6	1[2]				3						1	1	
Pecans	5		2		1		1		1					
Peppers, Bell	8		2	2		1	1				2			
	6		1	1		1	1				2			
Pineapples	8													8
	6													6
Plums	8					1					5	1	1	
	6					1					4		1	
Potatoes	16	2	1	1		4				1	1	6		
	12	2	1	1		2				1	1	4		
Pumpkins	5	1	1			1	1				1			
Radish	5	1		2		1					1			
Raspberries, Black and Red[3]	5	1				1							3	
Rice	16				11	1	2				2			
	12				7	1	2				2			
Rice, Wild	5					4					1			
Rye	5		1			2		2						
Safflower	5							2			3			

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Sorghum, Grain (milo)	12		1		1	4	2	1	3					
	9				1	3	2	1	2					
Soybeans (dried)	20		2		3	15								
	15		2		2	11								
Spinach	8	1	2				2			1	2			
	6	1	1				1			1	2			
Squash, Summer[5]	8	1	2	1		1	1				1	1		
	5	1	1	1		1					1			
Squash, Winter	5	1	1	1		1					1			
Strawberries	8	1	1	1		1					3		1	
	6	1		1		1					2		1	
Sugar Beets	12					5		1	1	1	2	2		
	9					5		1	1		1	1		
Sugarcane	8			3	3		1							1
	6			3	2									1
Sunflowers	8					3		4	1					
	6					2		3	1					
Sweet Potatoes	8		4	1	1		1				1			
	6		3		1		1				1			
Tomatoes	16	1	1	2		1					11			
	12	1	1	2		1					7			
Turnip Roots	5		2			1	1				1			

TABLE 5: SUGGESTED DISTRIBUTION OF FIELD TRIALS BY REGION FOR CROPS REQUIRING >3 TRIALS

Crop	Total No. of Trials[1]	Number of Trials in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Turnip Tops	5		2		1	1	1							
Watermelons	8		2	2		1	2				1			
	6		2	1			2				1			
Wheat	20		1		1	5	1	5	6			1		
	15		1		1	3	1	4	4			1		

1. Where two entries are provided for a crop (with the exception of mustard greens and summer squash as explained below), the second is for situations where a 25% reduction in the number of trials is possible due to the crop being a representative commodity used to obtain a crop group tolerance or due to the pesticidal use resulting in no quantifiable residues.
2. Either region is acceptable.
3. A minimum of five trials is required on any one blackberry or any one raspberry if a tolerance is sought on "caneberries" (see Table 3 or Table 4). A minimum of three trials is needed if a tolerance is sought on only blackberries or only on raspberries.
4. A minimum of eight trials is required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens (see Table 3). A minimum of five trials is required if a tolerance is sought on only mustard greens.
5. A minimum of five trials is required for a tolerance on "summer squash". If a tolerance is sought on "squash", at least 8 trials are required on summer squash as a representative commodity (see Table 4). Alternatively, five trials each could be conducted on summer squash and winter squash to obtain a tolerance on "squash".

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Alfalfa	99	8	3			51		14		13	4	6		
Almonds	100										100			
Apples	97	27	11			20				3	6	30		
Apricots	96										89	7		
Artichokes, globe	100										100			
Asparagus	97		3			28					38	28		
Avocados	100			9							91			
Bananas	99			<10										>90
Barley	99	2	2			29		36	2	6	3	19		
Beans, Dried	99	2				45		17	11	3	10	11		
Beans, Lima, Dried	99										97	2		
Beans, Lima, Succulent	97		46			12					28	11		
Beans, Mung	95						95							
Beans, Snap	97	14	16	9		45					3	10		
Beets, Garden	97	28	2			45	6				5		11	
Blackberries	95		7		3	6	6						73	
Blueberries[1]	94	11	36			40							7	
Bok choi	99		13	40							39			7

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Boysenberries	99												99	
Broccoli	100						5				92		3	
Brussels sprouts	97	2									95			
Buckwheat	96	15				15		66						
Cabbage	93	21	16	11		18	12		3		12			
Cabbage, Chinese	97	5	8	34							46			4
Cacao Bean	100													100
Canola[2]	90		15			25		20				30		
Cantaloupes	95	2	5			6	23				59			
Carrots	98			10		13	9				59	5	2	
Cauliflower	97	4		2		4					77		10	
Celery	99			23		9	4				63			
Cherries, Sour	100	11				75				9		3	2	
Cherries, Sweet	98	4				20				4	22	39	9	
Coconut	100													100
Coffee	100													100
Collards	99	4	60	8	4	6	7				10			
Corn, Field	97	3	6			86	2							
Corn, Pop	95					91			4					
Corn, Sweet	96	13	4	8		50					3	11	7	
Cotton	97		8		26		11		37		15			

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Cranberries	88	45				33							10	
Cucumber	94	3	36	10		27	10				5		3	
Currants	98												98	
Dates	100										100			
Eggplant	94	5	35	35	2	5					10			2
Endive (escarole)	96	5	13	66							12			
Figs	99										99			
Filbert/hazelnut	100												100	
Garlic	100									7	82	11		
Ginger	100													100
Grapefruit	100			73			13				14			
Grapes	96	5									86	5		
Guar	94								94					
Hops	94											94		
Kale	96	8	44	9	4	11	10				10			
Kiwi Fruits	99										99			
Kumquats	100			42							58			
Lemons	100			3							97			
Lentils	99							4				95		
Lettuce (head + leaf)	94	2[3]		4							88			
Limes	99			80							19			

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Loganberries	97												97	
Macadamia nut	100										3			97
Mandarins[x] (tangerines)	99			66							33			
Melons, honeydew	98						17				81			
Millet (proso millet)	99					29		35	35					
Mint	99					30						69		
Mustard Greens	97		24	5	12	15	20				21			
Nectarines	98	3	3								88	4		
Oats	97	8	2			61	3	20	3					
Okra	97		28	8	9		46				6			
Olives	100										100			
Onion, Dry Bulb	96	10	2			9	15		10	5	21	16	8	
Onions, Green	97	3	4			8	18		3		54	2	5	
Oranges, Sour and Sweet	100			72			2				26			
Papayas	96													96
Parsley	99	3	20	20		6	15				33			2
Pawpaws	100		100											
Peaches	97	7	39		3	9	6			2	29	2		
Peanuts	100		72	5			16		7					
Pears	95	7				2					33	53		

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Peas, Austrian Winter	100											100		
Peas, Garden, Dried	97											97		
Peas, Garden, Succulent	92	5	4			49					3	22	9	
Pecans	100		35	3	8	2	34		10	2	6			
Peppers, Bell	92	4	20	25		10	8		2		23			
Peppers, Non-bell	94		4	3		4			50	15	18			
Persimmons	93			3							90			
Pimentos	92		86							6				
Pineapples	100													100
Pistachios	100										100			
Plantains	100													100
Plums	98					3					90	2	3	
Pomegranates	99										99			
Potatoes	95	11	4	3		27				7	4	39		
Pumpkins	86	20	12			39	5				10			
Quinces	100										100			
Radishes	96	2		67		21					6			
Raspberries, Black and Red	97	8				15							74	
Rhubarb	94					22							72	

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Rice	100				70	3	13				15			
Rice, Wild	100					79					21			
Rye	97	4	13	2		32		42	4					
Safflower	97							44			53			
Sorghum, Grain (milo)	100		2		6	34	17	12	29					
Soybean (dried)	99		9		15	75								
Spinach	96	7	17		3	3	26			9	31			
Squash, Summer or Winter[5]	95	10	23	19	3	12	8				14	6		
Strawberries	99	9	6	11	2	10					43		18	
Sugar Beets	100					52		7	8	5	14	14		
Sugarcane	100			51	35		4							10
Sunflowers	100					35		58	7					
Sweet Potatoes	99		66	2	17		7				7			
Tangelos	100			61							39			
Tobacco	98		77			21								
Tomatoes	97	3	6	12		8					68			
Turnip roots	94	5	35	5	3	13	13				14	2	4	
Turnip tops	98		40	3	22	14	10		2		7			
Walnuts, Black and English	98										98			
Watermelons	94		21	19	5	8	21		7		13			

TABLE 6: REGIONAL DISTRIBUTION OF CROP PRODUCTION

Crop	Total % Production Accounted	Percentage of Crop Production (Acreage Basis) in Region												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Wheat	94		4		4	23	6	26	26			5		

1. Distribution of blueberry production based on tame (highbush) blueberries only.
2. Approximate distribution of canola production based on 1993 acreage information provided by Intermountain Canola.
3. Represents Regions 1 (NY) and 2 (NJ).
4. Distribution of mandarin (tangerine) production based on acreage information for "honey tangerines" plus "other tangerines".
5. Distributions of both summer squash and winter squash based on acreage information for "squash".

ATTACHMENT 7

METHODOLOGY FOR DETERMINING NUMBER OF FIELD TRIALS

Methodology:

(1) Assign a base number of field trials to each commodity based on acreage as follows:

Number of Acres	Number of Field Trials
>10,000,000	16
>1,000,000 - ≤10,000,000	12
>300,000 - ≤1,000,000	8
>30,000 - ≤300,000	5
>2000 - ≤30,000	3
>200 - ≤2000	2
≤200	1

(2) For commodities with acreage > 300,000 A, increase the number of required field trials one level (e.g. 5 to 8, or 8 to 12) if consumption ≥0.4% of total consumption (general population, children 1-6, or non-nursing infants).

(3) For commodities with acreage > 300,000 A, decrease the number of required field trials one level if consumption < 0.1% of total consumption.

(4) For commodities with acreage ≤ 300,000 A, increase the number of required field trials one level if consumption ≥ 0.02% of total consumption.

(5) For the column "REQ #FT", the number of required field trials was decreased one level for commodities with greater than 90% production in one region unless indicated otherwise by a footnote.

(6) A minimum of 16 field trials is required for commodities with production greater than 300,000 acres and comprising greater than 1% of dietary consumption for the U.S. general population, non-nursing infants, or children 1-6 (except sugarcane, see footnote 3).

(7) A minimum of 12 field trials is required for commodities with production less than 300,000 acres and comprising greater than 1% of dietary consumption for the U.S. general population, non-nursing infants, or children 1-6.

COMMODITY	BEST ACREAGE ESTIMATE (x1000)	PERCENT CONSUMPTION GENERAL POPULATION	PERCENT CONSUMPTION NON-NURSING INFANTS	REQ #FTs W/O 90%	REQ #FTs	FOOT NOTES
CORN, FIELD	63300.00	0.530	0.402	20	20	
SOYBEANS (DRIED)	59200.00	0.631	0.875	20	20	
WHEAT	61700.00	2.620	0.554	20	20	11
APPLES	601.00	1.260	3.391	16	16	
OATS	6120.00	0.153	0.402	16	16	2
ORANGES (SOUR AND SWEET)	791.00	2.313	1.439	16	16	
POTATOES	1310.00	2.091	0.601	16	16	
RICE	2800.00	0.294	0.710	16	16	2
TOMATOES	455.00	1.484	0.318	16	16	
ALFALFA	26000.00	0.000	0.000	12	12	
BARLEY	9180.00	0.106	0.075	12	12	
BEANS, DRIED	1750.00	0.267	0.054	12	12	15
CLOVER	37300.00	0.000	0.000	12	12	
CORN, SWEET	671.00	0.440	0.219	12	12	
COTTON	11000.00	0.038	0.003	12	12	
GRAPES	833.00	0.437	0.127	12	12	
GRASSES (CROP GROUP 180.34(f))	475000.00	0.000	0.000	12	12	
PEACHES	273.00	0.424	1.120	12	12	11
PEANUTS	1690.00	0.139	0.016	12	12	
SORGHUM, GRAIN (MILO)	11200.00	0.044	0.000	12	12	
SUGARBEETS	1350.00	0.617	0.207	12	12	3
ASPARAGUS	97.00	0.024	0.002	8	8	
BEANS, EDIBLE PODDED	289.00	0.372	0.440	8	8	15
BEANS, LIMA, SUCCULENT	51.00	0.048	0.022	8	8	
BEANS, SNAP	289.00	0.372	0.440	8	8	
BEANS, SUCCULENT SHELLED	51.00	0.048	0.022	8	8	15
BLUEBERRIES	59.00	0.017	0.043	8	8	
BROCCOLI	115.00	0.091	0.014	8	8	9,11
CABBAGE	98.70	0.182	0.010	8	8	11
CANOLA	278.00	0.000	0.000	8	8	7
CANTALOUPES	130.00	0.083	0.004	8	8	
CARROTS	98.00	0.322	0.786	8	8	
CAULIFLOWER	65.00	0.029	0.001	8	8	
CELERY	36.00	0.114	0.013	8	8	11
CHERRIES, SOUR	68.40	0.035	0.027	8	8	4
CHERRIES, SWEET	60.50	0.031	0.024	8	8	4
CUCUMBERS	130.00	0.134	0.014	8	8	
GRAPEFRUIT	189.00	0.271	0.059	8	8	
LETTUCE, HEAD	240.00	0.394	0.000	8	8	
LETTUCE, LEAF	51.00	0.025	0.002	8	8	16
MUSKMELONS	159.00	0.118	0.007	8	8	11,18
NECTARINES	33.00	0.024	0.000	8	8	
ONIONS, DRY BULB	246.00	0.199	0.022	8	8	11
PEARS	84.00	0.228	0.848	8	8	
PEAS, GARDEN, SUCCULENT	314.00	0.319	0.288	8	8	
PEAS, SUCCULENT SHELLED	314.00	0.319	0.288	8	8	15
PEPPERS, BELL	70.60	0.040	0.007	8	8	
PINEAPPLES	36.00	0.126	0.175	8	8	9
PLUMS	151.00	0.083	0.251	8	8	9
SPINACH	36.00	0.081	0.099	8	8	

COMMODITY	BEST ACREAGE ESTIMATE (x1000)	PERCENT CONSUMPTION GENERAL POPULATION	PERCENT CONSUMPTION NON-NURSING INFANTS	REQ #FTs W/O 90%	REQ #FTs	FOOT NOTES
STRAWBERRIES	53.00	0.064	0.015	8	8	
SUGARCANE	830.00	1.386	0.463	8	8	3
SUNFLOWERS	1980.00	0.008	0.000	8	8	
SWEET POTATOES	90.50	0.072	0.154	8	8	11
WATERMELONS	193.00	0.142	0.008	8	8	
ALMONDS	428.00	0.005	0.001	5	5	10
APRICOTS	24.00	0.063	0.207	5	5	
AVOCADOS	88.00	0.023	0.001	8	5	
BANANAS	24.20	0.426	0.555	5	5	5,11
BEETS, GARDEN	13.00	0.042	0.102	5	5	
BUCKWHEAT	81.00	0.002	0.000	5	5	
COCONUT	0.00	0.050	0.660	5	5	
COFFEE	75.00	0.086	0.000	8	5	
COLLARDS	15.00	0.035	0.009	5	5	
CRANBERRIES	27.00	0.060	0.008	5	5	
FLAX	430.00	0.000	0.000	5	5	
LEMONS	69.00	0.040	0.002	8	5	
MANDARINS (TANGERINES)	28.00	0.021	0.001	5	5	11
MELONS, HONEYDEW	29.00	0.034	0.003	5	5	
MILLET, PROSO	292.00	0.000	0.000	5	5	
MINT	122.00	0.001	0.000	5	5	19
MUSTARD GREENS	9.70	0.027	0.000	5	5	12
OKRA	5.70	0.027	0.000	5	5	
PEAS, DRIED	394.00	0.005	0.016	5	5	9,15
PECANS	453.00	0.010	0.000	5	5	
PUMPKINS	41.00	0.008	0.000	5	5	
RADISHES	46.00	0.003	0.000	5	5	
RICE, WILD	31.40	0.000	0.000	5	5	
RYE	546.00	0.008	0.000	5	5	
SAFFLOWER	211.00	0.003	0.000	5	5	
SQUASH, SUMMER	29.00	0.059	0.003	5	5	13
SQUASH, WINTER	29.00	0.060	0.198	5	5	13
TURNIPS	20.00	0.043	0.000	5	5	
ARTICHOKES, JERUSALEM	0.00	0.000	0.000	3	3	
BEANS, LIMA, DRIED	44.40	0.015	0.000	5	3	
BLACKBERRIES	7.90	0.018	0.000	3	3	11
CABBAGE, CHINESE	8.70	0.007	0.000	3	3	17
CACAO BEAN (COCOA)	0.00	0.077	0.008	5	3	
CAROB	0.00	0.000	0.000	3	3	
CHESTNUTS	2.32	0.000	0.000	3	3	
CHICKPEA (GARBANZO)	4.00	0.001	0.000	3	3	
CORN, POP	268.00	0.013	0.001	5	3	
CRABAPPLES	0.00	0.001	0.000	3	3	
EGGPLANT	5.30	0.011	0.000	3	3	
ELDERBERRIES	0.00	0.000	0.000	3	3	
ENDIVE (ESCAROLE)	6.00	0.002	0.000	3	3	
GARLIC	14.80	0.001	0.000	3	3	
GOOSEBERRIES	0.00	0.001	0.000	3	3	
HOPS	34.00	0.007	0.000	5	3	
HORSERADISH	0.00	0.000	0.000	3	3	

COMMODITY	BEST ACREAGE ESTIMATE (x1000)	PERCENT CONSUMPTION GENERAL POPULATION	PERCENT CONSUMPTION NON-NURSING INFANTS	REQ #FTs W/O 90%	REQ #FTs	FOOT NOTES
HUCKLEBERRIES	0.00	0.000	0.000	3	3	
KALE	6.20	0.003	0.000	3	3	
KOHLRABI	0.00	0.000	0.000	3	3	
LEEKS	0.00	0.000	0.000	3	3	
LENTILS	162.00	0.002	0.000	5	3	
LIMES	6.60	0.006	0.000	3	3	
MELONS, CASABA	0.00	0.001	0.000	3	3	
MELONS, CRENSHAW	0.00	0.000	0.000	3	3	
MULBERRIES	0.00	0.000	0.000	3	3	
MUSHROOMS	3.00	0.040	0.002	3	3	6
OLIVES	33.30	0.017	0.003	5	3	
ONIONS, GREEN	18.10	0.004	0.000	3	3	11
PARSLEY	5.10	0.007	0.001	3	3	
PARSNIPS	0.00	0.001	0.000	3	3	
PEANUTS, PERENNIAL	6.00	0.000	0.000	3	3	
PEAS, AUSTRIAN WINTER	36.40	0.000	0.000	5	3	
PEAS, EDIBLE PODDED	0.00	0.000	0.000	3	3	15
PEAS, GARDEN, DRIED	232.00	0.003	0.016	5	3	
PEPPERS, NON-BELL	27.70	0.016	0.000	3	3	
PISTACHIOS	52.00	0.000	0.000	5	3	
RASPBERRIES, BLACK AND RED	15.00	0.006	0.000	3	3	
RUTABAGAS	0.00	0.005	0.000	3	3	
SAINFOIN	0.00	0.000	0.000	3	3	
SALSIFY	0.00	0.000	0.000	3	3	
SESAME	0.00	0.001	0.000	3	3	
SWISS CHARD	0.00	0.003	0.000	3	3	
TANGELOS	20.00	0.005	0.000	3	3	
TOBACCO	681.00	0.000	0.000	3	3	8
WALNUTS, BLACK AND ENGLISH	214.00	0.009	0.005	5	3	
YAM, TRUE	3.50	0.003	0.006	3	3	
APPLE, SUGAR	0.30	0.000	0.000	2	2	11
ARRACACHA	0.30	0.000	0.000	2	2	
ARTICHOKES, GLOBE	12.00	0.006	0.000	3	2	
BEANS, MUNG	15.00	0.012	0.000	3	2	
BOK CHOI	1.70	0.001	0.000	2	2	17
BOYSENBERRIES	1.20	0.001	0.000	2	2	
BROCCOLI, CHINESE (GAI LON)	0.60	0.000	0.000	2	2	
BRUSSELS SPROUTS	4.40	0.013	0.007	3	2	
CALABAZA	2.00	0.000	0.000	2	2	
CARAMBOLA	0.50	0.000	0.000	2	2	
CASSAVA, BITTER OR SWEET	0.50	0.000	0.000	2	2	
CHICORY	0.42	0.001	0.000	2	2	
CURRANTS	0.34	0.001	0.000	2	2	
DATES	6.80	0.001	0.000	3	2	
DILL (DILL SEED, DILLWEED)	0.30	0.000	0.000	2	2	
FIGS	17.00	0.005	0.001	3	2	
FILBERTS/HAZELNUTS	28.70	0.001	0.000	3	2	
GINGER	0.30	0.002	0.000	2	2	
GUAR	6.70	0.000	0.000	3	2	
GUAVAS	1.20	0.000	0.000	2	2	

COMMODITY	BEST ACREAGE ESTIMATE (x1000)	PERCENT CONSUMPTION GENERAL POPULATION	PERCENT CONSUMPTION NON-NURSING INFANTS	REQ #FTs W/O 90%	REQ #FTs	FOOT NOTES
KIWIFRUITS	9.00	0.000	0.000	3	2	
LOGANBERRIES	0.24	0.000	0.000	2	2	
MACADAMIA NUTS	24.00	0.000	0.000	3	2	
MAMEY SAPOTE	0.30	0.000	0.000	2	2	
MANGOES	3.16	0.001	0.000	3	2	
MUSTARD, CHINESE	0.40	0.000	0.000	2	2	
PAPAYAS	3.90	0.010	0.000	3	2	
PASSION FRUIT	0.27	0.000	0.000	2	2	
PAWPAWS	0.00	0.000	0.000	3	2	
PERSIMMONS	2.60	0.001	0.000	3	2	
PIMENTOS	1.80	0.004	0.000	2	2	
PLANTAINS	12.50	0.003	0.000	3	2	
POMEGRANATES	3.50	0.000	0.000	3	2	
QUINCES	0.00	0.000	0.000	3	2	
RADISH, JAPANESE (DAIKON)	0.30	0.000	0.000	2	2	
RHUBARB	0.90	0.007	0.000	2	2	
TANIER	2.00	0.000	0.000	2	2	
TARO (DASHEEN)	1.70	0.000	0.000	2	2	
WATERCRESS	0.46	0.001	0.000	2	2	
ACEROLA	0.05	0.000	0.000	1	1	
ATEMOYA	0.10	0.000	0.000	1	1	
CALAMONDIN	0.01	0.000	0.000	1	1	
CRESS, UPLAND	0.10	0.000	0.000	1	1	
DANDELION	0.20	0.001	0.000	1	1	
GENIP	0.05	0.000	0.000	1	1	
GINSENG	0.20	0.000	0.000	1	1	
KUMQUATS	0.10	0.000	0.000	1	1	
LONGAN FRUIT	0.08	0.000	0.000	1	1	
LOTUS ROOT	0.03	0.000	0.000	1	1	
LYCHEE	0.20	0.000	0.000	1	1	
PEAS, CHINESE	0.10	0.000	0.000	1	1	
SHALLOTS	0.10	0.001	0.000	1	1	

FOOTNOTES

1) Acreage values in this table are presented to three significant figures.

2) The number of field trials required for these commodities (oats and rice) was increased 1 level from 12 to 16 due to high consumption by non-nursing infants.

3) The numbers of field trials required for sugar beets and sugarcane were not increased one level based on comprising $\geq$0.4% consumption for the general population (or increased based on >1% consumption as discussed in criterion (6) under "methodology") because (a) the major human food derived from these two commodities (sugar) is highly refined, and (b) neither are major national animal feeds.

4) Individual consumption estimates for sweet and sour cherries were obtained by weighting the total consumption of cherries by the production (acreage) of each.

5) Limited geographical production was not used as a criterion to reduce the number of field trials for bananas because of the small number of trials required and the large consumption of this commodity by infants and children.

6) The number of field trials required for mushrooms was decreased since mushrooms are generally grown indoors under relatively constant growing conditions likely leading to little residue variability.

7) Due to the expanding production and consumption of canola products, eight field trials will be required for this commodity.

8) The number of field trials for tobacco was reduced because of the limited importance of this commodity for dietary exposure assessment.

9) Limited geographical production was not used as a criterion to reduce the number of field trials for broccoli, pineapples, and plums because of the widespread high consumption of these commodities, and was not used to reduce the number of field trials required for peas, dry because of the high acreage and the large variety of peas represented by this commodity.

10) Since the number of field trials for almonds was already reduced based on low dietary consumption, a further reduction due to >90% production being in one region was not made.

11) Acreage information (given in thousands of acres) and consumption for the following commodities include values for both

the commodity itself, and the acreages and consumptions of other commodities for which the tolerance would apply as defined in 40 CFR 180.1(h):

apples, sugar: apple, sugar (0.2), atemoya (0.1)
bananas: bananas (11.7), plantains (12.5)
blackberries: blackberries (6.7), boysenberries (1.2)
broccoli: broccoli (114), broccoli, Chinese (gai lon, 0.6)
cabbage: cabbage (90), Chinese cabbage (8.7)
celery: celery (36), fennel (only consumption data available)
mandarins (tangerines): tangerines (15), tangelos (13)
muskmelons: cantaloupe (130), honeydew (29); consumption information is also available for casaba, crenshaw and Persian melons
onions, dry bulb: onions, dry bulb (231), garlic (14.6)
onions, green: green onions (18), shallots (0.1)
peaches: peaches (240), nectarines (33)
sweet potatoes: sweet potatoes (87), yams (3.5)
wheat: wheat (61577), triticale (152)

12) Eight field trials are needed if mustard greens are used as a representative commodity of the Brassica Leafy Greens crop subgroup (see Table 3).

13) Acreage estimates for all squash were divided by 2 to estimate acreage for summer and winter squash separately.

14) Acreage estimates are given as 0.000 when acreage information is not available for a commodity.

15) These bean/pea commodities include more than one type of bean/pea. The specific commodities included in each of these groups are shown below. The specific representative commodity for which field trials should be run in each case are those representative commodities provided in the proposed crop subgroup Federal Register notice.

beans, dried: include those commodities listed in the proposed crop subgroup 6-C as Lupinus spp., Phaseolus spp., Vigna spp., guar and lablab beans.

peas, dried: include those commodities listed in the proposed crop subgroup 6-C as Pisum spp., lentils and pigeon peas.

beans, edible podded: include those commodities listed in the proposed crop subgroup 6-A as Phaseolus spp., Vigna spp., jackbeans, immature soybean seeds, and swordbeans.

peas, edible podded: include those commodities listed in the proposed crop subgroup 6-A as Pisum spp., and pigeon peas.

beans, succulent shelled: include those commodities listed in the proposed crop subgroup 6-B as Phaseolus spp., Vigna spp. and broad beans.

peas, succulent shelled: include those commodities listed in the proposed crop subgroup 6-B as Pisum spp.

16) Consumption estimates for leaf lettuce include "lettuce-leafy varieties" and "lettuce-unspecified".

17) Individual consumption estimates for Chinese cabbage and bok choi were obtained by weighting the total consumption of the two commodities by the relative production (acreage) of each.

18) A tolerance for muskmelons may be obtained using residue data for cantaloupes.

19) If a tolerance is sought for either spearmint or peppermint separately, five field trials are still required.

"Provisionally Adopted by 19th CCPR
ALINORM 87/24A, para 251, 1987

GUIDELINES ON MINIMUM SAMPLE SIZES FOR AGRICULTURAL COMMODITIES FROM SUPERVISED FIELD TRIALS FOR RESIDUES ANALYSIS

The "Guidelines on pesticide residue trials to provide data for the registration of pesticides and the establishment of maximum residues limits" include a section entitled "Guide to Sampling" in which minimum sample sizes are recommended for a number of crops, selected as examples. Practical experience in sampling in recent years has indicated the need to reconsider the recommendations in the Guidelines for the sample sizes and the ad hoc Working Group on the Development of Residues Data and Sampling recommends that the ANNEX II which follows this ANNEX I replaces the relevant section in the Trials Guidelines.

The major changes are the results of adopting a general principle that, with certain exceptions, such as very small items like berries, nuts, grain and immature vegetables, it is more appropriate to recommend taking a number of crop units rather than a minimum weight. In many cases, the recommendation is to take 12 units for large items or 24 units for smaller items. The choice of 12 units permits easier planning of composite samples, for example, 3 units from each of 4 replicates (6 units for smaller items). It is useful too, in sampling tree fruits, where 6 fruits from each of 4 trees is recommended. The principle of taking 12 units is readily extended to crops such as cereals, fodders or grain where a minimum sample weight is proposed with sampling from 12 areas of the plot.

A number of crops can be harvested mechanically and in these cases 12 primary samples from the harvester as it proceeds through the treated plot is recommended.

Although it is not normally recommended it may sometimes be necessary to subsample bulky or heavy items before shipment to the residue laboratory. This practice must be limited to special sampling problems identified in ANNEX II always bearing in mind the importance of maintaining a fully representative sub-sample and avoiding any possible contamination or deterioration of the material. It is essential that it should only be done if a clean area is available and if the personnel involved have received specific instruction or training in this respect.

The ad hoc Working Party emphasised that the recommendations for minimum sizes are for samples of crops at the stage of growth at which they would be harvested for consumption when taken from supervised trials, which frequently involve relatively small plots. It may be necessary to take larger samples in certain circumstances, especially if larger plots or fields are being sampled. Larger samples of some crops may also be needed if particularly low limits of determination are involved (thus possibly requiring larger analytical samples) or for multi-residue determinations (requiring larger, or multiple, analytical samples). The small sample size required by most analytical methods is not the major factor in deciding the size of field samples - obtaining representative material must be the priority in the field.

Alternative considerations may apply when deciding on the quantities of immature crops required from residue dissipation trials.

ATTACHMENT 8

Sample Type	Codex Code No.	Previous Recommendation	New Recommendation
Fodder and sugar beets	VR 0596 AM 1051	5 kg (min. 5 plants)	12 plants
Potatoes	VR 0589	5 kg or 5 items	24 tubers or 12 if very large from at least 6 plants
Other root crops, eg. carrots, red beet, Jerusalem artichoke, sweet potato, celeriac, turnip, swede, parsnip, horseradish, salsify, chicory, radish, scorzonera	Group 016	5 kg (large) 2 kg (small items)	12 large roots or 24 (or more) small for minimum sample weight of 2 kg
Leeks	VA 0384	2 kg	12 plants
Spring onions	VA 0389	2 kg	24 plants (or more) for a minimum sample weight of 2 kg
Garlic, shallots	VA 0381 VA 0388	2 kg	24 bulbs from at least 12 plants
Small-leaf salad crops, e.g.. cress, dandelion, corn salad	Group 013	2 kg	0.5 kg from at least 12 plants (or sites in plot)
Spinach, chicory leaves	VL 0469 VL 0502 VL 0503	2 kg	1 kg from at least 12 plants
Lettuce	VL 0482 VL 0483	2 kg	12 plants or 1 kg from at least 12 plants if individual leaves are collected
Endive	VL 0476	2 kg	12 plants
Kale forage Kale	AV 0480 VL 0480	5 kg	2 kg from at least 12 plants sampled from at least 2 levels on the plant

Green cruciferous eg. fodder crops, rape mustard, green oil poppy	Group 023	-	2 kg from at least 12 separate areas of plot(b)
large brassica crops eg. cauliflower, cabbage	Group 010	5 kg or 5 items	12 plants
Brussels sprouts, broccoli	Group 010	2 kg	1 kg from at least 12 plants and for Brussels sprouts sampled from at least 2 levels on the plant
Kohlrabi	VB 0405	5 kg or 5 items	12 plants
Celery	VS 0624	2 kg	12 plants
Rhubarb	VS 0627	2 kg	12 sticks (or more) from at least 12 separate plants for minimum sample weight of 2 kg
Asparagus	VS 0621	2 kg	24 sticks (or more) from at least 24 separate plants for minimum sample weight of 2 kg
Globe artichoke	VS 0620	-	12 heads
Soybeans	VS 0541	1 kg	1 kg from at least 12 separate areas of plot
Peas, Phaseolus beans (French, Kidney, Runner etc),	Group 014	2 kg	1 kg (fresh green or dry seed as appropriate)
broad beans, field beans lentils	Group 015	2 kg	
Tomatoes, green peppers	Group 012	2 kg	24 fruits or 12 from large-fruiting varieties from at least 12 plants (more fruit if necessary for a minimum sample weight of 2 kg)

Aubergines (egg plants)	VO 0440	5 kg or 5 items	12 fruits from 12 separate plants
Cucumbers	VO 0424	5 kg or 5 items	12 fruits from 12 separate plants
Gherkins, courgettes squash	Group 011	2 kg	24 fruits from at least 12 plants (more if necessary to make a minimum weight of 2 kg)
Melons, gourds, pumpkins water melons	Group 011	5 kg or 5 items	12 fruits from 12 separate plants
Sweet corn	VO 0447	2 kg	12 ears (more if necessary to make a minimum weight of 2 kg)
FRUIT			
Citrus fruit eg. orange, lemon, clementine, mandarin, pomelo, grapefruit, tangelo, tangerine	Group 001	5 kg	24 fruit from several places on at least 4 individual trees (more if necessary for a minimum sample weight of 2 kg)
Pome fruit eg. apples, pears, quinces, medlars	Group 002	5 kg	
Large stone fruit, eg. apricots, nectarines, peaches, plums	Group 003	5 kg (2 kg for plums)	
Small stone fruit, eg. cherries	Group 003	2 kg	1 kg from several places on at least 4 trees
Grapes	FB 0269	2 kg	12 bunches, or parts of 12 bunches from separate vines to give at least 1 kg
Currants, raspberries and other small berries	Group 004	2 kg	0.5 kg from at least 12 separate areas or bushes

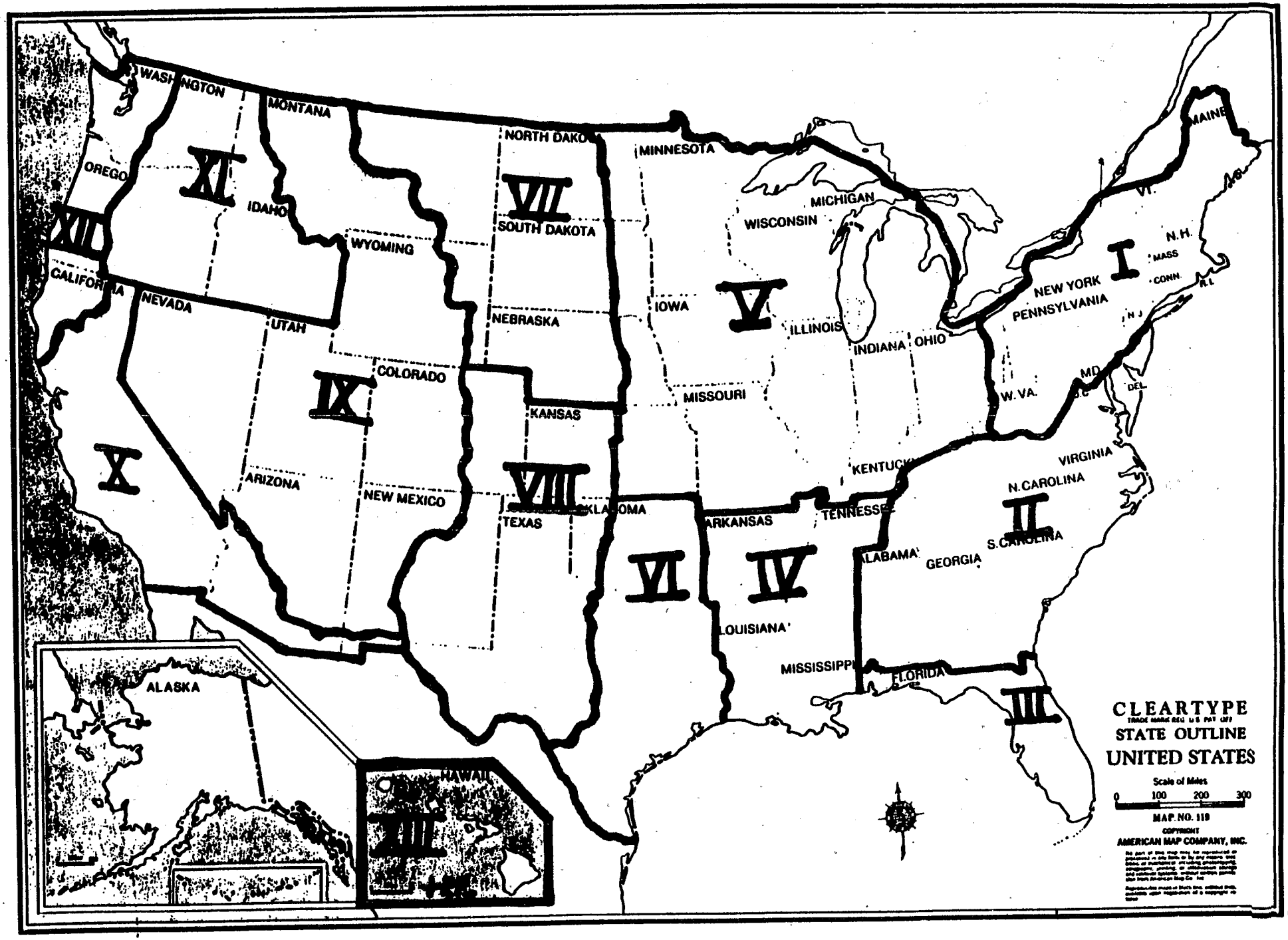
Strawberries, gooseberries	FB 0268 FB 0275 FB 0276	2 kg	1 kg from at least 12 separate areas or bushes
Miscellaneous, small fruits, eg. olives, dates, figs	Group 005	2 kg	1 kg from several places on at least 4 trees
Bananas	FI 0327	5 kg or 4 fruits from each of 5 bunches	24 fruits from at least 6 bunches from separate trees and from several places of each of the bunches
Miscellaneous fruit eg. avocados, guavas, mangoes, pawpaws, pomegranates, persimmons, kiwi fruit, litchi	Group 006	5 kg	24 fruit from at least 4 separate trees or plants (more fruit if necessary for a minimum sample weight of 2 kg)
Pineapples	FI 0353	5 kg or 5 items	12 fruit
Grain of wheat, barley oats, rye, triticale and other small grain cereals; maize (off the cob), rice, sorghum	Group 020	1 kg (2 kg maize)	1 kg from at least 12 separate areas of a plot or treatment lot (applies to both field and post-harvest trials)
Straw of the above crops	Group 051	1 kg	0.5 kg from at least 12 separate areas of a plot. (b)
Maize, straw/stover/ fodder (mature plants excluding cobs)	AF 0645	5 plants	12 plants (a)
Green or silage maize	-	5 plants	12 plants (a)
Green forage/silage crops of alfafa, clover, fodder peas and beans, vetch, sainfoin, lotus, fodder soybeans, ryegrass, fodder cereals, sorghum	Group 050	1 kg (smaller leaves) 2 kg (larger leaves)	1 kg from at least 12 separate areas of a plot

Dry hay of the above crops	Group 050	1-2 kg	0.5 kg from at least 12 separate areas of a plot (b)
Peanuts	SO 0697	1 kg (2 kg with fibre)	1 kg from at least 24 plants
Treenuts Walnuts, chestnuts almonds, etc	Group 022	1 kg	1 kg (with or without shells)
Coconut	TN 0665	5 kg or 5 items	12 nuts
Rapeseed, flax and wild mustard	Group 023	1 kg	0.5 kg from at least 12 separate areas of a plot (b)
Sunflower, safflower	SO 0702	1 kg	12 heads or 1 kg from 12 separate areas of a plot (b)
Cottonseed	SO 0691	1 kg (1 delinted) 2 kg (with fibre)	1 kg with or without fibre
Coffee, cocoa	Group 024	2 kg	1 kg (fresh or dry)
Garden herbs and medicinal plants, eg. parsley, thyme	Group 027 Group 028 Group 057	-	0.5 kg fresh 0.2 kg dry
Tea (dry leaves)	Group 066	1 kg	0.2 kg
Mushrooms	VO 0450	-	12 items or more with a minimum sample weight of 0.5 kg
Sugarcane	GS 0659	5 kg (20 cm of stem)	12x20 cms lengths of stem from 12 areas of the plot (a)
Hops (dry cones)	DH 1100	-	0.5 kg
Beer, wine, cider, Fruit juices	Group 070	-	1 litre

(a) Divide each stem with leaves attached into 3 equal lengths. Take top, middle and bottom portions respectively from each of three groups of four stems ensuring that parts of all 12 stems are included in the sample.

(b) Crops which are harvested mechanically can be sampled from the harvester as it proceeds through the crop.

ATTACHMENT 9



ATTACHMENT 10

REGIONAL MAP FOR TRIAL DISTRIBUTION:

BORDER DEFINITIONS

I. ME, NH, VT, MA, RI, CT, NY, PA,
NJ - N of Rt. 1,
MD - NW of I-95,
VA - N of I-64 and W of I-81,
WV - N of I-64 and E of I-77,
OH - E of I-77.

II. NC, SC, GA, DE,
VA - E of I-81 or S of I-64,
MD - SE of I-95,
NJ - S of Rt. 1,
WV - S of I-64,
KY - S of I-64 and S of BGP and E of I-65,
TN - E of I-65,
AL - Except Mobile and Baldwin Co.'s.

III. FL, AL - Mobile and Baldwin Co.'s.

IV. LA, AR, MS,
TN - W of I-65,
MO - E of Rt. 67 and S. of Rt. 60.

V. MI, IN, IL, WI, MN, IA,
OH - W of I-77,
WV - N of I-64 and W of I-77,
KY - N of I-64 or N of BGP or W of I-65,
MO - W of Rt. 67 or N of Rt. 60,
KS, NE, SD, ND - all E of Rt. 281.

VI. OK - E of Rt. 281/183,
TX - E of Rt. 283 or SE of Rt. 377.

VII. MT - E of Rt. 87 or E of I-15,
WY - E of I-25 or N of I-90,
ND, SD, NE - all W of Rt. 281,

VIII. KS - W of Rt. 281,
CO - E of I-25,
NM - E of I-25,
TX - W of Rt. 283 and NW of Rt. 377,
OK - W of Rt. 281/183.

SJK1/eh/D476

BORDER DEFINITIONS (cont'd)

IX. UT, NV,
NM - W of I-25 and N of I-10,
CO - W of I-25,
WY - W of I-25 and S of I-90,
MT - W of Rt. 87 and W of I-15,
AZ - NE of Rt. 89/93 and N of I-10.

X. CA - Except Mendocino, Humboldt, Trinity, Del Norte, and Siskiyou Co.'s,
AZ - SW of Rt. 89/93 or S. of I-10,
NM - S of I-10.

XI. ID,
OR & WA - E of Cascades.

XII. CA - Counties excluded from Reg. X,
OR & WA - W of Cascades

XIII. HI, PR

SJK1/eh/D476/2

ATTACHMENT 11

Number of Field Trials Required for Tolerances with Geographically Restricted Registration, and for 24(C) Special Local Needs Registrations

Throughout this document, additional guidance has been provided regarding field trial data requirements for tolerances with national registrations. This attachment provides guidance concerning the number of field trials required for tolerances with geographically restricted registrations, and 24(C) Special Local Needs (SLN) registrations. Sampling requirements and other criteria presented elsewhere in this document also apply to the data requirements discussed in this attachment. A flow chart follows the text below to facilitate determination of field trial data requirements.

Tolerances with geographically restricted registrations may be established for minor agricultural uses (1990 Farm Bill). Specifically (see 7/7/93 memorandum, Victor J. Kimm, Acting Assistant Administrator, OPPTS, to Honorable Bob Graham, U.S. Senate),

> The Administrator shall not require a person to submit, in relation to registration or reregistration of a pesticide for minor agricultural use under this Act, any field residue data from a geographic area where the pesticide will not be registered for such use.

Comments below address the data requirements for both tolerances with geographically restricted registration, and the additional state-specific data required for 24(C) SLN registrations. When discussing the number of required field trials below, the term "geographically restricted region" will apply to either of these situations.

The number of field trials required for a tolerance with geographically restricted registration is equal to the number of field trials required for the commodity for a national tolerance or registration, multiplied by the proportion (by acres) of the crop grown in that region. However, regardless of the acreage in the specific region for which the regional registration is requested, at least 2 field trials will be required (except in the case of very minor crops as specified elsewhere in this document which require only 1 field trial for national registration). Two composite samples per field trial are generally required. However, when 3 or fewer field trials are required for any registration, the registrant may choose to (a) obtain samples from 1X and 2X application rates from separate plots in each of 2 field trials (i.e., one composite sample taken from each of two 1X and two 2X separately treated plots, resulting in 4 total samples per field trial), or (b) perform 3 field trials in different locations at the 1X rate (2 composite samples obtained from each plot).

Field trial locations must be representative of growing conditions throughout the region covered by the regional registration.

For 24(C) SLN registrations requested for two neighboring states, data from one state will be accepted for a 24(C) use in a neighboring state only if (1) the states, or pertinent parts thereof, are in the same geographical region as defined in this document, (2) a sufficient number of field trials are available from the state to fulfill the requirements of the paragraph above for the acreage of commodity grown in both states, and (3) field trials are performed in sufficiently diverse areas such that conditions likely to be found in both states are represented in the field trials.

For crops requiring 8 or more field trials nationally, regional and 24(C) registrations will require multiple year field trial data. Multiple year data are required to account for variability due to varying climatic conditions and other factors which would normally be expected to be seen by obtaining field trial data from more diverse regions, but would not be seen for regional registrations since field trial data are obtained from more limited geographical areas. The total required number of field trials must be performed over at least 2 different years (e.g., if 4 total field trials are required, 2 would be performed in one year, and 2 in the next year). Multiple year data will not be required if sufficient nationally representative or multiple year data are available for other pesticide formulations of the same active ingredient or similar uses from which the Agency can estimate likely variability.

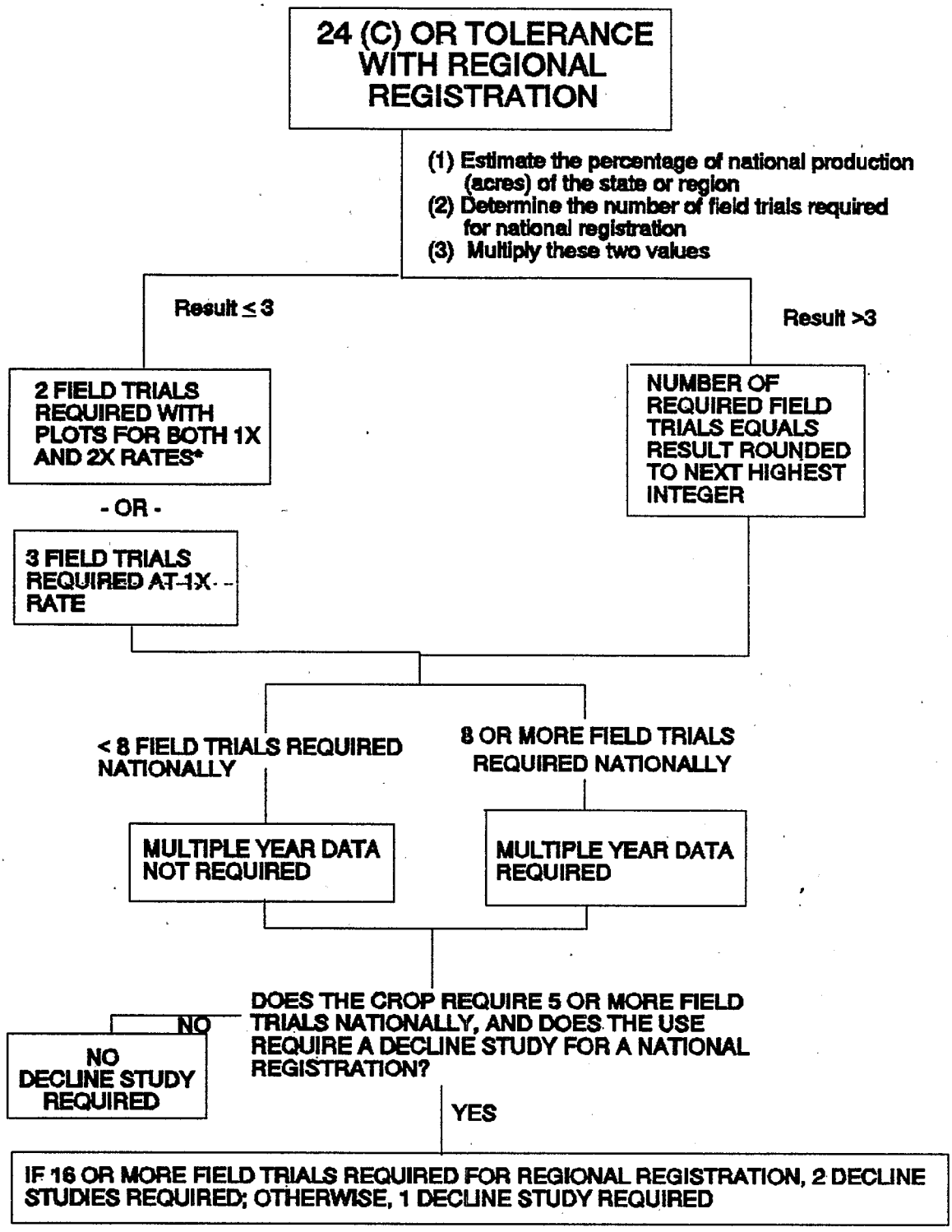
For crops normally requiring 5 or more field trials for a national registration, and uses requiring a decline study (discussed elsewhere in this guidance), **one or more** decline studies will be required for a 24(C) or regional registration. The number of decline studies required for a use will not exceed the number required for a national tolerance/registration for that commodity. See the flow chart for further details.

EXAMPLES

Example 1: A 24(C) SLN is desired for use of a pesticide on apples in Washington (WA). Since WA accounts for approximately 27% of national apple production, and since 16 field trials are required for apples nationally, 5 field trials will be required from WA for this use (0.27 x 16 = 4.3 or **5** field trials). Since greater than 8 field trials are required nationally (16), multiple year data will be required (3 field trials the first year, 2 the second year). Finally, if the use were one requiring a decline study, 1 decline study would also be required for this 24(C) use.

Example 2: A 24(C) SLN is desired for use of a pesticide on alfalfa in Iowa (IA). Since IA accounts for approximately 8% of alfalfa grown nationally, and since 12 field trials are required for alfalfa nationally, 2 field trials will be required from IA to support this registration (0.08 x 12 = 0.96, however, except for crops requiring only 1 field trial nationally, at least 2 trials are required for any regional registration; therefore, 2 field trials are required). Since greater than 8 field trials are required nationally (12), the two required field trials would have to be distributed over two years (one field trial in each of two years). Since alfalfa requires greater than 5 field trials for a national registration (12), one of these studies would have to be a decline study if the use pattern requires a decline study. For the other study, one sample from each of 4 separately treated plots (two at 1X and two at 2X rates) would be required.

Example 3: A tolerance with regional registration is requested for application of a pesticide to peanuts in the Southeastern U.S. (GA, 42%, AL, 14%, NC, 9%, FL, 5%, SC, 1%, total 71% of U.S. peanut production). Since 12 field trial are required for peanuts nationally, 9 field trials would be required for this use (0.71 x 12 = 8.5 or 9 field trials required). Since 12 field trials are required nationally (>8), the required field trials would have to be distributed over at least two years (preferably 5 the first year, four the second). If the use pattern was one requiring a decline study a single decline study would be required.



*For crops requiring only 1 field trial nationally, only 1 field trial will be required for a regional registration.

☆ U.S. GOVERNMENT PRINTING OFFICE:1994-521-539/81161