

Appendix C

L&R Committee Work Group on Moisture Loss

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***NOTE:** The following documents could not be included in this publication because they are only available in Adobe PDF format; NIST will provide copies on request. Please contact Lisa Warfield at (301) 975-3308 or at lisa.warfield@nist.gov or Ken Butcher at (301) 975-4859 or at kbutcher@nist.gov.

Detail of all Items
(In order by Reference Key Number)

Moisture Loss and Other Issues for Consideration by the NCWM Laws and Regulations Committee and the Board of Directors

INTRODUCTION

The Weights and Measures Division (WMD) prepared this document in 2007 at the request of NCWM Chairman Mike Cleary to detail several moisture loss and other package inspection issues to be studied under this project with the goal of developing recommendations for amendments to NIST Handbook 133 (HB 133) in 2008. There are four items listed below and most of the resource material is included to enable this document to serve as an agenda and comprehensive resource. The WMD provided this outline for consideration by the NCWM L&R Committee, the Board of Directors, and other interested parties with the goal of developing a consensus on whether or not there was sufficient justification to study the issues described below.

Item 1. Gel Soaker Pads

Several weights and measures officials are concerned that HB 133 does not provide adequate guidance on how to verify the net weight declaration on packages where “gel soaker pads” are used in the package to absorb moisture.

Based on information that the WMD has received, this discussion paper is provided as a technical examination of the use of “gel type” soaker pads when determining net weight. Gel soaker pads contain granules of a highly absorbent compound that soak up fluid and retain it so efficiently that the “usual” methods of drying (pressure, wiping, and air) do not allow the re-creation of “Used Dry Tare.” According to two manufacturers, “gel-based soaker pads” can absorb up to 50 times their original weights in fluid compared to “cellulose-based fluff pulp” which absorbs only two to four times its weight (see <http://www.thermasorb.com> and <http://www.stockhausen-inc.com>). Gel-type soaker pads are used by industry to: (1) extend shelf life; thus, reducing repackaging costs, (2) reduce bacterial growth, and (3) improve the “presentation of packages” by absorbing blood and fluid; eliminating free flowing liquid in the package.

Inspection problems with this type of tare arise when officials attempt to verify net weight declarations on packages which have been wrapped and labeled at a location other than where the commodity is inspected/tested since officials have no access to “unused dry tare.” Some officials report that it is impossible to dry these types of soaker pads using traditional drying procedures and have even attempted to use microwave ovens to establish “used dry tare.” WMD discourages the use of microwave ovens or other extreme drying methods for drying tare materials because (1) unused “dry” tare materials have a natural moisture content which cannot be reestablished using most heating methods (e.g., for gel-pads this could be 5 % or more); (2) the intensity/power of microwave ovens varies substantially from device to device so, given the range of variability, it would be impossible to suggest a power setting or heating time that could be considered reasonable, repeatable, and safe; and (3) a more practical concern is that an official could overheat tare material and damage the microwave or cause even more serious problems such as the possibility of fire.

WMD solicits recommendations and comments from all concerned who have interest in this topic. Please consider possible solutions to allow accurate measurement practices that permit officials to safely recreate “used dry tare” for net weight verification on products using “gel-type” material.

WMD believes the requirements of HB 133 are written broadly enough to apply to all types of tare materials including those which are “gel based.” Under the definition of “Used Dry Tare” officials use air drying, washing, scraping, pressure, or other techniques which can involve more than normal household procedures but do not go so far as to include laboratory procedures such as oven drying. The field test procedures in HB 133 were developed to provide uniform procedures to enable officials to dry out “used” tare to recreate as close as possible the weight of “unused tare material” that the packager used. When a packager uses a tare material that does not permit the recreation of unused dry tare (and the official does not have access to “unused dry tare” material or to readily

accessible reliable information on tare), the official is limited to drying at least two samples of the tare material as best he can using the procedures described by the handbook; he then can use an average tare to determine a net weight. If the packages are then found to be underweight, the packer must be permitted to provide information on whether or not the average tare value used by the official was reasonable or provide other information to the official to defend the net weight claims on the label. Since this is really the same opportunity any packer of any type of tare material has available to him, WMD believes the current guidance in HB 133 is adequate.

A test procedure in HB 133 is necessary to ensure weights and measures can continue to maintain marketplace surveillance to ensure equity and fair competition while still recognizing reasonable moisture loss or gain as required under both federal and state laws and regulations. The relevant sections describing the tare definition and determination procedures from fourth edition of HB 133 (2005) are shown below:

Used Dry Tare

Used Dry Tare is defined as follows: Used tare material that has been air dried, or dried in some manner to simulate the unused tare weight. It includes all packaging materials that can be separated from the packaged product, either readily (e.g., by shaking) or by washing, scraping, ambient air drying, or other techniques involving more than “normal” household recovery procedures, but not including laboratory procedures like oven drying. Labels, wire closures, staples, prizes, decorations, and such are considered tare. Used Dry Tare is available regardless of where the packages are tested. The net content procedures described in this handbook reference Used Dry Tare.

How is a tare weight determined?

Except in the instance of applying unused dry tare, select the packages for the initial tare sample from the sample packages. Mark the first two (three or five) packages in the order the random numbers were selected; these packages provide the initial tare sample. Determine the gross weight of each package and record it in block a, “Gross Wt,” under the headings “Pkg. 1,” “Pkg. 2,” “Pkg. 3,” etc. on the report form. Except for aerosol or other pressurized packages, open the sample packages, empty, clean, and dry them as appropriate for the packaging material.

NIST Handbook 133 is available online at <http://ts.nist.gov/WeightsAndMeasures/h1334-05.cfm>.

Item 2. Moisture Loss Guidance in NIST Handbook 133

The three items shown below were taken from the L&R Report of the 2004 89th NCWM Annual Meeting Proceedings and later agendas including an item from the Committee’s 2007 Interim Meeting agenda. The Committee withdrew two of these items in 2004 and asked NIST to review the moisture loss sections of HB 133, revise them to improve their readability, and, where appropriate, add additional information or clarifications.

NIST conducted the promised review but found there were several suggestions contained in these two items. A few of the suggestions raised substantive questions about what needs to be added to HB 133 and which questions would be the most useful or practical for field officials. NIST believes that responding to some of the suggestions or questions could lead to extensive revisions to the handbook. This level of discussion will take considerable time and effort for the Committee, and WMD would like to ensure everyone has a full understanding of the concerns and agrees to the necessity for change so time and resources will not be wasted. The Committee should review these sections and identify what information administrators need versus what information field officials need to perform their duties.

270-7 Amend NIST Handbook 133 Section 2.3. Moisture Allowances to Provide Clearer Guidance

(This Item was added to the agenda of the WG on Moisture Loss following the 2007 Interim Meeting)

Source: Northeast Weights and Measures Association (NEWMA)

Proposal: Amend NIST Handbook 133 (HB 133) Section 2.3, Moisture Allowances (pages 17 through 19 of Handbook 133) to provide clearer guidance.

Background: The issue of moisture loss is complex. Handbook 133 currently provides specific guidance on the determination and application of moisture allowances for only a limited number of commodities. Concerns have been raised that this guidance is confusing and difficult to understand, particularly with regard to when moisture loss is applied (i.e., at the time of inspection or subsequent to the inspection). Requests have been received to reword this section to make it easier to understand and apply.

In addition, HB 133 provides little guidance on the determination and application of moisture allowances for commodities other than those specifically listed. Weights and measures jurisdictions across the country have been struggling with how to properly handle moisture loss during packaging inspections and need more definite guidance on this issue.

The Committee did not believe it had the time or expertise to address properly the issue of moisture loss within the structure of the NCWM. The Committee decided to request activation of a NIST Moisture Loss WG to establish more effective and extensive guidance to the NCWM regarding the proper determination and application of moisture loss.

Discussion of this Item by the WWMA: The WWMA L&R Committee heard that a meeting was tentatively planned for November 2006; the meeting was delayed to allow time for everyone to identify and agree on the issues to be addressed by the group to ensure that expectations for the meeting results were clear. The Weights and Measures Division (WMD) agreed to fund the travel and attendance of one NCWM representative. Leading issues included providing additional guidance in HB 133 regarding the determination and application of appropriate moisture loss allowances in package inspections, with noted examples including how to address gel soaker pads in poultry/meat packages, as well as how to determine moisture allowances for pasta, rice, and other commodities for which no established moisture loss allowances exist. Additionally, guidance regarding application of moisture loss allowances at the point-of-pack needed to be addressed.

An industry representative urged involvement in the meeting and ensuing work on HB 133 amendments from the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to ensure input and consensus from all relevant agencies. He further emphasized the need to review and consolidate all decisions and directives from any and all court rulings regarding moisture loss issues. Factors to be considered in determining and applying appropriate moisture loss allowances and influences upon such losses included commodity stability limits and varying environmental conditions at packing plants such as relative humidity and constant temperature rooms maintained at different temperature levels. The industry representative also urged that guidance be provided to industry members regarding the types of data needed to be tracked and provided by packers/manufacturers in addressing moisture allowance determinations.

Discussion of this Item by the CWMA at its 2006 Interim Meeting: A comment was heard from industry that this needs to be addressed in order for businesses to be competitive. The USDA and FDA need to be involved in the development of this item. A meeting was tentatively scheduled for November prior to the NCWM Interim Meeting. There was general agreement that in order for this meeting to be effective, the USDA and FDA must be present. Comments were heard in support of using the New York proposal to correct the error in HB 133.

Item 3. WMD Package Inspection and Moisture Loss Guidance Letter – Withdrawn

WMD believed there was some useful information for weights and measures officials and industry contained in the 2005 Memorandum that WMD issued to state weights and measures officials and other interested parties, entitled “Verifying the Net Contents of Packaged Goods and Recommended Procedures for Moisture Allowances.” WMD withdrew the memorandum at the request of Kraft Foods which detailed a number of concerns about the guidance contained in the WMD communication. The Kraft Foods letter, dated January 31, 2006, was prepared by Steven Steinborn of Hogan and Hartson. WMD recommended the committee review both documents to resolve the corporation’s concerns where possible and determine if any information in the WMD letter can be revised and republished to assist weights and measures officials in dealing with net quantity of contents. The WMD memorandum and Kraft’s letter are presented in Reference Section II below.

Item 4. WMD Suggestions

a. Seek Greater Recognition of NIST Handbook 133 by FDA and other Federal Agencies.

WMD would like to avoid frequent amendments to HB 133 because, unlike NIST Handbook 44, it is not widely adopted automatically. Many jurisdictions adopt new versions of HB 133 using their Administrative Procedures Acts. Another consideration is that the USDA adopts versions of the handbook which then preempts other versions from being used to verify the net quantity of packages put up under that agency's supervision. In the past, WMD found that several jurisdictions used the wrong edition of HB 133 to take action against USDA-inspected products simply because they used a newer version of the handbook than had been adopted by the USDA. WMD believes that USDA adoption gives a strong endorsement and recognition to the handbook. WMD also believes the fourth edition of HB 133, whose core elements have been in use by the states since 1994, should be recognized by the FDA and all other agencies to eliminate any uncertainty over its use by the states. Perhaps it is time the NCWM consider petitioning the FDA to provide some type of formal recognition of the handbook. WMD believes that establishing a 5-year review cycle for HB 133 may be one way to ensure it is acceptable to other agencies, which will help avoid the confusion over which edition is currently in effect.

b. Create a new supplement or website to NIST Handbook 133 which would provide useful information to administrators, field officials and industry.

WMD would like to explore the possibility and usefulness of creating a new publication or website called NIST Handbook 133-1 which would provide supplementary information and guidance on net quantity of contents testing and moisture loss for administrators and industry. The publication or website would be "informative;" thus, it would not include regulatory requirements. Instead, it would be used to provide additional guidance and more examples than can be included in HB 133 itself. Such a publication or website could also be used to provide complete full-size copies of the various inspection forms and worksheets contained in HB 133 and other useful tools developed by jurisdictions. The publication or website could also include a variety of other information related to net contents verification and random sampling and could include appropriate information from federal regulations and policies as well as frequently asked questions (FAQs). Currently in NIST Handbook 130 (HB 130) Interpretations and Guidelines there are sections related to moisture loss, point-of-pack inspections and administrative procedures which may not be well known or readily accessible. These could be updated and moved to the new publication or website.

For example:

- 2.2.5. Lot, Shipment, or Delivery
- 2.5.6. Guidelines for NCWM Resolution of Requests for Recognition of Moisture Loss in Other Packaged Products
- 2.6.10. Model Guidelines for the Administrative Review Process
- 2.6.11. Good Quantity Control Practices
- 2.6.12. Point-of-Pack Inspection Guidelines

These documents are shown below in Reference Section I.

Another example of the type of package information which could be included in a publication or website for reference purposes is the following report on a meeting held at NIST in 2005 to address concerns over packer supplied tare values.

NIST Weights and Measures Today November 2005 Report of Meeting on Tare

On November 2, 2005, the Laws and Metric Group at NIST hosted a meeting to discuss ways to improve the communication of tare information between packers and retailers when meat products are packaged at a plant, but weighed and labeled at the retail store. Representatives from the meat

packing industry, the retail food industry, and several weights and measures agencies attended the meeting.

The Problem

There is a fundamental change occurring in the retail food marketplace. Retail food stores are shifting from having in-store meat cutters to purchasing already-packaged meat from an outside plant. The supplying plant provides the retail store with packaged meat (including tray, soakers, and overwrap), and the store is then responsible for weighing and labeling the package. In order to weigh and label these products properly, the retail store needs to know the weight of the packaging materials used by the plant (i.e., the tare weight). While this may sound simple and straightforward, it is not.

Retailers

Many retail food chains manage their tare weights from a central location. Tares are maintained at the central or regional office and downloaded to the individual stores on a routine basis. While individual stores may have the ability to override the tare provided in a download (e.g., when an official from weights and measures informs them that they are using an incorrect tare), this correction will be erased when the next download occurs. Several retail food chains believe that the centralized management of tare information is critical to the overall success of their meat departments. With little cutting and packaging being done at the retail level, stores rarely have experienced, professional staff in their meat departments. Without significant expertise at the store level, food retailers are reluctant to leave decisions regarding the use and amount of tare to individual store management.

Weights and Measures Officials

When weights and measures officials find inaccuracies in tares being used, often these inaccuracies are not being communicated to the food retailer's central or regional offices. If the food retailer's central or regional office is not informed that a tare value is inaccurate, then the tare value will not get changed in the next download. While some retail food chains require their store managers to submit copies of inspection reports to the central or regional office, many do not. Some chains leave that decision to the discretion of the individual store managers. Individual store managers may be reluctant to forward disparaging information about their store's performance to the central or regional office. As a result, when weights and measures officials find an inaccurate tare being used in a store and only notify store management of the correction necessary, that information may not be communicated to the people who really need to know—the people at the central or regional office who set the tare values for the entire chain of stores.

Packers

The weight of tare materials used at a meat packing plant varies regularly. Whenever the plant changes suppliers, whether it is suppliers providing soakers, trays, or overwrap, the tare must be reevaluated and changed. Whenever suppliers change the materials used in their products, the tare must be reevaluated and changed. Most meat packers monitor tare continuously and regularly make small adjustments to ensure their packages are accurate. While tare information is routinely shared with retailers, it is difficult to ensure that the correct tare goes on the correct package. Packers may ship individual packages from several different production lots (lots which may have been packaged using different tare materials) in a single shipment to a retailer's warehouse. The retailer's warehouse then further breaks up these package groups to distribute packages to individual stores. Even if accurate tare information for all packages is provided to the retailer's central or regional office, the retailer has difficulty using this information effectively since not all packages of the same product at the same location will necessarily have the same tare. In addition, new tare information provided to a retailer may only apply to packages still in the retailer's warehouse (and not those presently in the store). This means retailers must coordinate the updating of tare data with the placement of new packages on the store shelves.

Is There a Solution?

The question remains: How do you effectively ensure that the tare information for a particular package “travels” with the package from the point of production to the final retail destination? One suggestion has been to print tare information directly on individual packages. However, packers and retailers all agree that printing tare information on packages, shipping cases, or shipping invoice forms would not be effective. Packers order packaging materials and shipping containers months in advance and at that point could only guess as to what amount of tare would need to be preprinted on these materials. In addition, if tare information were provided on individual packages, shipping cases, or shipping invoices, that information would only be available at the retail store and would never reach the retailer’s central or regional office in time to be included in the next download. Most retail food chains do not want individual stores making independent decisions about what tares to use.

Ultimately, the key will be for packers and retailers to communicate more frequently and more effectively. To that end, the American Meat Institute (AMI) has agreed to contact other trade associations representing the retail and meat packing industries to ask for their help in reiterating to their members the importance of accurate net weight labeling at retail. AMI will encourage their packer and processor members to communicate tare values to retail customers whenever changes in tare values occur.

How Can Weights and Measures Officials Help?

Weights and measures agencies can help by sending copies of test reports (especially from failed inspections) to the corporate or regional office of the retailer. While ideally the corporate or regional office will receive this information from the retail store, retailers at this meeting stressed they would rather receive duplicate reports (from the weights and measures agency and the store) than none at all. Retailers consider it absolutely critical that weights and measures officials contact, communicate, and work with the corporate and regional offices early and often. Retailers specifically asked that weights and measures agencies not wait for problems to escalate before they get the corporate or regional offices involved. Weights and measures officials should conduct package inspections in full compliance with NIST Handbook 133 (HB 133). Inspectors are encouraged to properly clean tare materials during inspections to avoid imposing tares larger than they should be.

According to HB 133, Used Dry Tare is “tare material that has been air dried, or dried in some manner to simulate the unused tare weight.” Before adding this definition to HB 133, members of the NCWM and NIST did extensive testing to compare the weights of Unused Dry Tare (which the packer uses), and Used Dry Tare (which the inspector uses). If Used Dry Tare is dried and cleaned properly, its weight should not vary significantly from the Unused Dry Tare weight. In addition, NIST strongly discourages the use of microwave ovens when drying tare materials, particularly soaker pads. Past tests have shown that excessive heating of soaker pads and other tare materials can significantly alter their weight, and even start a fire as some officials have learned.

Following the 2007 Annual Meeting NIST WMD published the following article in its quarterly newsletter to provide additional guidance to officials on how to provide moisture allowances for packages.

MOISTURE LOSS AND GEL SOAKER PADS—WHAT DO I DO?

Tom Coleman

Weights and Measures Today – September 2007 – Volume 10 Number 3, Page 4

Moisture loss is the loss of weight or volume after packaging. Packaged products (e.g., cookies, granulated sugar), however, may gain as well as lose moisture. The amount of loss or gain depends on many factors including but not limited to the nature of the product, packaging material, length of time “offered for sale,” environmental conditions, and many other

combinations of “similar” circumstances. Loss of weight may include solvent evaporation and natural juices—not just the loss of water. Tare determinations can be very simple or a major concern depending on the type of tare material and the weight consistency of that substance. Unused dry tare (when available and applicable) may be the easiest of the tares to determine. Gel soaker pads may not be seen and tested as often, however they may prove to be equally basic. NIST Handbook 133 “Checking the Net Contents of Packaged Goods” provides the following guideline for all tare determinations:

“Tare material includes all packaging materials that can be separated from the packaged product, either readily (e.g., by shaking) or by washing, scraping, ambient air drying, or other techniques involving more than ‘normal’ household recovery procedures, but not including laboratory procedures like oven drying.” Except for aerosol or other pressurized packages, open the sample packages, empty, clean, and dry the tare material as appropriate for the packaging material. When testing packaged product using gel soaker pads, three types of tare may be used. Used dry tare – used dry tare is tare material that has been air dried or dried in some manner to simulate the unused tare weight. It includes all packaging materials that can be separated from the packaged product, either readily (e.g., by shaking) or by washing, scraping, ambient air drying, or other techniques involving more than “normal” household recovery procedures, but not including laboratory procedures like oven drying. Labels, wire closures, staples, prizes, decorations, and such are considered tare. Used dry tare is available regardless of where the packages are tested. Unused dry tare – if testing packages in retail store locations where they are packaged and sold in small quantities to the ultimate consumers, the basic test procedures may be modified by using samples of the packaging material if available in the store. Wet tare – if wet tare is used, follow the procedures described in the used dry tare section above, except make no effort to dry the tare material. The following six steps apply when gravimetrically testing any type of packaged product:

1. Identify and define the inspection lot.
2. Select the sampling plan.
3. Select the random sample.
4. Measure the net contents of the packages in the sample.
5. Evaluate compliance with the maximum allowable variation (MAV) requirement.
6. Evaluate compliance with the average requirement. If, when following these steps using either unused dry tare, used dry tare, or wet tare, the product is found to contain less than the quantity represented, or if there is a violation of the maximum allowable variation (MAV) requirement, provide a copy of the test results to the appropriate store authority. Once this has been accomplished, the “field” test is complete. If upon receipt of the “official” test report the manufacturer wishes to contest the inspection results based on the “loss or gain of moisture,” official notification shall be directed to the appropriate weights and measures administrator for consideration/verification.

***If testing flour, dry pet food or USDA packages of fresh poultry, franks, hotdogs, bacon, fresh sausage, and luncheon meats, specific instructions are provided in NIST Handbook 133, moisture allowances, page 17. Note: dry pet food means all extruded dog and cat foods and baked treat products packaged in Kraft paper bags and/or cardboard boxes with a moisture content of 13 % or less at the time of pack.

If you have any questions or need additional information regarding moisture loss, please contact Lisa Warfield at (301) 975-3308 or at lisa.warfield@nist.gov or Ken Butcher at (301) 975-4859 or at kbutcher@nist.gov.

REFERENCE SECTION I – EXCERPTS FROM THE INTERPRETATIONS AND GUIDELINES SECTION OF NIST HANDBOOK 130

The following are currently in NIST Handbook 130 (HB 130) Interpretations and Guidelines

2.2.5. Lot, Shipment, or Delivery

(L&R, 1981, p. 95)

Policy

The requirements for the average package net contents to meet or exceed the labeled declaration may be applied to production lots, shipments, or deliveries. Shipments or deliveries are smaller collections of packages than production lots that may or may not consist of mixed lot codes.

Emphasis in inspection activities should be placed on warehouse and in-plant testing without neglecting retail consumer protection.

Background

The Committee heard a petition from the California Brewers Association to define a lot as:

“A selection of containers under one roof produced by a single company of the same size, type and style, manufactured or packed under similar conditions with a minimum number to be equivalent to one production line shift.”

The intention of the petition is to focus Weights and Measures enforcement on production lots as opposed to small collections of packages on retail shelves, because the production lot is under the control of the packager.

An alternative proposal was made that would require mingling of lot and date codes in package inspection at warehouse locations.

The Committee has reviewed the proposals in light of Section 7.6. and Section 12.1. of the Uniform Packaging and Labeling Regulation which refers to “shipment, delivery, or lot.” If the petition is approved, the terms “shipment” and “delivery” would have to be dropped from this Uniform Regulation.

The Committee recognizes the inherent value of in-plant and warehouse inspection and is of the opinion that, wherever possible, such inspections should be carried out. At the same time, the Committee recognizes the need for the state and local weights and measures officials to protect the consumer at the level where the ultimate sale is made. Therefore, the Committee recommends no change to the Uniform Regulation.

The Committee looks forward to the work of the Special Study Group on Enforcement Uniformity of the NCWM which will be exploring the mechanisms that might be instituted to make in-plant inspection workable.

2.5.6. Guidelines for NCWM Resolution of Requests for Recognition of Moisture Loss in Other Packaged Products

(Exec, 1988, p. 94)

The Task Force on Commodity Requirements limited its work to only a few product categories, using these categories as models for addressing moisture loss. The gray-area concept is the result of this work.

Recognizing several candidates for future work in moisture loss, the Task Force recommends that the following guidelines for moisture loss be followed as far as possible by any industry requesting consideration:

1. There should be reasonable uniformity in the moisture content of the product category. For example, since pet food has final moisture contents ranging from very moist to very dry, some subcategorization of pet food needs to be defined by industry before the NCWM study of the issue.

2. The predominant type of moisture loss (whether into the atmosphere or into the packaging materials) must be specified.
3. Different types of packaging might make it necessary to subcategorize the product. For example, pasta is packaged in cardboard, in polyethylene, or other packaging more impervious to moisture loss. The industry should define the domain of packaging materials to be considered.
4. “Real-world” data is needed on the product as found in the retail marketing chain—not just laboratory moisture-loss data.
5. The industry requesting consideration of moisture loss for its product should collect data on an industry-wide basis (rather than from only one or two companies).

Information concerning the relative fractions of imported and domestically produced product should be available, for example, in order to assess the feasibility of interacting with the manufacturer on specific problem lots.

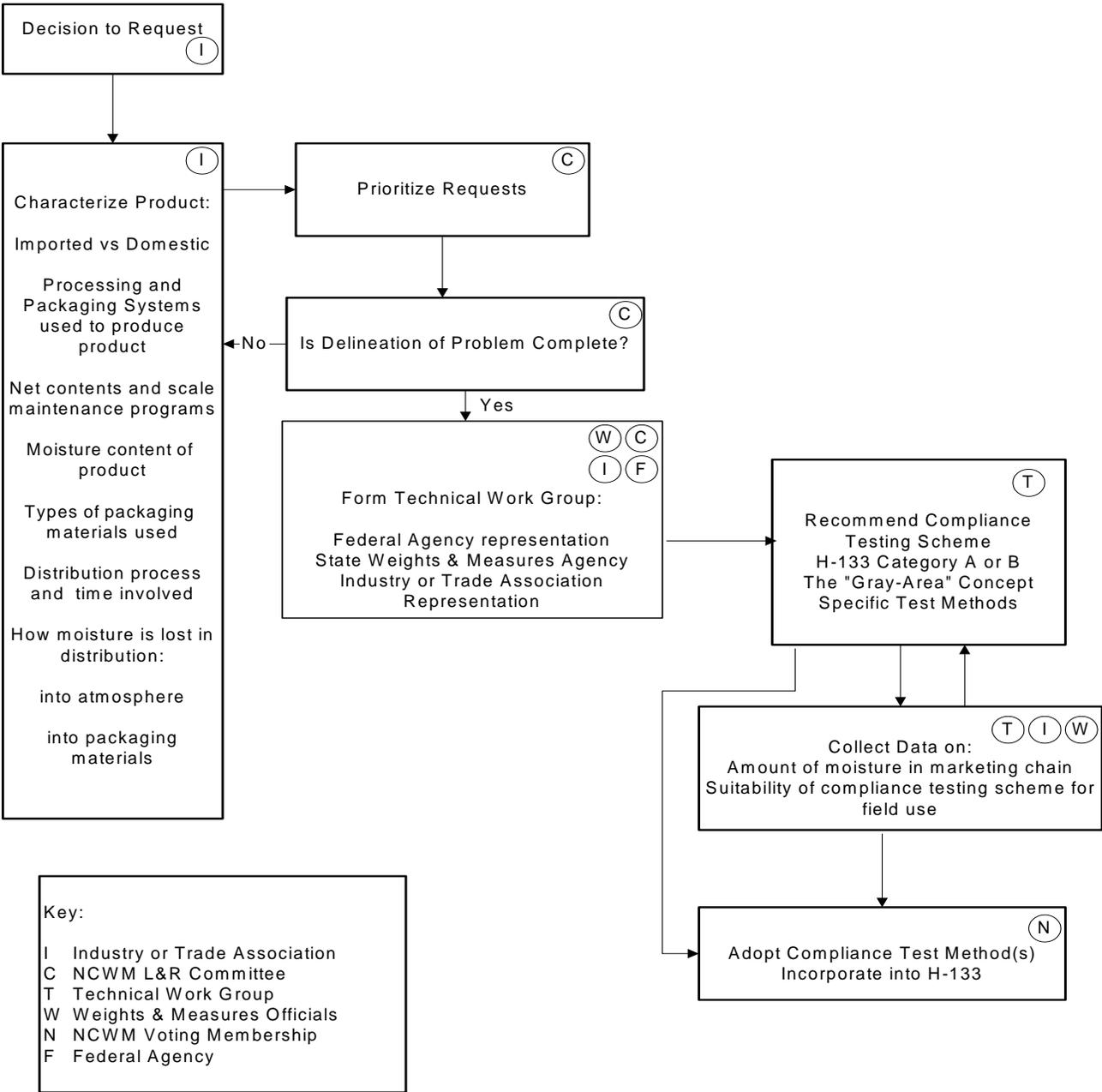
6. Moisture loss may occur either:
 - during manufacturing or
 - during distribution.

Data will be needed to show the relative proportion of moisture loss in these different locations since moisture loss is permitted only under good distribution practices. Geographical and seasonal variations may apply.

7. A description of the processing and packaging methods in use in the industry will be of great value, as will a description of the distribution system and time for manufacturing and distribution. A description of the existing net quantity control programs in place should be given, together with information on how compliance with Handbook 133 is obtained. A description of maintenance and inspection procedures for the scales should be provided, together with information on suitability of equipment and other measurements under Handbook 44.
8. A description of federal and local agency jurisdiction and test should be given, as well as any regulatory history with respect to moisture loss and short weight. Has weights and measures enforcement generated the request? What efforts have addressed the moisture loss issue prior to approaching the NCWM? Are the appropriate federal agencies aware of the industry's request to the NCWM?
9. The industry should propose the type of compliance system and/or moisture determination methodology to be used. The compliance scheme, if it contains industry data components, should be susceptible to verification (examples: USDA net weight tests for meat; exchange of samples with millers for flour) and should state what the companies will do to provide data to field inspection agencies in an ongoing fashion (as the gray-area approach requires). If in-plant testing is to be combined with field testing, who is to do such testing, and how is this to be accomplished? It should be possible to incorporate the proposed testing scheme into Handbook 133 to be used with Category A or B sampling plans.

When all the preliminary information recommended above has been collected, a field test of the proposed compliance scheme should be conducted by weights and measures enforcement officials to prove its viability. See the plan diagrammed on the next page.

Plan For NCWM Resolution of Individual Requests For Recognition of Moisture Loss



2.6.10. Model Guidelines for the Administrative Review Process

Purpose

These guidelines are provided to assist weights and measures programs in establishing an administrative review process. They are not intended to be the only process an agency may use nor are they intended to supersede any agency's existing process. Before implementing ANY process, it should be approved by legal counsel.

These guidelines ensure that persons affected by “inspection findings” (e.g., price misrepresentations or shortweight packages), or who are deprived of the use of their property (devices or packages placed under “stop” or “off-sale” order), are provided a timely-independent review of the action. The process enables affected persons to provide evidence which could be relevant in determining whether the enforcement action was proper. The purpose of the process is to ensure that a person's ability to conduct business is not hindered by improper enforcement actions. This process is independent of any other action (e.g., administrative penalties, prosecutions, etc.) that may be taken by the enforcement agency.

Background

In the course of their work, weights and measures officials take enforcement actions that may prohibit the use of devices or the sale of packaged goods (e.g., “stop-sale” or “off-sale” orders for packages and “stop-use” or “condemnation” tags issued on devices). Improper actions (e.g., not following prescribed test procedures, enforcing labeling requirements on exempted packages, or incorrectly citing someone for a “violation”) place the official and the jurisdiction in the position of being liable for the action if it is found that the action was “illegal.” In some cases, weights and measures jurisdictions could be ordered to pay monetary damages to compensate the affected party for the improper action.

This process is one way to provide affected persons an opportunity to present evidence which may be relevant in determining whether the order or finding has been properly made to an independent party. The procedure enables business operators to obtain an independent review of orders or findings so that actions affecting their business can be evaluated administratively instead of through litigation. This ensures timely review, which is essential because of the impact that such actions may have on the ability of a business to operate and in cases where perishable products may be lost.

Review Provisions

Parties affected by enforcement actions must be given the opportunity to appeal enforcement actions.

Inspectors are the primary contacts with regulated firms and thus are in the best position to ensure that the enforcement actions taken are “proper.” “Proper” means that inspections are conducted (1) within the scope of the authority granted by law, (2) according to recognized investigative or testing procedures and standards, and (3) that enforcement actions are lawful. The burden for proving that actions are proper falls on the weights and measures program, not on regulated firms.

Weights and measures officials are law enforcement officers; therefore, they have the responsibility to exercise their authority within the “due process” provisions of the U.S. Constitution. As weights and measure programs carry out their enforcement responsibilities in the future, more and more challenges to their actions and authority will occur. It is in the best interest of any program to establish strict operational procedures and standards of conduct to prevent the occurrence of improper actions that may place the jurisdiction in an untenable position in a court challenge of an enforcement action. The foundation for ensuring proper actions is training, clear and concise requirements, and adoption of and adherence to uniform test procedures and legal procedures.

Prior to taking enforcement actions, the inspector should recheck test results and determine that the information on which the action will be taken is accurate.

Inspections shall be conducted with the understanding that the findings will be clearly and plainly documented and reviewed with the store's representative.

During the review of the findings, the firm's representative may provide information which must be used by the inspector to resolve the problems and concerns before enforcement actions are taken. In some cases, the provided

information may not persuade the inspector to forego the action. In some cases the inspector and business representative may not understand the circumstances surrounding the violations, or there may be a conflict between the parties that they cannot resolve. In other cases, the owner or manufacturer may not learn that an enforcement action has occurred until long after the inspector leaves the establishment.

Steps:

1. Provide a framework that will help in resolving most of these situations where “due process” is of concern. Make sure that the responsible party (e.g., as declared on the package label) is notified of violations and receives copies of inspection reports. Establish standard operating procedures to assure the affected party of timely access to a representative of the weights and measures program so that the firm can provide the relevant information or obtain clarification of legal requirements.
2. Make the process as simple and convenient as possible. Especially in distant or rural areas where there are no local offices, the review should be conducted by a supervisor of the official taking the action if agreed to by the person filing the request for review.
3. The process should include notice that the firm can seek review at a higher level in the weights and measures program or an independent review by a third party. The following procedures are recommended:

- (a) Any owner, distributor, packager, or retailer of a device ordered out of service, or item or commodity ordered “off-sale,” or inspection finding (e.g., a price misrepresentation or a shortweight lot of packages) shall be entitled to a timely review of such order, to a prompt, impartial, administrative review of such off-sale order or finding.

A notice of the right to administrative review should be included on all orders or reports of findings or violations and should be communicated to the responsible firm (e.g., person or firm identified on the product label):

- (b) The administrative review shall be conducted by an independent party designated by the Director or before an independent hearing officer appointed by the Department. The officer shall not be a person responsible for weights and measures administration or enforcement.
- (c) No fees should be imposed for the administrative review process.

Sample Notice

You have the right to Administrative Review of this order or finding. To obtain a review, contact the Director of Weights and Measures by telephone or send a written request (either postmarked, faxed, or hand delivered) to:

(Name, Address or Fax Number of the Director or other Designated Official)

Your request should reference any information that you believe supports the withdrawal or modification of the order or finding.

- (d) The firm responsible for the product or the retailer may introduce any record or other relevant evidence.

For example:

- (i) Commodities subject to the off-sale action or other findings were produced, processed, packaged, priced, or labeled in accordance with applicable laws, regulations or requirements.
 - (ii) Devices subject to the “stop-use” order or “condemnation” were maintained in accordance with applicable laws, regulations or requirements.
 - (iii) Prescribed test procedures or sampling plans were not followed by the inspector.
 - (iv) Mitigating circumstances existed which should be considered.
- (e) The reviewer must consider the inspector's report, findings, and actions as well as any evidence introduced by the owner, distributor, packager, or retailer as part of the review process.
 - (f) The reviewer must provide a timely written recommendation following review unless additional time is agreed to by the department and the petitioner.
 - (g) The reviewer may recommend to the Department that an order be upheld, withdrawn or modified. If justified the reviewer may recommend other action including a reinspection of the device or commodity based upon information presented during the review.
 - (h) All actions should be documented and all parties advised in writing of the results of the review. The report of action should be detailed in that it provides the reasons for the decision.

2.6.11. Good Quantity Control Practices

Good Quantity Control Practices means that the plant managers should take all reasonable precautions to ensure the following quantity control standards or their equivalent are met:

1. A formal quantity control function is in place with authority to review production processes and records, investigate possible errors, and approve, control, or reject lots.
2. Adequate facilities (e.g., equipment, standards and work areas) for conducting quantity control functions are provided and maintained.
3. A quantity control program (e.g., a system of statistical process control) is in place and maintained.
4. Sampling is conducted at a frequency appropriate to the product process to ensure that the data obtained is representative of the production lot.
5. Production records are maintained to provide a history of the filling and net content labeling of the product.
6. Each “production lot” contains on the average the labeled quantity and the number of packages exceeding the specified maximum allowable variation (MAV) value in the inspection sample shall be no more than permitted in Tables 2-1 and 2-2 in NIST Handbook 133.
7. Packaging practices are appropriate for specific products and measurement procedures (e.g., quantity sampling, density and tare determinations) and guidelines for recording and maintaining test results are documented.
8. Personnel responsible for quantity control follow written work instructions and are competent to perform their duties (e.g., background, education, experience and training). Training is conducted at sufficient intervals to ensure good practices.

9. Recognized procedures are used for the selection, maintenance, adjustment, and testing of filling equipment to insure proper fill control.
10. Weighing and measuring devices are suitable for their intended purpose, and measurement standards are suitable and traceable to national standards. This includes a system of equipment maintenance and calibration to include recordkeeping procedures.
11. Controls over automated data systems and software used in quantity control ensure that information is accessible, but changeable only by authorized personnel.
12. Tare materials are monitored for variation. Label changes are controlled to ensure net quantity matches labeled declaration.

2.6.12. Point-of-Pack Inspection Guidelines

A. Weights and Measures Officials' Responsibilities

1. Conduct inspections during hours when the plant is normally open for business. Open the inspection by making contact with the plant manager or authorized representative (e.g., the quality assurance manager or the production manager).
2. Present the proper credentials and explain the reason for the visit (e.g., routine or follow-up inspection or consumer complaint, etc.).
3. Request access to quantity measurement equipment in the packing room, moisture testing equipment in the laboratory or in the packing room, and product packed on premise or stored in warehouse areas.
4. Obtain permission from a plant representative prior to using a tape recorder or a camera.
5. Conduct inspection-related activities in a professional and appropriate manner and, if possible, work in an area that will not interfere with normal activities of the establishment.
6. Abide by all the safety and sanitary requirements of the establishment and clean the work area upon completion of the inspection/test. Return borrowed equipment and materials.
7. To close the inspection, recheck inspection reports in detail and ascertain that all information is complete and correct.
8. Sample questions and tasks for Inspectors:
 - a. Inside Buildings and Equipment:
 - (i) Is all filling and associated equipment in good repair?
 - (ii) Are net content measurement devices suitable for the purpose being used?
 - (iii) Are standards used by the firm to verify device accuracy traceable to NIST?
 - b. Packing Room Inspection:
 - (i) Observe if the program for net quantity of content control in the packing room is actually being carried out.
 - (ii) Ensure that the weighing systems are suitable and tare determination procedures are adequate. If there are questions regarding tare determination, weigh a representative number of tare and/or filled packages.

(iii) For products labeled and filled by volume and then checked by weight, ensure that proper density is used.

c. Warehouse Inspection:

If an inspection is conducted:

- (i) Select lot(s) to be evaluated.
 - (ii) Determine the number of samples to be inspected. Use the appropriate sampling plan as described in NIST Handbook 133.
 - (iii) Randomly select the number of samples or use a mutually agreed on plan for selecting the samples.
 - (iv) Determine the average net quantity of the sample and use the standard deviation factor to compute the Sample Error Limit (SEL) to evaluate the lot.
 - (v) Look for individual values that exceed the applicable Maximum Allowable Variation as found in NIST Handbook 133.
 - (vi) Apply moisture allowances, if applicable.
 - (vii) Review the general condition of the warehouse relevant to package integrity, good quantity control, and distribution practices.
 - (viii) Prepare an inspection report to detail findings and actions.
9. Close the inspection – Review findings with Plant Representative.

After the inspection, meet with the management representative to discuss inspection findings and observations. Provide additional information as needed (e.g., information on laws and regulations or explanations of test procedures used in the inspection). Be informative, courteous and responsive. If problems/violations are found during the inspection/test, bring them to the attention of the appropriate person.

B. Plant Management Responsibilities

1. Recognize that inspectors are enforcing a federal, state or local law.
2. Assist the official in conducting inspection activities in a timely and efficient manner.
3. During the initial conference with the inspector, find out whether the inspection is routine, a follow-up, or the result of a consumer complaint. If a complaint, obtain as much information as possible concerning the nature of the complaint, allowing for an appropriate response.
4. The plant manager, quality assurance manager, or any designated representative should accompany the inspector.
5. Plant personnel should take note of the inspector's comments during the inspection and prepare a detailed write-up as soon as the inspection is completed.
6. When an official presents an inspection report, discuss the observations and, if possible, provide explanations for any changes deemed necessary as a result of the inspection/test.

Plant Management: Information that must be shared with the inspector.

1. Establishment name and address.
2. Type of firm and information on related firms or applicable information (e.g., sub-contractor, servant or agent).
3. General description and location of shipping and storage areas where packaged goods intended for distribution are stored.
4. Commodities manufactured by or stored at the facility.
5. Names of responsible plant officials.

Plant Management: Information that may be shared with the inspector.

1. Simple flow sheet of the filling process with appropriate net content control checkpoints.
2. Weighing or measuring device maintenance and calibration test records.
3. Type of quantity control tests and methods used.
4. Net content control charts for any lot, shipment, or delivery in question or lots which have previously been cited.
5. Method of date coding the product to include code interpretation.
6. Laboratory reports showing the moisture analysis of the products which are in question or have been previously cited.
7. Product volume of lot sizes or related information.
8. Distribution records related to any problem lots including names of customers.

REFERENCE SECTION II – OTHER MOISTURE LOSS GUIDANCE AND RELATED DOCUMENTS

This section contains the text from a WMD memorandum to state weights and measures directors and other interested parties and a letter from Kraft General Foods stating the reasons justifying a withdrawal of the WMD memorandum.

A. Text from the WMD Memorandum that was issued on January 1, 2006

Memorandum for State Weights and Measures Directors and Other Interested Parties

Subject: Verifying the Net Contents of Packaged Goods and Recommended Procedures for Moisture Allowances

This memo supersedes the April 3, 1995, memorandum from the Weights and Measures Division (WMD) concerning the impact of the Nutrition Labeling and Education Act of 1990 (NLEA) on net content testing by State and local weights and measures officials.

I am revising the earlier correspondence primarily in response to the National Conference on Weights and Measures' (NCWM) adoption of the fourth edition (January 2005) of the National Institute of Standards and Technology's Handbook 133 "Checking the Net Contents of Packaged Goods" (Handbook 133). Recent inquiries from State officials on the status of package inspection programs that test products subject to Food and Drug Administration (FDA) jurisdiction have further prompted a response. This memorandum describes guidance provided by FDA. Since 1985 that agency has advised NIST that Handbook 133 has not been in conflict with that agency's practices enforcing net quantity of content on packaged foods.

I. Recommendations for Verifying the Net Quantity of Contents of Packages Subject to FDA Jurisdiction

WMD recommends that weights and measures officials use the fourth edition of Handbook 133 (January 2005) for all products except those subject to regulation by the U.S. Department of Agriculture (USDA), which has adopted the third edition of Handbook 133 and its 4th Supplement.¹ NIST recently learned that the USDA may adopt the 2005 edition of Handbook 133 in the near future. These publications are available on the Internet.²

The Category A Sampling Plans in Handbook 133 provide a statistically valid sampling scheme and sample correction factors to enable you to determine if a sample passes or fails a test with a confidence level of at least 97 %. The test methods prescribed for foods are consistent with those used by the FDA.³

Weights and measures officials must apply both the "average" and "individual package" requirements in Handbook 133 to the packages they inspect because Federal and State laws and regulations relating to net quantity of content require officials to allow reasonable variations (both plus and minus errors in net contents) from the labeled net contents. By applying both requirements, officials avoid the appearance

¹ See 9CFR317.19 and 9CFR381.121b for the applicable meat and poultry regulations.

² The 3rd Edition and 4th Supplement required by USDA and the January 2005 4th Edition of Handbook 133 are free at <http://ts.nist.gov/WeightsAndMeasures/h1334-05.cfm> on the Internet.

³ Historically, the FDA has used enforcement procedures based on a 95 % confidence level that findings of underfill are accurate. The Category A Sampling Plans in the fourth edition of Handbook 133 are based on an approximate 97 % confidence level that the findings are accurate; therefore, these plans should be acceptable to use in testing packages under FDA jurisdiction.

they are imposing a “minimum” net content system⁴ while providing a high level of protection for consumers and ensuring fair competition in the marketplace.

Weights and Measures Officials should continue to test packages at retail and should consider Section 1.1. of Handbook 133 before taking enforcement action on small inspection lots of package:

Testing packages at retail outlets evaluates the soundness of the manufacturing, distributing, and retailing processes of the widest variety of goods at a single location. It is an easily accessible, practical means for State, county and city jurisdictions to monitor packaging procedures and to detect present or potential problems. Generally, retail package testing is not conducive to checking large quantities of individual products of any single production lot. Therefore, follow-up inspections of a particular brand or lot code number at a number of retail and wholesale outlets, and ultimately at the point-of-pack are extremely important aspects in any package-checking scheme. After the evaluation of an inspection lot is completed, the jurisdiction should consider what, if any, further investigation or follow-up is warranted. At the point-of-sale, a large number of processes may affect the quality or quantity of the product. Therefore, there may be many reasons for any inspection lot being out of compliance. A shortage in weight or measure may result from mishandling the product in the store, or the retailer’s failure to rotate stock. Shortages may also be caused through mishandling by a distributor, or failure of some part of the packaging process. Shortages may also be caused by moisture loss (desiccation) if the product is packaged in permeable media. Therefore, being able to determine the cause of an error in order to correct defects is more difficult when retail testing is used.

It is important to realize that the Category A Sampling Plans in Handbook 133, while statistically valid, may fail lots that contain the labeled net quantity of content approximately three times out of 100 tests. By basing enforcement actions on samples from multiple lots of the same product from the same manufacturer tested at different locations, you will have a better indication of whether or not an enforcement action is necessary. When a lot fails an inspection, NIST recommends you contact the manufacturer to obtain quantity control records and other production information on the lot to assist in your decision process. To ensure due process, we encourage jurisdictions to follow the NCWM’s Section 2.6.10. Model Guidelines for the Administrative Review Process in NIST Handbook 130 “Uniform Laws and Regulations in the area of legal metrology...” (Those guidelines are shown below this memorandum) for reference but, your agency’s general counsel may of course have you follow other procedures. When following up on possible violations with manufacturers, recognize they are required under Federal and State laws or regulations to follow current good manufacturing practices. The NCWM has also adopted guidelines in Section 2.6.11. on “Good Quantity Control Practices” that officials can use as a tool to assess quantity control systems. (These are provided below).

Weights and Measures officials should conduct inspections at the point of pack whenever possible so they will have access to larger lots of packages and can also assess the packager’s entire packaging system. The NCWM adopted guidelines in Section 2.6.12. on “point-of-pack inspections” to help officials conduct these inspections, (See below this memorandum).

We encourage jurisdictions to collaborate on conducting marketplace surveys to determine the level of compliance of commodity groups (e.g., store-packed random weight items, mulch, polyethylene sheeting, flour, milk, soft drinks, animal food, etc.) and to work together to follow up on possible problems at the point-of-pack where the packaging plant or distribution point is located in a jurisdiction other than where the packages failed to pass a test. The State of California conducts a wide variety of marketplace surveys which can serve as model for other states to follow. NIST encourages all states to follow the example set by California’s Division of Measurement Standards for monitoring compliance in the all areas of weights

⁴ Under a “minimum” net content system (these systems are common in European countries), no package in a sample may contain less than the net quantity of contents stated on the package label.

and measures enforcement. NIST will provide assist to states who want to conduct or collaborate in surveys...

Ensure that all samples are selected randomly. The statistical reliability of the sampling plans is valid only when the sample has been randomly selected from the inspection lot.

To be consistent with FDA inspection activities, utilize used dry tare when taking enforcement actions. The handbook permits unused dry tare to be used to conduct audits and to verify net weights of packages put up in retail stores.

Apply the average and individual package requirements to products tested at any point in distribution. Over the last ten years several jurisdictions have contacted WMD concerning industry claims that States can only take action on production lots. FDA advises that there are no provisions in the Federal Food, Drug, and Cosmetic Act or its legislative history that support this claim. Another issue that WMD has been asked about is the claim that the FDA has a “1 %” tolerance that States must permit. FDA advises that they have a policy for their field compliance staff to use in determining whether or not to request enforcement actions by the U.S. Justice Department. The only purpose for the policy is for FDA to prioritize agency resources, not to set a limit for State enforcement actions. The FDA also reports that it did not establish this policy as a statistical allowance or tolerance that could be easily abused by an unscrupulous packager.

Allow for reasonable moisture loss.

The following Federal regulation preempts any State or local requirement that is not identical:

21 CFR § 101.105

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

State and local jurisdictions must allow reasonable variations in net contents caused by the loss or gain of moisture in food products that occurs during good distribution practice. If not, a jurisdiction may be questioned if enforcement action is taken against the product. The moisture loss issue has challenged weights and measures officials and industry since the Federal Food, Drug, and Cosmetic Act allowing for moisture loss was passed more than 75 years ago. However, the fact that FDA has not adopted specific moisture allowances is not justification for not making reasonable allowances for moisture loss.

The NCWM has adopted moisture allowances (also called “gray areas”) for flour, dry pet food, chicken, and hot dogs. Under the “gray area” concept, any food found short in excess of the allowance is subject to enforcement action. If the product is found short, but within the allowance, the official would take additional steps (such as comparing the moisture content of a sample from the lot to the time-of-pack moisture content provided by the packer) to determine if the product is short because of underweighing at the time of pack, or if the shortage is due to “reasonable” moisture loss that occurred during distribution. WMD recommends that officials use the following guidelines with the “gray area” approach to allow reasonable moisture loss for the listed foods.

WMD only recommends moisture allowances. It is the individual jurisdiction's responsibility to make the final decision concerning appropriate moisture allowances. Final decisions should be made after considering moisture loss data provided by the packager.

II. Recommended Moisture Allowances for Some Foods

WMD has consulted with State and local weights and measures agencies and affected industries on moisture loss problems associated with hygroscopic foods. The following moisture allowances, beyond those already

addressed by the NCWM, are recommended. WMD used data from the FDA's Quantity of Contents Compendium as the major source for the numerical values for gray area recommendations. Moisture loss has been identified with flour, pasta, rice, cheese and cheese products, dried fruits and vegetables, fresh and frozen fruits and vegetables, coffee beans, and bakery products. Of all of these commodities, the extent of moisture loss variations is greatest for flour and pasta. Very little current data are available for many other commodities. However, WMD considers the need for allowances for affected commodities to be pressing and believes that States must make some allowance for these commodities until other data can be obtained for the respective commodities. If a recommended allowance is perceived as too lenient, weights and measures agencies may prevent abuses of the allowance through inspections at the point of pack. Allowances if too lenient provide are a disadvantage for firms with products in competition with packers where point-of-pack inspections may not be possible; consequently, such firms may wish to provide information to WMD so that we can recommend a more stringent allowance. Where allowances are too stringent, firms may also provide information justifying a more appropriate allowance. WMD suggests that firms desiring such an allowance be encouraged to work closely with the NCWM in view of its experience in this area. Even though the process of developing moisture allowances is time-consuming, affected firms will be provided some relief during the interim period if State and local agencies implement the following recommendations:

III. Moisture Allowances at Point of Pack

WMD recommends that moisture allowances at the point of pack not be made for packages taken immediately off the production line. However, regulatory officials may often encounter product at the point of pack that has been stored by the packer prior to shipment to other locations. In the past, moisture allowances have not been recognized in tests until the food is “introduced into interstate commerce;” however, since many manufacturers store the product for extended periods at the packing location, moisture loss should be recognized. It is recognized that moisture loss is a natural phenomenon that is not controlled or delayed by any specific schedule, and WMD recommends that, at some point during such storage, allowances be permitted for moisture loss. But, considering the multiplicity of foods, differences in packing materials, and the various environmental factors that affect moisture loss, it would be impossible for WMD to determine moisture loss that occurs on the packaging line or in the first few hours or days following the packaging of any one product type, let alone the tens of thousands of products that might be inspected at the point of pack. Certainly, some products begin to lose moisture immediately after packaging, but there must be some definitive guidance provided for weights and measures officials and industry.

This problem is not unique to the United States where we are trying to encourage State and local officials to focus more on point-of-pack inspections. WMD is aware that point-of-pack inspections are one of the primary tools used in European countries to control net contents in packaged goods. We have learned that in some of these countries officials make no allowance for moisture loss within the first 7 days of the date of pack for some products. As this is the only documented guidance on the issue available, WMD recommends that States consider a similar approach until other guidance on this issue is available. This will provide packers and officials with guidance on when moisture loss allowances must be applied and will enable officials to conduct inspections at point of pack to ensure that packers are not taking advantage of recognized allowances for moisture loss. To minimize the possibility of moisture loss considerations, officials should inspect the most recently packed items.

In 1995 WMD received comments on the 7-day recommendation from the Food Industry Weights and Measures Task Force (Task Force) of the Grocery Manufacturers of America. The Task Force was concerned the 7-day period was not reasonable because the data submitted to the NCWM to develop the gray areas for flour, dry pet food, and other products clearly showed that some products lose as much as 0.5 % to 1 % of their weight due to moisture loss in the first few days of packing. WMD acknowledged the industry's concerns about the 7-day period but believed then and now that the concerns can be addressed without dropping the recommendation. WMD believes it is crucial to have specific guidelines on moisture loss for use in point-of-pack inspections.

WMD recommends an exception to the 7-day period if the packer can provide daily moisture loss data collected using the following procedures. We have developed the following guidelines in collaboration with industry for packers to use the results of the short-term moisture loss studies at the point of pack. To be acceptable, the data

must be computed using the average moisture loss determined on a daily basis (e.g., the weight of each package in each of the sample control lots is determined every day for 7 days) in environmental conditions similar to those that exist when the product is being inspected. For example, an inspector visits a pet food plant in Ohio in the middle of July to conduct a point-of-pack inspection. If the product tested had been packaged 5 days before the inspection and is found underweight; the moisture loss data must reflect the loss that would occur in July not January. At least three sample control lots, consisting of at least 48 randomly selected packages, must be used to develop the moisture loss data. Each sample lot must be stored under the same conditions that are typical for the product (e.g., if the product is typically placed in a sealed case on a pallet and shrink wrapped, the sample lots must be stored under the same conditions. Moisture loss data obtained by removing the individual packages from the shipping case and storing them in a laboratory would not be acceptable). The three-sample control lots must be placed at various locations in the storage site. The average moisture loss value must be computed from the three-sample control lots with a 95 % prediction interval.

Since point-of-pack inspections are not routinely done in most jurisdictions at this time, there will be many situations where packers may not have “acceptable” moisture loss data for a particular product found to be underweight at the time of a point-of-pack inspection. In these cases, WMD recommends the packer be allowed to conduct a study using the criteria specified above. This data could then be provided to the weights and measures official for use in making a final determination whether or not moisture loss caused the product to be underweight. One benefit of this approach is that the moisture loss study can be conducted within a few days of the inspector finding the inspection lot underweight so the test will more closely reflect the environmental conditions under which the original inspection lot was subject.

A similar recommendation is included for fresh bakery products weighed within 1 day following the end of the day of pack (in this case the moisture loss data would have to be based on the amount of moisture lost on an hourly basis under the same conditions listed above for the 7-day period). WMD will provide technical assistance on request to any jurisdiction to resolve these individual moisture loss cases by working with you and the packer and will seek FDA assistance in resolving these situations.

IV. Recommended Moisture Allowances for Use at Point of Pack and Testing at Any Other Location

Provide the following allowances for moisture loss (expressed as a percentage of the labeled net quantity of contents):

1. No allowance for moisture loss should be made if:
 - (a) A food, other than a fresh bakery product, while stored by the packer, is weighed within 7 days following the end of the day of pack, except when the packer provides acceptable (see note below) documentation of the moisture loss for the product in storage at the point-of-pack, or
 - (b) A fresh bakery product, while stored by the packer, is weighed within 1 day following the end of the day of pack, except when the packer provides acceptable (see note below) documentation of the moisture loss for the product in storage at the point of pack, or
 - (c) The food is not subject to moisture loss, or
 - (d) The food is packaged in an air-/moisture-tight container (e.g., cans, glass bottles, enclosed in paraffin, etc).
2. Allow 1 % for the following foods: frozen fruits and frozen vegetables, and fresh baked breads, buns, rolls and muffins.
3. Allow 3 % for the following foods: flour, dry pet food, pasta, rice, cheese and cheese products, dried fruits and vegetables, fresh fruits and vegetables, coffee beans, and bakery products other than fresh baked breads, buns, rolls and muffins.

Note for Moisture Allowances at Point of Pack: The data must be computed using the average moisture loss determined on a daily basis (e.g., the weight of each package in each of the sample control lots is determined every day for 7 days) in environmental conditions similar to those that exist when the product is being inspected. For example, an inspector visits a pet food plant in Ohio in the middle of July to conduct a point-of-pack inspection. If the product tested had been packaged 5 days before the inspection and is found underweight; the moisture loss data must reflect the loss that would occur in July, not January. At least three sample control lots consisting of at least 48 randomly selected packages must be used to develop the moisture loss data. Each sample lot must be stored under the same conditions that are typical for the product (e.g., if the product is typically placed in a sealed case on a pallet and shrink wrapped, the sample lots must be stored under the same conditions. Moisture loss data obtained by removing the individual packages from the shipping case and storing them in a laboratory would not be acceptable). The three-sample control lots must be placed at various locations in the storage site. The average moisture loss value must be computed from the three-sample control lots with a 95 % prediction interval. If the packer does not provide the information, no additional moisture allowance should be permitted.

V. Moisture Loss for Products Not Listed in NIST Handbook 133

When officials test product for which no moisture loss guidance has been provided NIST can provide technical assistance. In the past NIST has published recommended moisture allowances for use at all locations including Point-of-Pack. If moisture loss studies are required, NIST will assist in the completion of such studies. If studies are a necessity, they should be a collaborative effort between officials and industry and can be very time consuming depending on the product. Because of the potential impact on interstate commerce, studies must be completed on a nationwide basis and not by individual jurisdictions unless circumstances justify only local consideration.

The amount of moisture lost from a package is a function of many factors not the least of which is the product itself (e.g., moisture content), packaging, storage conditions (e.g., temperature, humidity, air flow), time, handling and others. If a packaged product is subject to moisture loss officials must allow for “reasonable” variations caused by moisture either evaporating or draining from the product. Officials cannot set arbitrary moisture allowances based solely on their experience or intuition. Moisture allowances must be based on scientific data and must be “reasonable.” Reasonable does not mean that all of the weight loss caused by moisture evaporation or draining from the product must be allowed. As a result of product and moisture variability the approach used by official must be developed on a case-by-case basis depending on many factors to include, but not be limited to, the manufacturing process, packaging materials, distribution, environmental influence and the anticipated shelf life of the product.

NIST Handbook 130 provides a starting point for developing a workable procedure in Section 2.5.6. in the Interpretation and Guideline Section regarding “Resolution for Requests for Recognition of Moisture Loss in Other Packaged Products.” NIST WMD has worked and will continue to work extensively with the NCWM, The Laws and Regulations Committee, and industry to develop protocol for determining moisture allowances that can serve as models for future studies. Most studies involving nationally distributed products will require that products be tested during different seasons of the year and in different geographic locations to develop a nationally recognized moisture allowance. Some studies may require the development of laboratory tests used for inter-laboratory comparisons to establish moisture content in products at time-of-pack or at the time-of-inspection.

In some cases, manufacturers can and may provide valid moisture loss data for officials to consider in lieu of conducting studies. In cases like this, WMD will provide assistance to determine if the information is complete or if further documentation is required. For example, a major producer of bar soap has provided moisture loss evidence for consideration by officials to determine what, if any, moisture loss could be expected to occur; in some cases, this information has proven to be accurate as a result avoiding the need for national data collection.

Moisture loss or gain is a critical consideration for any net content enforcement effort and one that, in most cases, cannot be addressed by a field official. If moisture loss issues are to be deliberated, it is the regulatory official’s responsibility to resolve the packers concern utilizing available resources and due process procedures.

To fulfill this obligation officials may be required to utilize specialized test equipment and specific laboratory procedures. Additionally, the collection of adequate test data may require product examination over a broad geographical area and consideration of a wide range of environmental factors. If a national effort is required, a coordinated effort involving industry, trade associations, weights and measures officials, and federal agencies may be required. NIST will provide technical support upon request.

VI. Background Information on Federal Preemption

In the previous memorandum, we reported that FDA was expected to adopt regulations identical to those contained in the 4th Supplement of the third edition of Handbook 133 adopted by the NCWM in 1994. The FDA published proposed regulations regarding net quantity of contents test procedures for packaged food under its jurisdiction in the March 4, 1997, issue (62 FR 9826) of the *Federal Register*. FDA subsequently withdrew that proposal on November 26, 2004 (69 FR 68831). FDA based the withdrawal on the need to reduce its regulatory backlog and focus its resources on current public health issues. The withdrawal did not speak to the merits of the proposal. Based on the experience reported since the adoption of the substantive revisions in 1994, WMD believes that the latest edition of Handbook 133 provides the basis for nationally uniform test methods and other requirements consistent with the requirements in federal laws relating to net quantity of contents. Therefore, WMD recommends that state and local authorities test products according to the procedures outlined in the latest edition of Handbook 133 unless future FDA guidance or regulations specify otherwise. Moreover, it is extremely important that state and local jurisdictions continue to provide regulatory oversight so businesses can compete in a fair marketplace and consumers can depend on the representations of quantity upon which they make purchasing decisions.

a. Federal Preemption under the Nutrition Labeling and Education Act (NLEA) of 1990

The NLEA was signed into law on November 8, 1990, to amend Title 21 Section 343 of the Federal Food, Drug, and Cosmetic Act (FDCA). The Act requires nutrition labeling on foods and regulates health claims about food nutrients to help consumers select a more healthful diet. Under the Act, State and local laws not “identical” to corresponding FDA requirements are preempted. According to regulations under FDA [21 CFR Part 100.1 (c)(4)], the phrase “not identical” does not refer to the specific words in the requirement. Instead it means that the state or local requirement directly or indirectly imposes obligations or contains provisions that (1) are not imposed by or contained in an FDA requirement, or (2) differ from those specifically imposed by or contained in an FDA requirement or implementing regulation.

The preemption ensures uniformity in labeling requirements and prohibits non-uniform State and local laws, regulations, formal and informal policies, and other enforcement practices that prevent firms from conducting efficient and cost-effective business in all 50 States. Congress recognized that even though federal requirements may preempt more restrictive state requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh any loss in consumer protection that may occur as a result.

The ultimate goal of the NLEA is uniformity in laws, regulations, and test procedures—a goal shared by the NCWM and NIST alike. Under NLEA, state and local labeling requirements must be identical to many of the regulations promulgated under the Federal Food, Drug and Cosmetic Act, as amended by the NLEA, in Title 21 – Code of Federal Regulations, Parts 100 to 169 (current edition). Jurisdictions may continue to enforce state or local regulations on foods where there is no federal requirement and continue to enforce existing state and local laws if they are “identical” to FDA regulations.

b. Defining what is “Identical”

Federal preemption of the net quantity of contents regulations and test procedures occurred on November 8, 1991. On that date, state and local regulations on quantity of contents (e.g., net quantity of contents regulations, sampling plans, and test procedures) were preempted under the NLEA if they were not “identical” to federal requirements. The question is, “What is ‘identical’?” Both state and FDA regulations require packers to express an “accurate” statement of the quantity of contents of packaged food while permitting “reasonable” variations. The most common questions WMD receives are “do the test

procedures used by the states and FDA provide identical results” (e.g., do the sampling plans have equal confidence levels, and are the products weighed or measured using recognized procedures) and “are the criteria for defining reasonable variations (e.g., the values of maximum allowable variations, the sample correction factors, and allowances for moisture loss) consistent with those used by FDA?”

FDA's test procedures are based on those contained in “Official Methods of Analysis” of the Association of Official Analytical Chemists International (AOAC). Based on information provided by FDA, WMD believes the test procedures contained in the fourth edition of Handbook 133 are identical to the AOAC procedures. If officials implement the recommendations in this memo, they should be using test procedures equivalent to FDA's.

c. Preemption Extends Beyond Food Packages Introduced into Interstate Commerce

Federal courts have ruled that the FDA has jurisdiction over all food products made from ingredients shipped in interstate commerce, regardless of the amount of the ingredient present, even though the finished product has not moved in interstate commerce. Products that have not entered interstate commerce (e.g., bakery products offered for sale in the food store where they are baked and packaged) that are made of ingredients shipped in interstate commerce to the store are subject to the Food, Drug, and Cosmetic Act and, therefore, should only be tested according to the following recommendations in this memorandum until final regulations are adopted by the FDA.

This memorandum is not legal advice. You are encouraged you to review this memo with your State Attorney General or staff attorney before implementing any policy on these issues or before you take enforcement action against a product that falls under FDA or other federal jurisdiction.

Training and Technical Support

WMD is committed to supporting state and local jurisdictions in their package inspection programs by providing technical assistance and training classes on Handbook 133. If you need assistance, please contact Lisa Warfield at (301) 975-3308 or by e-mail at lisa.warfield@nist.gov.

NOTICE

The following documents could not be included in this publication because they are only available in Adobe PDF format. They are available from NIST upon request. Please contact Kenneth Butcher at (301) 975-4859 or at kenneth.butcher@nist.gov or Lisa Warfield at (301) 975-3308 or at lisa.warfield@nist.gov to obtain copies.

B. Letter from Kraft Foods Requesting that NIST Withdraw Letter on Moisture Loss

C. Chapter 3 from the Third Edition of NIST Handbook 133 and 4th Supplement 1994

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