



Date: May 18, 2017

From: Consumer Safety Officer, Program Assignment and Monitoring Branch, Division of Field Programs and Guidance, Office of Compliance, CFSAN, HFS-615

Subject: **AMENDED:** Collection of Selected Domestic and Imported Foods for Herbicides Analysis

Priority: Routine

DFPG#: 16-08
FACTS Assignment #: 11618100
ORA Concurrence #:FF16020501

To: DIBs, DCBs and FPM: HAF 3E, HAF 6E, HAF 5E, HAF 3W, HAF 4W, HAF 6E, HAF 4E, HAF 2W, HAF 5W, HAF 1W, HAF 5E, HAF 1E, and HAF 6W
Lab Directors: KCL, PSFFL and PNL

Info: DDs: HAF 3E, HAF 6E, HAF 5E, HAF 3W, HAF 4W, HAF 6E, HAF 4E, HAF 2W, HAF 5W, HAF 1W, HAF 5E, HAF 1E, and HAF 6W

This assignment has been amended since its issuance on February 11, 2016 to include analyzing laboratory information and revised sample numbers to be collected in FY 17. The amended section has been highlighted in yellow in the word document.

Please distribute copies of this assignment to all appropriate district/regional personnel. If your district is not listed then consider this copy for informational purposes only.

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1. General

- **Scope:**
 - Sample collection assignment to determine the presence and levels of glyphosate and acid herbicides in domestic cereal grains, corn, soybean, root/tuber vegetables, milk and eggs; and imported cereal grains, corn, soybean, and root/tuber vegetables.
 - Amount of samples collected: (b) (5)
- **Overall timeframe:** Sample collection start upon receipt of the assignment and (b) (5) (b) (5) Note: there are specific months for the collection of eggs and milk samples.
- **Analyte:** Glyphosate and Acid herbicides
- **Percentage domestic and import:** (b) (5)

- **Where to collect:** Domestic samples are to be collected at the warehouse and retail stores only. Import samples are to be collected at the port of entry.

2. Combined Interest for Investigators, Labs, and Compliance Officers

2.1 Objectives

- To determine the levels of selected herbicides (glyphosate and acid herbicides) in selected foods and generate data on the levels of herbicides in foods consumed by U.S. citizens.
- To take appropriate regulatory actions when violations of FD&C Act are found.

2.2 Background

Herbicides are widely used in the U.S. and around the world for weed control and as plant growth regulators for agricultural crops, lawns, and gardens. Herbicide active ingredients account for more than all the other types of pesticides combined, comprising over 60 % of the U.S. pesticide sales in 2007; fourteen of the top 25 most commonly used pesticides in the U.S. are herbicides. Included among them are glyphosate and the acid herbicides. Glyphosate is the most widely used pesticide in the world and the acid herbicides include five of the top 10 active ingredients used in the home and garden sector: mecoprop, dicamba, triclopyr, pelargonic acid, and 2,4-D (also one of the most commonly used pesticides in the world). Usage of 2,4-D is expected to triple in the coming year when crops genetically modified to resist it are introduced into the agrochemical market.

Most government reviews have concluded that glyphosate is relatively safe but controversy occurred recently when the International Agency for Research on Cancer (IARC) said glyphosate-containing formulations are probably carcinogenic to humans. The health effects of other herbicides include affecting the nervous system and hormone or endocrine system, and some are carcinogens.

FDA has never monitored glyphosate and the acid herbicides in its regulatory pesticide program. In its audit of the FDA's pesticide program, GAO noted that glyphosate and 2,4-D were among the most commonly used pesticides in the United States, but that FDA has rarely tested for these pesticides in its regulatory monitoring program or disclosed the fact that it does not test for these pesticides. In its response to the audit, FDA stated that it was considering whether glyphosate and 2,4-D would be added to its pesticide residue monitoring program.

2.3 Sampling Framework

Sampling Framework	
Product	cereal grains, corn, soybean, root/tuber vegetables, milk and eggs
Product Code	Barley 02A--02 Corn 02A--01 Oats 02A--03 Rice 02A--05/02A--06 Soybean 02A--10 Wheat 02A--09 Beet, garden 25J--08 Beet, sugar 25J--13 Carrot 25J--01 Potato 25J--06 Radish 25J--07 Sweet potato, yams 25J--12/25J--37 Turnip 25J--14 Peanuts 23A--07/23B--07 Egg 15A--01 (domestic samples only) Milk 09C--09 (domestic samples only)
Sample Size	No separate 702(b) portion is required. <u>Grains and Soybeans:</u> For each sample, collect 1 kg (2.2 lb.) grain sample representing the lot. <u>Potato, Beet, Carrot, Radish, Turnip and Sweet potato:</u> For each sample, collect 1 kg (2.2 lb.) or at least 10 units. <u>Peanuts:</u> For each sample, collect 0.5 kg (1.1 lb.) shelled/in shell peanuts. <u>Eggs:</u> For each sample, collect 12 (one dozen) whole chicken eggs from one lot. Domestic collection only. <u>Milk:</u> For each sample, collect 0.5 L of homogenized whole milk at retail from single lot. Domestic collection only.
Sample Type	Official
Sample Basis	Surveillance
FACTS Assignment Number	11618100
ORA Concurrence Number	ORA
DFPG Assignment #	16-08
Estimated cost per Sample	N/A

2.4 Resources and Reporting

Resources and Reporting	
Priority	Routine
Planning PAC	04F810 DSC Herbicide 03F810 DSC Emerging Issues 03F810 Entry Review 04F810 Import Field Examinations
Analytical planning PAC	04F810 DSA Herbicide
Reporting PAC	04004A
PAF	PES
Operation Code	31 DSC (Domestic Sample Collections) 41 DSA (Domestic Sample Analysis) 21 IFE (Import Field Examinations) 33 ISC (Import Sample Collections) 43 ISA (Import Sample Analysis)
Estimated accomplishment hours per– domestic sample collection Estimated accomplishment hours per– import sample collection	3.8 hours/operation 1.7 hours/operation
Estimated accomplishment hours per– domestic sample analysis Estimated accomplishment hours per– import sample analysis Estimated accomplishment hours per– Field Examination	5.9 hours/operation 5.4 hours/operation 4.4 hours/operation

2.5 State or External Involvement when applicable: N/A

2.6 Status Tracker

If needed, Contact Kaniz Shireen at kaniz.shireen@fda.hhs.gov.

3. Sampling Assignment and Information

3.1 Inspection Approach:

3.1.1 Import Entry Review

Review of the entry documents may be required prior to collection of a sample to determine if the product meets the criteria for collection.

Ensure proper PAC/PAF combinations are selected when creating work in OASIS. This may include updating product codes and rescreening lines. Note: If the proper PAC/PAF combinations are not available, please contact the DIO and Import Compliance Systems Branch (ICSB) contacts for this assignment.

- SAM/PES (PAC: 04004A)

Samples are to be collected from all countries of origin with the exception of U.S. Goods returned.

To the extent our current product coding system will allow, CFSAN has provided the most likely product code that fits each product. Some targeted products may not correlate with any of the available product codes. To ensure that these products are not overlooked for sampling, the districts must rely on the importer description, entry review documents or field examinations to determine if the correct product code was used.

3.1.2 Import Field Examinations

Field examination of the product labeling is necessary to determine if the product was properly declared. If examination of the product labeling indicates that the product does not meet the sampling criteria outlined in this assignment, the district may un-accomplish the sample and release the entry.

3.2 Sampling Approach

3.2.1 Import Sample Collections

- Collect samples per the normal sample collection procedure which can be found in the IOM, Chapter 6, Section 6.5, "Import Sample Collection".

Collect unprocessed single ingredient commodity only. Do not collect frozen products.

Refer to the Sampling Framework section above for sample size information.

Ship import samples to KAN-LAB only.

Collection Report Documentation

Please enter the following information in the REMARKS section of the collection report:

- "Analyze for Acid Herbicides per CFSAN/DFPG assignment #16-08."
- Contact information for district compliance so they can be contacted if the sample analysis is found to be CRO.

Example: Analyze for Acid Herbicides per CFSAN/DFPG assignment #16-08. CO Jane Doe, (123)456-7890

- 3.2.2 **Where to Collect:** Domestic samples are to be collected at the warehouse and retail stores only. Import samples are to be collected at the port of entry.