

# GUIDE<sup>1</sup> TO INSPECTIONS OF GRAIN PRODUCT MANUFACTURERS

## TABLE OF CONTENTS

**INTRODUCTION** .....Pg 1  
**TERMINOLOGY** .....Pg 1  
**EQUIPMENT** .....Pg 2  
**SECTION I: ELEVATORS** .....Pg 2  
     Safety Precautions  
     Raw Materials  
     Storage Facilities  
     Pesticide Usage  
**SECTION II: FLOUR MILLING** .....Pg 4  
     Raw Material  
     Production Equipment  
     Packaging Equipment  
     Finished Flour  
     Food Additives  
     Sanitation  
     Quality Control  
     Sample Collection  
**SECTION III: BAKERY PRODUCTS,  
 DOUGHS, BAKERY MIXES** .....Pg 8  
     Raw Materials  
     Processing  
     Sanitation  
     Standards

Sample Collection

**SECTION IV: MACARONI AND  
 NOODLE PRODUCTS**..... Pg 10  
     Raw Materials  
     Sanitation  
     Enrichment Operations  
     Economic  
     Standards  
     Sample Collection

## INTRODUCTION

This guide is divided into four Sections. Section I is applicable to inspections of grain elevators; Section II applies to mill inspections; Section III is applicable to bakery inspections; and Section IV is applicable to inspections of macaroni and noodle products. Prior to conducting inspections involving any grain product manufacturer, review the general inspectional instructions in IOM Chapter 5 (**Establishment Inspections**) and particularly those in IOM 530 (**Food Inspections**).

<sup>1</sup> Note: *This inspectional guidance is intended to provide guidance and instructions to FDA staff for obtaining information to help fulfill the Agency's plans regarding the inspection of grain product manufacturers. This Inspection Guide does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. It is intended for FDA personnel and is available electronically to the public.*

## TERMINOLOGY

**TAILINGS (OR OVERS)** - Material which does not pass through the first sieve screen of a sifter.

**MIDDS (OR MIDLINGS)** - The relatively fine pieces of wheat endosperm which will be reduced to flour by the reduction rolls.

**PREBREAK OR BREAK ROLL** - Rolls used to break wheat kernels, beginning the flour milling process. They consist of a pair of grooved, steel rolls rotating in opposite directions. One roll turns about 2 1/2 times faster than the other.

**REDUCTION ROLLS** - Smooth, steel rolls used to reduce the size of the endosperm particles or middlings(mids).

**STREAMS** - The various product flows in a flour milling operation, based on various factors such as particle size, ash content, component of the wheat kernel, i.e. endosperm (for flour), bran and germ as by-products, etc.

**STRAIGHT FLOUR** - Flour from a given wheat intended for human consumption.

**PATENT FLOUR** - A composite of the lowest ash content streams of a straight flour.

**CLEAR (OR FIRST CLEAR) AND SECOND**

**CLEAR FLOURS** - Flour from the streams of higher ash content flour. Second clear is the highest ash content.

**TREATED GRAIN** - Treated grain usually refers to seed grain which has been treated with a mold inhibitor or fungicide which contains a dye imparting color to the grain, i.e. pink wheat.

**PURIFIERS** - Reciprocating sieves using air currents to separate bran and classify particles.

**"THROUGH" FLOUR** - Flour that has gone through the entire system, including sifters, and is being added to the dry mixing machine.

## EQUIPMENT

There is a variety of specialized equipment used in grain product manufacturing inspections, and specialized terminology and equipment used in the grain product industry.

Specialized equipment includes:

**BOOT TRIER** - a long, rectangular, shallow scoop that is used to sample grain from the inspection port of the boot of a bucket elevator. **Note: never use the trier in an elevator that is operating.**

Material from a boot trier is examined by slicking or sieving.

**DOCKAGE SIEVES** - a set of #10 mesh, #20 mesh, #30 mesh sieves, and a bottom pan, used to sift grain or flour for insect contamination.

**FLOUR SLICK** - a wide stainless steel spatula used by passing the flat side of the tool through the material being examined. This spreads and compresses the material, and insects or other foreign objects in will pop to the surface of the "slicked" material.

**GRAIN BOMB** - a weighted cylinder on a line with a v-shaped bottom used to collect samples from bins where the grain surface cannot be reached with a grain probe. **Note: any bomb used in a grain elevator must be constructed of a material that will not cause sparking.**

**GRAIN CLOTH** - a cloth on which grain from a compartmented probe is poured for examination.

**GRAIN PROBE** - a long, slotted cylinder used to sample and examine cores of bulk grain from storage bins, rail cars, etc.

**CONVEYING SYSTEM EQUIPMENT** - devices used in elevators, mills and manufacturing plants to move materials from one site or point to another.

Common pieces of equipment include:

**Conveyor Belts** (wide, open rubber or composition belts moving at relatively high speeds.) They are used primarily in elevators to convey whole grain from one bin to another, in unloading trucks and railcars, or loading ships.

**Boots** (bottoms of bucket conveyors) - The drop-bottom type of boot cannot be examined internally while the mill is in operation. Some boots are mounted slightly above the floor, making the area underneath hard to clean. Examine stock under the boot which may serve as a source of contamination for the whole conveying system. Open slightly and note if the stock is loosely or tightly packed. If tightly packed, the boot has not been disturbed for some time.

Remove and sieve approximately one pint of static stock. Always examine the boots which handle the first and second tailings and the sixth or seventh middlings (mids). The 1st and 2nd tailings are the tailings off the shifters just after the 1st and 2nd break rolls. This is the start of the flour milling operation with the cleaned wheat being broken or ground. The 6th or 7th mids occur late in the milling process and are the fine pieces of endosperm entering the 6th or 7th reduction rolls.

**Heads** (tops of bucket conveyors) - Examine static stock which has collected on ledges within the heads. If the heads themselves cannot be entered, examine static stock in spouts as near to the heads

as possible.

**Spouts** - Inspect spouts through inspection ports and examine static stock on the undersides of the port covers, felting if used, and debris under metal lining in spouts.

**Screw conveyors** - Where there are many conveyors, concentrate on the longer ones. Examine static stock in screw conveyors not covered under specific mill equipment listed elsewhere. Special attention should be directed to conveyors which have been sealed against entry, dead stock at the ends, and to conveyor(s) moving flour from bulk storage.

**Elevator (legs)** - Examine through port openings. Check port lids for presence of insects, larva and webbing.

**Millerator** - A separator used as an initial cleaning step to remove coarse and fine materials from the grain stream.

## **SECTION I: ELEVATORS**

Wheat, rice, corn, oats, soybeans, and a variety of other harvested grain products are stored in elevators pending delivery to a food processing plant. Elevator storage should maintain these grains in a condition suitable for processing into human foods and animal feeds. This inspectional method is intended to evaluate the storage conditions of these grains to determine if they are adulterated with filth, chemicals and/or other contaminants.

Specialized equipment necessary will include **non-sparking** grain probes, and grain bombs, dockage sieves, grain cloth, **safety** flashlights, photography equipment **with high speed film (for use without flash equipment)**, blacklight, and hardhat.

Inspect all wheat and other human food grains found in elevators and storage warehouses, including grain under government loan programs, and grain intended for export. Where violative conditions are found, document and report in detail, including the origin, destination, and ownership of the grain and responsibility for the violations.

### **SAFETY PRECAUTIONS**

Never enter a boxcar, truck, barge, bin or flat storage facility (bulk warehouse storage) until you have assured it is safe, and a second Investigator is standing by to render assistance. Always make sure the plant management is aware of your location and inspection plan. Sampling railcars, whether in a rail yard or at a firm, should always be conducted with another Investigator. Since multiple probes are

usually necessary, a second Investigator on the ground outside the railcar facilitates packaging the sample from each separate probe. Grain in a boxcar, barge or truck is usually compacted, and using a grain probe can become quite strenuous. In hot weather, this can lead to dehydration and exhaustion. Also, there is the danger of an engine hooking onto the railcars, causing the grain car door to shut, trapping you inside. If you are in the process of probing, this shock can also cause injury from the probe itself, or throw you against the railcar walls, or out of the railcar altogether.

Become familiar with hazards and safety precautions before beginning any elevator inspections. See IOM 140 for detailed discussion of necessary safety precautions.

Wear a hard hat, (non-sparking, plastic, fiberglass, etc.). Be sure man-lifts are in proper working order before using, and follow the firm's rules on their use. Operate with caution.

Elevator storage facilities present a special hazard due to dust formation. Dust in combination with humidity creates an explosive atmosphere which may be triggered by sparks, arcing of photograph flash bulbs, ordinary flashlight operation, or any type of activity which produces sparks. In this type situation be extremely careful not to use spark producing equipment, such as non-safety flashlights and flash photography. Move carefully; striking of the nails in shoes on metal, scraping of a metal hardhat or metal equipment against a metal surface may also produce sparks. Wear rubber coverings (not plastic which may create static electricity) over shoes as necessary to prevent sparks from shoe nails.

The use of mold inhibitors in stored grains may pose a hazard to persons working in and around grain storage areas. The most often used chemicals are propionic acid, propionic and acetic acid mixtures, isobutyric acid, and ammonium isobutyrate. Check with plant personnel and determine if the stored grain has been treated, and when.

If grain has been treated observe safety precautions including:

1. Avoid breathing the chemical vapors. Use a respirator if necessary.
2. For the first few days after treatment, avoid entering closed areas where treated grain is stored.
3. Liquids can be absorbed through leather gloves and shoes so wear rubber gloves and shoes or rubber shoe covers. See caution on sparks above.
4. If it is necessary to handle freshly treated grain, wear safety goggles, rubber gloves and

aprons or equivalent protective covering.

5. If liquid contacts skin or eyes wash immediately and thoroughly with water. In case of liquid spills on clothing, change and wash the contaminated clothing as soon as possible.

6. If liquid is accidentally swallowed, wash mouth with water and drink milk preferably mixed with egg whites to neutralize the acids. **CONTACT YOUR LOCAL POISON CONTROL CENTER IMMEDIATELY.**

Be especially careful using a grain probe to sample grains. The probe has very sharp doors which close over the individual grain compartments. If you hold the probe with your hand or fingers over the openings when you close the doors, you can cause severe cuts to your hand or fingers. Before closing the doors on the probe, make sure your fingers and hand are grasping the probe at a solid point. Always look at the position of your hands when closing the doors on a grain probe.

### **RAW MATERIALS**

Determine what examinations are made of incoming wheat or grain:

-Evaluate equipment and facilities used for such examinations, i.e., blacklight and blacklighting facilities used to detect treated kernels (pink wheat) and aflatoxin contamination.

-Appraise the operators' qualifications to operate testing equipment.

-Review test results for both incoming and outgoing grain shipments.

-Determine the disposition of rejected grain.

-Examine incoming and outgoing grain for evidence of contamination.

-Investigate the procedures and controls for selecting grain shipped for human food processing.

-Inspect vehicles used to transport grain for human consumption and determine rejection rate for such vehicles.

### **STORAGE FACILITIES**

Inspect exterior and interior of elevator for rodent harborages and for evidence of rodents.

Examine elevator and boot pit area, bins, headhouse and tunnels for evidence of rodent, insect and bird activity and the unsafe/prohibited use of rodenticides or other pesticides.

To demonstrate actual evidence of rodent or bird contamination of stored grain, count the number of pellets, or bird droppings on the surface in terms of number per unit area (number/square foot, etc.).

Also note any evidence of tracks, urine stains, and nests as well as avenues of rodent or bird traffic, etc.

Count rodent pellets per pint found in the grain from the top two inches or so in a specified area. For comparison probe the depths of the bin and examine this grain.

Examine a sufficient number (i.e. square root of the number of bins up to a maximum of ten) of bottom and top bin grain samples for evidence of rodent pellets, insects, insect damaged grain, and treated grain to assure grain is not adulterated.

Check for deliberate blending of contaminated and non-contaminated grain.

Be alert for condensate in grain bins and moldy or moisture damaged grain.

### **PESTICIDE USAGE**

Investigate the firm's rodent and insect control program. Obtain the names and active ingredients of rodenticides and pesticides used, frequency of use, and precautions taken. When careless use of rodenticides or pesticides is suspected, obtain documentary samples, with exhibits, and discuss with management immediately. Obtain complete documentation to demonstrate the culpability of those responsible for placement and use of the rodenticide or pesticide.

## **SECTION II: FLOUR MILLING**

Do not conduct flour mill inspections without first receiving on-site training. Also, become familiar with the vocabulary specific to this industry.

Refer to IOM 140 and Section I: Elevators, of this guide for safety precautions prior to conducting any inspections of mills or elevators. Care must be taken when opening equipment for inspection purposes. Pneumatic systems pose a special hazard caused by blow back. In addition to the instructions and information provided in IOM 530 and 21 CFR 137 Cereal Flour and Related Product Standards, direct attention to the following areas when conducting inspections of flour milling operations:

At the start of the inspection, prior to entering any equipment, collect and examine cleaned and uncleaned wheat and correlated flour samples as instructed below.

Inspectional equipment necessary for flour mill inspection, and sampling, includes a flour slick, boot trier, industrial safety-type flashlight, three sieves (#10, #20, and #30), and a deep-bottom pan.

Collect flour samples in unbreakable containers, such as clean milk type cartons. Flour for moisture analysis should be collected in clean glass jars. Do this outside the plant because of the potential for glass breakage.

Check wheat samples for rodent pellets, ergots, toxic weed seeds, moldy, treated and insect damaged kernels. Examine the coarse separates from the millerator for rodent pellets and the fine screenings for insects.

Uncleaned wheat - Sample falling, blended grain dropping on or off a conveyor immediately before the first cleaning unit. Do not sample grain actually on a belt or conveyor of any type.

Collect approximately one-pint portions every ten minutes over a half hour period (four samplings) to yield two quarts of grain. Take a complete cross-section of the stream each time. When finished, visually examine for pellets, insects, insect damaged kernels, ergots, toxic weed seeds, moldy grain, color and odor for treated grain. If the sample of uncleaned wheat appears to be above defect action levels, inspect grain storage on site for dirty wheat. Visual examination of the unclean wheat will also show the adequacy of the firm's cleaning process.

Collect one two-quart sample each day of the inspection. However, if it appears over-tolerance wheat (in whole, or as part of the blend) is being used, collect additional samples at approximately four-hour intervals during the course of the inspection.

If the mill is blending suspect and passable wheat, obtain a two-quart sample from each bin being used for the blend and submit to the laboratory for analysis. See Compliance Policy Guide Manual, section 555.200- Adulterated Food Mixed with Good Food.

Cleaned wheat - If contaminated wheat is being used, collect a sample of cleaned wheat from each lot comprising the blend. Otherwise, collect one sample of cleaned wheat without regard to the identity of the lot. Take one-pint portions at approximately ten-minute intervals to yield two quarts of grain. Visually examine for pellets, insects, insect damaged kernels, and moldy grain and check for treated grain.

Sample the cleaned wheat before it enters any equipment in the mill which begins breaking the wheat kernel into pieces. This first equipment is usually the break rolls (or in some mills, the prebreak rolls). If the mill uses any kind of prebreak which makes a small amount of flour for human food, treat this system as the first break. If, however,

the mill uses an entoleter (an impact machine used to destroy living insects and insect eggs, break unsound wheat and remove the insect fragments and unsound wheat), and all aspirations go into feed, sample the cleaned wheat after this treatment.

If the mill does not use an entoleter or prebreak roll, the wheat may be sampled prior to entering one of the first break rolls or within the roll housing. It is not necessary to sample the streams going to all of the first break rolls.

3. Flour - The flour sample should represent the production from the lot of cleaned wheat previously sampled. To avoid knocking insects into the stream, do not enter the flour milling equipment for the purpose of inspection and sampling between the time of sampling cleaned wheat and sampling flour. This sample should be collected after the grain has passed through the entire milling stream. This may require a twenty to thirty minute delay between sampling the clean grain and the finished flour. Determine the time lag for grain from first break to finished flour and collect your samples accordingly.

Sample each generally recognized flour stream which is going to food use after the final aggregation and, if possible, after rebolting (sifting). Make sure that no blending with flour from other sources (bulk storage tanks, etc.), has occurred. Sample half-pint portions at approximately ten-minute intervals until one quart from each stream has been collected.

Include information as to the percentage of total flour production represented by each aggregate flour stream sampled on the C/R. Report the percentage extraction of the wheat represented by the aggregate streams sampled. These figures will permit the calculation of the analytical results to a straight flour.

The purpose of this sampling is to look for insect filth. For the evaluation of sanitary conditions in a flour mill, it is important to look for the distribution of insect filth derived from the use of insect-infested grain. In order to follow the insects through the milling equipment the size of the streams must be taken into consideration. A small stream, even if highly contaminated, may carry fewer fragments per hour than a very large stream showing much less contamination per unit weight. The size of the individual flour streams can be expressed as a percentage of the total flour made. When the insect fragments are counted in the individual flour streams, and this count is multiplied by the stream percentage, the result is the number of fragments the stream would contribute to a straight flour.

If further inspection reveals no problem at the mill, the flour samples may be discarded. However, if inspectional conditions warrant, submit samples to

the laboratory for examination. Collect investigational subsamples of flour stock which exhibit the violative condition of specific equipment (See Production Equipment, Packaging Equipment, and Sample Collection section). Identify stock examined or collected with its particular section of the mill flow. If gross infestation is found, sample "backwards" and "forward" from this point to determine the problem source and magnitude.

If you can positively identify insects found during a flour mill inspection, list them by species such as: *Tribolium* (for both confused and rust red flour beetles), weevil (for both rice and granary weevils), flat grain beetle, saw-toothed grain beetle, etc.. If you are not positive as to species, identify them generally as to type, e.g. weevil type, moth type, beetle type, etc. Representative insects should be collected for verification by the laboratory.

If mill infestation is found, obtain detailed information and documentation covering the firm's fumigation practices, including the dates of spot and general fumigations over the past year. The mill may use methods other than fumigation, such as heat, to control infestation. Report on those practices as well.

Mills usually produce a patent, first clear, and second clear flour, or a combination of these. Determine the percent contribution each flour makes to the total flour output. For example, 70% of the total flour may be patent, 25% may be first clear and 5% may be second clear. Minor variations in the percentage figures do occur from time to time and the miller may use this fact to abstain from giving you such figures. Obtain the miller's best estimate of these flour percentages.

Determine the firm's practices with regard to inspection and cleaning of equipment. If a self-inspection program exists, review a representative number of their reports.

Check metal detection and removal devices for effectiveness.

#### **RAW MATERIAL**

Inspect the elevator and grain storage facility. See "Section I: Elevators" of this guide for instruction.

#### **PRODUCTION EQUIPMENT**

Examine flour production equipment. Use caution when examining any of this equipment while in operation, both to protect yourself as well as the equipment. Except in a small mill, it may not be feasible to examine all equipment, but some of all types of equipment should be examined. Also look

for lubricant and heat transfer fluid leaks. The equipment may be considered in seven categories, as follows:

1. Rolls - Examine static stock in the feeder box, on ledges in upper housing, in the housing beneath the rolls, and in the corners of the hopper itself.
2. Sifters - Examine static stock as far up and down from the spout opening as possible. Square spout openings usually contain ledges within the spout. Examine felt gaskets or packing, and tailover stock from rebolt sifters. If insects are found, examine the systems ahead of the rebolt.
3. Purifiers - Examine static stock in the feeder box, on ledges in the upper and lower housing, and the sieve to see whether or not insects are tailing over. Examine the tailover spout and static stock at the end of the conveyor.
4. Conveying system - Examination of conveying system components is addressed in the introduction to this guide. Common components include boots (during inspection of flour mills always examine the boots which handle the first and second tailings and the sixth or seventh midds), heads, spouts, screw conveyors (special attention should be directed to conveyors which have been sealed against entry, to dead stock at the ends, and to conveyor moving flour from bulk storage), and elevators.
5. Suction trunking - Dust collected from the break and reduction rolls, purifiers, and sifters is almost always processed into flour, and if infested, serves to contaminate the equipment beyond the point of entry of these dust streams into the flour stream. Examine at elbows and dead ends or wherever there are accumulations of dust.
6. Dust collectors - Examine stock discharged from these collectors for insects particularly where static stock in corresponding suction trunking is found infested. The stocking-type dust collector is more difficult to clean than other types, particularly when infested by moths. A slight blow with the hand on a cyclone dust collector usually serves to dislodge static stock from the inside.
7. Bran and shorts dusters - Obtain entry to some of the bran and shorts dusters, and examine static stock from the housing and the spouts beneath.

#### **PACKAGING EQUIPMENT**

Wooden packer bins, including those with metal liners, should be examined for crevices, shoulders, and braces which could hold static stock and harbor

insects. Infestation in packer bins is almost certain to produce identifiable filth in packaged flour.

Some packaging machines are designed to allow a space between the bottom of the bin and the top of the packer. This space may be caulked with bags, or a cloth sleeve and if not properly cleaned may provide a harborage for insects.

When flour is removed from bulk storage tanks to be blended or packed, it may become contaminated by the passage through infested conveying equipment. Examine the blending equipment for dead ends, static stock in conveyors, spouts, etc. If any flour is being rebolted (sifted) after storage in bulk, examine the rebolt tailings. Report the type of sifter and the size of the cloth or wire with which this machine is clothed.

### FINISHED FLOUR

Check bulk storage tanks and finished flour conveying systems for insects. Use extreme care when examining empty bulk tanks.

Give attention to the sanitary condition of stocks of malt flour or other flour received for blending. Malt flour is highly susceptible to insect infestation.

Examine the small flour bin used to adjust bag net weights, and its contents, near the semi-automatic packers. Such bins may be neglected during clean-up.

Determine type and amount of enrichment used per batch, or per day if a continuous mixing operation is used. Check calibration on enrichment metering devices. If enrichment analysis is made by the firm or contract lab, determine sample size, method of collection, and review recent assay results.

### FOOD ADDITIVES

Review food additives and enrichment in storage to determine if allowed in standards (21 CFR 137). Calculate percentages or amounts in the finished product per CWT (hundred weight or 100 lbs.) of flour (remember to be consistent with the units utilized in the standards.). Enrichment held for a year or more, or held at abnormally high temperatures or humidity, may have deteriorated.

Check use of bleaching agents, artificial aging agents, optional ingredients. Refer to 21 CFR 137.

### SANITATION

The bag stock should be inspected for rodent or insect damage/harborage. Also examine bags or other storage containers for chemical contamination, e.g. oil impregnated cloth.

Check the sanitary condition of railcars, truck trailers, bulk trucks and barges awaiting loading.

Determine mill's rejection criteria, if any, for contaminated transport vehicles. Ascertain cleanup procedure for railcars and other vehicles, and determine if it is followed.

Sacks, cloth, tape, etc. used to caulk openings in elevator legs, spouts, and other equipment should be examined for insects.

### QUALITY CONTROL

Review assay records for compliance with flour standards (moisture, ash, protein, enrichment) rodent hairs, insect fragments, aflatoxins or mycotoxins (reference Compliance Policy Guide Manual, section 555.400), and other contaminants.

### SAMPLE COLLECTION

Filth: 301(k) - Where insanitary conditions are detected in the processing areas of an intrastate firm, consider documenting 301(k) violations for regulatory consideration, if the state or local authorities are unable or unwilling to correct the situation, or have requested FDA handle the case. See IOM subsection 405.4

Your sample should include the following (the 702(b) portion should be separately identified and retained):

1. A minimum of three quarts of flour, in duplicate: collecting 1 qt. from each of three previously unopened bags taken from the same lot being dumped into the conveyor. If two or more lots are being blended, sample a minimum of three bags from each lot.

2. Collect up to 3 quarts of flour, in duplicate, if that much is available, from each static point. Filth exhibits should be collected to document the insanitary conditions and made part of the sample.

3. Collect a minimum of six quarts of "through" flour, in duplicate, as the dry mix is being made. To accurately reflect the condition of the flour passing through the system, the subs of "through" flour must be obtained before the conveyor has been opened for inspection and the static flour disturbed.

Filth - Cereal products, especially flour, are sampled: (a) on the basis of microscopic filth, or (b) because of gross filth due to insanitary transportation or storage facilities.

1. Microscopic filth - When sampling flour for microscopic filth, samples should be collected from the lower grades of flour. (e.g.: clear and straight flour). Patent flours will show a low level of microscopic filth because of the milling and purification processes.

Select units to be sampled at random. If different codes are present, sample each code separately. Packages of less than 11.4 kg (25 lbs): Collect

twelve intact bags and submit "as is". Packages of 11.5kg (25 lbs.) or larger, use a flour trier. Open bags at seams and remove top layer of flour before inserting trier. Take about one pint sub-divisions from each of twelve bags of the same code. See IOM 452 for sample handling and preparation.

**Gross Filth** - This is "selective sampling" See IOM 427 for detailed sampling instructions and IOM 452 for sample handling and preparation.

**Vitamins and minerals** - Samples will be collected on assignment basis or if inspectional conditions warrant.

1. Retail Packages 4.5kg (10 lbs or less) - Collect twelve intact packages in duplicate of the same code.

2. Bulk and Retail Packages 4.5kg (Larger than 10 lbs) - Collect 12 - 453 gm (1 lb) subs in duplicate from each of twelve different containers of the same code. Remove flour or other cereal product with a trier inserted the full length of the container. Prepare each sub in individual airtight containers and protect against sunlight by wrapping in opaque paper. Do not fumigate samples.

**Net weight** - Refer to IOM 428 for guidance. Also, obtain a moisture sample of two cores of flour from each of six other weighed packages. Insert the flour trier from one corner diagonally through the package. Immediately place the two cores in a clean, dry air tight container which has stood open for a few minutes near the lot of flour sampled. Close the container immediately using a different one for each package. Identify each with the gross weight of the package from which taken. Do not fumigate.

**Mycotoxins and Aflatoxins** - See IOM Sample Schedule Chart 6.

**Pesticides** - See IOM Sample Schedule Chart 3.

## **SECTION III: BAKERY PRODUCTS, DOUGHS, BAKERY MIXES**

Review IOM 530 and 21 CFR 136, Bakery Products Standards, prior to conducting bakery inspections.

### **RAW MATERIALS**

When 301(k) violations are suspected, collect a "through" flour sample as the dough is being made. "Through" flour is that which has gone through the entire system, including sifters, and is being added to the dough mixing chamber. To accurately reflect

the conditions of the flour passing through the system, the subs of "through" flour must be obtained before the conveyor has been opened for inspection and the static flour disturbed.

If no insanitary conditions are found, this sample can be discarded. Report sources and types of egg and milk products. If frozen eggs are used, determine if they are pasteurized, received under a Salmonella free guarantee or if firm tests critical raw materials for microbial load including Salmonella and other pathogens.

Determine what procedures and controls are in place regarding the sanitary condition of vehicles in which raw materials are received.

Determine if raw materials requiring refrigeration are refrigerated.

Determine what examination is made of raw materials before use and any attempt to "blend off" contaminated raw materials with clean raw materials.

### **PROCESSING**

Determine any areas in the process where a "bottle-neck" occurs allowing in-process products amenable to microbial contamination to remain at room temperature for long periods of time.

Determine effectiveness of metal detection and removal devices.

### **SANITATION**

Open inspection ports, where possible, and examine static accumulations for mold growth, and insect and/or rodent infestations. Particular attention should be given to flour bins, elevator boots, conveyor systems, sifters, dump scale apparatus, production line flouring devices, dough proofers, overhead supports and ledges, and transport vehicles.

Determine disposition of salvaged material and returned goods.

If possible, inspect equipment prior to production to determine adequacy of clean-up and sanitizing operations.

Determine time-temperature abuses which may allow growth and possible toxin formation of microbial contaminants.

Be alert for poorly designed conveyors or equipment which might add to microbial load through product delay or "seeding".

### **STANDARDS**

Determine method of adding enrichment to the product whether by use of enriched flour, enriched salt, or enrichment wafers. If enrichment analyses

are made by the firm or contract laboratory, determine sample size, method of collection, and review the most recent assay results.

Obtain formulations of standardized products and determine if the firm's manufacturing and enrichment practices results in products conforming with 21 CFR 136.115.

### **SAMPLE COLLECTION**

Where sample size is indicated, 702(b) portions should be separately identified and retained.

Filth 301(k) - Where insanitary conditions are detected in the processing areas of an intrastate firm, consider documenting a 301(k) violation for regulatory consideration if the state or local authorities are unable or unwilling to correct the situation, or have requested FDA handle the case. You may also consider discussing the situation with the Center for Food Safety and Applied Nutrition (CFSAN) and Office of Chief Counsel (OCC). See IOM section 405.4.

Your sample should include the following:

1. A minimum of three quarts of flour, in duplicate: Collect one quart samples from each of three previously unopened bags from the same lot as being dumped into the conveyor. If two or more lots are being blended, sample a minimum of three unopened bags from each lot.
2. Collect up to three quarts of flour, in duplicate, from each static point. Filth exhibits should be collected to document the insanitary conditions and should be made part of the sample.
3. A minimum of six quarts of "through" flour, in duplicate, should be collected as the dough is being made.

Filth 301(a) - Sample from the square root of the number of shipping containers in the lot with a minimum of six and a maximum of eighteen subsamples, in duplicate. Each subsample should weigh at least 453 gm (1 lb.). If the product is not in shipping cases, sample the square root of the number of retail packages with a minimum of 6 and a maximum of eighteen subsamples of at least 453 gm (1 lb.) each, in duplicate. If the retail packages (loaves, cakes, etc.), do not weigh 453 gm (1 lb.), each sub should consist of sufficient retail units to equal at least 453 gm (1 lb.).

Microbiological - Collect a representative sample consisting of a minimum of 10 intact units collected in duplicate. Minimum size for each sub is at least 113 gm (4 oz).

If the product is to be analyzed for Salmonella, follow the Salmonella Sampling Plan in IOM Sample Schedule Chart 1.

Enrichment, Minerals and Nutrition Labeling -

Bread, rolls, baked or unbaked product: Compliance samples should consist of 12 subsamples of at least 1 lb. each (454 gm) collected in duplicate. Collect consumer size retail packages (2 - 1 lb. subs from each of 12 cases) from separate cases of the same code. Protect enrichment samples from sun by wrapping in opaque paper. Determine and record by sub the gross weight.

Standards - If unauthorized ingredients are being used in a standardized product, collect a sample of the ingredient for identification and a sample of the standardized product in which the optional ingredient is being used.

For official 301(a) or 301(k) samples, collect a minimum of six subs [each 226 gm (8 oz.)] of finished product, in duplicate, and 1 - 226 gm (8 oz.) sub of each unauthorized ingredient.

Economic - See IOM 428 for instructions.

Food Additives - Collect a sample consisting of 1 - 226 gm (8 oz) sub of the food additive and a minimum of six subs of finished product in duplicate, each sub to consist of a minimum of 226 gm (8 oz).

Color Additives - See IOM Sample Schedule Chart 9. Chart 9 also contains guidance for sample size of the color additive itself.

Sample Preparation - See IOM 452 for sample handling and preparation.

## **SECTION IV: MACARONI AND NOODLE PRODUCTS**

Review IOM 530 and 21 CFR 139 - Macaroni and Noodle Products Standards prior to conducting these inspections.

### **RAW MATERIALS**

Describe storage and handling of raw materials that would contribute to vermin and microbiological contamination.

Report processes in detail that are designed to remove contaminants, including metal fragments, from the raw material before being incorporated into the finished product.

Report types, egg solid content and suppliers of egg products.

Determine if egg products are pasteurized, received under a Salmonella free guarantee, or if firm tests critical raw materials for microbial load including Salmonella and other pathogens.

Determine what procedures and controls are in place regarding the sanitary condition of vehicles in which raw materials are received.

## SANITATION

Evaluate adequacy of cleanup practices before operations begin. Examine extrusion worms, dies, kneading plates, rollers, slicers, cutting machines, drying rods and dryer conveyors.

Determine the type, concentration, and use of sanitizing agents. Check availability and location of handwashing facilities and hand dip solutions.

Examine flour handling systems for evidence of insect infestation. See Section II: "Flour Milling" of this guide for 301(k) evidence development.

Examine scrap grinder, drying cabinets, screened bottom dryer trays and dowels used to handle long goods (spaghetti) for evidence of insect activity and cleanliness.

Determine disposition of scrap material, salvage, or returned goods, etc.

Provide in-depth coverage of all time/temperature relationships affecting possible build up of Staphylococcus, Salmonella and/or other microbiological organisms of health significance. Particular attention should be directed to egg-water and egg-water-flour mixing operations.

## ENRICHMENT OPERATIONS

Determine type and amount of enrichment used per batch, or per day if a continuous mixing operation is used. Check calibration on enrichment metering devices. If enrichment analysis is made by the firm or contract laboratory, determine sample size, method of collection, and review most recent assay results.

## ECONOMIC

Slack Fill. Prepare an authentic pack as full as practical when: (1) Elbow macaroni container is less than 80% filled, (2) Long macaroni, spaghetti, and vermicelli containers are less than 70% filled.

## STANDARDS

See 21 CFR 139, Macaroni and Noodle Products.

1. Egg solids - Products under 21 CFR 139.150, 139.160, & 139.180, except chow mein noodles, must contain 5.5% of the total solids as egg solids. Any one of the following egg quantities added to 100 lbs. of flour should result in compliance:

- a. 9.43 kg (20 lbs. 13oz.) commercial liquid whole eggs.(24.7% egg solids).
- b. Approximately 187 large eggs.
- c. 4.54 kg (10 lbs.) commercial liquid yolk (51.2% egg solids).
- d. 2.40 kg (5 lbs. 5 oz.) commercial dried whole

eggs (96.9% egg solids).

5. 2.40 kg (5 lbs. 5 oz.) commercial dried egg yolk (97% egg solids).

In continuous mixing operations it may be possible to compare the total weight of egg ingredient with the total weight of flour used in a production.

If the firm is using other optional ingredients in lieu of flour, such as farina or semolina, further calculations may be necessary. CFSAN Division of Plant Product Safety (HFS-305) at 301-436-1400 can assist in determining if the firms formulation will result in a compliant product.

2. Addition of artificial color to eggs - Report addition of beta-carotene or other artificial color to eggs. Colors are not permitted.

Compare the color of each egg ingredient being used with that in unopened containers.

## SAMPLE COLLECTION

### Investigational

1. Filth - Collect samples of returned goods, scrap or other recycled materials when finished product adulteration is suspected from these sources.

2. Microbiological - If conditions warrant collecting investigational samples for microbiological contamination, sampling should include the following areas:

- a. Scrapings from egg slurry mixing vessels, particularly those re-used without cleaning and sanitizing.
  - b. Scrapings from gratings over mixer blenders through which egg slurry passes.
  - c. Scrapings of macaroni dough from mixer-blender.
  - d. Scrapings from production equipment such as extrusion worms and dies, kneading plates, rollers, slicers, cutting machines, drying rods and dryer conveyors.
  - e. Scrap material where recycled into the process.
  - f. Product before and after drying.
  - g. Each raw material before and after blending.
  - h. Sample eggs, finished egg noodles, and other egg-containing finished products for Salmonella examination. (See IOM Sample Schedule Chart 1 - Salmonella Sampling Plan)
  - i. At least ten intact units of suspect finished product(s) from the day's production, and from the previous day's production.
3. Standards - Collect product formula and 113

- 226 gm (4-8 oz.) subsamples of egg ingredients, flour, and finished product when a deficiency in egg solids is suspected.

Collect 113 - 170 gm (4-6 oz.) sub-divisions of the suspect color, finished product, egg ingredient, and subs from a previously unopened container of egg ingredient where the addition of artificial color is suspected.

Official

1. Filth

a. Retail Packages 226 gm to 1.36 kg (8 oz. to 3 lbs.)

Number of subs in sample - Sample the square root of the number of cartons in the lot with a minimum of six, and a maximum of eighteen.

Number of packages per sub

<u>Package Size</u>	<u>No. Pkgs/Sub</u>
226 - 283 gm (8 oz. - 10 oz.)	3
340 - 453 gm (12 oz. - 1 lb.)	2
.906 - 1.36 kg (2 lb. - 3 lb.)	1

b. Bulk Cartons (9.1 kg - 20 lb)

<u>No. Ctns. in Lot</u>	<u>No. Ctns. to Collect</u>
2-30	2
30-60	3
60-90	4
90-120	5
over 120	6

2. Microbiological - Collect a representative sample consisting of 20 intact units. Minimum size for each intact unit is 113 gm (4 ozs). If egg noodles are analyzed for Salmonella, refer to IOM Sample Schedule Chart 1 - Salmonella Sampling Plan.

3. Enrichment (vitamin, mineral, & nutritional labeling)

Retail packages - Collect a representative sample consisting of at least 12 - 226 gm (8 oz.) intact retail units in duplicate from each lot. All subs should be the same code.

Bulk cartons - Collect 12 - 226 gm (8 oz) subs in duplicate from different cartons in the lot.

4. Egg solids or other analysis

Retail packages - Collect sufficient sample to total 2.7 kg (6 lbs) in duplicate with a minimum of three packages.

Bulk Cartons - Collect 453 gm (1 lb.) subs in duplicate from six different bulk cartons in the lot.

5. Slack fill - Collect five packages in duplicate from each of four different shipping cases.