**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 101, 161, and 501**

**[Docket No. 92P–0441]**

## Food Labeling; Net Quantity of Contents; Compliance

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revise its human and animal food labeling regulations that pertain to declarations of net quantity of contents on food packages. This action would establish specific procedures for checking conformance to net contents labeling requirements nationwide, and provide consumers with information that accurately reflects the actual contents of the package. These procedures include analytical methods for evaluating declarations in terms of mass or weight, volume, and count. FDA is also proposing to require that food packed in a pressurized container bear a declaration of the net mass or weight of the contents expelled when the instructions for use are followed, and to clarify when net content declarations expressed in terms of mass or weight are to be based on the contents without the packing medium (i.e., drained weight). Further, the agency is proposing to revise the standard of identity for fresh oysters. This proposal is based on petitions submitted by the National Conference on Weights and Measures (NCWM) and on comments that FDA received on one of these petitions.

**DATES:** Submit written comments by June 2, 1997. Submit written comments on the information collection requirements by April 3, 1997.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

**SUPPLEMENTARY INFORMATION:**

Preamble Outline



### I. Background

#### A. *General*

Since the earliest days that it applied to food, Federal law has required that the label of food in package form bear an accurate statement of the quantity of the contents of the package. On March 3, 1913, an amendment to the Food and Drugs Act of 1906 required that statements be accurate, but it provided that ''reasonable variations shall be permitted, * * * by rules and regulations'' (37 Stat. 732). Under this provision, FDA adopted regulations in 1914 that stated:

(i) The following tolerances and variances from the quantity of the contents marked on the package shall be allowed:

(1) Discrepancies due exclusively to errors in weighing, measuring, or counting which occur in packing conducted in compliance with good commercial practice.

* * * * *

(3) Discrepancies in weight or measure due exclusively to differences in atmospheric conditions in various places, and which unavoidably result from the ordinary and customary exposure of the packages to evaporation or to the absorption of water.

Discrepancies under classes (1) * * * of this paragraph shall be as often above as below the marked quantity. The reasonableness of discrepancies under class (3) of this paragraph will be determined on the facts in each case.

(Regulation 29(I) of the Rules and Regulations for the Enforcement of the Food and Drugs Act; see Food Inspection Decision No. 154, Regulation of Marking the Quantity of Food in Package Form, May 11, 1914)

When Congress passed the Federal Food, Drug, and Cosmetic Act (the act) in 1938, Congress retained much of the earlier language concerning reasonable variations. Section 403(e)(2) of the act (21 U.S.C. 343(e)(2)) states that a food shall be deemed to be misbranded if the package does not bear a label containing ''an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided that under clause (2) of this paragraph reasonable variations shall be permitted * * *.''

Under this provision, FDA's current labeling regulations in parts 101 (for human food) and 501 (for animal food) (21 CFR parts 101 and 501), specifically §§ 101.105 (a) and (q), and 501.105 (a) and (q) state:

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure. * * *

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(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.

Although §§ 101.105(q) and 501.105(q) make it clear that FDA requires that firms include an accurate statement of the quantity of contents of the package, and that variations from the stated quantity not be unreasonably large, the regulations provide almost no guidance about what constitutes an ''accurate statement'' of quantity, or about what constitutes an ''unreasonably large'' variation. However, §§ 101.105(q) and 501.105(q) states that reasonable variations from moisture loss or gain, and unavoidable deviations in good manufacturing practice (GMP), will be recognized. These sections make it clear that an individual package need not contain exactly the amount of the product stated on the label.

To ensure that net weight label statements reflect the quantity of food in a package with appropriate accuracy, FDA conducts field examinations of packaged products and has provided its personnel with guidance on how to conduct these examinations (Sec. 562.300 Compliance Policy Guides Manual (CPG) 7120.19). FDA rarely, if ever, conducts field examinations at a retail store. Its investigators usually do field examinations at food storage warehouses or at manufacturing plants. Agency employees examine 48 individual packages (e.g., retail units) collected at random from the lot of the food product being inspected. When a field examination reveals that the quantity declared on the label does not accurately reflect the amount of the product present in the packages, a portion of the packages (a subsample) is reevaluated in agency laboratories. If the laboratory analysis confirms the finding of the field examination, and the average contents of the subsample is 1 percent or more short of the weight on the label (short weight), agency likely will consider regulatory action. The 1-percent guideline serves to focus the agency's limited resources on those instances in which the economic deception is significant. FDA has not provided guidance for assessing compliance for net contents declarations made in terms of volume or count.

*B. Past Attempts to Define ''Reasonable Variations''*

In 1980, to provide more specific guidance about what constitutes a reasonable variation, FDA proposed to revise its regulations concerning declarations of net quantity of contents on packages of human food (45 FR 53023, August 8, 1980) by doing the following:

(1) Deleting the general provisions in § 101.105(q) that provide for ''reasonable variations'' caused (a) by loss or gain of moisture during the course of good distribution practice or (b) by unavoidable deviations (other than those from moisture loss) in GMP, and

(2) Adding a new § 101.106 that would specify the amount of ''reasonable variation'' that would be permitted for: (a) Moisture loss in specific foods and (b) unavoidable deviations in all foods with declarations of quantity in terms of weight.

The attempt to provide this guidance did not prove practicable. Most of the 85 comments that FDA received on the proposal either disapproved of it or suggested major revisions. These comments were predominantly from industry and State and local governments. Many comments asserted that the proposed regulations were unnecessary because no chronic short weight problem with food commodities had existed for more than a decade. Some added that, without such a problem, it would be improper for FDA to revise existing regulations solely to help State and local regulators in making judgements about whether variations from stated net weight declarations were ''reasonable.''

Many industry comments contended that the specific provisions of proposed § 101.106 could not be practicably substituted for existing general provisions of § 101.105(q).

Some comments objected that, because the moisture loss provisions of proposed § 101.106 were limited to such a small number of food classes, an enormous economic burden would be placed on the affected industry. The comments stated that manufacturers of the large number of foods that were not yet included in § 101.106 would be forced to overfill food packages by approximately 9 percent until FDA revised § 101.106 to provide moisture loss tolerances for them. The comments advised that, in some cases, it would take several years to gather data to justify these revisions, and that, once the data were gathered, it could take several more years for FDA to issue the revisions. The comments maintained that overpacking during these time periods would have large economic consequences.

In addition, one comment suggested that any specific maximum moisture loss provisions might be taken by a dishonest manufacturer as a license to underfill down to the ''legal'' limit. Weights and measures officials would be unable to detect such intentional underfillings because local inspectors relying on the regulation would have to assume that a variation that was within the limit specified by the regulation was the result of moisture loss. The comment said that the violation could only be detected through laboratory analysis or by checking the product before it left the manufacturer's premises. The comment stated that the obvious losers in this situation would be the consumer and the honest packer who continued to deliver full value to the consumer.

Other comments objected that proposed § 101.106 was inadequate with respect to unavoidable deviations (other than those from moisture loss) that resulted even though GMP was followed. Some comments pointed out that none of these provisions concerned products whose declarations of quantity of contents were expressed in terms of volume or count. As a result, such products would be permitted no variation from their labeled declarations of net quantity of contents. The comments argued that such a situation would be clearly contrary to the intent of Congress.

Comments pointed out that the proposed unavoidable deviations provisions may also not be adequate for certain bakery products. For example, one comment contended that the net weight of yeast-leavened products is much more difficult to control than is the net weight of liquids and fine powders. The comment stated that bakers could comply with the proposed net weight provisions only with substantial overpacking and significant price increases.

Because FDA was concerned that there were significant problems with proposed § 101.106, and that this regulation could have considerable adverse economic impact on the affected industry, the agency did not issue a final rule in this matter. The agency withdrew the proposed rule on December 30, 1991 (56 FR 67440).

*C. The Basis for Preemption*

Section 403A of the act (21 U.S.C. 343–1) provides that State food labeling requirements are preempted when they are the type required by section 403 (b), (c), (d), (e), (f), (h), (i)(1), (i)(2), (k), (q), and (r) of the act but are not identical to those requirements. It also preempts any requirement for a food that is the subject of a food standard of identity established under section 401 of the act (21 U.S.C. 341) that is not identical to such standard of identity or that is not identical to the requirement of section 403(g). FDA's regulations that pertain to net contents declarations of human and animal food, which are issued under

authority of section 403(e) of the act, are therefore preemptive of State and local laws and regulations that pertain to net contents declarations on human and animal food.

Thus, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of food labeling outweigh any loss in consumer protection that may occur as a result.

However, Congress also provided in section 403A(b) of the act that States may petition for an exemption from preemption, and that FDA may initiate rulemaking to grant such an exemption, where the State rule:

(1) Would not cause any food to be in violation of any applicable requirement under Federal law,

(2) Would not unduly burden interstate commerce, and

(3) Is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

In the Federal Register of January 6, 1993 (58 FR 2462), the agency issued final regulations that set out the procedures for the submission, and for agency review, of petitions for exemption from preemption, and the information that the petitioner should supply. Section 100.1 sets forth the requirements that a State petition must meet to justify an exemption from preemption.

### *D. The Impact of Preemption on Net Contents Declarations*

FDA's regulations that pertain to net contents declarations on human and animal foods are very general, and typically, as stated above, the agency's enforcement of these regulations takes place at the point of distribution or manufacture. FDA's sampling approach, involving examination of 48 randomly selected packages for each sample, often cannot be used in retail stores, where an inspection lot [1] may contain less than 48 packages. State and local regulatory agencies, unlike FDA, focus their enforcement efforts on retail stores. To facilitate retail level inspections, they may have adopted specific regulations and policies that differ from FDA's. These differences include sampling procedures that are more suitable to retail inspection.

For example, to determine whether net contents declarations are sufficiently accurate, most State and local agencies use a guide that is published by the National Institute of Standards and Technology (NIST). NIST is charged by Congress with primary responsibility in matters concerning weights and measures. It maintains standard units of weight and measure that serve as authoritative references for the Federal Government.

The NIST guide that is used by State and local agencies is referred to as ''NBS Handbook 133—Third Edition'' and is entitled ''Checking the Net Contents of Packaged Goods'' (Handbook 133) (Ref. 1). NIST has published four supplements to this guide. With passage of the 1990 amendments, many State and local agencies have grown concerned that some courts may rule that they are preempted from following some or all of their enforcement procedures for net contents declarations because Handbook 133 is not part of the regulations that FDA has adopted to implement section 403(e) of the act.

### *E. The Need for Consistent Test Procedures for Human and Animal Food*

Historically, FDA has regulated the labeling of food intended for animals and of food intended for humans similarly when and where appropriate. For example, current animal food labeling regulations regarding the statement of identity, declaration of net contents, listing of ingredients, and declaration of name and address of manufacturer, packer, or distributor are identical to those for food for human consumption with only minor exceptions. This consistency in approach reflects the act but also is an attempt to provide consumers with equivalent labeling information on human and animal food. It also provides one standard for the feed/food industry and a common basis for the Government to conduct its inspections. FDA is not aware of any basis for deviating from this approach with respect to declarations of net quantity of contents.

## II. The NCWM Petition for Exemption From Preemption

### *A. The Contents of Petition*

On November 9, 1992, NCWM submitted a petition (Docket No. 92P–0441) (the 1992 NCWM petition) on behalf of officials representing most of its State regulatory agency membership. The petition requested that FDA grant to those State and local governments that use Handbook 133 an exemption from Federal preemption for the net contents declarations provisions in sections 403(e)(2), 502(b)(2), and 602(b)(2) of the act (21 U.S.C. 343(e)(2), 352(b)(2), and 362(b)(2)) of the act for food, drugs, and cosmetics. NCWM is a voluntary standards-writing body whose membership includes State and local weights and measures officials, and Federal Government, industry, and consumer representatives. NCWM is also an internationally recognized forum for establishing uniformity in weights and measures laws, regulations, and procedures for testing the accuracy of net contents declarations.

Handbook 133 contains procedures, using statistical sampling techniques, for determining whether packages of a wide variety of commodities conform to legal requirements for net contents declarations. NCWM stated that packaged products must meet two basic requirements under Handbook 133:

(1) The average quantity of contents of the packages in a lot, shipment, or delivery must equal or exceed the quantity printed on the label. The sampling plans and random sample selection criteria used to determine the average quantity of contents are based on practical sampling procedures that are similar to those used in quality control programs.

(2) The variation of individual package contents from the labeled quantity must not be ''unreasonably'' large. ''Unreasonably'' large variations are identified through use of values that Handbook 133 refers to as maximum allowable variations (MAV's). The MAV's cited in Handbook 133 are those values below which errors are ''unreasonable.'' MAV's are based on field studies of actual variability in packaging plants, warehouses, and retail outlets. Product samples may not have more than a permitted number of packages (based on the number of packages in the sample) with net contents deviations below the labeled contents that are more than the MAV's. MAV's apply only to shortages in package contents.

NCWM advised that 47 States use Handbook 133 to conduct net contents inspections of packaged goods. NCWM contended that the requested exemption would achieve, to the maximum extent possible, national standardization in net contents inspection procedures. It asserted that manufacturers, packagers, and consumers need the protection that can be provided by the inspection programs conducted by State and local inspectors using Handbook 133. NCWM advised that industry support for

[1] ''Inspection lot,'' for purposes of this document, means the collection of packages from which the sample is collected that consists of the same food, with the same label (but not necessarily the same production lot code or, in the case of random packages, the same actual quantity), and from the same packer.

Handbook 133 has been ''overwhelming.''

NCWM claimed that, because of the number of States that use Handbook 133, there is already considerable uniformity among the States. It also stated that procedures in Handbook 133 have not, and will not, cause any food to be in violation of FDA requirements. NCWM asserted that the use of Handbook 133 in State and local enforcement programs provides legitimate and specific protection for consumers in areas where FDA resources and activities have historically been limited; that Handbook 133 provides specific MAV's and testing procedures that are not set by Federal law; and that Handbook 133 provides clear and uniform notice to packers, wholesalers, and retailers of net weight compliance procedures and requirements.

Therefore, according to NCWM, no unreasonable burden on interstate commerce exists under the current system, and no burden, and no significant economic impact, would result if the exemption were granted. In addition, NCWM maintained that granting the requested exemption would be consistent with the intention of the 1990 amendments to provide national uniformity in certain aspects of food labels and labeling.

*B. Comments on the NCWM Handbook 133 Petition*

In response to the submission of the 1992 NCWM petition, the Grocery Manufacturers of America, Inc., the American Bakers Association, the American Frozen Food Institute, the International Dairy Foods Association, the National Food Processors Association, the National Pasta Association, and the Snack Food Association joined to form the Food Industry Weights and Measures Task Force (Task Force). The Task Force represents the majority of food manufacturers in the United States.

On behalf of the Task Force, GMA submitted a letter, dated June 4, 1993, commenting on the petition. The Task Force advised that it had previously submitted a letter to NCWM conveying its endorsement of NCWM's petition requesting the adoption of Handbook 133 for use as the standard throughout the United States to ensure uniformity in measurement procedures and quantity declarations for all food products. However, the Task Force pointed out that the 1992 NCWM petition had been filed before the January 6, 1993, regulation on exemptions from preemption was published (58 FR 2462 at 2468). The Task Force also expressed the opinion that the petition could not succeed because it does not meet all of the criteria specified in the final regulation.

The Task Force explained that the 1992 NCWM petition does not itemize or cite with required particularity each petitioning State's requirement that has been preempted. The Task Force stated that no more than 18 of the States that joined in the filing of the petition have enacted Handbook 133 as a final rule, and that the remainder of the States that joined in the filing of the petition have requirements that are either not described by the petition or are too informal to support a citation. The Task Force stated that these remaining States have legal requirements that are therefore different from Handbook 133 and that are most likely different from FDA's current net contents declaration requirements. The Task Force maintained that Handbook 133 is not functioning as a nationally uniform standard, and that the requirements of the petitioners are so disparate and undetermined that a blanket exemption would be virtually meaningless.

*C. Denial of Exemption From Preemption*

FDA is denying the petition for exemption of Handbook 133 from preemption because, as the Task Force pointed out, the 1992 NCWM petition was submitted before the publication of the January 6, 1993, final rule, and it does not satisfy all of the criteria specified in the final rule. The petition does not itemize or cite with required particularity each petitioning State's requirement that has been preempted. Furthermore, the petition does not address several of the issues that a petition is required to address under § 100.1, including: (1) Comparing the costs of compliance with the State and Federal requirements on the sale and the price of the food product in interstate commerce, and (2) the effect of the State requirement on the availability of the food product to consumers. The petition also does not include information showing that it is practical and feasible for producers of food products to comply with the State requirement.

Further, with respect to drugs and cosmetics, sections 502(b)(2) and 602(b)(2) of the act are not specifically preemptive of State and local law as is section 403(e) of the act. In addition, there are no provisions under the act for the agency to grant exemptions from preemption of the drug and cosmetic provisions.

III. Suggestions to the Agency About the Actions the Agency Should Take if It Denied the 1992 NCWM Petition

Although the Task Force recommended that FDA deny the 1992 NCWM petition, it stressed that there is a great need for a uniform, national standard for ensuring that net contents declarations are accurate. The Task Force also pointed out that a national standard could be most effectively provided through FDA regulations that would be preemptive of State and local regulations. The Task Force stressed that, without such a standard for determining compliance for net contents declarations, substantial burdens on interstate commerce occur because nonuniform labeling requirements necessitate either a multiplicity of labels or levels of fill to meet each of the different requirements, or the understating of the net contents declaration sufficiently to meet the ''most onerous State requirement.'' It stated that neither option serves the best interests of consumers or packagers.

The Task Force stated that there are major costs to industry, and ultimately to consumers, associated with the burdens on interstate commerce from overfilling to meet the most stringent requirements of State regulatory agencies. The Task Force pointed out that the agency's August 8, 1980, proposal (45 FR 53023 at 53026) advised that a nationwide survey had revealed that consumers routinely receive a 4-percent overfill for the average of all packaged foods purchased. That proposal also advised that the GMA had stated that a 4-percent overfill translates into a 4-percent cost increase, and that such a cost increase may involve added annual costs in the billions of dollars per year.

The Task Force requested that FDA incorporate a modified Handbook 133 into its regulations. The Task Force suggested a number of modifications that it believed should be included in any FDA-adopted version of Handbook 133. In subsequent comments on the 1992 NCWM petition in letters dated June 24, 1994, and September 15 and 22, 1994, the Task Force reconfirmed its belief that its suggested modifications should be adopted, and it suggested changes in FDA regulations to implement some of those modifications.

The 1992 NCWM petition itself asked that, if FDA decides to deny the requested exemption, the agency join with NCWM, NIST, and other Federal agencies to harmonize all net content requirements and test procedures using Handbook 133 as the basis for such work.

After filing its petition, NCWM also provided suggestions concerning harmonization. The NIST Handbook 133 Working Group (the Working Group), a committee of NCWM charged with the responsibility of recommending changes in Handbook 133, submitted a letter to FDA (Docket No. 92P–0441), dated November 15, 1993, commenting on the petition. The Working Group requested that FDA incorporate a modified Handbook 133 into the agency's regulations if the agency denies the petition. The Working Group suggested a number of modifications to Handbook 133 that it believed would help FDA to develop a revised version of Handbook 133. NCWM subsequently adopted the suggested modifications, and NIST published them in ''Supplement 4, October 1994'' (the 1994 Handbook). However, the agency points out that the 1994 Handbook has not yet been issued as a new edition of Handbook 133. The 1994 Handbook consists of Handbook 133 and the substantive changes provided in Supplement 4. The details of sampling, analytical, and compliance procedures of the 1994 Handbook are contained in both documents. Although the agency is denying the petition to adopt modified Handbook 133, FDA has considered Handbook 133 and the changes provided in Supplement 4 very carefully in developing this proposal.

## IV. The Need for Rulemaking

Although many State and local regulatory agencies do have enforcement approaches patterned after Handbook 133, NIST has stressed that the approaches are not all uniform (Ref. 3). NIST pointed out that uniform enforcement approaches may be assured only where State and local regulatory agencies use the most current version of Handbook 133 (e.g., the 1994 Handbook). NIST advised, however, that some State and local regulatory agencies have not formally adopted the most current version of Handbook 133 and are using older versions. In addition, NIST advised, not all State and local agencies that use a particular version of Handbook 133 conform with its provisions. Further, as pointed out by the Task Force and as acknowledged in the 1992 NCWM petition, some State and local jurisdictions do not use Handbook 133 at all.

NIST pointed out the potential for dramatically increased overfilling costs without the agency formally adopting the most current version of Handbook 133 as a standard. NIST stated:

> Handbook 133 contains two widely varying approaches with differing statistical bases for determining whether contents declarations are sufficiently accurate. In Handbook 133, these approaches are designated as ''Category A'' and ''Category B'' approaches. Both approaches address the appropriate sample size corresponding to the size of the inspection lot, and the maximum number of packages permitted to exceed the MAV established for the package size that is being examined. However, for most inspection lots, especially the larger ones, sample sizes are larger under the ''Category A'' approach than under ''Category B.'' Also, only the ''Category A'' approach provides correction factors that must be used in a statistical evaluation of the analytical findings to provide assurance that the findings actually represent the fills that are present throughout the entire inspection lot. Under the ''Category B'' approach, the absence of the correction factors means that an inspection lot that is actually in compliance could be found violative 50 percent of the time. Under the ''Category A'' approach, the same lot is likely to be found violative only 3 percent of the time. (Ref. 3)

NIST advised that before the 1994 Handbook, it was common practice for State and local regulatory agencies to use the ''Category B'' approach because it is simpler to use and biased in favor of consumers rather than industry (Ref. 3). Because of concern about the large differences in the statistical bases between the ''Category A'' and ''Category B'' approaches, the 1994 Handbook provides that the ''Category A'' approach is to be used for all situations where regulatory action may result. The ''Category B'' approach is to be used only in meat and poultry plants that are subject to the jurisdiction of the U.S. Department of Agriculture (USDA).

However, NIST pointed out that the simplicity of the ''Category B'' approach provides strong incentive for regulatory agencies to continue using the ''Category B'' approach where they have not formally adopted the most current version of Handbook 133. Thus, different jurisdictions may still have significantly different enforcement approaches. Furthermore, because some State and local regulatory officials do not use the ''Category A'' approach, firms recognize that regulatory action may be taken against inspection lots that are actually in compliance. Manufacturers are, therefore, as a practical matter, forced to systematically and significantly overfill their packages.

Although FDA has no data concerning the extent of current overfilling, the survey that it cited in 1980 (45 FR at 53023 at 53026) supports the Task Force's contention that expenses associated with overfilling constitute a significant burden on interstate commerce. FDA notes that the same survey suggests that the amount spent on overfilling may be in the billions of dollars annually. These expenditures raise the price of the overfilled packages. Thus, if adopted, the uniform approach set out in this proposal should reduce the amount of overfilling and the increased prices associated with overfilling.

Furthermore, the Task Force pointed out that overfilling misleads consumers about the nutrient content in a serving of food. For example, the nutrition labeling information on a food package declares the nutrient profile of the food in terms of the number of servings present in a package. If a food package is overfilled, a serving of a food contains more nutrients (e.g., calories, fat, and cholesterol) than is stated on the label. Thus, a consumer attempting to reduce intake of certain nutrients for health reasons from an overfilled food package would not recognize that nutrient reductions are less than the consumer would expect.

Based on these factors, the 1992 NCWM petition and the comments on the 1992 NCWM petition, have convinced the agency that the diversity in approaches to enforcement of net contents declaration labeling requirements on foods among State and local regulatory agencies has created significant burdens on interstate commerce.

As pointed out in section I.C. of this document, Congress included preemption provisions in the 1990 amendments to provide national uniformity to facilitate interstate commerce. Although FDA has no authority to require State and local agencies to adopt specific procedures for enforcement of net contents declaration labeling requirements, the preemptive effect of the provisions that FDA adopts will mean that, to the extent that such agencies adopt requirements that relate to net contents declarations, they will have to adopt requirements that are consistent with FDA's requirements. Given this fact, to the extent that FDA identifies ''reasonable variations'' in its regulations, the affected industry will know when net content deviations are likely to be considered violative. Such knowledge should help firms to reduce overfilling of packages and should facilitate interstate commerce by making the establishment of uniform target fill levels practicable for all package sizes.

FDA's current approach to declarations of net quantity of contents of foods cannot practicably serve as a national standard, however. Rather than having regulations that identify ''reasonable variations'' for a variety of situations, FDA relies on a case-by-case approach for determining whether variations are reasonable. With respect

to assessments concerning whether an inspection lot conforms to net contents labeling provisions of the act, FDA looks at analytical findings of each sample and decides whether the statistical characteristics of those findings support a conclusion that the lot is violative. The agency does not have an established procedure for adjusting net contents findings with correction factors such as those in the ''Category A'' approach. Admittedly, the guidance in FDA's CPG 7120.19 (which directs FDA field personnel to consider regulatory action where the average contents of the subsamples is 1 percent or more under fill, i.e., less than the declared net quantity of contents) may serve to minimize the impact of the lack of such correction factors, but, as mentioned previously in this document, 1-percent criterion in the CPG was intended only to conserve agency resources.

Without an established procedure for adjusting net contents findings with correction factors, a case-by-case approach would not be likely to produce national uniformity because each State and local enforcement agency could set its own policy for determining when variations are reasonable. For example, different statistical approaches might be used for concluding that a lot is violative. There would be a significant potential for such a situation happening with the large number of State and local regulatory agencies in the United States. Moreover, as mentioned previously in this document, FDA's sampling approach cannot be used in retail stores, where inspection lots often consist of less than 48 units. In view of these facts, FDA finds that there is a need to initiate rulemaking proceedings on net contents determinations.

FDA recognizes that the regulation that it is proposing is prescriptive and complex. Normally, in this time of Government reinvention, this is not the type of regulation that FDA would be proposing. However, FDA tentatively finds that to establish a uniform national system under which manufacturers can be assured net quantity of contents will be tested the same way regardless of the jurisdiction, it must adopt detailed regulations. FDA welcomes comment on this tentative judgment.

One alternative that the agency considered was to issue the detailed provisions that are contained in the proposed regulations as guidance rather than as regulations. FDA has tentatively concluded, however, that guidance would not be effective to correct the problems that both industry and NCWM have asked FDA to address. Section 403A(a)(2) of the act (21 U.S.C. 343–1(a)(2)) states that no State or political subdivision of a State may establish a requirement of the type required by section 403(c) of the act that is not identical to the requirement of such section. Thus, apparently, in the absence of a Federal regulation, State and local jurisdictions could not adopt regulations, even regulations that reflect Federal guidance. Consequently, the effect of an FDA decision to rely on guidance rather than regulations would be to continue the national, State, and local systems that rely on case-by-case determinations. Because such a system would deprive consumers and industry of the benefits listed above, FDA has tentatively rejected this alternative. However, the agency invites comments on the appropriateness of this choice.

## V. The Foundation of the New Proposed Rule

During its review of the 1994 Handbook, FDA tentatively concluded that NCWM is correct. If the 1994 Handbook is appropriately modified, it can serve as a national standard for determining the accuracy of net contents declarations. The statistical base of the procedures for determining compliance in this handbook is such that there should be little need for unnecessary overfilling of packages to ensure compliance. Use of the detailed sampling, analytical, and compliance procedures in the 1994 Handbook can minimize case-by-case decisions affecting compliance testing and can provide a basis to make uniform guidance practicable. Further, the 1994 Handbook identifies ''reasonable variations'' for both average and individual fills, as well as some moisture loss variations. In addition, the 1994 Handbook has been developed by NCWM through a long-established process, spanning approximately 30 years, and it is based on a consensus of regulators, industry, and consumer advocates. All of the published editions of the NCWM Handbook have had histories of successful implementation. Because the 1994 Handbook has been developed through this consensus building process, FDA findsconsiderable merit in the suggestions by industry, NIST, and NCWM that FDA adopt, as part of its regulations, the testing procedures in the 1994 Handbook, with some appropriate revisions.

However, while the 1994 Handbook does contain many desirable features, there are some obstacles to the agency's incorporating the 1994 Handbook into its regulations. Much of the material in the 1994 Handbook is not necessary or appropriate for agency rules on net contents declarations on packaged food. For example, there are many methods of analysis in the 1994 Handbook for products that are not foods or that are not regulated by FDA. Further, there is considerable background information that would not need to be codified. Even if FDA were to adopt the 1994 Handbook with a number of exceptions for irrelevant provisions, the large quantity of material (more than 250 pages), and the long list of exceptions that the agency would have to include with such adoption could be very confusing to all affected parties. Thus, FDA finds that it is not practicable to adopt the 1994 Handbook in its entirety.

Nonetheless, many aspects of the 1994 Handbook can serve as the foundation for regulations on net quantity of contents. In view of the fact that the Handbook 133 portion of the 1994 Handbook is already a widely used national model, and that NIST was one of the primary authors of Handbook 133 and the 1994 Handbook, FDA tentatively concludes that it should use the 1994 Handbook as a starting point for its regulations. This approach was suggested by the Task Force when it requested that FDA incorporate Handbook 133 in a modified form into the agency's regulations. Therefore, FDA set out to craft a regulation based on the 1994 Handbook.

In developing specific provisions of the proposed regulations, FDA worked closely with NIST, as was suggested by the petition and comments on the petition. FDA used NIST as its primary technical resource because of the worldwide recognition of that agency's expertise in all issues concerning weights and measures. Also, NIST's involvement in developing Handbook 133 and the 1994 Handbook has made that agency uniquely qualified to help in FDA's review of the 1994 Handbook.

As mentioned in section III. of this document, NCWM requested that FDA include them in agency efforts to establish national uniformity in net contents requirements if the agency decided to deny the requested exemption. FDA did not grant this request, however, because of concerns that, given its diverse membership, NCWM participation might create procedural problems in developing this proposal. However, NIST is extremely active in NCWM. NIST's involvement in developing of this proposed rule, and the significant NCWM technical material in the 1994 Handbook, has minimized the significance of FDA's decision not to have NCWM participate.

VI. Provisions of the Proposed Rule

*A. Existing Provisions*

FDA examined its existing regulations that pertain to declarations of net contents for human and animal food in §§ 101.105 and 501.105 to identify all provisions that bear on the accuracy of measurements and to determine what revisions, if any, need to be made. The agency found that §§ 101.105(b)(2), (g), and (q) and 501.105(b)(2), (g), and (q) contain information that bears on the accuracy of measurements. The remaining paragraphs in §§ 101.105 and 501.105 cover a broad range of topics concerning declarations of net quantity of contents that are not relevant to the accuracy of measurements of content. For example, type size requirements for letters and numerals in declarations (§ 101.105(h)) and location requirements for such declarations (§ 101.105(f)) have no bearing on the accuracy of the quantity declaration.

Given the distinction between the provisions that bear on accuracy of quantity declarations and those that bear on how those declarations are to be presented, FDA has decided to move § 101.105(b)(2) and (g) into a new section. FDA is also redesignating § 101.105 as § 101.200 and moving it to a new subpart H of part 101. The proposed new section that FDA is creating out of § 101.105(b)(2) and (g), proposed § 101.201, will contain the other provisions that relate to the accuracy of net contents declarations in subpart H of part 101. The agency sees no reason, however, to repeat the same provisions in parts 101 and 501 when it may cross-reference them. Accordingly, with the exception of §§ 101.200 and 101.201, FDA is proposing to cross-reference the provisions in part 101 in part 501 (proposed § 501.105(g)).

In addition to redesignating certain provisions that had appeared in § 101.105, FDA is proposing to make a number of substantive changes in the provisions that it is redesignating. A description of these proposed changes follows.

1. Reference Temperatures

Liquid food products may be held for sale at room temperature or at other colder temperatures that refrigerate the products or cause them to be frozen. Sections 101.105(b)(2) and 501.105(b)(2) affect the accuracy of measurements by specifying the temperatures at which volume measurements of frozen, refrigerated, and other liquid foods are to be made to determine whether they meet the net quantity of contents requirements. These temperatures are to approximate the temperature at which the food is customarily sold. The temperature at which the volume of food is to be measured is referred to in this proposal as the ''reference temperature.''

The reference temperature affects measurement accuracy because the volume that is occupied by any food varies with the temperature of the product. Sections 101.105(b)(2) and 501.105(b)(2) and the 1994 Handbook contain reference temperatures for frozen, refrigerated, and other liquid foods. Although there is consistency between agency regulations and the 1994 Handbook for refrigerated foods and other foods, §§ 101.105(b)(2) and 501.105(b)(2) provide that statements of fluid measure for a frozen liquid food shall express the volume ''at the frozen temperature.'' However, the Handbook 133 portion of the 1994 Handbook contains a frozen food reference temperature of 0 °F (−17.8 °C). Unless FDA also establishes a specific reference temperature for frozen liquid food, considerable variation could occur in volumetric measurement for the same volume depending on the temperature of the product at the time that it is tested.

For example, it is possible to approximate the behavior of liquids with high water content by calculating the volumetric changes predicted for water: At −20 °C (−4 °F), the density of water is 0.993550 grams (g) per cubic centimeter, and at 0 °C (+32 °F), the density of water is 0.9998425 g per cubic centimeter. Thus, 12 fluid ounces of frozen orange juice at 0 °C (+32 °F) would occupy 354.9 millimeters (mL), but at −20 °C (−4 °F), it would occupy 357.1 mL, a difference of 0.6 percent. Since defrosting freezers that cycle between −10 and +20 °F are used routinely at retail outlets to store and display frozen foods (Ref. 3), it is important to define a reference temperature for frozen liquids to ensure that there is consistency and predictability in the temperature at which such products are tested. FDA is therefore proposing to establish a reference temperature for frozen food. For consistency with reference temperatures in the agency's ongoing metric labeling rulemaking proceedings (see 58 FR 29716 May 21, 1993, and 58 FR 67444 December 21, 1993), the agency has rounded the metric temperature to the nearest whole number, −18 °C, and placed it before 0 °F in proposed § 101.201(a)(2)(i) and proposed § 501.105(b)(2)(i).

2. Accuracy Within Reasonable Variations

As mentioned previously in this section of the document, paragraphs (g) and (q) of §§ 101.105 and 501.105 both relate to accuracy of net quantity declarations. These paragraphs are somewhat redundant in that they both require that the net contents declaration be accurate. However, while paragraph (g) requires that the declaration reveal the quantity of food in the package exclusive of wrappers and other material packed therewith, paragraph (q) provides that the net contents of an individual package need not precisely meet the labeled declaration. It recognizes that reasonable variations may be caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in GMP. Paragraph (q) also requires, however, that such variations not be unreasonably large.

Given the basic redundancy in these two paragraphs, FDA has tentatively decided to combine them as §§ 101.201(b) and 501.105(g) and to remove paragraph (q) in both human and animal food regulations. The proposed paragraph, however, carries forward the two basic aspects of the current provisions. It requires that the declaration of net quantity of contents provide an accurate statement of the quantity of contents of the package and defines an accurate statement as one that conforms to all requirements for the declaration set forth in subpart H. It also recognizes that there may be reasonable variations in the net content declarations and refers to §§ 101.240, 101.245, and 101.250 to define what constitutes a ''reasonable variation.''

Although the proposed provisions of subpart H establish the procedures and analytical methodology that will, if finalized, be used in enforcement decisions by Federal, State, and local regulatory agencies, manufacturers will be free to use any alternate procedures and analytical methodology that they find appropriate. However, FDA strongly recommends that manufacturers use the same procedures and analytical methodology that appear in subpart H. Where firms elect to adopt a different approach than the recommended approach, firms would be advised to compare their approach to that in subpart H to ensure that their approach produces similar results.

3. Pressurized Containers

Section 101.105(g) addresses what the net contents declarations on pressurized containers is to present. It states, in part:

* * * In the case of foods packed in containers designed to deliver the food under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on

the container are followed. The propellant is included in the net quantity declaration.

Paragraph (g) does not address, however, whether the declaration is to be in terms of solid or fluid measure when the product is expelled as a gaseous suspension of fine solid or liquid particles.

Aerosol-packaged products and similar pressurized products are often dispensed as suspensions. Sections §§ 101.105(a) and 501.105(a) provide that net contents declarations for food products are to be in terms of fluid measure if the product is liquid, and in terms of weight if the product is solid, semisolid, or viscous or a mixture of solid and liquid. The agency has interpreted § 101.105(a) with respect to aerosols in the Fair Packaging and Labeling Manual Guide 7563.7 (Guide 7563.7), which states:

> We have not objected to the use of units of volume to declare the net contents of aerosol preparations that would be liquid if not combined with the propellant, and a net weight statement in avoirdupois units for products that would be solids if not combined with a propellant.

While this position is consistent with § 101.105(a), it is not consistent with the Handbook 133 portion of the 1994 Handbook, which requires that such net contents declarations be expressed in terms of weight. The inconsistency between Guide 7563.7 and Handbook 133 was brought to the agency's attention a number of years ago when FDA received a petition from NCWM (Docket No. 90P–0180) that requested, in part, that FDA amend its regulations for foods to require that declarations of quantity of contents on aerosol-packaged products and on similar pressurized packages be expressed in terms of net mass or weight.

NCWM pointed out in that petition that State and local regulatory agencies have regulated these products on the basis of net mass or weight for many years. NCWM explained that, for aerosol and other pressurized packages, an expression of quantity in terms of mass or weight is the only net contents declaration that could practicably be checked by regulatory inspection officials and used successfully in the packer's filling operation. NCWM also pointed out that it could be difficult for consumers to make value comparisons between similar products where some are labeled in terms of volume, and some are labeled in terms of mass or weight. Further, NCWM advised that because State and local officials have long required net contents declarations on self-pressurized containers to be in terms of net mass or weight, such declarations have become an industry-wide practice. Consistent with State and local requirements, the Handbook 133 portion of the 1994 Handbook provides for net contents declarations on such products only in terms of mass or weight, with the expelled propellant being included in the net contents declaration.

Based on the arguments set forth in the 1992 NCWM petition, the fact that FDA knows of no human or animal aerosol foods with net contents declarations that are expressed in terms of volume, and the fact that FDA is using the 1994 Handbook as a starting point for its regulations, the agency has been persuaded to propose that net contents declarations on aerosol foods be expressed in terms of mass or weight. This approach will apparently cause the least amount of disruption in labeling, while removing a significant inconsistency between the agency and State and local requirements. Accordingly, the agency is proposing to redesignate § 101.105(a) as § 101.200(a) and revise newly redesignated § 101.200(a) and revise § 501.105(a) to provide that a food packaged in a self-pressurized container shall bear a net contents declaration in terms of the mass or weight of the food and the propellant that will be expelled when the instructions for use as shown on the container are followed.

4. Mass or Weight of the Packing Medium

Section 101.105 does not address when net contents declarations that are expressed in terms of mass or weight are to be declared as the mass or weight of the contents without the packing medium, which is commonly referred to as the ''drained mass or weight'' or the ''drained solids.'' The agency tentatively concludes that new § 101.200 should address this matter.

For many years, FDA has advised firms that the net contents declaration should include the packing medium if it is generally consumed as part of the food. Conversely, where solid foods are packed in a salt brine or other medium that is always, or almost always, discarded before serving, the agency has expected that the label would disclose the drained weight. For example, FDA's Fair Packaging and Labeling Manual Guide 7699.2 states that the appropriate net contents declarations for canned artichokes, canned clams, canned mushrooms, green olives in brine, and canned wet-pack shrimp are in terms of drained weight. However, the agency's case-by-case approach to determining when a packing medium is always or almost always discarded before serving would be difficult to implement uniformly if many different regulatory agencies are making such assessments.

The congressional mandate for national uniformity suggests that FDA should provide more specific direction in this matter. However, FDA notes that it has already dealt with the issue of when a food should be declared in terms of its drained weight in its regulation on serving sizes (§ 101.12). The agency's nutrition labeling requirements provide for declaration of nutrient information in terms of the serving size based on the reference amounts customarily consumed as set forth in § 101.12, and that section specifically provides for cases where the reference amounts are in terms of drained solids.

Thus, FDA no longer has to make case-by-case assessments about whether the packing medium is always or almost always discarded before serving. Instead, the agency can now refer to § 101.12 in determining whether net contents declarations must include the packing medium. Therefore, FDA is proposing to require in § 101.200(a) that, except where the reference amount customarily consumed per eating occasion is in terms of drained solids in accordance with § 101.12, a food that is packed or canned in liquid, and that is required to bear a net contents declaration in terms of weight, shall bear a declaration expressed in terms of the total net contents including the liquid.

FDA points out that, for many years, it has had a policy of permitting both drained weight and net weight to be stated on the principal display panel (PDP) of a food label. However, some State regulatory agencies prohibit both drained weight and net weight from appearing on the PDP of a label because they consider one of the weight declarations to be in conflict with section 4(b) of the Fair Packaging and Labeling Act (FPLA), which prohibits qualifying words or phrases from appearing with the required net contents declaration. FDA advises that it does not believe that its policy in this regard conflicts in any way with section 4(b) of the FPLA.

Although neither the language of the FPLA nor the regulations established thereunder provide clear guidance, the legislative history of the FPLA does. The May 25, 1966, Senate Report No. 1186, which addressed the meaning of the prohibition of supplemental statements, states:

> Subsection 4(b) prohibits the qualification of the separate net quantity statement by any modifying words or phrases. However, a supplemental statement of the net quantity of

contents set apart from the separate net quantity of contents, required by the bill, may be modified by nondeceptive words or phrases, so long as such words or phrases do not tend to exaggerate the amount of the commodity contained in the package. For example, where a package contains a separate net quantity statement in conformity with promulgated regulations, such as ''6 oz. net weight,'' the package could also contain in a supplemental statement, apart from the required net quantity statement, the phrase ''6 oz. of fast acting X detergent'' but could not contain the statement ''6 jumbo oz. of X detergent'' at any place on the package* * *.

From the above quote, it is obvious that the required declaration of net quantity may not contain statements designed to imply that one product is different in quantity from others declaring the same net contents. It is also obvious that Congress wanted the required declaration to be separate from supplemental statements designed to promote product sales. FDA has a regulation, § 101.105(o) (which would be redesignated as § 101.200(o)), that is intended to ensure that such separation exists by permitting supplementary net quantity statements on label panels other than the PDP. However, there is no indication in Senate Report No. 1186, or elsewhere in the legislative history of the FPLA, that congressional concern about a ''supplementary statement'' was intended to encompass other forms of nonmisleading information about the quantity of contents than the one required. To the contrary, the broad congressional policy declared in section 2 of the FPLA states: ''Packages and labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons'' (15 U.S.C. 1451). Declaration of a statement of net quantity of contents in terms of both drained weight and net weight would not be inconsistent with this policy because such declarations advise consumers of the amount of food and the accompanying packing medium, thereby assisting purchasing decisions.

Although the agency does not consider it necessary to codify the present policy of permitting both drained weight and net weight to be declared on the PDP of a food label, FDA solicits comments on whether it should codify this policy into its regulations.

*B. New Provisions*

In response to suggestions from State and local regulatory agencies and the affected industry, FDA has tentatively determined that, for national uniformity, it should adopt new regulations that set out the specific details of the techniques and methods that it will use in assessing the accuracy of net contents declarations. The agency turns now to those regulations.

1. Definitions

The 1994 Handbook, Appendix C has a glossary that contains almost 100 different terms and their definitions to help users follow its requirements. The 1994 Handbook also contains a number of additional definitions in various locations throughout the handbook. With one exception, which is discussed below, the definitions used in the 1994 Handbook have been accepted and used by regulated industry and regulatory agencies for a number of years.

FDA tentatively finds that any regulations that it adopts based on this proposal will profit if they include a similar set of definitions. The definitions will not only make the regulations understandable, but they will help to foster consistency with the 1994 Handbook. FDA is therefore proposing, in § 101.205, to define a number of terms that it has used in the proposed regulations. FDA has drawn heavily on the 1994 Handbook for these definitions because of the long history embodied in the 1994 Handbook, and because the definitions were arrived at by NCWM after consideration of the views of both industry and regulatory agencies.

The agency is not, however, proposing to define all of the terms defined in the 1994 Handbook because some of the terms in the 1994 Handbook pertain to products that FDA does not regulate.

Where FDA is including terms in proposed § 101.205 that are defined in the 1994 Handbook, it is, for the most part, incorporating the 1994 Handbook definitions. The agency has, however, made minor changes in the definitions for clarity.

A few terms that are used in the regulations, however, have either not been defined in the 1994 Handbook or are defined in the 1994 Handbook in a way that is not fully satisfactory. A discussion of these terms, and of the definitions that FDA is proposing for them, follows.

a. *Sample standard deviation.* In § 101.205(o), the agency is proposing to adopt the following commonly recognized definition for ''sample standard deviation:''

*Sample Standard Deviation (s)* means a statistic used as a measure of dispersion (i.e., differences of individual values from the mean) in a sample. It is calculated as follows:

$s = (\Sigma(xi - x)2/(n - 1))^{1/2}$ or equivalently (and primarily for calculations without a computer),

$s = ((\Sigma xi^2 - (\Sigma x_i)^2/n)/(n - 1))^{1/2}$.

Where:

$\Sigma$ means ''the sum of,''

xi means the ith individual package error,

n means the sample size, and

x means the average of the package errors, that is, the sum of the package errors divided by the number of packages in the sample.

This definition is a commonly recognized definition for ''sample standard deviation'' (Ref. 3).

FDA points out that it is proposing the use of this definition for samples collected using either of the random selection approaches set forth in the 1994 Handbook. The 1994 Handbook provides for the collection of a sample through either: (1) A single-stage approach of randomly selecting the individual packages directly from the lot, or (2) a multistage approach of first randomly selecting the larger storage units (e.g., cartons or pallets), followed by random selection of the individual packages. While the proposed definition of ''sample standard deviation'' is mathematically fully correct only where the single-stage approach is used, FDA has tentatively decided that the definition can be used when a multistage approach is used for three reasons. First, NIST has recommended its use in this circumstance (Ref. 3). Second, its use will minimize the complexity of these regulations. Third, NIST advised (Ref. 3) that any errors introduced by using this definition with a sample collected using a multistage approach will not be significant.

The single-stage approach is generally used at retail locations on smaller lots of packages that are not in cartons or on pallets. The multistage approach is generally used for larger lots, such as those found in food storage warehouses (e.g., in locations where foods are found in shipping cases, containing 12, 24, or 48 individual packages, which are typically stored on several different pallets). In the first stage of a multistage sampling approach, an official randomly selects one or more pallets from all of the pallets available from which to collect samples. In the second stage, the official randomly selects one or more shipping cases from the selected pallets. Finally, in the third stage the official opens the shipping cases and randomly selects individual packages from the shipping cases for use as the sample packages in determining lot compliance.

For a multistage approach, a more complicated calculation of the standard

deviation than the one that FDA is proposing is theoretically appropriate. For multistage samples, the average of the package errors within each of the larger storage units can be used to determine the sample standard deviation rather than the package errors for each package regardless of the storage unit in which the packages are contained.

Nonetheless, FDA is proposing to provide that the more simple approach to computing sample standard deviation be used. NIST recommended that FDA not increase the level of complexity for regulatory officials in calculating the sample standard deviation (Ref. 3). NIST said that any increase in complexity would significantly increase the risk that regulatory officials would make mistakes in classifying an inspection lot as violative, and that the difference in the results obtained using the two methods would be minor. Therefore, NIST stated, it would not justify the increased time and costs related to net quantity of contents inspections if the more complex calculation were required. NIST also stated that the harm that could result from the potential mistakes caused by the increased complexity of the calculation could far exceed any benefits of calculating standard deviation in a more theoretically appropriate manner. Thus, NIST recommended that FDA require the use of the less complex approach for determining sample standard deviation. It pointed out that this approach is normally used in the food industry for statistical process quantity control.

FDA agrees with NIST and is proposing in § 101.205(p) to define ''sample standard deviation'' based on the less complex approach suggested by NIST. FDA requests comments on the adequacy of this proposed definition.

b. *Gravimetric test procedure.* FDA is proposing in § 101.205(c) to define the term ''gravimetric test procedure'' as an analytical procedure that involves measurement by mass or weight. The proposed regulations contain a number of different gravimetric procedures, and the proposed definition should simplify the description of these procedures by eliminating the need to include a lengthy discussion of measurement by mass or weight. FDA requests comments on whether there are any problems created by this approach.

c. *Dry animal food.* In § 501.105(u), FDA is proposing that the term ''dry animal food'' mean animal food packaged in paperboard boxes or kraft paper bags that has 13 percent or less moisture at time of pack. This definition is derived from a definition of the term ''Dry pet food'' in the 1994 Handbook[2] that serves to designate a class of food entitled to certain adjustments for moisture loss that are discussed subsequently in this preamble. As proposed, FDA's definition is the same as that in the 1994 Handbook except that the agency is proposing to use the term to encompass all animal food rather than only food used for pets. The 1994 Handbook does not contain any indication as to what it precisely means by the term ''pet.'' In view of the lack of such specificity, and the fact that FDA knows of no reason to differentiate between pet and non-pet animal food, the agency tentatively concludes that the definition can apply to all animal food.

According to NIST (Ref. 3), the 13-percent moisture content limitation in the proposed definition was developed in cooperation with the Pet Food Institute, a trade association that represents a majority of the manufacturers of pet foods. NIST stated that NCWM developed the limitation for dry animal food based on moisture loss studies that were conducted using products from several manufacturers. The laboratory tests conducted as part of those studies revealed that the maximum moisture level of the products used in the field studies was less than 13 percent. NIST advised that it was not aware of any concerns on the part of packers over the NCWM definition because it is only intended to be used to identify the types of dry animal foods subject to moisture loss and serves no other purpose. Most packers are required under many state animal food laws and regulations to provide moisture content information in the guaranteed analysis displays on pet food packages. Therefore, FDA is proposing to adopt this definition.

2. Sample Collection

The 1994 Handbook provides that the ''Category A'' approach is to be used on FDA regulated commodities for determining whether net contents declarations are sufficiently accurate. The ''Category A'' approach addresses, in part, the sample collection procedure to be used for evaluation of the accuracy of the net contents label declaration. For this approach, the 1994 Handbook provides that the size of the sample taken depends on the size of the lots being sampled.[3] The handbook provides for four basic sample sizes. Where the lots consist of less than 12 packages, all of the packages in the lot are included in the sample. Where there are 12 to 250 packages, 12 packages are to be taken as the sample. Where there are 251 to 3,200 packages, 24 packages are to be taken as the sample. Where there are more than 3,200 packages, 48 packages are to be taken as the sample. All packages in the sample are collected through random selection procedures that are discussed subsequently in this preamble.

NIST pointed out in its letter to FDA that the sample collection procedure under the ''Category A'' approach can be readily used for both retail and wholesale inspections (Ref. 3). NIST advised that sample collection under this approach does not make unreasonable demands on inspection time through overly large sample sizes. Furthermore, NIST pointed out that the ''Category A'' approach was developed from a consensus position of the NCWM after consideration of the views of both regulators and the regulated industry. NIST stressed that the ''Category A'' sample collection procedure is easy to use and appropriate for use in verifying the net quantity of contents of packaged food at all levels of wholesale and retail trade.

FDA tentatively agrees with NIST's assessment of the ''Category A'' sample collection procedure in the 1994 Handbook. The practicability of implementation of this procedure, coupled with the consensus agreement on the approach, have led FDA to tentatively conclude that this procedure represents a reasonable approach to sampling. The agency is therefore proposing to adopt, in § 101.210, the Category A sample collection procedure from the 1994 Handbook.

3. Measuring Equipment

One of the fundamental aspects of any approach to ensuring that net contents declarations on food packages are accurate is to ensure that accurate measurements are made. To this end, FDA is proposing to address: (1) Selection of appropriate measuring equipment and (2) standardization of that equipment to ensure that it is accurate. FDA's hope is that these provisions will allow all affected parties to have confidence in the measurements made under the standard. FDA expects that this confidence will mean that regulatory agencies will be comfortable in embracing and implementing the approach set out in these regulations, and that the regulated industry will be able to establish uniform practicable target fill levels for all package sizes, regardless of the ultimate distribution location, with confidence that the fill

[2] The 1994 Handbook's definition appears in Table 3–3 on page B–17 of the Handbook 133 portion, of the 1994 Handbook.

[3] See Chapter 2 and Table 2–1 in Appendix B of the Handbook 133 portion of the 1994 Handbook.

levels will meet the local regulatory standards. With uniform target fill levels, firms should be able to significantly reduce overfilling of packages, thereby reducing production costs and providing consumers with more accurate nutritional information.

FDA notes that the 1994 Handbook contains procedures for both the selection and standardization of measuring equipment. These procedures pertain primarily to balances and volumetric measures (i.e., measuring devices for use in the measurement of volumes of liquids, such as standard measuring flasks, graduates, and cylinders (see Chapters 2 through 5 of the 1994 Handbook)). Many of these procedures (or ''tolerances'' as the 1994 Handbook often refers to them) are incorporated into the 1994 Handbook through reference to the NIST Handbook 44 (Ref. 4) (referred to subsequently as ''Handbook 44''). Handbook 44 is widely recognized as the national standard for accuracy requirements for scales and balances (Ref. 3). In addition, both the 1994 Handbook and Handbook 44 contain instructions (or ''test procedures'' as the 1994 Handbook refers to them) for the calibration of equipment to ensure that its accuracy is consistent with measurement standards maintained by NIST.

FDA sees considerable merit in the 1994 Handbook procedures for selection and standardization of measuring equipment. The agency has therefore, with a very few exceptions (which are discussed below where relevant to a particular type of equipment), used these procedures as the basis for the equipment requirements in these proposed regulations. A discussion of these proposed requirements follows:

a. *Equipment selection*—i. *Thermometers.* In § 101.215(a), FDA is proposing to require that any thermometer used in measuring net contents (e.g., to bring a product to an appropriate reference temperature before measuring the volume) have graduations no larger than 1° (2° Fahrenheit). This proposed selection criterion reflects the standard that appears in Chapter 4 of the Handbook 133 portion of the 1994 Handbook. NIST advised FDA (Ref. 3) that graduations larger than these could mean that it would not be possible to determine whether the appropriate reference temperature has actually been achieved, and, consequently, significant volumetric measuring errors could occur. NIST also pointed out that this criterion has been in Handbook 133 for many years. NIST advised that this criterion can be applied to any type of thermometer (e.g., the commonly used mercury-in-glass thermometer or electronic device). FDA tentatively concludes, based on these factors, that 1°C or 2°F constitute the appropriate minimum graduations for thermometers that are to be used under these regulations.

ii. *Linear measuring equipment.* The 1994 Handbook contains no requirements for selection criteria for linear measuring equipment. However, in its letter to FDA, NIST suggested (Ref. 3) that any regulations on ensuring the accuracy of net quantity of contents declarations should include provisions on linear measuring devices because such devices are used in a variety of ways to determine net contents. For example, depth gauges are used to measure the headspace from the top of a package to the level of the product, and that distance is used to calculate the volume of product in the package (see analytical method in proposed § 101.225(f)).

NIST pointed out that while the 1994 Handbook contains no selection requirements for linear measuring equipment, it does contain a number of recommendations for such selections.[4] However, NIST expressed concern about these recommendations. NIST's concern focused on the suggestion in Handbook 133 that a 36-inch ruler be used for measurements of 25 inches or less, and that a 100-foot tape be used for measurements of greater than 25 (in). NIST explained that these provisions might be too inflexible in some circumstances to be practicable. NIST stated that it did not seem logical that a 36-inch ruler that could be used for measurements of 25 inches or less could not also be used to measure a slightly longer distance (e.g., 30 (in)). Thus, NIST suggested that FDA adopt a requirement for use of a tape or ruler of appropriate length, with a minimum graduation of 1/64 inch (or 0.5 milliliter (mm)) or less for equipment of 25 (in) or less or a minimum graduation of 0.1 inch (2 mm) for equipment of greater than 25 (in), without any limit on the distances that these devices can be used to measure.

NIST stated that the requirement should also express the 25-inch linear criterion as a metric value of 63.5 cm, explaining that the metric recommendations in section 5.3.1 of Handbook 133 are incorrect because of an inadvertent conversion error (Ref. 3). Also, NIST stated that the metric expressions of maximum permitted measurement errors in section 5.3.1 (i.e., 0.4 mm and 2.5 mm) should be expressed in terms of graduation values commonly found on precision metric tapes and rulers (i.e., 0.5 mm and 2 mm), rather than precise equivalents.

FDA is proposing in § 101.215 (b)(1) and (b)(2) to adopt the requirements that NIST suggested for tapes and rulers. As discussed above, FDA has tentatively determined that it will facilitate interstate shipment of product, and thus be of significant value, if the agency established standards for equipment used in determining the accuracy of net quantity of contents declarations. Given the well-recognized expertise of NIST on weight and measure matters, FDA considers it appropriate for the agency to defer to NIST in the development of those standards.

FDA is not proposing a standard for selection of calipers and depth gauges used to determine the level of fill in packages labeled by volume (headspace). NIST suggested only that a caliper or a depth gauge used to make such measurements be suitable in design and measuring range, and that the values of its smallest measurement unit be suitable for the purpose for which it is to be used. Neither NIST nor FDA is aware of more specific criteria that could be proposed for these measuring instruments (Ref. 3). NIST stated that specific requirements regarding suitability would be difficult to develop because of the broad range of container sizes that could be encountered in the marketplace.

Given the lack of specificity of NIST's suggestion, FDA is not proposing to incorporate it in the agency's regulations, although the agency urges regulatory officials and manufacturers to adhere to the guidance contained in NIST's recommendation. FDA also requests comments on whether there are objective selection criteria that should be used for calipers and depth gauges.

iii. *Volumetric measuring equipment.* In § 101.215(c), the agency is proposing the following selection criteria for volumetric measuring equipment that pertain to the graduations on, and the size of, the equipment:

*a. Size.* In § 101.215(c)(1), FDA is proposing to require that a volumetric measure used in fluid volumetric determinations be of such size that no volume less than 25 percent of the maximum capacity of the volumetric measure is measured. For example, a graduate with a capacity of 4 fluid ounces could not be used to measure volume of less than 1 fluid ounce. While the proposed requirement may not be readily apparent in the 1994 Handbook, NIST advised (Ref. 3) that it is actually present through incorporation by reference of Handbook 44.

[4] See section 5.3.1, page 5–6 of the Handbook 133 portion of the 1994 Handbook.

In its letter to FDA, NIST advised (Ref. 3) that, the criterion was developed by NIST many years ago and has been widely used by most State and local regulatory agencies since its development.[5] The criterion is based on the fact that when small amounts are measured, the error that comes within individual gradient can constitute a rather large percentage of the product measured. The 25-percent limit provides a means of controlling this factor.

NIST pointed out that section 4.44, ''Graduates,'' in Handbook 44 provides tables specifying the design criteria for graduates (one type of volumetric measure) that limit their lower measuring range. These tables use the 25-percent criterion as the basis for prohibiting measurements below certain capacities of the graduate.

*b. Graduations.* In § 101.215(c)(2), FDA is proposing a selection criterion for volumetric measuring equipment that pertains to the maximum size of each individual graduation appearing on the volumetric measure. For such graduations, the agency is proposing to require that any volumetric equipment have a maximum graduation value related to the MAV. (As discussed previously in this preamble, one of the basic requirements of the 1994 Handbook is that the variation of individual package contents from the labeled quantity not be ''unreasonably'' large. The 1994 Handbook defines unreasonably large deviations in terms of the MAV, which varies with the size of the package.) The proposed criterion, which NIST advised has been in Handbook 133 since 1981 (Ref. 3) and has been widely accepted, requires that volumetric measuring equipment have a maximum graduation of no greater than ⅙ of the MAV for the labeled net quantity of contents of the package being measured. NIST explained in its letter to FDA that the criterion is intended to ensure that volumetric measuring equipment can accurately detect MAV deviations (Ref. 3).

NIST pointed out that frequently the ⅙ MAV criterion will not result in an exact equivalent to most graduations provided on volumetric measures. Under such circumstances, the most commonly used graduation should be selected. For example, where a 100 mL flask is to be used for a volumetric measurement, proposed § 101.245(f) (Table 3 ''Liquid or Dry Volume MAV's for Individual Packages Labeled in Metric Units'') provides that the MAV for the flask is 5.5 mL. When this MAV is divided by 6, a graduation criterion of 0.917 mL results. Thus, graduations smaller than 0.917 mL must be present on the 100 mL volumetric measure. NIST states that the most common graduation on a flask conforming to such a criterion would be a 0.5 mL graduation. Flasks marked 0.1 mL graduations could also be used but would rarely be available. A 100 mL buret marked with 0.1 mL graduations could be used. Flasks marked only with 1 mL or larger graduations would not meet the ⅙ MAV criterion.

Given the well-recognized expertise of NIST on weight and measure matters, it is appropriate for FDA to defer to NIST in the development of this ⅙ criterion. FDA tentatively concludes that the graduations that will result under this criterion will be adequate to enable regulatory officials to make accurate and fully informed judgments with respect to the MAV. FDA is therefore proposing to adopt the standard.

iv. *Gravimetric measuring equipment.* In § 101.215(d), FDA is proposing criteria for selecting gravimetric measuring equipment. These criteria are intended to ensure the appropriateness of the equipment used to measure the contents of the package being evaluated. The proposed criteria are a reiteration of those in the 1994 Handbook (including references to Handbook 44 in the Handbook 133 portion of the 1994 Handbook). FDA tentatively finds that more criteria are needed to guide the selection of gravimetric equipment than are needed to guide the selection of other types of measuring equipment because of the great complexity of gravimetric equipment. For gravimetric equipment, not only must the graduations on a balance be appropriate, but the design of equipment must also be appropriate for measurement of the package. In addition, the equipment must be functioning properly to make the measurement, and many factors may affect the way the equipment functions.

*a. Gravimetric equipment design.* With respect to gravimetric equipment design, proposed § 101.215(d)(1) (i) and (ii) provide that the portion of the balance on which the package is placed for weighing (i.e., the load receiving element) must be large enough to hold the package and be of sufficient weighing capacity for the package. Proposed § 101.215(d)(1)(iii) requires that, based on the 1994 Handbook, the balance have a minimum number of graduations, referred to as ''scale divisions'' (i.e., 100). FDA is proposing this number based on the 1994 Handbook (see page 2–11, Table 3 of Handbook 44). NIST advised FDA that at least 100 divisions are necessary to permit reliable assessments of the performance of a balance.

In addition, FDA is proposing a ⅙ MAV criterion for the maximum size of the individual scale divisions. This criterion is consistent with the ⅙ MAV volumetric graduation criterion, and FDA is proposing it for the same reasons that underlie the volumetric graduation criterion. Assessment of conformance with this criterion will also be made in a manner that is consistent with the approach discussed previously for the volumetric graduation criterion, except that the appropriate gravimetric tables (e.g., Tables 1 and 2 in the proposed regulation would be used to determine the MAV. NIST advised FDA that the proposed ⅙ gravimetric criterion has also been in Handbook 133 since 1981 (Ref. 3) and has been widely accepted.

*b. Gravimetric equipment performance.* With respect to gravimetric equipment performance, FDA is proposing selection criteria that will ensure that balances are sensitive enough to measure small variations in the net contents of different packages, which may be made with different packaging materials, without weighing errors attributable to the balance that would create an unfair bias concerning the weighing results. These sensitivity criteria will focus on ensuring that any balance selected for making measurements will not produce unacceptable errors (subsequently referred to as ''rejection criteria'') in a variety of performance tests.

Details of four performance tests are set forth in proposed § 101.215(d)(2). The proposed provisions require that the tests be performed before each initial daily use, use at a new location, or use in the presence of any indication of abnormal equipment performance, and that the balance be found in such tests not to exceed the criteria in the regulation for rejection. FDA is proposing to require that the tests be conducted before use of the balance because the sensitivity of the measuring device can be affected by handling and transportation to the test location, routine wear of mechanical or electrical components, and environmental factors at the test location such as temperature and air currents.

All of the proposed tests involve multiple weighings of test loads consisting of a variety of calibrated test weights (referred to as ''mass standards''). The proposed procedures, which reflect the procedures set forth in section N.1., page 2–11, Handbook 44, include an ''increasing load test'' (§ 101.215(d)(2)(i)), which is conducted by applying mass standards to the

[5] FDA also has imposed the 25-percent criterion on its field personnel for many years (see section 428.21 of FDA's Investigations Operations Manual).

balance in increasing increments (e.g., 1, 2, 3, and 4 pounds (lb)—up to 10 percent more than the package gross weight) and, for most types of balances, a ''decreasing load test'' (§ 101.215(d)(2)(ii)), which is conducted by reversing the increasing load test procedure. In addition, FDA is proposing a test involving off-center loading (called a ''shift test'' in Handbook 44) (§ 101.215(d)(2)(iii)), to determine whether a balance accurately weighs packages placed anywhere on the load receiving element (e.g., the scale platter or pans). Finally, FDA is proposing a ''repeatability performance test'' (§ 101.215(d)(2)(iv)), wherein mass standards are weighed at least twice.

NIST stated in its letter to FDA (Ref. 3) that the proposed test procedures are appropriate for balances used in determining the net contents of packaged food, and that these test procedures are based on the procedures in Handbook 44 for verifying the accuracy of balances used in supermarkets. NIST also advised that, although there are four different performance tests, only 2 to 3 minutes are required to complete them. In fact, NIST pointed out they are often looked upon as simply one test comprised of four different weighing procedures. NIST explained that each of the four different procedures is needed because each duplicates one of the most common ways that weighing devices are used. NIST stated that improperly functioning balances may not always register the same quantity with increasing and decreasing loads, repeated weighings of the same quantity, and weighings of the same quantity in different locations of the load receiving element. NIST stressed that it is important to evaluate balance performance using all common weighing procedures that may be used. To illustrate the long history of use and acceptance of the proposed test procedures, NIST pointed out (Ref. 3) that similar test procedures were published on January 31, 1945, by NIST (then called the National Bureau of Standards) in NBS Handbook H37, ''Testing of Weighing Equipment.''

As mentioned, FDA is proposing that balances not have errors exceeding the rejection criteria in any of the performance tests. The agency sets out the proposed rejection criteria in proposed § 101.215(d)(3). Under this provision, if the criteria are exceeded in any individual weighing that is a part of a performance test, the balance does not meet the gravimetric selection criteria, and the balance may not be used to determine whether an inspection lot is violative.

The gravimetric selection criterion concerns the size of the error that will trigger rejection when that error is expressed in terms of a number of scale divisions (see proposed § 101.215(d)(1)(iii)) on the balance. In the 1994 Handbook, this criterion varies according to the type of balance used and the weight of the individual package unit being tested. The 1994 Handbook expresses this criterion in terms of two classes of balances that are identified in Handbook 44 as Class II and Class III balances. (Class I balances pertain to the most precise type of balances that are used primarily for weighing precious stones. These balances are not used for weighing food.) Class II balances are analytical balances which are generally found only in laboratories. Class III balances are generally used at supermarkets by investigators in the field. A Class III balance might have only 3,000 scale divisions, whereas a Class II balance might have more than 50,000 scale divisions.

Proposed Table 1 in § 101.215(d)(3)(i) is derived from the 1994 Handbook. It contains directions on how to determine the class of the balance based on value of the smallest balance division and the minimum and total number of balance divisions. Proposed Table 2 in § 101.215(d)(3)(ii), which is also derived from the 1994 Handbook, contains directions on how to determine the number of balance divisions for rejection based on the class of the balance and the weight of the package in terms of the total number of balance divisions.

The criteria for rejecting a balance have been set forth in Handbook 133 since July 1986.[6] According to NIST, these criteria were developed in conjunction with the Scale Manufacturers Association, a national trade association that represents the majority of U.S. manufacturers of weighing devices. Although FDA is proposing the same criteria as those in the 1994 Handbook, FDA is not proposing to use the term ''tolerance'' to identify the standard proposed in Table 2 in § 101.215 because that standard focuses on the number of errors for rejection rather than the number of errors that are permitted.

c. *Equipment standardization.* FDA is also proposing a category of requirements that pertain to the standardization of other types of measuring equipment. NIST recommended (Ref. 3), and FDA agrees, that it is therefore appropriate that all Federal requirements for standardization incorporate the NIST standard units of weight and measure. Thus, FDA is proposing in § 101.215(e) that all measuring equipment be standardized to the NIST standard units of measure.

As recommended by NIST (Ref. 3), FDA is proposing that the standardization take place through either direct or indirect comparison with NIST standards. For example, a mass standard used in the field may be compared to either the corresponding NIST mass standard or to a mass standard that has itself been directly compared to the corresponding NIST mass standard. NIST advised that the comparison should be made in a manner consistent with well-recognized procedures developed by that agency. Specifically, NIST recommended use of calibration procedures found in NBS Handbook 145, Handbook for the Quality Assurance of Metrological Measurements, November 1986 (Ref. 5), for all measuring equipment other than time measuring devices. For time measuring devices, NIST recommended use of its standard operating procedure (SOP), Specifications and Tolerances for Reference Standards and Field Standard Weights and Measures, Specifications and Tolerances for Field Standard Stopwatches (Ref. 6).

NIST also advised, however, that Handbook 145 is being updated to include, in part, the SOP for stopwatches. In view of current updating of Handbook 145, FDA tentatively concludes that it is not necessary to propose procedures for standardizing stopwatches. The agency intends to incorporate the most up-to-date version of the test procedure for stopwatches in Handbook 145 in any final rule that may issue based on this proposed rule. If the anticipated revision of Handbook 145 has not been completed by the time of the final rule is issued, FDA may rely on NIST's SOP for stopwatches in the final rule.

NIST recommended that, except for volumetric glassware, the comparison to NIST standards be made on a routine basis (e.g., annually for equipment used on a weekly basis) (Ref. 3). NIST also advised that where neither Handbook 145 nor the SOP for stopwatches specifically provides calibration procedures for a particular type of measuring device, the requirement that calibration be done with a standard traceable to NIST can be satisfied by using nationally accepted standards and procedures that are traceable to NIST. NIST advised that calibration certificates or reports of tests of

[6] Section 3.1 of Handbook 133 incorporated the criteria by referencing the tolerances described in section T.N.3.2, page 2–22 of Handbook 44.

equipment should be maintained by FDA field offices to ensure that appropriate calibration intervals are met (Ref. 3).

Also, NIST provided guidance concerning the amount of error that it would consider acceptable in calibration procedures for stop watches, thermometers, linear measuring devices, volumetric measures, and mass standards (Ref. 3).

Because NIST is the Federal authority in matters concerning weights and measures, FDA tentatively concludes that it should follow NIST's recommendations in these matters. By following the recommendations of the agency with the most expertise on these matters in the Federal Government and whose views are informed by regular contacts with NCWM and the States, FDA should be able to establish a uniform national system that will be as efficient and workable as possible. FDA is therefore proposing to adopt NIST's recommendations for standardizing the types of equipment enumerated in the discussion that follows.

(*i*). *Stopwatch standardization.* In § 101.215(e)(1), FDA is proposing to require that any stopwatch used in procedures for measuring net contents not have an error exceeding ±2 seconds in a 3-hour time period. This proposed requirement is a reiteration of the provision on stopwatches that appears on page 3–34, section 3.13.1 of the Handbook 133 portion of the 1994 Handbook, except that the maximum permissible error pertains to the error during a 3-hour, rather than 2-hour time period. NIST stated that, except for an inadvertent typographical error, Handbook 133 would contain a 3-hour time period (Ref. 3). NIST explained that the Handbook 133 stopwatch criterion was based on Federal Specification GG–S–764C, which provides that a 3-hour time period be used for standardization.

(*ii*). *Thermometer standardization.* In § 101.215(e)(2), FDA is proposing to require that any thermometer used in procedures for measuring net contents not have an error exceeding ±1° Celsius (2 °F). This proposed requirement reflects the provision pertaining to thermometers that appears on page 4–4, section 4.2 of the Handbook 133 portion of the 1994 Handbook.

(*iii*). *Linear measure standardization.* The 1994 Handbook contains no requirements for linear measure standardization. As pointed out above, however, NIST advised (Ref. 3) that the proposal should include such requirements because linear measuring devices may be used in a variety of ways to determine net contents. NIST advised further that the 1994 Handbook does contain a number of recommendations for standardization of some linear measuring devices (see section 5.3.1, page 5–6 of the Handbook 133 portion of the 1994 Handbook). NIST stated that section 5.3.1 inch-pound recommendations could serve as a basis for requirements in the proposal pertaining to tapes and rulers. The recommendations provide, in part: (1) That, for measurements of 63.5 cm (25 in) or less, measurement errors shall be no greater than ±0.39 mm (± 1/64 inch), and (2) that, for measurements greater than 63.5 cm (25 in), measurement errors shall be no greater than ±2.5 mm (± 0.1 inch). NIST recommended that FDA proposes to include provisions that reflect these recommendations in the regulation.

FDA tentatively concludes that it should generally follow NIST's recommendations in matters concerning weights and measures. FDA is therefore proposing to adopt NIST's recommendations for standardization of tapes and rulers.

For calipers and depth gauges used to determine the level of fill in packages labeled by volume (headspace), the agency is also proposing standardization criteria based on information provided by NIST (Ref 3). NIST recommended that FDA establish an error limit of ± 50 micrometers for lengths of up to 400 mm; of ± 100 micrometers for lengths of 400 mm to 800 mm; and of ± 150 micrometers for lengths of 800 to 1,000 millimeters. NIST explained that such a requirement is needed to ensure that measurement errors attributable to these measuring instruments not adversely affect the results of the test. NIST based its recommendation for these error limits on the accuracy requirements for mechanical and electronic calipers and depth gauges that the American Society of Mechanical Engineers is considering including in its industry standard (ASME B89 1.14) (Ref. 7) for these devices.

FDA agrees with NIST that there is a need for standardization of these devices and is deferring to NIST for the appropriate standards. In proposed § 101.215(e)(3)(iii), Table 3, FDA is proposing to adopt the error limits for calipers and depth gauges that are recommended by NIST.

(*iv*). *Volumetric standardization.* In proposed § 101.215(e)(4), FDA is proposing a requirement that any flask or cylinder used in a procedure for measuring net contents not exceed error limits that vary according to the full capacity that is measured by the device. This proposed requirement reflects the error limits for flasks and cylinders that appear in Appendix I, page I–3 of the Handbook 133 portion of the 1994 Handbook. These error limits have been in Handbook 133 since before 1971 and are widely accepted as reasonable and appropriate. NIST advised FDA (Ref. 3) that, although error limits should be provided for both inch-pound and SI units of measure (volumetric measures may be graduated in either system of measure), all error limits should be expressed in terms of SI units only (i.e., mL) because metric measures are used more frequently in laboratories where standardization generally occurs. Therefore, the error limits that FDA is proposing in § 101.215, Table 4 are in SI units. Also, NIST pointed out that the error limits have been developed for liquids at the reference temperature that is closest to most common room temperature so as to minimize the adjustments in glassware and calibration liquid temperature that will have to be made to determine whether error limits have been exceeded.

(*v*). *Gravimetric standardization.* In § 101.215(e)(5), FDA is proposing to require that gravimetric measuring equipment used to measure net contents not exceed error limits that vary according to the size of the individual mass standard and the type of balance (i.e., Class II or Class III) used for the measurement. For Class III error limits, the proposed requirement reflects the error limits for field standard weights that appear on pages I–1 and I–2 in Appendix I of the Handbook 133 portion of the 1994 Handbook. These widely recognized error limits have been in Handbook 133 since 1981. As with volumetric standardization, while error limits need to be provided for both in inch-pound and SI units of measure (gravimetric measures may be graduated in either system of measure), all error limits are proposed to be expressed in terms of SI units only (i.e., mL) because metric measures are used more frequently in laboratories where standardization generally occurs.

For Class II balances, however, NIST recommended (Ref. 3) that significantly smaller error limits be adopted because these balances can reliably measure far smaller quantities than Class III balances. NIST advised that, while it had published some guidance concerning appropriate error limits in Class II balances (i.e., National Bureau of Standards Circular 547, Section 1, which is out of print), FDA should rely on Tables X5.1 and X5.2 of American Society of Testing and Materials (ASTM) Standard Specification E 617–91, Standard Specification for Laboratory Weights and Precision Mass Standards (Ref. 8) because the ASTM

Tables are more current than Circular 547.

Given NIST's expertise, FDA has tentatively decided to accept its recommendation. FDA is proposing to include the ASTM values in Tables 5 and 6 for Class II balances and 7 and 8 for Class III in § 101.215(e)(5).

FDA requests comments on the appropriateness of doing so.

4. Analytical Procedures

The 1994 Handbook provides specific instructions for a wide variety of methods of analysis for determining the net contents of the packages in samples. These methods are found in Chapters 3, 4, and 5 of the Handbook 133 portion of the 1994 Handbook. The methods fall into two broad categories. The first category consists of general test methods (referred to as ''core methods'' in this preamble) that are for use for all products. The 1994 Handbook contains core methods of analysis for determining net mass or weight, drained mass or weight, volume, count, and tare weight. The second category consists of core test methods that have been modified for use with specific products. The 1994 Handbook contains modified methods of analysis for determining the net mass or weight of aerosols, vacuum packed coffee, flour, and frozen foods. Also, the 1994 Handbook contains modified methods of analysis for determining the drained mass or weight of frozen foods and glazed raw seafood. With respect to volume, the 1994 Handbook contains modified methods of analysis for determining the net contents of mayonnaise, salad dressing, ice cream, frozen desserts, and fresh oysters.

FDA sees considerable merit in the 1994 Handbook's approach of providing directions for the use of analytical methodology because such directions will help to ensure uniform implementation of the methodology and thus contribute significantly to uniform enforcement. Without such directions, there would be a significant opportunity for analytical findings to differ among those who perform the analysis. FDA has therefore included in this proposal specific instructions to follow with respect to how to perform analytical procedures. The instructions are derived largely from methodology in the 1994 Handbook.

The agency is proposing procedures for determining net mass or weight in § 101.220, for volume in § 101.225, for count in § 101.230, and for tare in § 101.235. Consistent with methodology in the 1994 Handbook, each of the proposed sections sets out core procedures for use for all foods. In addition, the proposed sections on determining mass or weight and on determining volume include additional procedures for use with specific foods or for use in specific circumstances, which are explained in the proposed provisions.

Although the proposed methods have been taken largely from the 1994 Handbook, FDA has made several nonsubstantive changes for clarity and brevity. For example, the 1994 Handbook contains a number of methods for use only with certain specific foods. As mentioned above, these methods are generally core test procedures that have been modified for use with the particular food. These modifications are intended to facilitate the measuring process for the specific foods. However, while the modifications may be helpful for making the measurement, many of the descriptions of the modified methods include detailed measuring instructions that are not critical to achieving accurate analytical results (Ref. 3). The agency's tentative view is that it would be unnecessarily redundant to include each of the specific modifications of core methods in the regulation. Instead, FDA is proposing the general core procedures with some modifications for clarity.

In addition, where the 1994 Handbook methods are consistent with methodology in ''Official Methods of Analysis of the Association of Official Analytical Chemists International (AOAC),'' 16th ed., 1995, FDA is proposing to incorporate by reference the appropriate AOAC method in the regulation rather than the 1994 Handbook method because this approach is consistent with the agency's general preference for using AOAC methods. This preference is reflected in 21 CFR 2.19 of FDA's regulations which states that it is the policy of the agency in its enforcement programs to utilize AOAC methods where the analytical method is not prescribed in a regulation. Where the 1994 Handbook methods are not consistent with AOAC methodology, and the AOAC method appears to be more appropriate than that in the 1994 Handbook, FDA is proposing to adopt the AOAC method rather than the 1994 Handbook method. The combined use of more general core methodology and the incorporation of AOAC methods by reference in the proposal makes the proposed provisions significantly shorter than the corresponding provisions in the 1994 Handbook. As a result, the proposed provisions should be easier for affected parties to follow.

In a number of instances, FDA is proposing methodology that differs significantly from that in the 1994 Handbook. These differences are specifically addressed as follows.

a. *Proposed § 101.220, net mass or weight.* As mentioned above, analytical procedures pertaining to net mass or weight appear in proposed § 101.220, which contains both general procedures for making particular types of net mass or weight determination for foods, referred to as the ''core procedures,'' and more specific procedures for determining the net mass or weight of certain specific foods. Regardless of which type of measuring procedure is used, it will need to be performed on appropriate equipment and in an appropriate manner. FDA is proposing to reflect this fact in § 101.220(a), which states that all measuring equipment must conform to § 101.215, and that good weighing procedures must be used for all measurements. FDA considered proposing a prescriptive provision setting forth specifically what good weighing procedures must include. However, the agency has tentatively concluded that there are simply too many factors that may affect what procedures should be used for determining weight in a particular situation. FDA does, however, expect that all weighings will be performed on balances that: (1) Have been properly leveled; (2) are maintained at a zero reading when empty; (3) are properly dried after each weighing of moist packages (e.g., frost crystals on packages); and (4) are used in a manner that is consistent with the balance manufacturer's instructions.

The core procedure for net mass or weight is set out in proposed § 101.220(b)(1). This provision describes the general steps to follow in making this type of measurement. FDA is proposing that net mass or weight be determined by subtracting the average used tare mass or weight, determined in accordance with § 101.235, from the gross mass or weight of each package in the sample. This core procedure has been included in the Handbook 133 portion of the 1994 Handbook since 1981. Simply stated, what this provision means is that to determine the net weight of the contents of a package, it is necessary to subtract the weight of the packaging from the gross weight of the package. The appropriateness of this approach is clear as a matter of common sense.

In § 101.200(b)(2), FDA is proposing a specific procedure for determining net weight of unglazed frozen seafoods and vegetables. The proposed procedure is incorporated by reference from the ''AOAC,'' 16th ed., 1995 section 963.26, under the heading ''Net Contents of

Frozen Food Containers Procedure 1963.'' The proposed procedure is not identical to the procedure in Section 3.12, page 3–33 of the Handbook 133 portion of the 1994 Handbook. (Handbook 133 advises that all frozen products should be measured with the core net weight procedure that appears in that Handbook.) However, as stated above, where AOAC procedures are available, FDA is proposing to require that those procedures be used, unless the agency provides in this preamble a reason for requiring other procedures. Section 963.26 of Official Methods of Analysis of the AOAC specifically pertains to frozen vegetables and, by reference in section 35.1.02(b) of this AOAC analytical manual, to unglazed frozen seafoods. FDA tentatively concludes that use of the more specific AOAC procedure is appropriate because it clarifies that the weight of any frost found inside the food package is added to the weight of the seafood to determine the net contents. (Frost inside the package generally comes from the liquid portion of the food, whereas frost outside the package generally comes from the atmosphere.)

The core procedure for determining drained mass or weight appears in proposed § 101.220(c)(1). This procedure is similar to the core procedure for net mass or weight in that the drained weight is calculated by subtraction of a tare weight from a gross weight. However, under proposed § 101.220(c)(1), the tare weight is calculated by including the weight of any liquid drained from the product with the weight of the other packaging materials. The tare weight is measured by placing the product on an appropriate sieve that is positioned at an appropriate angle on a receiving pan, placing all packaging materials on that same pan, draining the product for exactly 2 minutes, and weighing the pan after removal of the sieve containing the product (proposed § 101.220(c)(1) (i) to (iii)). This core procedure does not directly measure the weight of the drained food remaining in the sieve used to drain the liquid from the food.

FDA developed the proposed § 101.220(c)(1) after close review of both the drained weight core procedure in section 3.10, page 3–24, of Handbook 133 and the existing AOAC procedures for drained weight in ''Official Methods of Analysis of the AOAC,'' 16th ed., 1995, section 968.30, under the heading ''Canned Vegetables Drained Weight Procedure.'' The drained weight procedures in both documents are quite similar, but there are some differences. FDA is proposing to resolve the differences by adopting some elements from both documents for its core procedure.

Both the AOAC procedure and the Handbook 133 procedure provide for drained weight determinations using a 203-mm (8-inch) U.S. No. 8 standard test sieve for packages with net quantity of contents of 1.36 kg (3 lb) or less and a 12-inch (305 mm) U.S. No. 8 standard test sieve for packages with net contents greater than 1.36 kg (3 lb). However, the Handbook 133 procedure does not provide for use of a different size sieve for canned tomatoes, as the AOAC procedure does. The AOAC procedure specifies that for canned tomatoes, a U.S. No. 11.3-mm (7⁄16-inch) standard test sieve is to be used. Given that AOAC procedures are generally better suited for FDA enforcement purposes than Handbook 133, the agency is proposing to require in § 101.220(c)(1)(ii) that drained weight for canned tomatoes be determined with a U.S. No. 11.3-mm (7⁄16-inch) standard test sieve.

In one respect, however, the Handbook 133 drained weight core procedure is more appropriate than the AOAC core procedure for canned vegetables. The AOAC procedure is not specific about how the drained solids should be weighed. Thus, under the AOAC procedure, weighings could be made either (1) Through direct weighings of the sieve with the drained solids, followed by subtracting the weight of the sieve, or (2) through indirect weighings involving subtraction of the weight of the drained liquid and package tare weight from the package gross weight. NIST has advised (Ref. 3) that the 1994 Handbook procedure is preferable because the indirect approach provides less opportunity for continued drainage of the solids after the specified drain time. NIST explained that with the indirect procedure, when the sieve is removed the precise weight of the drained liquid is obtained, whereas with the direct approach, the solids continue to drain during weighing, resulting in a lower drained product weight.

FDA recognizes that, if it were to permit use of both direct and indirect drainage procedures, there would be an opportunity for drained weights to differ depending upon which procedure is used. Such differences would be contrary to the agency's goal of establishing a system that ensures that there will be as much uniformity in measurements as possible. Accordingly, FDA is proposing to provide for only indirect weighing in the drained weight procedure in § 101.220(c)(1).

The agency notes that in the food standard regulations on canned fruit (21 CFR part 145) and canned vegetables (21 CFR part 155) there are drained weight procedures that are based on the direct weighing procedure. If FDA adopts the procedure set forth in § 101.220, it will consider whether to propose to revise those regulations for consistency with § 101.220 or to remove the procedures from those regulations.

With respect to procedures for specific products, the agency is proposing in § 101.220(c)(2) to incorporate by reference AOAC procedures for determining drained weight for glazed vegetables and frozen seafood (except for frozen shrimp and crab meat) (AOAC section 963.18), frozen shrimp (AOAC section 967.13), and frozen crab meat (AOAC sections 967.13 and 970.60) and, in § 101.220(d), shucked oysters (AOAC section 953.11). Corresponding procedures appear in Handbook 133 in sections 3.14 (page 3–35), 3.13 (page 3–35), and 4.16 (page 4–43). The Handbook 133 procedures differ from the AOAC procedures in only two respects. First, section 3.13 provides for thawing the frozen shrimp or crab meat in a plastic bag in a water bath, whereas AOAC sections 967.13 and 970.60 provide for thawing the product directly in the water bath at a specific temperature without being placed in any bag. In addition, section 4.16 of Handbook 133 provides for draining the liquid from the shucked oysters with a U.S. No. 8 standard test sieve, whereas AOAC 953.11 provides for draining this liquid with a custom designed sieve referred to as ''skimmer.'' Again, without a specific reason to do otherwise, FDA is proposing to require that the AOAC procedure be followed.

b. *Proposed § 101.225, volume.* Proposed § 101.225 contains both general procedures for determining the net volume of most foods and more specific procedures for determining net volume of specific foods.

In § 101.225(a), FDA is proposing to require that measuring equipment conform to § 101.215, and that good weighing and measuring procedures be used for all measurements.

The core procedures for net volume appear in proposed § 101.225 (b) and (c). Both procedures have been in Handbook 133 since 1981 and are widely recognized as valid and appropriate methods (Ref. 3). They are essentially the same as core procedures appearing in chapter 4 of the Handbook 133 portion of the 1994 Handbook.

The procedure prescribed in proposed § 101.225(b) uses only a volumetric measure to determine the net contents. It involves pouring the entire contents of a package into a volumetric measure (see proposed § 101.201(a) for appropriate reference temperature) and

comparing the liquid level with the graduations on the measure.

The procedure prescribed in proposed § 101.225(c) uses both a volumetric measure and a balance to determine the net contents, with most measurements involving a gravimetric procedure for net volume. Initially, the proposed procedure requires that a test demonstrate that individual packages within the sample have constant product density (weight/volume at the appropriate reference temperature). For this product density test, the same measured amount of product from two individual packages is weighed. Where the weight is the same in both cases, information from the weighings is used to calculate the volumes of the remaining individual packages of product in the sample from the weights of those packages. NIST explained (Ref. 3) that the product density test must demonstrate the same measured weight in both cases because only when product density is constant among all of the individual packages within the sample may the weights of the packages be used to calculate the volumes of those packages. If used in other circumstances, net volume determinations made using proposed § 101.225(c) could have significant errors. When product density is constant, however, the gravimetric procedure in proposed § 101.225(c) is considerably faster than the procedure in proposed § 101.225(b) because, under § 101.225(c), most packages are simply weighed, while under § 101.225(b), all packages must be opened, their contents poured into a volumetric measure, and the liquid level of these contents compared with the graduations on the measure.

NIST pointed out that although the gravimetric procedure proposed in § 101.225(c) basically relies on constant variability, some flexibility must be provided for in the procedure because most types of balances display weight in the form of a digital reading that has been rounded by computerized components within the balance to the nearest whole scale division (Ref. 3). Thus, the balance may introduce variation of as much as one-half scale division. In the presence of such balance variation, more than a one scale division difference must be present to conclude that differences in weights are attributable to the food rather than to the balance. Thus, NIST advised, only where more than one scale division is present between the 2 volumes weighed in the product density test should proposed § 101.225(c) contain a provision prohibiting its use to determine net volume because the product density is not constant (see proposed § 101.225(c)(3)(v)).

NIST advised (Ref. 3) that proposed § 101.225(c) may appear different from the Handbook 133 gravimetric procedure for volume to some affected parties because of the presence of the above stipulation that the procedure not be used where more than a one scale division difference between packages is present. However, NIST pointed out (Ref. 3) that Handbook 133 actually needs this stipulation to be properly updated. NIST explained that the existing gravimetric procedure in Handbook 133 was developed for the types of scales and balances used by weights and measures officials in the 1960's and 1970's, which did not have the computerized components with the capability of rounding to the nearest whole scale division.

In § 101.225 (d), (e), (f), and (g), the agency is proposing measuring procedures for specific products. In paragraphs (d) and (e), FDA is proposing to incorporate by reference AOAC procedures for determining net volume for shucked oysters, clams, or scallops and for ice cream and frozen desserts. Corresponding procedures appear in Handbook 133 in sections 4.16 (page 4–43), and 4.15 (page 4.38). The Handbook 133 procedures differ in only a few respects. For shucked oysters, clams, or scallops, the AOAC procedure includes specific procedures for preparing the food for measurement that are not contained in Handbook 133. For ice cream and frozen desserts, the AOAC procedure includes specific procedures for handling and freezing the food that are not included in Handbook 133. Also, the AOAC procedure in Method I (AOAC 968.14) provides that kerosene is the immersion fluid for the measurement, rather than cold water, as provided for in Handbook 133.

NIST points out (Ref. 3) that there could be significant problems for field regulatory officials to safely transport and handle kerosene. NIST stated that kerosene is specified in the AOAC procedure to ensure that the food will not mix with the immersion liquid. NIST also advised, however, that water of 0.56 °C (33 °F) or below may be used as the immersion liquid provided there are no visual indications of mixing.

Based on NIST's position on this matter and the deference that it considers to be due NIST, FDA tentatively concludes that it should permit the use of sufficiently cold water for measuring the volume of ice cream and frozen desserts. FDA is therefore proposing to permit substitution of water of 33 °F (0.56 °C) or below for kerosene in the AOAC procedure, provided that the food does not mix with the water.

In § 101.225(f), FDA is proposing a volumetric depth gauge procedure that may be used to determine volume where the food has a smooth and level headspace (e.g., oils, syrups, and other viscous liquids). The proposed procedure involves determining the headspace of the package at the point of contact with the food using a depth gauge; emptying, cleaning, and drying the package; and determining the amount of water necessary to refill the package to the headspace present with the food. The proposed procedure reflects the procedure in section 4.6.1, page 4–12, of the Handbook 133 portion of the 1994 Handbook but with a few differences because of the NIST recommendations (Ref. 3).

FDA is proposing to require a 6-inch bubble level rather than at least a 10-inch level because NIST advised that 6-inch levels are adequate for the intended purpose and more commonly available than 10-inch levels (Ref. 3). Also, the agency is proposing no restrictions on the size of the micrometer depth gauge because the test procedure can be used on a wide variety of package sizes that may require the use of depth gauge rods of different lengths (Ref. 3). Further, section 4.6.1 of Handbook 133 states that the size of the micrometer measuring rod shall be 0 to 9 (in), but NIST recommended that no size be stipulated. NIST advised that, when this section of Handbook 133 was written, NCWM intended to provide guidance in selecting commonly available equipment appropriate for use in testing most products, but there was no intent on the part of NCWM to limit the procedure's use to measurements of less than 9 (in) (Ref. 3).

In § 101.225(g), FDA is proposing a volumetric air space procedure that may be used to determine volume where the food does not have a smooth and level headspace (e.g., mayonnaise). The proposed procedure involves determining the amount of air space above the product in the package and then the total container volume. Subtracting the airspace volume from the total container volume gives the product volume. The proposed procedure reflects section 4.8, p. 4–20 and section 4.14.2, p. 4–36, of the Handbook 133 portion of the 1994 Handbook.

There is, however, one significant difference between all of the procedures proposed in § 101.225 and the corresponding Handbook 133 procedures. The difference concerns reference temperatures. As mentioned previously in this preamble, a

''reference temperature'' is the temperature at which the fill of a food sold by volume must meet the declared net quantity of contents (see proposed § 101.205(m)). This temperature is important in measurements to determine the net volume because the volume that is occupied by any food varies with temperature. Where the temperature falls below the reference temperature, the volume decreases. As a result, a product that contains the declared net quantity of contents at the reference temperature could measure below the declared net quantity at a reduced temperature. If a regulatory official made a measurement at a reduced temperature, an appropriately labeled product might be considered violative. Such a situation would be unfair to the manufacturer. To prevent this situation, Handbook 133 prohibits measurement where product temperatures are below the appropriate reference temperature. Conversely, measurement at a temperature higher than the reference temperature could be unfair to consumers, but Handbook 133 does not address this situation.

To be fair to both consumers and manufacturers, the volumetric methodology that FDA is proposing in § 101.225 provides that the food be brought to the appropriate reference temperature before measurement of its volume. However, there is often no practicable way to maintain the reference temperature while all subsamples are being measured. The 1994 Handbook provides for this situation by advising that officials have some flexibility with respect to these temperatures in making fluid measurements, but it does not specify how much flexibility is appropriate. Without any constraints on this flexibility, there is reduced assurance of uniformity of enforcement. However, NIST suggested that one way to identify an appropriate amount of flexibility would be to specify those reference temperature ranges at which there would be no more impact in volume measurements than 0.01 percent of the measured volume (Ref. 3). NIST stated that measurements should be performed from −18 °C (0 °F) to −15 °C (5 °F) for frozen food, from 1.7 °C (35 °F) to 7.2 °C (45 °F) for refrigerated food, and from 20 °C (68 °F) to 22.7 °C (73 °F) for other foods. NIST explained that these temperature ranges would afford needed flexibility in making measurements (Ref. 3).

As the agency has stated repeatedly in this document, it has tentatively decided to follow all of NIST's recommendations on matters of weights and measures. FDA is therefore proposing to adopt NIST's recommendations for appropriate reference temperature analytical ranges in § 101.225(b)(1). Under this provision, all measurements of net volume are to be made at the NIST-recommended temperatures, unless FDA has specifically provided otherwise.

There is a second difference between § 101.225 and Handbook 133 concerning measuring devices used ''to deliver'' liquids. All volumetric measures are calibrated either ''to deliver'' or ''to contain'' a volume of liquid. The graduations of ''to deliver'' volumetric measures represent the volume of liquid in the vessel that can be poured from it. The graduations of ''to contain'' volumetric measures represent the volume of liquid in the vessel and do not represent the volume of liquid that can be poured from it (some liquid is inevitably retained after pouring). However, both types of measures actually measure the same quantity, and both types may be used to determine the volume of any liquid, provided appropriate procedures for use are followed. With proper use, the accuracy of the measurements from either type of volumetric measure is equivalent.

''To contain'' volumetric measures must be cleaned and dried between each use because the measure was calibrated and marked in comparison to a cleaned and dried volumetric standard. However, ''to deliver'' measures do not have to be prepared in this manner because they have been calibrated to deliver a specific amount of liquid after a specific drain time that is marked on the measures. These measures only have to undergo an initial wetting and draining treatment. Section 4.3.c. of Handbook 133 provides a set of directions for preparing these measures for use. The directions, which are consistent with the recommendations of NIST for such calibration (Ref. 3) have been reiterated in proposed § 101.225(b)(2)(ii).

However, some manufacturers of volumetric measures may use different emptying and drainage times in calibration procedures than those currently in Handbook 133. Where they do so, the manufacturer designates the appropriate time for emptying (including pouring out the liquid and draining it) or draining (excluding the time for pouring out most of the liquid) the measure. (Most manufacturers that do designate such a time, express it in terms of a draining time (Ref. 3).) NIST recommends that when a manufacturer designated emptying or drainage time appears on a measure, that time be used.

In view of this recommendation and of the fact that it is logical to assume that greater accuracy would consistently result from following the manufacturer's recommendation, when it is present, than more general procedures, FDA is proposing in § 101.225(b)(2)(ii)(B) to differ from Handbook 133 provisions by requiring the use of the manufacturer's delivery recommendations when they are present. FDA requests comment on the appropriateness of its approach.

FDA points out that its Investigations Operations Manual (IOM) directs its personnel to use only ''to contain'' volumetric measures, whereas the proposed provisions do not include this restriction because of the recommendations mentioned above by NIST (Ref. 3). If FDA adopts this proposal, the IOM will be modified to reflect this change.

c. *Proposed § 101.230, count.* Chapter 5 of the Handbook 133 portion of the 1994 Handbook contains two core procedures for checking net contents declared by count. The procedure may be used in all situations that involve counting the contents of each individual package. However, a gravimetric test procedure may also be used to determine count where product density (weight/volume at the appropriate reference temperature) is constant among all of the individual packages within the sample. (As discussed previously in this preamble, gravimetric procedures for other forms of expression of net contents provide reliable results only where product density does not vary among individual food packages.)

FDA is proposing the Handbook 133 individual count as a core procedure in § 101.230(a) and the gravimetric count core procedure in § 101.230(b). Where it may be used, the gravimetric procedure for net count is considerably faster than the procedure in proposed § 101.230(a), because most packages are simply weighed rather than being subjected to the procedure where all packages are opened, and their contents individually counted.

To determine whether the product density is constant, proposed § 101.230(b)(1) prescribes a product density test that requires that, for two individual packages, the net contents be weighed at the reference temperature and individually counted. These values are used to calculate the net weight of the package with the labeled count. For both packages, the labeled count must be calculated to weigh the same amount. As discussed previously in this document, because most types of balances may introduce some variation in measurements from computerized components that round to the nearest whole scale division, more than a one scale division difference must be

present to conclude that differences in weights are attributable to the food rather than to the balance. Thus, where more than one scale division is present between the two calculated weights of the labeled count in this product density test, proposed § 101.230(b)(1)(v) prohibits the use of the gravimetric procedure to determine net count because the product density is not constant.

Where more than one scale division is not present, proposed § 101.230(b)(2) contains a gravimetric measuring procedure wherein the balance used in the product density test is also used to determine the net weights of the individual packages in the sample, and the product density is used to convert the net weights to net counts. This procedure reflects the core procedure appearing in Chapter 5[7] of the Handbook 133 portion of the 1994 Handbook. This procedure has been in Handbook 133 since 1981.

The proposed procedure may appear to be different from the Handbook 133 procedure because of the presence of the stipulation against use of the procedure where there is a two or more scale divisions difference in the product density test. However, NIST recommended incorporating this stipulation to update the Handbook 133 gravimetric procedure for net volume (Ref. 3). As stated previously, the Handbook 133 procedure was developed for the types of scales and balances used by weights and measures officials in the 1960's and 1970's.

FDA points out that the core procedures for count in proposed § 101.230 (a) and (b), if adopted, will be used primarily for dietary supplements in tablet, capsule, or other unit dosage form rather than for food in conventional food form. For such dietary supplements, consumer value comparisons are facilitated primarily by information concerning the amount of dietary ingredient in the unit form and the number of such units in the food package. A statement in terms of the net weight alone is often of little practical value to purchasing decisions. For dietary supplements in unit form, FDA generally requires that declarations of net quantity be expressed in terms of net count, with statements of net contents in other forms being voluntary expressions.

With respect to food in conventional food form, only a few products (e.g., chewing gum) may express net contents in terms of only count. The agency solicits comments concerning whether it should require that declarations of net quantity of contents on dietary supplements in unit form include information concerning the amount of dietary ingredient in a unit of the supplement, as well as information in terms of count.

d. *Proposed § 101.235, tare.* The Handbook 133 portion of the 1994 Handbook defines ''tare weight'' as the weight of a container, wrapper, or other material that is deducted from the gross weight to obtain the net weight. With respect to other material that is deducted from the gross weight, regulatory officials have had differing opinions concerning whether food particles adhering to the container and liquids from the food absorbed in the container must be included in tare weight. Because of a lack of agreement in this area, Handbook 133 contains definitions of tare to accommodate all positions of the officials. Any of the definitions may be used with the gravimetric methods of analysis in Handbook 133, and significant variation in analytical findings may result from this flexibility.

Handbook 133 contains definitions for ''dry tare,'' ''dried used tare,'' and ''wet tare.'' ''Dry tare'' is defined as unused tare that comprises all packaging materials (including glue, labels, and ties) that contain or enclose a product, including prizes, gifts, coupons, or decorations that are not part of the product. ''Dried used tare'' is defined as used tare for which an effort is made to reconstruct the unused tare weight by removing the food from the tare by washing, scraping, wiping, ambient air drying, or other techniques involving more than ''normal'' household recovery procedures but not including such laboratory procedures as oven drying because oven drying can damage the tare material and result in invalid tare determinations. ''Wet tare'' is defined as used tare when no effort is made to reconstruct unused tare weight. For wet tare determinations, only readily separable food product is removed. Wet tare may include food particles that adhere to packaging materials, as well as fluids that may have been absorbed into these materials. As a result, free flowing fluids that have drained from the food may not be included in the net mass or weight of the food. With used wet tare, there is a significant possibility that there will be large variations in tare weight (Ref. 3). These variations may differ with the type of product, packaging materials (e.g., with absorbent packaging material), and handling and storage conditions. Additional variations in wet tare may be caused by the procedures used to determine wet tare, such as how long the product is allowed to drain before it is removed from the packaging and weighed.

NIST pointed out (Ref. 3) that these variations make it difficult for packers to set accurate fill levels because, in most cases, they must overpack to accommodate the largest possible wet tare determination that could be found with the product. Because of variations in wet tare determinations and the fact that dry tare is generally not available in sampling locations such as warehouses and retail stores, NIST recommended (Ref. 3) that FDA require that tare determinations be made with only dried used tare.

In response to NIST's recommendation, and in view of the fact that FDA has evaluated net contents declarations with dried used tare for many years, FDA is proposing in § 101.235(a) that only dried used tare be used in quantity of contents determinations. The agency is not proposing that unused dry tare be permitted because the agency is proposing these rules for national uniformity, and there may be some weight differences in the two types of dry tares from a variety of factors such as absorbed packing medium. The procedures that FDA is proposing for determining dried used tare are those that are currently set out in the 1994 Handbook. The agency considers them appropriate because they have been widely accepted by State and local regulatory agencies and industry for more than 30 years (Ref. 3).

With respect to how many tares must be weighed to determine the average tare that will be used in gravimetric procedures to determine the net contents, the Handbook 133 portion of the 1994 Handbook provides for 2 approaches for determining the average value. However, the 1994 Handbook permits only one of these approaches to be used. This approach is set out in ''Alternative Tare Procedures,'' in section 2.11.4., page 2–22 of Handbook 133, with modifications made by the 1994 Handbook.

The ''Alternative Tare Procedures'' involve a 2-stage procedure. An initial small tare sample size is weighed, and the variation within the individual packages of that initial sample is used to make a decision on how many additional individual packages must be weighed before calculating the average tare. The initial test is needed because tare weight can vary considerably from package to package (e.g., plastic buckets, glass bottles, and metal cans). If this tare variation is sizeable in comparison with the net weight variation, the net weights calculated for the sample packages can be erroneous.

[7] Section 5.1.3, page 5–3, of Handbook 133.

To minimize erroneous findings, the 1994 Handbook identifies values of ratios of the tare weight divided by the net weight that will ensure that no more than 5 percent of the gross weight variation results from variation in tare. (Before the 1994 Handbook revisions of Handbook 133 were made, the contribution of this variation in tare could be 25 percent of the gross weight. The contribution was limited because of concern that tare errors might influence the net weight results to too large a degree.) In some cases, where there is a large variation in package tare weights, all of the packages in the sample may have to be opened, and the average tare determined using the tare values for each of these packages.

NIST recommended that FDA adopt the 1994 Handbook procedures for determining the numbers of tare weights to be obtained (Ref. 3). Again, because FDA is not aware of any potential problems with these procedures, and because of NIST's expertise, FDA has tentatively decided to follow NIST's recommendation with respect to appropriate tare weight. Therefore, proposed § 101.235 (b) through (i) incorporates a procedure for determining fare weight that is modeled after the 1994 Handbook.

5. Compliance Procedures

As explained previously, the 1994 Handbook uses the ''Category A'' approach to ascertain conformance with net quantity labeling requirements. This approach has two aspects: Procedures for sample collection, and procedures for using the package characteristics of a sample to determine whether the inspection lot is violative. The sample collection aspect of the ''Category A'' approach, which was discussed earlier in this preamble, serves as the basis for FDA's proposed § 101.210. This section of the preamble pertains to the other aspect of the ''Category A'' approach, which may be characterized as ''compliance procedures.'' Compliance procedures minimize the number of case-by-case decisions by prescribing specific steps to determine whether the requirements for declarations of net contents have been met.

a. *Requirements pertaining to average package fills.* According to NIST (Ref. 3), the insistence in the 1994 Handbook that the average quantity of contents of the packages in a lot, shipment, or delivery be equal to or exceed the quantity printed on the label is the primary tool for protecting consumers. Most State and local regulatory actions result from this aspect of the 1994 Handbook (Ref. 3). The focus on the average quantity of contents provides good assurance that, while individual packages within an inspection lot may fluctuate, on a lot basis, consumers will receive the amount of food declared on the label (Ref. 3).

i. *Industry concern about average requirements.* The industry Task Force stressed that it is concerned about Handbook 133's focus on average quantity of contents because decisions about whether regulatory actions are warranted are usually made based on inspection lots. The Task Force argued that it is not appropriate to subject an inspection lot to regulatory action based solely on an average requirement because if this is done, it will not be possible to tell whether the problems found in an inspection lot are the result of underfilling or of the reasonable variations permitted for a production lot under section 403(e)(2) of the act. The Task Force stressed that, within each production lot, net contents will often rise above and fall below the declared net contents, but that the average net contents of the production lot will meet the declared net contents.

Given the fluctuations among packages, however, the Task Force said that inspection lots may not be representative of their larger parent production lots. The Task Force explained that inspection lots are generally small parts of much larger production lots. Because of distribution practices, the inspection lot usually represents an interval of production and not a random sample of the production lot. Thus according to the Task Force, the averaging out at the declared contents level that occurs in the production lot may not occur in the inspection lot.

The Task Force expressed particular concern over regulatory action based on very small inspection lots. The Task Force contended that net content examinations of inspection lots should be used primarily as ''audit tools,'' and that actions against an inspection lot should only be taken if a firm's quality control records show that there were problems with the production lot at the plant, or if access to such records is denied to regulatory officials.

The Task Force also argued that FDA should establish a statistically valid sampling variation allowance that is not reduced for small sample sizes. The Task Force explained that even package filling operations that comply with GMP cannot guarantee that each inspection lot with as few as 10 to 30 units will always have the same average net contents. The Task Force requested that a sampling variation allowance based on two standard deviations of the sample mean be applied to all in-plant, wholesale, and retail inspection samples.

ii. *NIST position on industry concern.* NIST maintained that it is fair to industry for regulatory agencies to follow the 1994 Handbook and to take regulatory action against inspection lots if they are found to be violative based on samples analyzed using the average requirement because of the mathematical approach that undergirds that requirement.

iii. *Mathematical approach.* The 1994 Handbook requires that a sample of the inspection lot be drawn from the entire inspection lot, using random selection procedures. Such procedures are necessary if a reliable mathematical evaluation of net contents findings is to be made. Random selection of the sample means that, using the net contents of the individual packages in the sample, it is possible to derive a reliable picture of the range of possible average net contents values for the inspection lot. The range of possible average net contents values will be correct 97 or more times out of 100 (or, in statistical terms, with 97 or more percent confidence).

The 1994 Handbook uses the range of possible average net contents values for the inspection lot to estimate the uppermost average package error that could be present in the inspection lot with 97 or more percent confidence. (As explained previously in this document, the package error is the difference between the measured net quantity of contents and the labeled quantity on the package.) If the package error calculated using the 1994 Handbook is less than 0, it would mean that the net contents of a significant number of packages in the inspection lot would not meet the declared net contents, and that inspection lot is violative.

Under the 1994 Handbook, the range of possible average net contents values for the inspection lot is calculated by: (1) Determining the net contents of all individual packages in the sample; (2) Determining the package errors for all of the individual packages in the sample (again, the package error is the difference between the measured net quantity of contents and the labeled quantity on the package); (3) Determining the average package error for the sample; and (4) Determining the range statistic, that is, a value that, when combined with the average package error for the sample (by addition to and subtraction from this error), will be used to make a reliable estimate of the range (i.e., the difference between the greatest and smallest values) of average package error values that may be present in the inspection

lot. The range statistic, is determined by: (a) Determining the standard deviation (s) of package errors within the sample (s is a statistic used as a measure of dispersion (i.e., differences of individual values from the mean) in a sample); (b) Selecting from a mathematical table (found in Column 2 of Table 1 in proposed § 101.240) the appropriate statistic that will be used to account for the number of individual packages in the sample. There is a 97 percent confidence incorporated in the estimate of the range of possible variations of average package error within the inspection lot. (Any estimate of the range of possible variations in average package error within the inspection lot using the average package error of the sample will vary with the sample size because the reliability of such an estimate is greater as more individual measurements are made. The 1994 Handbook refers to the statistic that it uses to account for sample size and the desired confidence as the ''Sample Correction Factor'' (SCF). The SCF gets larger as the sample size gets smaller. For the SCF values in Table 1 of proposed § 101.240, the level of desired confidence for estimates about the inspection lot is that they be correct 97 or more times out of 100 (or, in statistical terms, with 97 or more percent confidence). (The 97 percent confidence aspect of the SCF statistic is consistent with Task Force requests for a sampling variation allowance based on two standard deviations of the sample mean.); and (c) Multiplying ''s'' by the appropriate SCF to determine the range statistic, that is the sample error limit (SEL). The SEL is a statistical value that allows for the uncertainty between the average error for the sample and the average error for the inspection lot.

The 1994 Handbook uses the SEL to estimate the uppermost average package error that could be present in the inspection lot with 97 or more percent confidence. This package error is determined by adding the SEL to the average package error of the sample. If this uppermost average package error in the inspection lot is less than 0, the 1994 Handbook, as stated above, classifies the inspection lot violative.

iv. *Fairness of the 1994 Handbook approach.* To illustrate fairness in the 1994 Handbook's approach to reasonable variations in the average net quantity of contents in the inspection lot, NIST referred to a number of hypothetical sampling situations with varying sample net weights (Ref. 3). All of these situations pertained to inspection lots with a total declared net weight of 48 oz (3 lb) and with varying package errors within a sample size of 12 individual packages. NIST advised that because it used a computer for all of its calculations in these situations, the formula it used for determining the standard deviations of the package errors in each of the situations was $s=(\sum(x_i-x)^2/(n-1))^{1/2}$.

Situation A: Inspection lot size: 250 packages

Package error range: 3 oz (−1.5 oz to +1.5 oz)

Package errors among the 12 packages within the sample: +1, −1.5, +0.5, −1, +1, −1.5, −1.5, −1, +0.5, −1.5, +1.5, −1.5

Average package error: −0.42 oz

*Calculation of SEL*

Standard deviation (s): 1.203 sample correction factor (SCF) for sample size of 12 from Table 1, § 101.240: 0.5774 SEL=1.203×0.5774=0.69 oz

*Compliance Status of Inspection Lot*

Avg package error + SEL=−0.42+0.69=0.27 oz 0.27 meets the 0 or greater criterion discussed above, so the lot is in compliance

*Permitted Reasonable Variations in Package Errors*

Estimation of Allowance for Reasonable Variation Range Within Inspection Lot = sample avg package error ± SEL=−0.42 oz ±0.69 oz=−1.11 oz to 0.27 oz

*Permitted Reasonable Variations in Average Net Weight*

48 oz−1.11 oz to 48+0.27 oz=46.89 oz to 48.27 oz

*Maximum Percent Shortage Within Reasonable Variations*

1.11 divided by 48×100=2.3%

Situation B: Inspection lot size: 250 packages: Package error range: 0.16 oz (−0.17 oz to −0.01 oz) (note that all errors are negative). Package errors among the 12 packages within the sample: −0.17, −0.01, −0.01, −0.01, −0.01, −0.01, −0.01, −0.02, −0.01, −0.02, −0.01, −0.01. Average package error: −0.02 oz

*Calculation of SEL*

Standard deviation (s): 0.0458 SCF for sample size of 12 from Table 1, § 101.240: 0.5774 SEL=0.0458×0.5774=0.03 oz

*Compliance Status of Inspection Lot*

Avg package error + SEL=−0.02+0.03=0.01 0.01 meets the 0 or greater criterion, so lot is in compliance

*Permitted Reasonable Variations in Package Errors*

Estimation of Allowance for Reasonable Variation Range Within Inspection Lot = sample avg package error ± SEL=−0.02 oz±0.03 oz=−0.05 oz to 0.01 oz

*Permitted Reasonable Variations in Average Net Weight*

48 oz−0.05 oz to 48+0.01 oz=47.95 oz to 48.01 oz

*Maximum Percent Shortage Within Reasonable Variations*

0.05 divided by 48×100=0.10%

Situation C: A small inspection lot, all of which is included in the sample, with mixed production codes (such as those often found in retail marketplace). Inspection lot size: 12 packages. Package error range: 1.49 oz (−1.5 oz to −0.01 oz) (note that all errors are negative). Package errors among the 12 packages within the sample: −1.50, −0.19, −0.5, −0.09, −1.40, −0.03, −0.01, −0.02, −0.01, −0.01, −0.01, −0.02 Average package error: −0.32 oz

*Calculation of SEL*

Standard deviation (s): 0.5448 sample correction factor (SCF) for sample size of 12 from Table 1, § 101.240: 0.5774 SEL=0.5448×0.5774=0.32 oz

*Compliance Status of Inspection Lot*

Avg package error+SEL=−0.32+0.32=0.00 0.00 meets the 0 or greater criterion, so lot is in compliance

*Permitted Reasonable Variations in Package Errors*

Estimation of Allowance for Reasonable Variation Range Within Inspection Lot=sample avg package error ±SEL=−0.32 oz±0.32 oz=−0.64 oz to 0.00 oz

*Permitted Reasonable Variations in Average Net Weight*

48 oz−0.64 oz to 48+0.00 oz=47.68 oz to 48.00 oz

*Maximum Percent Shortage Within Reasonable Variations*

0.64 divided by 48×100=1.3%

NIST stated (Ref. 3) that these illustrations disclose that the foundation of the 1994 Handbook's approach to permitting reasonable variations in the average net quantity of contents lies in its evaluation of the significance of the standard deviation (s) of package errors within the sample.

For small inspection lots (about which the Task Force expressed the greatest concern), NIST stated (Ref. 3) that the 1994 Handbook's approach provides sufficient allowance for the variations that are likely to occur.

NIST advised that the Situation C illustration demonstrates that there is little foundation to industry's concern that small inspection lots are at a significant disadvantage under the 1994 Handbook. NIST explained that the 1994 Handbook includes, as requested by the Task Force, an SEL that is not reduced for small sample sizes. NIST stated that the approach that is reflected in proposed § 101.210 provides for collection of smaller sample sizes for smaller inspection lots (e.g., 12 individual packages for an inspection lot of 250 packages versus 48 individual packages for an inspection lot of more than 3,200 packages). As stated above, smaller sample sizes result in larger SCF's and, in turn, in larger SEL's. The larger SEL's permit greater adjustment of the average sample net quantity of contents before application of the 0 or greater criterion for the average sample package error that is discussed above. As a result, it is more likely that a small inspection lot with an underweight average will be accepted than that the lot will be rejected.

NIST pointed out (Ref. 3) that because those firms that pack with greater variability from a variety of sources, including poor quality control, will get larger correction allowances than firms packing with smaller variability, firms with poor quality control might get undue benefit from the 1994 Handbook approach to calculating the SEL. However, NIST advised also that it knows of no way to prevent larger allowances under such circumstances. FDA solicits comments about alternative approaches that might prevent a firm from taking advantage of the proposed allowances. In the absence of contrary information, however, FDA's tentative view is that abuse of the approach in the 1994 Handbook would not be likely because firms have far more to gain from savings from better quality control of product filling practices than from a larger SEL.

Further, NIST pointed out that the Situation C illustration demonstrates that small lots are likely to be permitted reasonable variations from inclusion of different manufacturing codes in the inspection lot. NIST explained (Ref. 3) that including of multiple manufacturing codes in the same inspection lot significantly increases the chance of an inspection lot sample having a larger standard deviation than would occur with a single code because different codes are generally packaged at different times and possibly by different filling machines. Differing codes may well mean that portions of the inspection lot were packaged days, weeks, or even months apart. Under such circumstances, there is an increased likelihood that differences in filling practices cause larger variability between individual fills within the packages included in the sample, thereby driving the standard deviation upward with a corresponding increase in the SEL.

NIST points out, however, that the 1994 Handbook's manner of calculating SEL, which provides for reasonable variations for small inspection lots, is not consistent with well recognized academic approaches to determining appropriate sampling variation allowances. Such academic approaches (Ref. 9) provide that the size of the sampling variation allowance be reduced as the percent of the lot that is sampled is increased. For example, when inspection lots are 100 percent sampled, the SEL would always be 0. However, under the 1994 Handbook, the SEL would rarely, if ever, be 0. As a result, the 1994 Handbook provides for significant sampling variation allowance. In the previously discussed Situation C illustration, the SEL of 0.32 oz would mean that a sample with every package fill below the labeled package fill would be classified as in compliance.

However, NIST advised that large permitted variations in small inspections lots are not inconsistent with consumer protection because where any but the smallest shipments are involved, there would be little practical impact on the SEL reduction. For example, the SEL is reduced by only 5 percent with inspection lots of 125 units and, with inspection lots of 3200, the SEL is reduced by only 1 percent (Ref. 3). Accordingly, FDA tentatively concludes that this inconsistency with academic approaches should not affect its decision to propose the 1994 Handbook approach for determining the SEL. FDA suggests, however, that regulatory officials should attempt to collect samples from the largest inspection lots practicable to minimize the impact of the large variations that are permitted in small inspection lots.

For large inspection lots, fairness under the 1994 Handbook's approach results primarily from the way the SEL reduces the probability that nonviolative lots will be rejected. Furthermore, the 1994 Handbook restricts violative findings to the inspection lot, even where arguments could be made for broader applicability. For example, NIST has pointed out (Ref. 3) that if the inspection lot is found to be in violation after application of the SEL, and if the inspection lot is composed or made up of packages randomly selected from the entire production lot, then there is every reason to believe that the production lot as a whole was in violation. However, NIST advises that the 1994 Handbook does not suggest regulatory action against the production lot under such circumstances. NIST stated that restraint under such circumstances further illustrates that it is not unfair to industry to base regulatory action on inspection lots.

v. *Practicability.* NIST maintained (Ref. 3) that it would be impracticable for regulatory attention to be focused on the production lot instead of the inspection lot. NIST explained that the designation of the production lot may be artificial because it is, in fact, often only a segment of continuous production. The segment may be large or small, depending upon whether the packager uses more than one code during a day. NIST advised that in the United States, the only restriction on the definition of the production lot for net contents purposes is one established by USDA for meat and poultry products. Meat and poultry package production lots can consist of no more than 8 hours' production. Generally, however, the definition is left entirely to the manufacturer or may be dictated by other considerations (such as tracing batches of ingredients that are susceptible to spoilage or contamination). In the European Union, by contrast, a production lot is defined as no more than 10,000 packages (Ref. 10).

In addition, it is not unusual for U.S. firms to be shipping packages from a given production lot out of a plant while more packages from that same lot are still being produced. Thus, according to NIST (Ref. 3), it is common not to be able to sample from an entire production lot, even when the sample is taken at the packaging location. Therefore, if actions were to be taken only against production lots, NIST suggested that it would be necessary to circumscribe what would constitute a production lot. Also, it would be necessary that the lot be held for some period of time, so that regulatory officials would have an opportunity to take a random sample of the entire production lot.

vi. *FDA's tentative position about industry concern.* FDA points out that the language of section 403(e)(2) of the act charges the Secretary of Health and Human Services and, by delegation,

FDA with the responsibility of ensuring that food packages have an ''accurate'' quantity of contents declaration, but that the act states also that reasonable variations shall be permitted. The first aspect of section 403(e)(2) protects consumers from being misled about package net contents and facilitates retail value comparisons. The second aspect protects industry by making clear that this requirement is to be enforced in a reasonable manner. Neither aspect of this provision is subordinated to the other. Thus, the agency must attempt to strike an appropriate balance between the interests of consumers and of industry in any approach to enforcing section 403(e) that it adopts.

As previously discussed in this preamble, FDA has tentatively concluded that the diversity in approaches to enforcement of net contents declaration labeling requirements on foods among State and local regulatory agencies has created significant burdens on interstate commerce. Firms shipping a product to several States must overfill their products to meet the most stringent State's requirement. Some adjustment in the balance between consumer and industry interests in net contents declarations is therefore necessary to alleviate the burden on industry that is produced by this diversity in approaches.

Further, to the extent that FDA identifies in its regulations what are ''reasonable variations'' under section 403(e)(2) of the act, the affected industry will be in a better position to judge at what point contents deviations are likely to be considered violative. Such knowledge should help firms reduce overfilling of packages and should facilitate interstate commerce by making the establishment of more uniform target fill levels practicable for all package sizes. Also, consumers will be better informed about the amount of food that they are purchasing.

FDA does not agree, however, that net content examinations of inspection lots should be used only as ''audit tools.'' The agency is not persuaded that there is an inequity to the affected industry from a regulatory approach that focuses on the inspection lot when it is an increment of a much larger production lot. FDA tentatively finds that NIST has presented persuasive evidence that the mathematical approach in the 1994 Handbook is fair when used on inspection lots of all sizes. Thus this approach together with the large individual package variations permitted by the large MAV's, permits reasonable variations in the average net quantity of contents. FDA is not aware of any Federal, State, or local regulatory officials that have ever attempted to follow the production lot regulatory approach that is suggested by the Task Force. Most State regulations require that the average of the ''lot, shipment, or delivery'' meet or exceed the labeled net contents (Ref. 3). In practice, all inspection agencies at Federal, State, and local government levels, including FDA, inspect what is available for inspection and do not determine what might have originally comprised the shipment or delivery. Even where the same production lot codes are inspected at the manufacturing plant, inspection agencies focus only on the compliance of the packages from which the sample was taken, not whether the production lot complied. This focus is necessary because the sample will not necessarily be taken from the entire production lot. For example, as NIST pointed out, a production lot may take hours to package, and shipments of the earliest packaged portions of that production lot may be shipped before the entire lot has been packaged. Thus, the entire production lot may not be available for inspection.

FDA therefore tentatively concludes that it is appropriate for regulatory action to be based solely on evaluations of inspection lots. The agency tentatively concludes that acting on this basis is the only practicable way of providing meaningful levels of consumer protection from net quantity violations. It would not be practicable to require that industry hold a production lot for a specified period of time. Such a requirement would likely be a significant hardship for firms, who frequently must fill orders without delay. Without such a requirement, however, focusing on the production lot could not provide any consumer protection because such lots will likely be distributed before the agency has an opportunity to examine it.

vii. *Proposed compliance procedures; average requirements.* Accordingly, FDA is proposing in § 101.240 to adopt the 1994 Handbook Category A compliance procedures for average net contents requirements. Most aspects of the proposed compliance procedures are taken directly from the 1994 Handbook, although FDA has made a number of nonsubstantive changes for clarity and brevity. The proposed provisions identify specifically when inspection lots are to be classified as violative because of average package errors in weighing, measuring, or counting. Again, the package error is the difference between the measured net quantity of contents and the labeled quantity on the package.

As proposed, § 101.240 provides step-by-step instructions on how to calculate the average package error, and, when this average error is a negative value, how to make adjustments in the average error to determine whether the error is sufficiently large to cause the inspection lot from which the sample is taken to be considered violative. Two adjustments in the average error are provided for in § 101.240. One adjustment involves calculation of the standard deviation and using that value to calculate, as discussed above, the highest possible estimate of average net contents within the inspection lot.

The other adjustment in the average error involves making an allowance for moisture loss that may have taken place in the samples selected for measurement (proposed §§ 101.240(b)(2) and 101.250). FDA is proposing in proposed § 101.250 to identify the extent to which moisture loss affects these violative findings. Under proposed § 101.240(b)(2), the appropriate moisture allowance provided for the specific food in § 101.250 is added to the average package error after it has been adjusted by the SEL.

viii. *Exemption from average requirements.* NIST has advised FDA (Ref. 3) that, for statistical reasons, the compliance of an inspection lot containing packages labeled in terms of count of 50 items or less should not be based on a determination of an average count. NIST stated that their statisticians have advised them that normal distribution does not reliably occur until counts exceed 50. NIST explained that many packages labeled by count, for example, ''10 sticks'' of gum, do not have a normal distribution around a mean value. This failure derives from the fact that there are either 10 sticks in a package of gum, or there are fewer than 10 sticks (no matter how rarely this might occur). The package is constructed such that it cannot hold 11 sticks. Because only negative package errors can occur, it will not be possible to obtain an average net contents meeting the declared net contents where any shortage in net contents is present.

After the count exceeds 50 units, however, there is no reason for package construction to prevent positive package errors, and average package counts may reasonably be expected to meet labeled packaged counts. For these reasons, FDA is proposing an exemption in the first sentence of § 101.240 for packages labeled with net contents declarations of 50 or less units from average net contents requirements. (The agency is proposing to exempt packages with a declaration in terms of count that are

subject to proposed § 101.245(e) from the average requirements of proposed § 101.240. Proposed § 101.245(e) imposes requirements for declarations in terms of count where the declaration is 50 items or less.)

In view of the fact that an average requirement would not be appropriate for packages labeled in terms of a count of 50 units or less, and the fact that MAV's are relatively crude measures of unavoidable deviations, FDA is concerned that some compliance criterion be included in these regulations for such packages to provide adequate consumer protection.

NIST pointed out (Ref. 3) that the 1994 Handbook contains a unique approach for dealing with this problem,[8] and that this approach is valid even though packages may not be subject to package errors. For all sample sizes, the 1994 Handbook contains specific limits on the number of packages in the sample that may have any shortage. The limits are: (1) For samples of 2 through 12 packages—no more than 1 package, (2) For samples of 24 packages—no more than 2 packages, and (3) For samples of 48 packages—no more than 3 packages.

NIST suggested that FDA adopt the 1994 Handbook's approach to this problem. The presence in the Handbook 133 portion of the 1994 Handbook of the same specific limits on the number of packages in the sample that may have any shortage in count indicates that the suggested approach is an accepted means of providing consumer protection where net contents are in terms of count, and the declared count is 50 or fewer units. Its presence in Handbook 133 also evidences a long history of use of the limits by State and local regulatory agencies. Thus, FDA has incorporated the suggested compliance criteria into the proposed regulation. Because the proposed compliance criteria do not address average fill requirements, FDA is proposing to include them in § 101.245(e), the section pertaining to the procedures for individual packages, rather than in § 101.240, the section pertaining to compliance procedures for average fills. FDA requests comment on this proposed approach.

b. *Requirements pertaining to individual package fills.* As mentioned above, the 1994 Handbook provides that the variation of individual package contents below the labeled quantity may not be ''unreasonably'' large. The handbook identifies ''unreasonably'' large errors through MAV's, and the handbook contains MAV's for a wide variety of package sizes.

NIST advised FDA (Ref. 3) that it developed the MAV's for NCWM in the 1970's based on net contents tests of thousands of samples of common package sizes of food and nonfood items that were labeled primarily by weight, volume, or count. The tests were made only on inspection lots whose average net contents equaled or exceeded the labeled net contents because NIST believed that such lots were more likely to have been packaged under GMP than lots with average net contents below the declared weight. NIST wanted to identify MAV's from data generated using packages prepared in accordance with GMP to avoid development of unreasonably lenient individual compliance criteria. NIST looked for identifiable correlations between the package sizes and amount of variation from labeled net contents. NIST found no such correlations, noting only that the percent variation from labeled contents appeared slightly larger with smaller package sizes than with larger package sizes.

In view of the lack of significant identifiable correlations, NIST developed MAV's based on the data available for each specific package size tested. For each size, a variation was derived that would be an MAV that would encompass the largest variation below the labeled quantity that an individual package might be expected to have 99 percent of the time. The specific derivation of these MAV's was complex, but NIST developed them in a manner that may be closely compared to the procedure of prohibiting only those deviations that are 3 standard deviations or more below the labeled quantity (see previous discussion of standard deviation). NIST acknowledged (Ref. 3) that development of MAV's in this manner resulted in crude measures of unavoidable deviations, but it stressed that such measures provide some uniform control for unreasonably large individual deviations. NIST stressed that such control is preferable to no control or to case-by-case evaluations of the acceptability of each large individual deviation. NIST also pointed out that the crude nature of MAV's is offset by the fact that the primary tool for protecting consumers in the 1994 Handbook is the principle that the average net contents in the sample must meet or exceed the label declaration.

NIST recommended (Ref. 3) that FDA propose to adopt the MAV's in the 1994 Handbook. One State agency, however, asserted that Handbook 133 MAV's are too lenient, and that FDA should adopt more stringent (i.e., smaller) values for the MAV's. The State submitted a list of smaller MAV values for consideration but did not provide evidence that these MAV's were developed using data collected on a national basis, or that the suggested values represent current packaging practices.

FDA has considered that the original data on which NIST based its MAV values were collected in the 1970's, and that packagers have become more sophisticated in their ability to reduce packaging variations. The agency recognizes that because MAV's are crude measures of unavoidable deviations, it would be best if MAV's could be revised in accordance with current technology in the food industry. However, limited resources prevent FDA from undertaking the extensive studies needed to do so at this time. Moreover, FDA does not believe that it is appropriate to propose the tighter MAV's submitted by the State regulatory agency in view of the lack of evidence that these MAV's would prove practicable on a national level.

Further, FDA points out that the 1994 Handbook does, to some degree, make the MAV's more stringent than they were in Handbook 133 before the 1994 revisions. Before the 1994 revisions, Handbook 133 permitted differing numbers of units to exceed the MAV's, depending upon the sample size, before the product was deemed out of compliance. The permitted numbers varied from 0, for samples consisting of 30 or fewer units, to 7, for samples consisting of 250 units. Handbook 133 provided that sample sizes of 50 units were permitted 2 MAV's. The 1994 Handbook permits no more than 1 MAV for the largest sample sizes of 48 units. Thus, the 1994 Handbook decreases by at least 50 percent the maximum number of MAV's permitted to be found in a sample.

Accordingly, the agency is proposing in § 101.245(f), consistent with the recommendation of NIST, to adopt the MAV's in the 1994 Handbook. However, the agency is not proposing MAV's for count for packages with 50 or fewer units because, as pointed out by NIST, such MAV's would serve no practical purpose. For such packages, as discussed previously, FDA is proposing in § 101.245(e) that, if more than 1 package from a sample of 12 or less contains less than the labeled count where the inspection lot size is 250 packages or less; if more than 2 packages from a sample of 24 packages contain less than the labeled count where the inspection lot size is between 251 to 3200 packages; or if more than 3 packages from a sample of 48 packages contain less than the labeled count

[8] See section 5.2, page 54, Handbook 133.

where the inspection lot is more than 3200 packages, the inspection lot be classified as violative.

c. *Proposed compliance procedures; individual requirements.* As explained above, FDA is proposing in § 101.245, to adopt the 1994 Handbook Category A compliance procedures for individual weight requirements. FDA has taken most aspects of the proposed compliance procedures directly from the 1994 Handbook. However, the agency has made a number of nonsubstantive changes for clarity and brevity.

As proposed, § 101.245 provides step-by-step instruction on how to determine the appropriate MAV for the labeled net quantity of contents using the appropriate table § 101.245(f) (i.e., Tables 1 and 2 for mass or weight, Tables 3 and 4 for liquid or dry volume, and Table 5 for count except where the count is 50 units or fewer, where MAV's are not applicable). Where there are any negative package errors and moisture loss adjustments that are provided for in § 101.250, the errors are adjusted with the appropriate allowance for that food by adding the allowance to each of the negative errors. For example, if the labeled package size on a package of frozen fruit is 2 lb, and a 1-percent moisture loss allowance is permitted under § 101.250, the MAV of 0.07 lb from Table 2 is increased by adding 0.02 lb to give an adjusted MAV of 0.09 lb.

Once the MAV is determined, proposed § 101.245(d) identifies those situations in which the occurrence of package errors larger than the MAV cause the inspection lot to be violative. Where an inspection lot is sufficiently small that under proposed § 101.210(b), the sample consists of less than 48 individual packages, proposed § 101.245(d)(1) provides that the sample is violative if it contains any negative package errors that exceed the MAV or adjusted MAV, as appropriate, for the labeled net quantity of contents. Where an inspection lot is sufficiently large that under proposed § 101.210(b), the sample size consists of 48 individual packages, proposed § 101.245(d)(2) provides that the sample is violative if it contains more than 1 negative package error that exceeds the MAV or adjusted MAV, as appropriate, for the labeled net quantity of contents. As explained previously in this preamble, the agency is proposing limits on individual package fills for packages with declarations of net quantity in terms of count that have 50 or fewer units in lieu of average net quantity requirements. Because these limits are more stringent than any MAV limits would be, no practical purpose would be served by identifying MAV's for such packages. Consequently, the agency is proposing in § 101.245(d)(1) that such packages be exempt from the above violative MAV criteria.

d. *Impact of compliance procedures on existing policy.* FDA intends that the procedures that it adopts as a result of this rulemaking, if any, will supersede FDA's CPG 562.300 (formerly CPG 7120.19), which directs FDA field personnel to consider regulatory action where the average contents of the subsamples is 1 percent or more short weight. FDA intends to revoke the CPG at the time that it publishes a final rule in this proceeding.

e. *Section 101.250, moisture loss*—i. *Background.* As mentioned previously in this preamble, current FDA regulations permit reasonable variations for moisture loss but do not define limits for such variations. The agency has tried to deal with the issue of how to define the limits on variations for many years. FDA's Quantity of Contents Compendium contains the results of studies that date back to the early 1940's to determine variations because of moisture loss.

The agency attempted to use information from its moisture loss studies to establish limits for moisture loss in its 1980 proposal (45 FR 53023, August 8, 1980). However, there was considerable opposition to that proposal. Comments objected because the proposed moisture loss allowances were for only a small number of food classes, because it would be very time-consuming and expensive to develop data to justify new allowances, and because firms would have to overfill packages until rulemaking was completed. There was also concern that any specific maximum moisture loss provision might be taken by the dishonest manufacturer as a license to underfill down to the ''legal'' limit. Because FDA was concerned that there were significant problems with the regulation that it proposed, and that there could be considerable adverse economic impact on the affected industry, the agency did not issue a final rule in this matter.

In 1988, NCWM attempted to deal with this issue on a product by-product basis by including in Handbook 133 its ''gray area'' approach. Under this approach, any product found short weight in excess of the ''gray area'' limit would be subject to legal action. If the product is found short weight but within the ''gray area'' limit, the inspecting agency would take additional steps (such as comparing of laboratory moisture determinations at the time of sampling and at the time of pack from quality control records) to determine whether the product is short weight because of underweighing at the time of pack or because of ''reasonable'' moisture loss that occurred during distribution.

The 1994 Handbook includes ''gray area'' limits for two foods regulated by FDA—flour and dry pet food (hereafter referred to as ''dry animal food''). For both products, the ''gray area'' limit is 3 percent. NIST advised FDA (Ref. 3) that NCWM considered two approaches in developing these limits. Under one approach, products would be permitted the maximum loss that could be expected to occur throughout the shelf life of the product. Under the other approach, which was the one ultimately adopted by NCWM, a lower, negotiated limit would be established. For example, some studies in dry regions of the United States showed that flour and dry pet food lose from 6- to 9-percent moisture on store shelves. In more humid regions of the United States, some studies showed that these products lose from 1- to 2-percent moisture. NIST advised that the 3-percent limits that were ultimately set by NCWM were supported by the pet food industry through the Pet Food Institute and the flour industry through the Millers National Federation.

FDA agrees with the NCWM approach of establishing a limit on cognizable moisture loss somewhere between the maximum loss and the minimum loss that occurs throughout the shelf life of the product. It would not be practical to establish a multiplicity of limits to reflect the humidity swings that occur in the different parts of the United States throughout the seasons and from year to year. Also, it would not be fair to consumers in more humid areas of the country to establish limits based on losses in the driest areas of the country (where the largest moisture losses generally occur) because large allowances for moisture loss would be provided where very little losses would occur given the high humidity. The NCWM approach represents a rational approach for dealing with moisture loss in all areas of the United States. It provides reasonable, but not total, relief to the affected industry.

Even though FDA sees considerable merit in the ''gray area'' approach in the 1994 Handbook, the agency does not believe that it would be practicable for it to adopt this approach. The agency does not have authority under the act to obtain the quality control records at the point of pack to determine whether underweighing actually takes place. Moreover, limits for only two foods have been established. Even though, as

NIST has advised, limits are being developed for rice and pasta, there are simply too few limits established for foods subject to moisture loss for this approach to be viable at this time. Accordingly, FDA is not incorporating the ''gray area'' approach into this proposal.

ii. *The Proposed approach.* While FDA and some State and local agencies attempt to make case-by-case allowances for variations in moisture loss, other State and local agencies take the position that no allowances are permitted because FDA has not provided specific guidance concerning appropriate allowances. Even though the latter position is arguably not consistent with section 403(e)(2) of the act, it is not uncommon for regulatory agencies to employ it (Ref. 3). In large measure, the regulated industry appears to have decided not to contest the lack of allowances for moisture where agencies have chosen not to permit such allowances. Thus, firms shipping foods subject to moisture loss to jurisdictions that do not make allowances for such loss may be incurring significant costs from overfilling, or they may be being subjected to regulatory action. Based on these facts, FDA tentatively concludes that the current case-by-case approach to providing moisture loss variations has not produced the type of consistent results that are necessary to facilitate interstate commerce.

Although the regulated industry objected to FDA's 1980 attempts to define reasonable variations for moisture loss, in view of the above problems, industry response may be more positive if a more practicable approach is presented. FDA has therefore revisited the possibility of defining these variations and concluded that it should again propose to define what would constitute a reasonable variation but with significantly more flexibility than it proposed in 1980.

FDA's tentative view is that it is appropriate and practicable to establish a regulatory approach for net contents declarations that is tied to whether the inspection takes place at the point of manufacture or at some other location. For inspections at the point of manufacture, the agency is proposing that measurements be made of the accuracy of the net contents declaration. Because inspections at the point of manufacture would mean that there was no opportunity for any moisture loss to have taken place, no allowance for moisture loss would be provided. Such inspections would deter firms from underfilling to the extent of the allowances that FDA is proposing to establish for inspections that occur outside the plant.

The agency is proposing to establish moisture loss allowances, similar to those established by NCWM for flour and dry animal food, that reflect available moisture loss information. The allowances will serve to guide all affected parties about maximum permissible moisture losses. State and local regulatory agencies will be able to use these allowances in conducting inspections at both retail and wholesale marketplaces. These allowances will provide both the regulatory agencies and the industry with objective standards for determining whether an inspection lot is violative. Thus, this two pronged approach, which uses standards tied to the place at which the inspection occurs, will protect both consumers and the regulated industry.

iii. *At point of pack.* FDA tentatively concludes that, as a general rule, no allowance for moisture loss is reasonable at the point of manufacture. Clearly, at the time that products come off the production line, the contents declaration should be accurate. At that time, regulatory officials may reliably determine whether firms are attempting to take undue advantage of any moisture loss allowance that has been established.

However, regulatory officials may often encounter product at the point of pack that has been stored before shipment to other locations. The agency recognizes that allowances for moisture loss are appropriate after some period of storage. In view of the multiplicity of foods that may be subject to moisture loss and the agency's limited resources, however, it would be difficult for FDA to establish minimum storage times for each commodity before moisture loss might affect the contents measurement.

FDA asked NIST how other regulatory agencies have resolved this problem. NIST advised the agency that a number of European countries permit no moisture loss within the first 7 days following the end of the date of pack (Ref. 3) and recommended that FDA adopt a similar approach. Because NIST believes that this European approach has merit, the agency has provided in the proposed § 101.250(a)(1) that no allowance for moisture loss will be made if the food (other than a fresh bakery product for reasons discussed subsequently in this preamble) is weighed within 7 days following the end of the day of pack.

However, a number of comments on the 1980 proposal pointed out that fresh bakery products may suffer moisture loss within a very short time after production, and that such products often have a short shelf life (often as little as 3 to 5 days). As a result, FDA tentatively concludes that fresh bakery products should not be subjected to the 7-day no moisture loss rule at point of pack. The agency is therefore proposing to permit no moisture loss only within 1 day following the end of the day of pack for fresh bakery products in § 101.250(a)(2). Bakery products other than fresh baked breads, buns, rolls, and muffins will, as proposed, be subjected to the 7-day no moisture loss rule at point of pack. The agency solicits comments about the impact of proposed § 101.250(a)(2) for bakery products.

In proposed § 101.250(b), FDA is providing that after one day, fresh baked breads, buns, rolls, and muffins would still be in compliance if they lost 1 percent of their moisture. This allowance is based on data submitted in response to the 1980 proposal.

In proposed § 101.250(c), FDA is permitting a 3-percent moisture loss for these products after 7 days following the end of the day of pack. This proposed allowance is based on the data available from NIST (see discussion below). FDA is proposing to permit a similar moisture loss for dry animal food (see § 501.105(g)).

NIST advised that there may be many other foods that also suffer moisture loss within very short time periods after production, and that such products also have a short shelf life. Further, NIST advised that the 1-day period may be too rigid for some fresh bakery products. NIST was not able to identify these products but did suggest an alternative approach that it considered practicable and that could justify allowance of moisture loss on a more specific product basis at the point of pack or any other storage location. The approach that NIST suggested involved moisture loss data collection at the manufacturing plant followed by storage for specific time periods in specific locations and by measurements of the net quantity of contents (Ref. 3).

According to NIST, the collection could take place on a daily basis under environmental conditions similar to those that exist where the packages under inspection are stored (e.g., if the product is typically placed in a sealed case on a pallet and shrink wrapped, the control lots would be stored under those conditions, rather than under laboratory conditions). NIST suggested that the data be based on at least 3 control lots, with each lot consisting of at least 12 randomly selected individual packages that are collected on the same day, and consisting of at least 48 randomly selected individual packages in the 3 lots combined. NIST advised that

individual packages should be weighed upon collection and then daily (or hourly in the case of rapid dramatic moisture loss) throughout the duration of the study. The moisture loss allowance should be calculated with a 97-percent level of confidence.

NIST pointed out also that where moisture loss varies with climatic changes in environmental conditions, the data should be collected at an appropriate time to justify a finding of moisture loss. For example, where an inspection is made of current production at a food processing plant in the middle of July, and moisture loss varies significantly from winter to summer, data collected in January cannot be relied on to establish or calculate moisture loss during the inspection.

FDA agrees that the proposed rule should permit firms to gather justification for more specific moisture loss allowances where firms believe that it would be in their best interest to do so. Accordingly, FDA is proposing in § 101.250(d) to permit firms to determine more specific allowances in the manner suggested by NIST. As proposed, these allowances would not be limited to the point of pack if firms wish to gather data to demonstrate that allowances are justified at other locations. FDA is proposing that the data to support an allowance be gathered in the manner suggested by NIST and described above.

iv. *Other than point of pack.* FDA has reexamined all old moisture loss data that it has collected to determine which commodities may be subject to moisture loss and the amount of loss that might be expected. Most of this data appears in FDA's Quantity of Contents Compendium (Ref. 11) which contains a variety of data collected from the 1920's through the 1970's. The agency also consulted with NIST about which commodities have come to the attention of State and local agencies because of moisture loss. 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 (Ref. 3). Of all of these commodities, the extent of moisture loss variations is best known for flour. In fact, very little is known about the extent of moisture loss for most of the other commodities. However, because of NCWM's work, considerable reliable data support an allowance limit of 3 percent for flour (as well as dry animal food) (Ref. 12).

For other commodities, data are considerably less dependable, either because of the age of the studies for the commodities or because of the limited scope of the studies. In its 1980 proposal, FDA proposed to establish an allowance of 1 percent for frozen fruits and frozen vegetables in certain packaging based on data in the Quantity of Contents Compendium. NIST advised (Ref. 3) that representatives of the frozen food industry believe that a 1-percent allowance for that industry is reasonable. Also, a comment on the 1980 proposal from a trade association representing the bakery industry stated that fresh bread, buns, and rolls are subject to a moisture loss of only about 1 percent. FDA is therefore proposing a new § 101.250(b) to provide a 1-percent allowance for frozen fruits and vegetables when they are weighed more than 7 days following the end of the day of pack, and for fresh bread, buns, and rolls when they are weighed more than 1 day, but less than 7 days, following the end of the day of pack.

Except for flour, dry animal food, frozen fruit and vegetables, and fresh bread, buns, and rolls, FDA is not aware of data that would permit the agency to estimate specifically what allowances should be provided for each of the other commodities identified as undergoing moisture loss during distribution. Some data were submitted in 1980 that showed moisture losses for other products of as high as 20 percent, but the person submitting these data stated that, in the studies in which the data were derived, the packaging of the products had been punctured to permit moisture loss. FDA advises that such deviations from actual marketing conditions make these studies of dubious value.

However, because NIST has thoroughly evaluated the need for allowances in one major food commodity (i.e., flour, Ref. 12) and has concluded that a significant moisture loss allowance must be provided, and because, as explained above, many other food commodities also need some allowance for moisture loss, the agency tentatively finds that it must take some action to establish allowances for those commodities that are subject to moisture loss problems until sufficient data are provided by the affected industries. Accordingly, FDA is proposing in § 101.250(c) that the commodities that it identified above as undergoing moisture loss during distribution be provided with the same 3-percent allowance that it is proposing for flour more than 7 days following day of pack.

The proposed allowance is a crude estimate of reasonable variations for commodities other than flour. FDA's tentative view is that the allowance is not too lenient because packers are subject to inspection at the point of pack. The agency recognizes, however, that point of pack inspection of foreign firms may not be likely. Thus it hopes that, during the comment period, interested parties will develop and submit data on which it can establish reliable moisture loss allowances. The agency suggests that firms interested in developing such data work closely with NCWM, which has expertise in this area.

Nonetheless, some restriction on the proposed allowances for moisture loss seems warranted based on the type of packaging. Certainly, no allowance should be made where the food is packaged in an air tight container (e.g., cans, glass bottles, food enclosed in paraffin). FDA is therefore proposing that foods in such containers will not be permitted any moisture allowance (§ 101.250(a)(4)). Further, the agency is proposing that if the food is not subject to moisture loss, no allowance is permitted (§ 101.250(a)(3)).

*C. Oysters*

The traditional method of sale for packaged raw oysters out of the shell (''shucked'') is by fluid volume (consumer-sized packages are sold by the pint) rather than by drained weight. Given this traditional trade practice, to facilitate value comparisons, FDA tentatively concludes that it needs to establish a limit on the amount of free liquid in packages of oysters. Without such a limit, poor manufacturing and packaging practices may result in excessive water in shucked oyster packages. NIST explained that shucked oysters sold by fluid volume are often packed by methods that can introduce excessive water into the package (Ref. 3). For example, water may be introduced by:

(1) Storing the shucked oysters in an ice slush before packing;

(2) Cleaning the shucked oysters for a several-hour period with aerated water; and

(3) Not draining the oysters as they are being placed in the package; or

(4) Adding the oysters to containers that already have water in them.

NIST advised that NCWM has found that these practices are widespread and particularly prevalent in the warmer months (Ref. 3). NIST pointed out that without enforceable controls on the amount of free liquid in the containers, only continuous inspection could practicably control these practices.

NIST stated that commercial oyster buyers often specify a minimum net weight for oysters in an attempt to control poor packaging practices (e.g., some buyers specify a ''4-pound gallon''

or a ''6-pound gallon,'' meaning there has to be 4 or 6 lbs of oysters in a gallon). However, the packages are not marked as to the amount of solids.

In addition, packages that have more fluid and less solids cannot be visually identified, even when sitting side-by-side with packages containing significantly lesser amounts of free liquid. Studies conducted by the Virginia Department of Agriculture have shown that observers could not identify packages that contained only 15-percent free liquid from those that contained 60 percent (Ref. 3). (NIST stated that although NCWM recognizes that other similar shellfish products (e.g., scallops) may have similar problems as oysters, it was not aware that adequate studies have been performed to justify establishing a limit on the amount of free liquid in packages of those products.)

Although FDA limits the amount of free liquid in packaged raw oysters to 5 percent § 161.130(c)(2)(ii) (21 CFR 161.130(c)(2)(ii)), this limit can only be enforced at the packing plant. As a result, for many years there has been a significant void in surveillance activities concerning the free liquid requirement. Seafood trade associations have advised FDA that, although western U.S. oysters have low amounts of free liquid, southeastern U.S. oysters typically have between 5- and 15-percent moisture (Ref. 3). Retail market studies conducted by State weights and measures agencies over a 2-year period in 1989 and 1990 at the request of NCWM found that packagers could meet a 15-percent limit in free liquid (Ref. 3).

NIST has advised that, in 1991, NCWM adopted a standard of fill for fresh oysters that are removed from the shell that limits the free liquid to 15-percent by weight (Ref. 3).

For this reason, NCWM adopted the 15-percent criterion [9] to limit the free liquid to a reasonable and specific level. NIST recommends (Ref. 3) that, for national uniformity, FDA revise its regulations to permit no more than 15-percent free liquid in shucked oysters.

FDA tentatively agrees with the recommendation of NIST that a 15-percent criterion should be established. Accordingly, the agency is proposing to add this limit to the standard of identity for oysters in § 161.130(d).

In addition, FDA is aware that the names for the species of oysters currently identified in § 161.130 are outdated (i.e., *Ostrea gigas, O. virginica,* and *O. lurida*). These names need to be revised to maintain consistency with accepted scientific nomenclature set forth in American Fisheries Society Special Publication 16, ''Common and Scientific Names of Aquatic Invertebrates From the United States and Canada: Mollusks'' (Ref. No. 13). In that publication, the respective scientific names of these species names appear as ''*Crassostrea gigas*, *C. virginica*, and *Ostreola conchaphila*.'' FDA is therefore proposing to revise § 161.130 to reflect the updated nomenclature. FDA emphasizes that this proposed change will not have any substantive impact on the food standard for oysters. The proposed change does not change the oyster species covered by § 161.130.

[9] Section 1.5.2.3. of the Uniform Method of Sale of Commodities Regulation.

## VII. The Impact on Other Rulemaking Proceedings

FDA points out that, in the Federal Register of May 21, 1993 (58 FR 29716), and December 21, 1993 (58 FR 67444), it proposed revisions to § 101.105 to accommodate new statutory requirements for declaration of net contents in metric units and to reorganize existing provisions of contents labeling provisions for clarity. Except for redesignating § 101.105 as § 101.200 and the specific changes proposed in this document, FDA does not intend that the earlier proposals be affected by this rulemaking. Because the earlier proposals initiated a reorganization of § 101.105, the actual location in new § 101.200 of the proposed provisions may differ from that identified in this proposal. Although FDA is not addressing the changes initiated in the May 21, 1993, and December 21, 1993, proposals in this preamble, the agency points out that it proposed to change the headings of all quantity of contents regulations from ''Declaration of net quantity of contents when exempt'' to ''Declaration of net quantity of contents.'' Thus, any confusion about ''when exempt'' in the heading of proposed §§ 101.200 and 501.105 will be addressed in rulemaking based on the May 21, 1993, and December 21, 1993, proposals.

## VIII. Animal Products

As mentioned in section VI.A. of this document above, FDA considers it logical to continue to have the same requirements for human and animal food with respect to declarations of net quantity of contents. The agency sees no reason to reiterate all of the same provisions in both parts 101 and 501 when it can cross-reference those provisions in part 101 that pertain to net contents in part 501. To that end, the agency is proposing to revise § 501.105 in the same manner as it is proposing to revise § 101.200 (current § 101.105) and to cross-reference all remaining changes. In addition, as stated in section VI.A. of this document, FDA is proposing to define ''dry animal food'' in proposed § 501.105(u).

However, FDA is proposing one difference in how quantity of contents is declared on human and animal food. The difference pertains to whether, for an animal food packed in liquid with a net contents declaration in terms of weight, the liquid should be included in the net weight declared. For human food, FDA is proposing in § 101.220(c) procedures for measuring drained weight. The focus on drained weight derives from the provisions of the act on nutrition labeling and, specifically, on serving size, which focuses on the amount of food customarily consumed. There are no equivalent provisions in the animal food labeling regulations. Section 403(q) of the act, on nutrition labeling, only applies to food intended for human consumption. In view of the lack of such a reference regulation, and the fact that FDA knows of no need to address requirements concerning liquid packing media in animal food, FDA is not proposing a parallel provision on drained weight in § 501.105.

The accuracy provisions for animal food regulations are slightly different from the provisions in proposed § 101.200 for human food because of the previously discussed differences in the proposed animal and human food provisions. Instead, proposed § 501.105 excepts provisions of § 101.200 from incorporation with the rest of subpart H of part 101. Because proposed § 501.105 contains all the provisions of proposed § 101.201, FDA is also not incorporating the latter provision in § 501.105.

## IX. Analysis of Impacts

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach which maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a

substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of the rule on small entities. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. The agency acknowledges that some provisions of this rule may have significant impact on a substantial number of small entities. Finally, the agency, in conjunction with the administrator of the Office of Management and Budget (OMB), finds that this is not a major rule for the purpose of congressional review (Pub. L. 104–121).

*A. The Compelling Public Need for a Regulation*

FDA is proposing this rule in order to establish specific procedures for checking conformance to net contents labeling requirements. As discussed previously in this preamble, the preemptive nature of regulations pertaining to net contents results in these procedures being the only ones that State and local jurisdictions can adopt if they decide to ensure the accuracy of net contents declarations. State and local jurisdictions are likely to bring a degree of rigor to enforcement of these standards that reflects the preferences of the populations that they represent. However, there is no reason to believe that consumers in different jurisdictions have different preferences about the specific statistical methods for determining conformance to net contents labeling requirements. Further, to the extent that FDA defines ''reasonable variations'' in its regulations, the affected industry will know at what point contents deviations would be considered violative. Such knowledge should help firms to reduce overfilling of packages and facilitate interstate commerce by making the establishment of more uniform target fill levels practicable for all package sizes. Currently food packagers selling food in interstate commerce must meet different standards for determining quantity of fill in different jurisdictions, depending on the analytical method of determining compliance used in each jurisdiction. FDA is proposing to establish provisions to remedy this situation.

*B. Costs*

Because the requirements in this proposed rule would allow industry to reduce overfilling of package contents, the agency believes that, except possibly for the amendment to the oyster standard discussed in section VIII.B. of this document, this proposal will cause no compliance costs to be incurred by industry. To the extent that this proposal will preempt the current activities of State and local agencies, these entities may incur some costs of switching to the new method of determining compliance with these fill rules. For example, some State and local agencies may need to retrain some inspectors.

FDA has no information on the potential need for retraining or the costs of retraining. However, the agency believes these costs will be small because the measures that FDA is proposing are generally consistent with those of NCWM, which are used by most of the States.

The agency is proposing to amend the standard of identity for oysters to limit the amount of free liquid to 15 percent. The agency has no data on the extent to which shellfish shippers pack oysters with more than 15-percent free liquid. However, the agency believes that this does not occur frequently, and that the cost of complying with the proposed standard will be small. This conclusion is based on information from NIST stating that, because NCWM adopted a 15-percent free liquid standard, there have been no reports of widespread complaints about the moisture content of shucked oysters. The agency requests comment on the cost complying with this proposed standard.

*C. Benefits*

An important benefit of this proposed rule is in establishing a uniform standard for determining compliance with accuracy requirements for net contents declarations across the national food market. A food packager considering entering a market in a State different from those to which it currently ships will not need to be concerned with determining whether it will need to adjust the degree to which it fills its packages. The same standard will apply in all States. Another benefit may be to consumers of food in single serving packages. In using the nutrition information on the nutrition labels, consumers will have information that more accurately reflects the actual contents of the package if the degree of package overfill is reduced.

*D. The Initial Regulatory Flexibility Analysis*

If finalized, this rule will establish a national standard for enforcing net contents declarations. Given that the standard for net contents declarations that FDA is proposing, except possibly for the amendment to the oyster standard discussed in section VIII.D. of this document, will impose no compliance costs on industry, the agency believes that there will be no significant impact from these provisions on a substantial number of small businesses. However, because there is some uncertainty related to the costs of compliance, FDA is voluntarily doing this Initial Regulatory Flexibility Analysis. The agency requests comments on its judgment.

The only provision of this proposed rule that may have a significant impact on a substantial number of small businesses is the proposed amendment of the standard of identity for shucked oysters, which, if adopted, will establish a ceiling on the amount of free liquid at 15 percent by mass or weight. There are approximately 400 shellfish shucking-packing or repacking plants in the United States on the Interstate Certified Shellfish Shippers List (ICSSL) for November 1995. There are approximately 100 foreign shellfish shucking-packing or repacking plants that ship to the United States on the ICSSL for the same period. With few exceptions, these are single plant businesses, and all of the businesses have fewer than 500 employees. The agency has no data on the extent to which shellfish shippers pack oysters with more than 15-percent free liquid. However, it seems likely that excessive filling with free liquid does not occur frequently based on information from NIST stating that since NCWM adopted a 15-percent free liquid standard, there have been no reports of widespread complaints about the moisture content of shucked oysters. The agency requests comment on the impact of this provision on small shellfish shippers.

FDA has several alternatives to the proposed limit of 15-percent free liquid by mass or weight for shucked oysters. The agency could establish a lower limit or a higher limit. Shellfish shippers have a cost incentive to ship the maximum allowable amount of free liquid in shucked oysters. Therefore, the higher the limit set by regulation, the more free liquid packages will contain. For this reason, the agency wants to avoid setting an unnecessarily high limit on free liquid. The agency requests comment on the impact of various limits on free liquid on small shellfish shippers.

Another approach could be to require label declaration of the percent free liquid, by mass or weight, in the package. The advantages of such a policy are: (1) That the standard is less prescriptive, (2) that consumers are informed by the label as to the amount of free liquid in the package, and (3) that processors are not penalized for shipping packages with less free liquid than their competitors, but instead they

are given an incentive to reduce the amount of moisture in the package. The disadvantages of such a policy are: (1) That frequent label changes may be necessary to accurately label packages where the amount of free liquid varies, (2) that the process of measuring the amount of free liquid with enough frequency to ensure that the packages are labeled accurately may be costly, and (3) that it permits what many consider to be a deceptive practice to continue. The agency requests comments and suggestions on alternatives to the proposed limit of 15-percent free liquid by mass or weight.

X. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, or other third party disclosure requirements. Thus, there is no ''information collection'' necessitating clearance by the Office of Management and Budget. FDA tentatively concludes that the moisture loss study described in section 101.250 would generally not be presented to the agency unless, during the course of an investigation, questions have been raised about underfill. Thus the moisture loss study would be exempt from Paperwork Reduction Act (PRA) requirements under 5 CFR 1320.4. To ensure the accuracy of this tentative conclusion, FDA is asking for comment on whether this proposed rule to establish procedures for determining whether label net quantity of content statements are accurate imposes any paperwork burden.

XI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Commerce, National Bureau of Standards, ''NBS Handbook 133-Third Edition,'' ''Checking the Net Contents of Packaged Goods;'' Supplement, September 1990; Suppl. 2, October 1991; and Suppl. 3 October 1992; U.S. Government Printing Office, Washington, DC, 20402–9325.
2. NIST Handbook 133, 3d ed., Supplement 4, U.S. Government Printing Office, Washington, DC, 20402–9325, October 1994.
3. NIST letter to FDA, December 12, 1996.
4. NIST Handbook 44, ''Specifications, Tolerances and Other Technical Requirements for Weighing and Measuring Devices'', October, 1994.
5. NBS Handbook 145, Handbook for the Quality Assurance of Metrological Measurements, Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402, November 1986.
6. Specifications and Tolerances for Reference Standards and Field Standard Weights and Measures, Specifications and Tolerances for Field Standard Stopwatches (undated).
7. American Society of Mechanical Engineers Voluntary Standard Designated as ASME B89 1.14.
8. American Society of Testing and Materials Standard specification E 617–91, Standard Specification for Laboratory Weights and Precision Mass Standards.
9. Fuller, Wayne A., Sample and Surveys, American Mathematical Society Short Course on Modern Statistics: Methods and Application, San Antonio, TX, pp. 1 to 18, 1980.
10. United Kingdom, Department of Trade, ''Code of Practical Guidance for Packers and Importers, Weights and Measures Act,'' Issue No. 1, pp. 10 to 12, 1979.
11. ''Quantity of Contents Compendium,'' June 1966.
12. NBS Special Publication 734, ''Report of the 72d National Conference on Weights and Measures,'' pp. 63 and 64, 83 and 84, 141, and 148 to 157, 1987.
13. American Fisheries Society Special Publication 16, ''Common and Scientific Names of Aquatic Invertebrates From the United States and Canada: Mollusks.''

List of Subjects

*21 CFR Part 101*

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

*21 CFR Part 161*

Food grades and standards, Frozen foods, Seafood.

*21 CFR Part 501*

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 101, 161, and 501 be amended as follows:

## PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New Subpart H (consisting of §§ 101.200 through 101.250) is added, § 101.105 of subpart G is redesignated as § 101.200 of new subpart H, and newly redesignated 101.200 is amended by revising the section heading, paragraphs (a) and (b), and by removing and reserving paragraph (q), to read as follows:

### Subpart H—Net Quantity of Contents

Sec.



## Subpart H—Net Quantity of Contents

### § 101.200 Declaration of net quantity of contents.

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This declaration shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. If the food is liquid the declaration must be expressed in terms of fluid measure. If the food is solid, semisolid, or viscous, or a mixture of solid and liquid the declaration shall be expressed in terms of weight. If the food is a fresh fruit, fresh vegetable, or other dry commodity that is customarily sold by dry measure the declaration statement may be expressed in terms of dry measure. Except as provided for in § 101.12, a food that is packed or canned in liquid, and is required to bear a contents declaration in terms of weight, shall bear a declaration expressed in terms of the total net contents including

the liquids. Where the reference amount in § 101.12 is declared in terms of drained solids, the contents declaration shall be in terms of drained weight. If the food is packaged in a self-pressurized container, the statement shall be in terms of the mass or weight of the food and the propellant that will be expelled when the instructions for use as shown on the container are followed. If there is a firmly established general consumer usage or trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Food and Drug Administration determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers an opportunity for consumer confusion, it will by regulation designate the appropriate term or terms to be used for such commodity.

(b)(1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof.

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

* * * * *

**§ 101.201 Accuracy of net quantity declaration.**

(a) In making volume measurements, the measurement shall be made:

(1) In the case of frozen food that is sold and consumed in a frozen state, at − 18 °C (0 °F);

(2) In the case of refrigerated food that is sold in the refrigerated state, at 4 °C (40 °F); and

(3) In the case of other foods, at 20 °C (68 °F).

(b) The declaration of net quantity of contents shall provide an accurate statement of the quantity of contents of the package. For purposes of this section, an accurate statement is one that conforms to all requirements for the declaration set forth in this subpart. Sections 101.240, 101.245, and 101.250 of this subpart describe what constitutes a reasonable variation in net content declarations that is the result of loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice. All net contents measurements shall be made in accordance with the procedures and methodology set forth in this subpart. Any net quantity of contents declarations that overstate the amount of product in the container by an amount that is more than that can be attributed to a reasonable variation under these regulations will misbrand the product under section 403(e) of the Federal Food, Drug, and Cosmetic Act.

**§ 101.205 Definitions.**

For the purposes of this subpart the following definitions apply:

(a) *Drained mass or weight* means the mass or weight of solid or semisolid food representing the contents of a package obtained after a prescribed method for removal of the liquid has been employed.

(b) *Dried used tare* means the mass or weight of a container, wrapper, or other material (e.g., glazing on frozen seafood) that is deducted from the gross mass or weight of a package to obtain the net mass or weight. The tare mass or weight comprises all packaging materials (including glue, labels, ties, etc.) that contain or enclose a food, as well as all packaging materials (including prizes, gifts, coupons, decorations, etc.) that are not part of the food. The food is removed from the tare by washing, scraping, wiping, ambient air drying, and other techniques involving more than ''normal'' household recovery procedures, but not including such laboratory procedures as oven drying.

(c) *Gravimetric test procedure* means an analytical procedure that involves measurement by mass or weight.

(d) *Gross mass or weight* means the combined mass or weight of the package including its contents, packing materials, labels, etc.

(e) *Inspection lot* means the collection of packages from which the sample is collected that consists of the same food, with the same label (but not necessarily the same lot code, or in the case of random content packages the same actual quantity), from the same packer.

(f) *Maximum allowable variation* (MAV) means the value of the largest deviation of net quantity of contents below the labeled declaration of net quantity of contents that, where the sample consists of less than 48 individual units, is reasonable for any individual unit, or, where the sample consists of 48 units, is reasonable for any more than one individual unit.1

(g) *Net quantity of contents* means that quantity of packaged food (e.g., in terms of mass or weight, volume, or numerical count) remaining after all necessary deductions of the tare mass or weight from the gross mass or weight.

(h) *Net mass or weight* means the mass or weight of solid or semisolid food plus any liquid that accompanies the food.

(i) *Package error* means the difference between the measured net quantity of contents of an individual package and the declared net quantity of contents on the package label. When the individual package contains less net contents than the declared net contents, the difference is referred to as the ''negative package error.''

(j) *Random sample* means that every package in the lot has an equal chance of being selected as part of the sample.

(k) *Range* means the difference between the largest value and the smallest value in any set of numbers.

(l) *Reference temperature* means the temperature at which the fill of a food sold by volume must meet the declared net quantity of contents.

(m) *Sample* means a random sample of a group of packages taken from a larger collection of packages and providing information that can be used as a basis for making a decision concerning the larger collection of packages or of the package production process.

(n) *Sample size* means the number of packages in a sample.

(o) Sample standard deviation (s) means a statistic used as a measure of dispersion (i.e., differences of individual values from the mean) in a sample. It is calculated as follows:

$s=(\Sigma(x_i-x)^2/(n-1))^{1/2}$ or equivalently (and primarily for calculations without a computer),

$s=((\Sigma x_i^2-(\Sigma x_i)^2/n)/(n-1))^{1/2}$.

Where:

$\Sigma$ means ''the sum of,''

$x_i$ means the ith individual package error,

n means the sample size, and

x means the average of the package errors, that is, the sum of the package errors divided by the number of packages in the sample.

(p) *Sample error limit (SEL)* means a statistical value that allows for the uncertainty between the average error for the sample and the average error for the inspection lot with a 97-percent level of confidence. It is computed by multiplying a factor appropriate for the sample size (found in column 2 of Table 1, of § 101.240) times the sample standard deviation.

(q) *Tare sample* means the packages selected for use in determining the average used tare mass or weight.

(r) *Total tare sample size* ($n_t$), means the number of packages used to determine the average used tare mass or weight.

(s) *Volumetric measure* means a measuring device for use in the

measurement of volumes of liquids (e.g., standard measuring flasks, graduates, cylinders, etc.).

**§ 101.210 Sample collection.**

The following procedures shall be used to collect samples for determining the net quantity of contents of packaged food:

(a) Determine the number of packages in the inspection lot;

(b) Find the inspection lot size in column 1 of Table 1 of this section, and determine the appropriate sample size from column 2 of Table 1; and

TABLE 1.—SAMPLING PLANS

| Column 1 inspection lot size | Column 2 sample size |
|---|---|
| 11 packages or less ..... | All packages. |
| 12 to 250 packages ..... | 12 packages. |
| 251 to 3,200 packages ..... | 24 packages. |
| More than 3,200 packages ... | 48 packages. |

(c) Select a random sample of the packages from the inspection lot.

**§ 101.215 Measuring equipment.**

(a) *Thermometer selection.* Graduations on a thermometer shall be no larger than 1 °C (2 °F).

(b) *Linear equipment selection.* (1) A tape or ruler used to measure dimensions of 63.5 centimeter (25 inches) or less shall be at least as long as the distance to be measured and flexible enough for the measurement and shall have a minimum graduation of 0.5 millimeter (or 1/64 inch) or less.

(2) A tape or ruler used to measure dimensions of more than 63.5 centimeters (25 inches) shall be at least as long as the distance to be measured and flexible enough for the measurement and shall have a minimum graduation of 2 millimeters (1/16 inch).

(c) *Volumetric equipment selection.* Volumetric equipment shall meet the following requirements:

(1) A volumetric measure used in fluid volumetric determinations shall be of such size with respect to the labeled net quantity of contents of the package that no volume less than 25 percent of the maximum capacity of the volumetric measure is measured; and

(2) Have graduations that are not greater than 1/6 of the maximum allowable variation (MAV) for the labeled net quantity of contents of the package being measured.

(d) *Gravimetric equipment selection.* Gravimetric equipment shall meet the following requirements:

(1) A balance may only be used if it has the following features:

(i) It has a load receiving element of sufficient dimensions to hold the packages during weighing;

(ii) It has a load receiving element of sufficient weighing capacity for the package size being tested;

(iii) It has at least 100 scale divisions, and each division is no larger than 1/6 of the MAV for the package size being weighed. The total number of scale divisions on the balance is calculated by dividing the scale or balance capacity by the minimum scale division (e.g., a scale or balance with a capacity of 5,000 grams and a minimum scale division of 0.1 gram has 50,000 scale divisions);

(2) Before each initial daily use, use at a new location, or use in the presence of any indication of abnormal equipment performance, the balance shall be found not to exceed the rejection criteria of paragraph (d)(3)(ii) of this section in all measurements made as part of the following performance tests, which use mass standards that have been calibrated in accordance with paragraph (e) of this section:

(i) For all types of balances, conduct an ''increasing load performance test'' with all test loads centered on the load receiving element. The test shall start with the scale on zero and progress with increasing test loads to an upper ''maximum test load'' of approximately 10 percent more than the gross mass or weight of the package to be weighed. At least four test loads of approximately equal value shall be used to test the device up to the ''maximum test load,'' and the accuracy of the balance shall be determined at each test load;

(ii) For all types of balances, other than one with a beam indicator or equal-arm balance, conduct a ''decreasing load performance test'' with all test loads centered on the load receiving element. The test shall use the same test loads used in the ''increasing load performance test'' of paragraph (d)(3)(i) of this section and shall start at the ''maximum test load.'' The test loads shall be removed from the load receiving element in the reverse order of the increasing load test until all test loads are removed and the accuracy of the balance determined at each test load; and

(iii) For all types of balances, conduct an ''off-center load performance test'' with the test loads located as follows:

(A) Except for an equal arm balance, no test loads are centered on a load receiving element. The test shall use a test load equal to one-half of the ''maximum test load'' used for the ''increasing load performance test'' of paragraph (d)(3)(i) of this section. The test load shall be placed in the center of four separate quadrants, equidistant between the center and edge of the load receiving element and the accuracy of the balance determined in each quadrant. For example, where the load receiving element constitutes a rectangle or circle, the test load would be placed in the center of the circles in the following diagrams:

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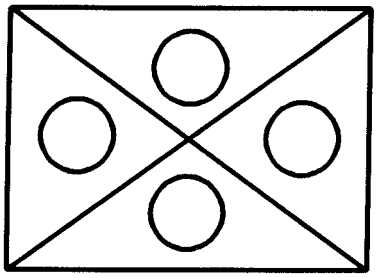

Diagram 1. Off-Center Loading Pattern for Regular or Square Balance Pans

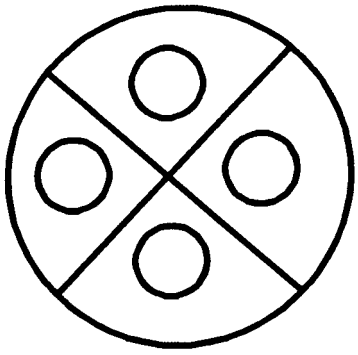

Diagram 2. Off-Center Loading Positions for a single pan balance

(B) For an equal arm balance, both load receiving elements are tested with the same test loads on both elements at the same time. The test shall use test loads equal to one-half of the ''maximum test load'' used for the ''increasing load performance test'' of paragraph (d)(3)(i) of this section. On one receiving element, the test load is centered on the load receiving element. On the other load receiving element, the test load is instead placed in the center of four separate quadrants, equidistant between the center and edge of the load receiving element and the accuracy of the balance determined in each quadrant. This test is repeated with the positions of the test loads switched between load receiving elements. For example, in the first half of the test, the test load would be placed in the center of the circles in the following diagram:

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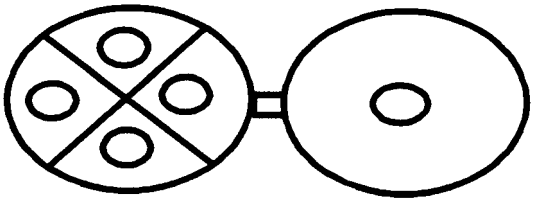

Diagram 3. Off-Center Loading Positions for an Equal Arm Balance. Each side is tested using the same pattern.

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(iv) For all types of balances, conduct a ''repeatability performance test'' with the ''maximum test load'' centered on the load receiving element. The ''maximum test load'' shall be weighed at least twice, and the accuracy of the balance determined with each measurement;

(3) A balance may only be used if it does not have an error that exceeds the number of smallest units of measure (i.e., balance divisions) for rejection established by the procedures set forth below:

(i) Determine in Table 1 of this section the Class of the balance that is appropriate in light of the minimum balance division and the total number of balance divisions to be used for the net contents measurement. For example, with a balance with a minimum balance division of 1 gram and 50,000 total balance divisions the appropriate tolerance class is ''Class II'';

TABLE 1.—BALANCE CLASSES

| Value of smallest balance division [1] | Minimum and total number of balance divisions | Balance class |
|---|---|---|
| 1 milligram to 0.5 gram (g) | Device has more than 100, but not more than 100,000 balance divisions. | II |
| 0.1 g or more | Device has more than 5,000, but not more than 100,000 balance divisions. | II |
| 0.1 g to 2 g<br>0.0002 pound (lb) to 0.005 lb<br>0.005 ounce (oz) to 0.125 oz | Device has more than 100, but not more than 10,000 balance divisions. | III |
| 5 g or more<br>0.01 lb or more<br>0.25 oz or more | Device has more than 500, but not more than 10,000 balance divisions. | III |

[1] On some balances, manufacturers have designated a verification balance division for testing purposes. Where the verification balance division is less than or equal to the minimum balance division, the verification division shall be used instead of the minimum balance division. Where balances are made for use with standard test weights (e.g., an equal arm balance), the smallest test weight used for the measurement is the minimum balance division.

(ii) Determine in Table 2 of this section the number of balance divisions for rejection that is appropriate for the test load and the balance class to be used for the net contents measurement. For example, with a test load of up to 20,000 balance divisions and a Class II balance, ± 2 is the appropriate number of balance divisions for rejection. In this situation, the balance may not be used if it has an error of two balance divisions in any of the performance tests set forth in paragraph (d)(3) of this section;

TABLE 2.—BALANCE DIVISIONS FOR REJECTION

| Balance class II test load in balance divisions | Balance class III test load in balance divisions | Number of balance divisions for rejection |
|---|---|---|
| 0 to 5,000 | 0 to 500 | 1 |
| 5,001 to 100,000 | 501 to 4,000 | 2 |
| Not Applicable | 4,001 or more | 3 |

(e) *Accuracy standardization.* When compared directly or indirectly to standards provided by the National Institute of Standards and Technology (NIST), all equipment identified in this paragraph shall be standardized before initial use in accordance with the calibration instructions set forth in NBS Handbook 145, Handbook for the Quality Assurance of Metrological Measurements, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. Copies of this publication may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Except for volumetric glassware, the comparison to NIST standards shall be done on a routine basis (e.g., annually for equipment used on a weekly basis). The standardization shall ensure that the equipment does not have an error that exceeds the following rejection criteria:

(1) *Stop-watch standardization.* A stop-watch shall not have an error exceeding ±2 seconds in a 3-hour time period;

(2) *Thermometer standardization.* A thermometer shall not have an error exceeding ±1 °C (2 °F);

(3) *Linear measure standardization.* (i) A tape or ruler used to measure dimensions of 63.5 centimeters (25 inches) or less shall not have a measurement error greater than ±0.39 millimeter (±1⁄64 inch);

(ii) A tape or ruler used to measure dimensions of more than 63.5 centimeters (25 inches) shall not have a measurement error greater than ±2 millimeter (±0.1 inch); and

(iii) A caliper or depth gauge shall not exceed the error limits in Table 3 of this section.

TABLE 3.—ERROR LIMITS FOR CALIPERS AND DEPTH GAUGES

| Measured length in millimeters | Error limit in micrometers |
|---|---|
| 0 to 400 | ±50 |
| 400 to 800 | ±100 |
| 800 to 1000 | ±150 |

(4) *Volumetric standardization.* An error in volumetric measuring equipment shall not exceed the error limits in Table 4 of this section; and

TABLE 4.—Error Limits for Flasks and Cylinders [1]

| Capacity at 20 °C (68 °F) | Error limits for the full capacity | Error limits for individual graduations |
|---|---|---|
| 50 milliliter (mL) cylinder. | ±0.3 mL± | ±0.3 mL |
| 2 fluid ounces (59 mL) cylinder. | ±0.3 mL | ±0.30 mL |
| 100 mL flask | ±0.2 mL | ±0.06 mL |
| 1 gill (118 mL) flask. | ±0.2 mL | ±0.10 mL |
| 200 mL flask | ±0.3 mL | ±0.10 mL |
| ½ pint (236 mL) flask. | ±0.3 mL | ±0.10 mL |
| 250 mL flask | ±0.3 mL | ±0.10 ml |
| 1 pint (473 mL) flask. | ±0.4 mL | ±0.15 mL |
| 500 mL flask | ±0.5 mL | ±0.15 mL |
| 1 quart (946 mL) flask. | ±0.7 mL | ±0.30 mL |
| 1,000 mL flask | ±0.8 mL | ±0.22 mL |
| ½ gallon (1,892 mL) flask. | ±1.0 mL | ±0.30 mL |
| 2,000 mL flask | ±1.2 mL | ±0.33 mL |
| 1 gallon (3,785 mL) flask. | ±1.2 mL | ±0.30 mL |

[1] For volumetric measures less than 50 mL, full capacity error limits do not apply. For these volumetric measures apply ±0.10 mL to individual graduations. For a capacity intermediate between two capacities listed below the tolerances prescribed for the lower capacity shall be applied. For volumes greater than 3,785 mL (1 gallon) apply ±0.02 percent of nominal capacity for error limits at full capacity and ±0.3 percent of the minimum graduation for error limits for individual graduations.

(5) *Gravimetric standardization.* (i) Errors in mass standards used to test Class II balances, as described in paragraph (d) of this section, shall not exceed the error limits in Tables 5 and 6 of this section.

TABLE 5.—ERROR LIMITS FOR INCH-POUND MASS STANDARDS USED TO TEST TOLERANCE CLASS II BALANCES

| Mass standard in pounds | Error limits in milligrams |
|---|---|
| 100 | ±910 |
| 50 | ±450 |
| 25 | ±23 |
| 10 | ±91 |
| 5 | ±45 |
| 2 | ±18 |
| 1 | ±9 |
| 0.5 | ±K4.5 |
| 0.2 | ±1.8 |
| 0.1 | ±1.1 |
| 0.05 | ±0.77 |
| 0.02 | ±0.45 |
| 0.01 | ±0.34 |
| 0.005 | ±0.27 |
| 0.002 | ±0.19 |
| 0.001 | ±0.15 |

TABLE 5.—ERROR LIMITS FOR INCH-POUND MASS STANDARDS USED TO TEST TOLERANCE CLASS II BALANCES—CONTINUED

| Mass standard in ounces | Error limits in milligrams |
|---|---|
| 8 | ±4.5 |
| 4 | ±2.3 |
| 2 | ±1.3 |
| 1 | ±0.86 |
| 0.5 (½) | ±0.59 |
| 0.25 (¼) | ±0.43 |
| 0.2 | ±0.38 |
| 0.125 (⅛) | ±0.31 |
| 0.1 | ±0.29 |
| 0.0625 (1⁄16) | ±0.24 |
| 0.05 | ±0.23 |
| 0.03125 (1⁄32) | ±0.19 |
| 0.02 | ±0.17 |
| 0.015625 (1⁄64) | ±0.15 |
| 0.01 | ±0.14 |

TABLE 6.—ERROR LIMITS FOR SI MASS STANDARDS USED TO TEST TOLERANCE CLASS II BALANCES

| Mass standard in kilograms | Error limits in milligrams |
|---|---|
| 50 | ±1000 |
| 25 | ±500 |
| 20 | ±400 |
| 10 | ±200 |
| 5 | ±100 |
| 2 | ±40 |
| 1 | ±20 |
| **Mass standard in grams** | **Error Limits in milligrams** |
| 500 | ±10 |
| 300 | ±6 |
| 200 | ±4 |
| 100 | ±2 |
| 50 | ±1.2 |
| 30 | ±0.90 |
| 20 | ±0.70 |
| 10 | ±0.50 |
| 5 | ±0.36 |
| 2 | ±0.26 |
| 1 | ±0.20 |
| **Mass standard in milligrams** | **Error Limits in milligrams** |
| 500 | ±0.16 |
| 300 | ±0.14 |
| 200 | ±0.12 |
| 100 | ±0.10 |
| 50 | ±0.085 |
| 30 | ±0.075 |
| 20 | ±0.070 |
| 10 | ±0.060 |
| 5 | ±0.055 |
| 2 | ±0.05 |
| 1 | ±0.05 |

(ii) Errors in mass standards used to test tolerance Class III balances, as described in paragraph (d) of this section, shall not exceed the error limits in Tables 7 and 8 of this section.

TABLE 7.—ERROR LIMITS FOR INCH-POUND MASS STANDARDS USED TO TEST TOLERANCE CLASS III BALANCES

| Mass standard in pounds | Error limits in grams |
|---|---|
| 100 | ±4.5 |
| 50 | ±2.3 |
| 25 | ±1.1 |
| 20 | ±0.91 |
| 10 | ±0.45 |
| | Error limits in milligrams |
| 5 | ±230 |
| 2 | ±91 |
| 1 | ±70 |
| 0.5 | ±45 |
| 0.2 | ±18 |
| 0.1 | ±9.1 |
| 0.05 | ±4.5 |
| 0.02 | ±1.8 |
| 0.01 | ±1.5 |
| 0.005 | ±1.2 |
| 0.002 | ±0.87 |
| 0.001 | ±0.7 |
| Mass standard in ounces | Error limits in milligrams |
| 8 | ±45 |
| 4 | ±23 |
| 2 | ±11 |
| 1 | ±5.4 |
| 0.5 (1/2) | ±2.8 |
| 0.25 (1/4) | ±1.7 |
| 0.2 | ±1.6 |
| 0.125 (1/8) | ±1.3 |
| 0.1 | ±1.3 |
| 0.0625 (1/16) | ±1.1 |
| 0.05 | ±1.0 |
| 0.03125 (1/32) | ±0.87 |
| 0.02 | ±0.75 |
| 0.015625 (1/64) | ±0.69 |
| 0.01 | ±0.60 |

TABLE 8.—ERROR LIMITS FOR SI MASS STANDARDS USED TO TEST TOLERANCE CLASS III BALANCES

| Mass standard in kilograms | Error limits in grams |
|---|---|
| 50 | ±5 |
| 20 | ±2 |
| 10 | ±1 |
| 5 | ±0.5 |
| 2 | ±0.2 |
| 1 | ±0.1 |
| Mass standard in grams | Error limits in milligrams |
| 500 | ±70 |
| 300 | ±60 |
| 200 | ±40 |
| 100 | ±20 |
| 50 | ±10 |
| 20 | ±4 |
| 10 | ±2 |
| 5 | ±1.5 |
| 2 | ±1.1 |
| 1 | ±0.9 |

TABLE 8.—ERROR LIMITS FOR SI MASS STANDARDS USED TO TEST TOLERANCE CLASS III BALANCES—CONTINUED

| Mass standard in kilograms | Error limits in milligrams |
|---|---|
| 500 | ±0.72 |
| 300 | ±0.61 |
| 200 | ±0.54 |
| 100 | ±0.43 |
| 50 | ±0.35 |
| 30 | ±0.30 |
| 20 | ±0.26 |
| 10 | ±0.21 |
| 5 | ±0.17 |
| 2 | ±0.12 |
| 1 | ±0.10 |

**§ 101.220 Analytical procedures, net mass or weight.**

The following procedures shall be used to determine the net quantity of contents of packaged foods labeled in terms of mass or weight:

(a) Make all measurements with equipment that conforms to § 101.215. Good weighing procedures shall be used to ensure accurate results (e.g., operate scales or balances in accordance with the manufacturers instructions, and conduct tests in locations where the environment does not adversely affect results);

(b)(1) The following core procedure shall be used to determine net mass or weight, except where a different specific procedure is provided for in paragraph (b)(2) of this section:

(i) Determine the gross mass or weight of the package;

(ii) Determine the average used tare mass or weight in accordance with provisions of § 101.235; and

(iii) Determine net mass or weight by subtracting the average used tare mass or weight determined in (b)(1)(ii) of this section from the gross mass or weight of each package in the sample.

(2) For unglazed frozen seafoods and vegetables, the method prescribed for unglazed frozen foods in the ''Official Methods of Analysis of the Association of Official Analytical Chemists International,'' 16th ed., 1995, section 963.26, under the heading ''Net Contents of Frozen Food Containers Procedure 1963,'' which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51, shall be used to determine net mass or weight. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c)(1) The following core procedure shall be used to determine drained mass or weight except where a different specific procedure is provided for in paragraph (c)(2) of this section:

(i) Determine and record the following:

(A) The tare mass or weight of the receiving pan; and

(B) The gross mass or weight of each individual package of the sample;

(ii) Use a 203 millimeters (8 inch) U.S. No. 8 standard test sieve for packages with net quantity of contents of 1.36 kilograms (3 pounds) or less, or a 305 millimeters (12 inch) U.S. No. 8 standard test sieve for packages with net contents greater than 1.36 kilograms (3 pounds); except that, for canned tomatoes obtain either a 203 millimeters (8 inch) or 305 millimeters (12 inch) (as appropriate) U.S. No., 11.3 millimeters (7/16 inch) standard test sieve;

(iii) Pour the contents of the package into the appropriate dry sieve with the receiving pan beneath it; incline the sieve at an angle of 17° to 20° to facilitate drainage. Do not shake or shift material on the sieve. Drain exactly 2 minutes;

(iv) Immediately weigh the receiving pan, liquid, wet container, and any other tare material (do not include weight of sieve and food). Record this value as the total tare mass or weight for the package and receiving pan;

(v) Subtract the tare mass or weight of the receiving pan determined according to paragraph (c)(1)(i) of this section from the mass or weight obtained in paragraph (c)(1)(iv) of this section to obtain the tare mass or weight (which includes the mass or weight of the liquid packing medium);

(vi) Subtract the tare mass or weight determined according to paragraph (c)(1)(v) of this section from the appropriate package gross mass or weight determined according to paragraph (c)(1)(i) of this section to obtain the net weight of that package. Determine the package error by subtracting the net mass or weight from the labeled mass or weight; and

(vii) Repeat the procedure provided for in paragraphs (c)(1)(ii) through (c)(1)(vi) of this section for the remaining packages in the sample. Clean and dry the sieve and receiving pan between measurements on each package.

(2) The following procedures shall be used to determine drained mass or weight for the foods noted. The procedures in this paragraph shall be conducted in accordance with the specified section ''Official Methods of

Analysis of the Association of Official Analytical Chemists International,'' 16th ed., 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC:

(i) For glazed vegetables and for frozen seafood, except for frozen shrimp and crabmeat, the method prescribed for glazed seafoods in section 963.18, under the heading ''Net Contents of Frozen Seafoods,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(ii) For frozen shrimp and crabmeat, the method prescribed for frozen shrimp and crabmeat in section 967.13, under the heading ''Drained Weight of Frozen Shrimp and Crabmeat,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(iii) For frozen crabmeat, the method prescribed for in paragraph (c)(2)(ii) or the method prescribed for frozen crabmeat in section 970.60, under the heading ''Drained Weight of Frozen Crabmeat,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(d) For shucked oysters, the percent of liquid by weight that is removed by draining shall be determined by using the method prescribed for such foods in section 953.11, under the heading ''Drained Liquid from Shucked Oysters,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (c)(2) of this section.

**§ 101.225 Analytical procedures, volume.**

The following procedures shall be used to determine the net quantity of contents of packaged foods labeled in terms of volume:

(a) Conduct all measurements on equipment that conforms to § 101.215 Good weighing and measuring procedures shall be used to ensure accurate results (e.g., operating scales or balances in accordance with the manufacturer's instructions, and conducting tests in locations where the environment does not adversely affect results).

(b) The following procedure shall be used to determine net volume, except where a different procedure is provided for in paragraphs (c), (d), (e), and (f) of this section:

(1) Bring the package and its food to the appropriate temperature as set forth in § 101.201(a), within the following temperature ranges:

(i) In the case of frozen food, −18 °C (0 °F) to −15 °C (5 °F);

(ii) In the case of refrigerated food, 1.7 °C (35 °F) to 7.2 °C (45 °F); or

(iii) In the case of other foods, 20 °C (68 °F) to 22.7 °C (73 °F).

(2) Prepare a clean volumetric measure of appropriate capacity for use;

(i) If the volumetric measure is calibrated on a ''to contain'' basis, immediately before each measurement, the volumetric measure shall be dried.

(ii) If the volumetric measure is calibrated on a ''to deliver'' basis, immediately before each use, the volumetric measure shall be filled with water to a point slightly below the top graduation on the neck. Start a stopwatch and invert the volumetric measure gradually, so that the walls are splashed as little as possible, to approximately an 85° angle and completely empty the volumetric measure.

(A) If the volumetric measure is marked with a standardized emptying time, hold the measure in the inverted position until the stopwatch indicates that the entire standardized time has expired, and touch off the drop of water that adheres to the tip.

(B) If no standardized emptying time is provided, pour the food in a steady stream so that virtually all of the product is delivered within 30 seconds (± 5 seconds). If a drainage time is designated by the manufacturer for the volumetric measure, hold the volumetric measure in the inverted position until any time designated on the measure has elapsed, or until the stopwatch indicates that 10 seconds have elapsed beyond the time necessary to completely empty the container. Touch off the drop of water that adheres to the tip.

(iii) If the food effervesces or foams when opened or poured (such as carbonated beverages), add two drops of a defoaming agent to the bottom of the volumetric measure before filling with the food.

(iv) For additional measurements of a food, use water to wash or rinse and prepare the volumetric measure between each measurement of liquid food from the sample packages (dry or drain the volumetric measure as described in paragraph (b)(2)(i) or (b)(2)(ii) of this section, as appropriate);

(3) If the food requires mixing for uniformity, it should be mixed before opening each package (e.g., in accordance with any shaking instructions specified on the package label);

(4) Empty the food into the volumetric measure holding the package in a nearly vertical position, but tipping so that the bottom of the container will drain. Drain the container into the volumetric measure for 1 minute after the stream of liquid breaks into drops; and

(5) Position the volumetric measure vertically with the surface of the liquid at eye level. For foods that are clear liquids, place a shade of some dark material immediately below the meniscus and read volume from the lowest point of the meniscus. For foods that are opaque liquids, read volume from the center of the top rim of the liquid surface.

(c) Except where a different procedure is provided for in paragraphs (d) and (e) of this section, the following gravimetric procedure may be used to determine net volume if the product density requirements of this paragraph are met:

(1) Select a volumetric measure equal to or one size smaller than the labeled volume and determine the tare mass or weight of the measure;

(2) Prepare the package and volumetric measure for measurement by following the provisions of paragraphs (b)(1), (b)(2), and (b)(3) of this section;

(3) Determine acceptability of the food density variation on two packages selected for tare determination in accordance with provisions of § 101.235 as follows:

(i) Determine the gross mass or weight of the first food package;

(ii) Pour an amount of the food from the first food package into a volumetric measure exactly to a specified mark on the neck of the measure. The amount of the food that is elected to be poured is referred to as the volume standard ($vol_{std}$) for this procedure;

(iii) Weigh the filled volumetric measure and subtract the tare mass or weight of the measure to obtain the net mass or weight of the food;

(iv) Determine the net mass or weight of the $vol_{std}$ of the food from a second package using the procedure in paragraph (c)(3)(iii) of this section; and

(v) If the difference between net mass or weight of both packages exceeds one division of the scale or balance, the net quantity of contents may not be determined by the gravimetric procedure in this paragraph; instead, use the totally volumetric procedure provided for in paragraph (b) of this section;

(4) Determine the ''nominal gross mass or weight'' as follows:

(i) Determine the average used tare mass or weight of the sample in

accordance with provisions of § 101.235. Include the packages used to determine acceptability of this procedure as part of the tare;

(ii) Use the net mass or weight of the known volume ($Vol_{std}$) as determined in paragraphs (c)(3)(iii) and (c)(3)(iv) of this section and calculate the average of the two values for the average net mass or weight (net $wt_{avg}$);

(iii) Calculate the average net mass or weight of the labeled volume (avg. wt $v_1$) of the food using the formula:

Avg. wt $v_1$=(net $wt_{avg}/vol_{std}$) × labeled volume of net contents;

(iv) Calculate the ''nominal gross mass or weight'' (nom. gr. wt) using the formula:

Nom. gr. wt = avg wt $v_1$ + average used tare mass or weight;

(v) Weigh the remaining packages in the sample;

(vi) Subtract the nominal gross mass or weight from the gross mass or weight of each package to obtain package errors in terms of weight;

(vii) Calculate the average error of the sample (i.e., the total error divided by the sample size); and

(viii) If the average error is a negative number, calculate package error for each package in terms of volume using the formula:

Package error (volume) = [package error in weight] divided by [average weight of both standard volumes of paragraph (c)(3) of this section (net wt avg)] multiplied by [volume of standard volume ($vol_{std}$)]

(d) For shucked oysters, clams, or scallops, use the method prescribed for such foods in the ''Official Methods of Analysis of the Association of Official Analytical Chemists International,'' 16th ed., 1995, section 937.08, under the heading ''Volume of Shucked Oysters, Clams or Scallops,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC;

(e) The volume displacement procedure prescribed for ice cream and frozen desserts in the ''Official Methods of Analysis of the Association of Official Analytical Chemists International,'' 16th ed., 1995, section 968.14, under the heading ''Weight per Unit Volume of Packaged Ice Cream'' Method I, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. This procedure may be used to determine volume where appropriate; except that water of 33 °F (0.56 °C) or below may be used rather than the kerosene displacement liquid in that procedure, provided that the food does not mix with the ice water;

(f) The volumetric depth gauge procedure set forth below may be used to determine volume where the food has a smooth and level headspace (e.g., oils, syrups, and other viscous liquids):

(1) Make all measurements on a surface that appears to be level when tested with a bubble level that is at least 15 centimeters (6 inches) in length;

(2) Bring the temperature of both the food and the water to be used to measure the volume of the food to the appropriate temperature provided for in § 101.201(a), achieving a temperature within the range designated in paragraph (b)(1) of this section;

(3) Determine the headspace of the package at the point of contact with the food using a depth gauge with a fully rounded rather than a pointed rod end. If necessary, the package shall be supported to prevent the bottom of the container from distorting;

(4) Empty, clean, and dry the package;

(5) Refill the container with distilled water measured from a volumetric measure to the original food headspace level found in paragraph (f)(3) of this section until the water touches the depth gauge; and

(6) Determine amount of water used in paragraph (f)(5) of this section to obtain the volume of the food and calculate the ''package error'' for that volume;

(g) The volumetric air space procedure set forth in this paragraph may be used to determine volume where the food does not have a smooth and level headspace (e.g., mayonnaise):

(1) Acquire the following equipment specifically for use in this procedure:

(i) 500-milliliter buret;

(ii) Rubber bulb syringe; and

(iii) Plastic Disks three-millimeter (1/8 inch) thick disks with diameters to correspond to the seat diameter or larger than the brim diameter of each container tested. Diameter tolerance is ±0.05 millimeter (±0.002 inch). The outer edge should be beveled at a 30° angle with the horizontal to 0.8 millimeter (1/32 inch) thick at the edge. There should be a 20-millimeter (3/4 inch) diameter hole through the center of the disk and a series of 1.5-millimeter (1/16 inch) diameter holes 25 millimeters (1 inch) from the outer edge. All edges should be smooth;

(2) Make all measurements on a surface that appears to be level when tested with a bubble level that is at least 15 centimeter (6 inch) in length;

(3) Bring the temperature of both the food and the water used to measure the volume of the food to the appropriate temperature designated in § 101.200(b) within the tolerances provided for in paragraph (b)(1) of this section;

(4) Open the first package and place a disk larger than the package container opening over the opening;

(5)(i) Add water to the container using flask (or flasks), graduate, or buret corresponding to labeled capacity of the container. If it appears that the contents of the flask may overfill the container, do not empty the flask. Add water until all of the air in the container has been displaced and the water begins to rise in the center hole of the disk. Stop the filling procedure when the water fills the center disk hole and domes up slightly due to the surface tension;

(ii) If the water dome breaks on the surface of the disk, the container has been overfilled and the test is void; dry the container and start over; and

(iii) Do not add additional water after the level of the water dome has dropped;

(6) Record the amount of water used to fill the container and subtract 1 milliliter (0.03 fluid ounce) (this is the amount of water in the disk hole) to obtain the air space capacity;

(7) Empty, clean, and dry the package container;

(8) In accordance with procedures set forth in paragraph (5) of this section, refill the package container with water measured from a volumetric measure to the maximum capacity of the package and record the amount of water used as the container volume; and

(9) From the container volume in paragraph (g)(8) of this section, subtract the air space capacity in paragraph (g)(6) of this section to obtain the volume of the food and calculate the ''package error'' for that volume, where ''Package error'' equals labeled volume minus the measured volume of the food.

**§ 101.230 Analytical procedures, count.**

The following procedures shall be used to determine the net quantity of

contents of packaged foods labeled in terms of count:

(a) Count each unit in each package of the sample to determine the net quantity of contents of packaged foods labeled in terms of count; or

(b) If the product density requirements of paragraph (b)(1) of this paragraph are met, the following gravimetric procedure may be used to determine count:

(1) Determine acceptability of the food density variation on two packages selected for tare determination in accordance with provisions of § 101.235 as follows:

(i) Determine the gross mass or weight of the first food package;

(ii) Open the package and determine the net weight and the exact number of food units in the first food package;

(iii) Calculate the weight of the labeled count of the package using the formula:

Weight of labeled count=[labeled count] divided by [count found] multiplied by [net weight];

(iv) Determine the weight of the labeled count of the food from a second package using the procedure set forth in paragraph (b)(1) (i) to (iii) of this section;

(v) If there is a difference between net mass or weight of the weight of the labeled count calculated from the two packages that exceeds one division of the scale or balance, the net quantity of contents may not be determined by the gravimetric procedure in this paragraph; instead, use the procedure provided for in paragraph (a) of this section;

(2) Determine the ''nominal gross mass or weight'' as follows:

(i) Determine the average used tare mass or weight of the sample in accordance with provisions of § 101.235. Include the packages used to determine acceptability of this procedure as part of the tare;

(ii) With the two determinations of count and net mass or weight of that count as determined in paragraph (b)(1) of this section, calculate the average count ($count_{avg}$) and the average net mass or weight ($net\ wt_{avg}$);

(iii) Calculate the average net mass or weight of the labeled count (ave. wt $c_1$) of the food using the formula:

Avg. wt $c_1$ = (net $wt_{avg}/count_{avg}$) × labeled count of net contents;

(iv) Calculate the ''nominal gross mass or weight'' (nom. gr. wt) using the formula:

Nom. gr. wt = avg wt $c_1$ + average used tare mass or weight;

(3) Weigh the remaining packages in the sample;

(4) Subtract the nominal gross mass or weight from the gross mass or weight of each package to obtain package errors in terms of weight;

(5) Calculate the average error of the sample (i.e., the total error divided by the sample size); and

(6) If the average error is a negative number, calculate package error for each package in terms of count using the formula:

Package error (count) = [package error in weight] divided by [average weight of both known counts of paragraph (b)(2) of this section (net $wt_{avg}$)] multiplied by [average of count of paragraph (b)(2) ($count_{avg}$)]

**§ 101.235 Tare determination.**

The following procedures shall be used to make tare determinations for the net quantity of contents of packaged foods:

(a) If the net quantity of contents is determined by weighing, an average dried used tare mass or weight shall be used to determine net mass or weight, unless the dried used tare mass or weight of each package in the sample is determined individually. If the inspection lot consists of 11 packages or less, the average dried used tare mass or weight shall be computed with 2 tare samples. If the inspection lot consists of 12 or more packages the average used tare mass or weight shall be computed with 2 tare samples except, if the package is made of glass, or if it is an aerosol container, and the sample size is 24 or 48 packages, 3 tare samples shall be used to compute the average dried used tare mass. Under other situations, the average dried used tare mass or weight shall be computed using the tare sample size ($n_t$) listed in Table 1 of this section for the different sample sizes (n) as follows:

(b) Select an initial tare sample size (''$n_{it}$'') as specified in paragraph (a) of this section to determine if additional tare samples are required. Any of the sample packages may be used as tare samples;

(c) Determine the gross mass or weight for each tare sample;

(d) Determine the tare mass or weight of each package in the initial tare sample ($n_{it}$) and the range of masses or weights of the tare samples (abbreviated as ''$R_t$''). If the range in the mass or weights of the initial tare sample is zero, no additional tare samples must be taken;

(e) Determine the net mass or weight of each package and, except for random weight packages, the range of net masses or weights in the initial tare sample (abbreviated as ''$R_c$''). For random weight packages ''$R_c$'' is determined using the range of the package errors in the initial tare sample, not the range of net masses or weight;

(f) Calculate the ratio of the range of net masses or weights ($R_c$) to the range of masses or weights in the initial tare sample size ($R_t$) (i.e., divide $R_c$ by $R_t$);

(g) From Table 1 of this section, determine the total tare sample size corresponding to the $R_c/R_t$ ratio determined in paragraph (f) (e.g., if the ratio of $R_c/R_t$ is 3.72, the sample size is 48, and the initial tare sample size is 2, the total tare sample size is 10). Where the number of packages listed in the Table 1 of this section for $R_c/R_t$ equals the initial tare sample size, the initial tare sample shall serve as the total tare sample; and

(h) Determine the average dried used tare mass or weight by adding the mass or weight of all of the tare samples required for the total tare sample size and divide that value by the total number of tare samples.

(i) TABLE 1.—TOTAL TARE SAMPLE SIZE (ABBREVIATED AS $n_t$)

| Ratio $R_c/R_t$ | Number of packages in sample [1] | | | | |
|---|---|---|---|---|---|
| | n=12 | n=24 | | n=48 | |
| | $n_{it}$=2 | $n_{it}$=2 | $n_{it}$=3 | $n_{it}$=2 | $n_{it}$=3 |
| 0.2 or less | 12 | 24 | 24 | 48 | 48 |
| 0.21–0.40 | 12 | 23 | 23 | 46 | 46 |
| 0.41–0.60 | 11 | 22 | 22 | 44 | 44 |
| 0.61–0.80 | 10 | 21 | 21 | 41 | 41 |
| 0.81–1.00 | 10 | 19 | 19 | 38 | 38 |
| 1.01–1.20 | 9 | 18 | 18 | 35 | 35 |
| 1.21–1.40 | 8 | 16 | 16 | 32 | 32 |

(i) TABLE 1.—TOTAL TARE SAMPLE SIZE (ABBREVIATED AS $n_t$)—Continued

| Ratio $R_c/R_t$ | Number of packages in sample [1] | | | | |
|---|---|---|---|---|---|
| | n=12 | n=24 | | n=48 | |
| | $n_{it}$=2 | $n_{it}$=2 | $n_{it}$=3 | $n_{it}$=2 | $n_{it}$=3 |
| 1.41–1.60 | 7 | 15 | 15 | 29 | 29 |
| 1.61–1.80 | 7 | 13 | 13 | 27 | 27 |
| 1.81–2.00 | 6 | 12 | 12 | 24 | 24 |
| 2.01–2.20 | 5 | 11 | 11 | 22 | 22 |
| 2.21–2.40 | 5 | 10 | 10 | 20 | 20 |
| 2.41–2.60 | 4 | 9 | 9 | 18 | 18 |
| 2.61–2.80 | 4 | 8 | 8 | 16 | 16 |
| 2.81–3.00 | 4 | 7 | 7 | 15 | 15 |
| 3.01–3.20 | 3 | 7 | 7 | 13 | 13 |
| 3.21–3.40 | 3 | 6 | 6 | 12 | 12 |
| 3.41–3.60 | 3 | 6 | 6 | 11 | 11 |
| 3.61–3.80 | 3 | 5 | 5 | 10 | 10 |
| 3.81–4.00 | 2 | 5 | 5 | 10 | 10 |
| 4.01–4.20 | 2 | 4 | 4 | 9 | 9 |
| 4.21–4.40 | 2 | 4 | 4 | 8 | 8 |
| 4.41–4.60 | 2 | 4 | 4 | 8 | 8 |
| 4.61–4.80 | 2 | 4 | 4 | 7 | 7 |
| 4.81–5.00 | 2 | 3 | 3 | 7 | 7 |
| 5.01–5.20 | 2 | 3 | 3 | 6 | 6 |
| 5.21–5.40 | 2 | 3 | 3 | 6 | 6 |
| 5.41–5.60 | 2 | 3 | 3 | 5 | 5 |
| 5.61–5.80 | 2 | 3 | 3 | 5 | 5 |
| 5.81–6.00 | 2 | 2 | 3 | 5 | 5 |
| 6.01–6.20 | 2 | 2 | 3 | 5 | 5 |
| 6.21–6.40 | 2 | 2 | 3 | 4 | 4 |
| 6.41–6.60 | 2 | 2 | 3 | 4 | 4 |
| 6.61–6.80 | 2 | 2 | 3 | 4 | 4 |
| 6.81–7.00 | 2 | 2 | 3 | 4 | 4 |
| 7.01–7.20 | 2 | 2 | 3 | 3 | 3 |
| 7.21–7.40 | 2 | 2 | 3 | 3 | 3 |
| 7.41–7.60 | 2 | 2 | 3 | 3 | 3 |
| 7.61–7.80 | 2 | 2 | 3 | 3 | 3 |
| 7.81–8.00 | 2 | 2 | 3 | 3 | 3 |
| 8.01–8.20 | 2 | 2 | 3 | 3 | 3 |
| 8.21–8.40 | 2 | 2 | 3 | 3 | 3 |
| More than 8.40 | 2 | 2 | 3 | 2 | 3 |

[1] Including those already opened for initial tare determination.

**§ 101.240 Compliance procedures; average requirement.**

Except where the sample contains packages with a declaration in terms of count that is subject to § 101.245(e), or where the sample consists of only one package, the determination as to whether the declaration of net quantity of contents on the packages in an inspection lot is violative under section 403(e) of the Federal Food, Drug, and Cosmetic Act is to be made using the procedures set forth below:

(a) Calculate the average error of the sample (i.e., the sum of the individual minus and plus package errors divided by the sample size);

(1) If the average error is zero or a positive number, the sample conforms with the average requirement;

(2) If the average error is a negative number, use the following procedure to determine the sample error limit (SEL):

(i) Calculate the sample standard deviation; and

(ii) Obtain the sample correction factor (SCF) from column 2 of Table 1 of this section for the appropriate sample size;

TABLE 1.—SAMPLE CORRECTION FACTORS (SCF)

| Column 1 sample size | Column 2 sample correction factor |
|---|---|
| 1 package | Apply Individual package requirement (maximum allowable variation (MAV) |
| 2 packages | 1.414 |
| 3 packages | 1.155 |
| 4 packages | 1.000 |
| 5 packages | 0.8944 |
| 6 packages | 0.8165 |
| 7 packages | 0.7559 |
| 8 packages | 0.7071 |

TABLE 1.—SAMPLE CORRECTION FACTORS (SCF)—Continued

| Column 1 sample size | Column 2 sample correction factor |
|---|---|
| 9 packages | 0.6667 |
| 10 packages | 0.6325 |
| 11 packages | 0.6030 |
| 12 packages | 0.5774 |
| 24 packages | 0.4082 |
| 48 packages | 0.2887 |

(b) Multiply the sample standard deviation(s) by the SCF to calculate the SEL;

(1) If the average error, disregarding the minus sign, is a smaller number than or equal to the SEL computed in paragraph (b) of this section, the sample complies with this section.

(2) If the average error, disregarding the minus sign, is a larger number than the SEL computed in paragraph (b) of this section, the inspection lot shall be

classified violative; except that, if the sample consists of a product for which a moisture loss allowance has been established in § 101.250, the appropriate allowance percent (A%) provided for in that section shall be used to calculate an adjusted sample error limit ($SEL_{adj}$) according to the formula:

$$SEL_{adj} = s \times SCF + (A\% \times \text{labeled contents}/100)$$

**§ 101.245 Compliance procedures; maximum variations.**

An inspection lot shall be classified violative if the net quantity of contents of the sample does not conform to the individual package requirements as determined by the procedures set forth below:

(a) Determine amount of each negative package error in the sample;

(b)(1) In accordance with the appropriate table in paragraph (f) of this section (i.e., Tables 1 and 2 for mass or weight; Tables 3 and 4 for liquid or dry volume; and Table 5 for count except where the count is 50 units or less where MAV's are not applicable), determine the MAV for the labeled net quantity of contents;

(2) Where an allowance for moisture content change is permitted in § 101.250 the MAV shall be adjusted to provide for the change by adding the percent of the labeled mass or weight attributable to the moisture change to the MAV (e.g., if the labeled package size is 2 pounds, and a 1-percent moisture loss could reasonably be expected, the MAV of 0.07 pound from Table 2 of this section is increased by adding 0.02 lb to give an adjusted MAV of 0.09 lb);

(c) Determine the number of negative package errors that exceed the MAV or adjusted MAV, as appropriate, for the labeled net quantity of contents;

(d)(1) Except where the sample contains packages with a declaration in terms of count that is subject to paragraph (e) of this section, any negative package error found in accordance with paragraph (c) of this section results in the inspection lot being classified violative if the sample consists of less than 48 packages;

(2) Except where the sample contains packages with a declaration in terms of count that is subject to paragraph (e) of this section, more than one negative package error found in accordance with paragraph (c) of this section results in the inspection lot being classified violative if the sample consists of 48 packages;

(e) For declarations in terms of count where the declaration is 50 items or less, if more than 1 package from a sample of 12 or less contains less than the labeled count where the inspection lot size is 250 packages or less; or if more than 2 packages from a sample of 24 packages contain less than the labeled count where the inspection lot size is between 251 to 3,200 packages; or if more than 3 packages from a sample of 48 packages contain less than the labeled count where the inspection lot is more than 3,200 packages, the inspection lot shall be classified as violative; and

(f) The Tables of MAV's are as follows:

TABLE 1.—MASS MAV'S FOR INDIVIDUAL PACKAGES LABELED IN METRIC UNITS

| Metric units | |
|---|---|
| Labeled mass or weight in grams (g) or kilograms (kg) | MAV in grams |
| Less than 36 g | 10 percent of labeled quantity. |
| From 36 to 54 g | 4. |
| More than 54 to 82 g | 5. |
| More than 82 to 118 g | 7. |
| More than 118 to 154 g | 9. |
| More than 154 to 209 g | 11. |
| More than 209 to 263 g | 13. |
| More than 263 to 318 g | 15. |
| More than 318 to 381 g | 16. |
| More than 381 to 426 g | 18. |
| More than 426 to 490 g | 20. |
| More than 490 to 572 g | 22. |
| More than 572 to 635 g | 24. |
| More than 635 to 698 g | 25. |
| More than 698 to 771 g | 27. |
| More than 771 to 852 g | 29. |
| More than 852 to 971 g | 32. |
| More than 971 g to 1.125 kg | 35. |
| More than 1.125 to 1.35 kg | 40. |
| More than 1.35 to 1.60 kg | 45. |
| More than 1.60 to 1.80 kg | 50. |
| More than 1.80 to 2.10 kg | 55. |
| More than 2.10 to 2.64 kg | 65. |
| More than 2.64 to 3.08 kg | 70. |
| More than 3.08 to 3.80 kg | 80. |
| More than 3.80 to 4.40 kg | 85. |
| More than 4.40 to 5.20 kg | 100. |
| More than 5.20 to 6.80 kg | 115. |
| More than 6.80 to 8.20 kg | 130. |
| More than 8.20 to 10.60 kg | 145. |
| More than 10.60 to 14.30 kg | 170. |
| More than 14.30 to 19.25 kg | 200. |
| More than 19.25 to 24.70 kg | 230. |
| More than 24.70 kg | 2 percent of labeled quantity. |

TABLE 2.—WEIGHT MAV'S FOR INDIVIDUAL PACKAGES LABELED IN INCH-POUND UNITS

| Inch-pound units | | |
|---|---|---|
| Labeled mass or weight in Pounds (lb) or Ounces (oz) | Pounds | MAV ounces |
| 0.08 lb or less, 1.28 oz or less. | 10 percent of labeled quantity | |
| More than 0.08 to 0.12 lb<br>More than 1.28 to 1.92 oz | 0.008 | 1/8 |
| More than 0.12 to 0.18 lb<br>More than 1.92 to 2.88 oz | .012 | 3/16 |
| More than 0.18 to 0.26 lb<br>More than 2.88 to 4.16 oz | .016 | 1/4 |
| More than 0.26 to 0.34 lb<br>More than 4.16 to 5.44 oz | .020 | 5/16 |
| More than 0.34 to 0.46 lb<br>More than 5.44 to 7.36 oz | .024 | 3/8 |
| More than 0.46 to 0.58 lb<br>More than 7.36 to 9.28 oz | .028 | 7/16 |
| More than 0.58 to 0.70 lb<br>More than 9.28 to 11.20 oz | .032 | 1/2 |
| More than 0.70 to 0.84 lb<br>More than 11.20 to 13.44 oz | .036 | 9/16 |
| More than 0.84 to 0.94 lb<br>More than 13.44 to 15.04 oz | .040 | 5/8 |
| More than 0.94 to 1.08 lb<br>More than 15.04 to 17.28 oz | .044 | 11/16 |
| More than 1.08 to 1.26 lb | .048 | 3/4 |
| More than 1.26 to 1.40 | .052 | 13/16 |
| More than 1.40 to 1.54 lb | .056 | 7/8 |
| More than 1.54 to 1.70 lb | .060 | 15/16 |
| More than 1.70 to 1.88 lb | 0.064 | 1 |
| More than 1.88 to 2.14 lb | .070 | 1 1/8 |
| More than 2.14 to 2.48 lb | .078 | 1 1/4 |
| More than 2.48 to 2.76 lb | .086 | 1 3/8 |
| More than 2.76 to 3.20 lb | .094 | 1 1/2 |
| More than 3.20 to 3.90 lb | .11 | 1 3/4 |
| More than 3.90 to 4.70 lb | .12 | 2 |
| More than 4.70 to 5.80 lb | .14 | 2 1/4 |
| More than 5.80 to 6.80 lb | .15 | 2 1/2 |
| More than 6.80 to 7.90 lb | .17 | 2 3/4 |
| More than 7.90 to 9.40 lb | .19 | 3 |
| More than 9.40 to 11.70 lb | .22 | 3 1/2 |
| More than 11.70 to 14.30 lb | .25 | 4 |
| More than 14.30 to 17.70 lb | .28 | 4 1/2 |
| More than 17.70 to 23.20 lb | .31 | 5 |
| More than 23.20 to 31.60 lb | .37 | 6 |
| More than 31.60 to 42.40 lb | .44 | 7 |
| More than 42.40 to 54.40 lb | .50 | 8 |
| More than 54.40 lb | 4.2 percent of labeled quantity | |

TABLE 3.—LIQUID OR DRY VOLUME MAV'S FOR INDIVIDUAL PACKAGES LABELED IN METRIC UNITS

| Metric units | |
|---|---|
| Labeled volume in milliliters (mL) or liters (L) | MAV in mL |
| 3 mL or less | 0.5[1]. |
| More than 3 to 8 mL | 1.0[1]. |
| More than 8 to 15 mL | 1.5[1]. |
| More than 15 to 22 mL | 2. |
| More than 22 to 67 mL | 3.5. |
| More than 67 to 126 mL | 5.5. |
| More than 126 to 170 mL | 7.5. |
| More than 170 to 222 mL | 9. |
| More than 222 to 347 mL | 11. |
| More than 347 to 503 mL | 15. |
| More than 503 to 621 mL | 18. |
| More than 621 to 798 mL | 22. |
| More than 798 to 917 mL | 26. |
| More than 917 to 1.153 L | 30. |
| More than 1.153 to 1.627 L | 37. |

TABLE 3.—LIQUID OR DRY VOLUME MAV'S FOR INDIVIDUAL PACKAGES LABELED IN METRIC UNITS—Continued

| Metric units | |
|---|---|
| Labeled volume in milliliters (mL) or liters (L) | MAV in mL |
| More than 1.627 to 2.041 L | 44. |
| More than 2.041 to 2.514 L | 52. |
| More than 2.514 to 3.046 L | 59. |
| More than 3.046 to 4.732 L | 74. |
| More than 4.732 to 5.489 L | 89. |
| More than 5.489 to 7.098 L | 104. |
| More than 7.098 to 8.044 L | 118. |
| More than 8.044 to 10.173 L | 133. |
| More than 10.173 to 11.593 L | 148. |
| More than 11.593 to 16.561 L | 177. |
| More than 16.561 to 18.927 L | 207. |
| More than 18.927 to 23.659 L | 237. |
| More than 23.659 to 26.734 L | 266. |
| More than 26.734 L | 1 percent of labeled quantity. |

[1] Use laboratory glassware.

TABLE 4.—LIQUID OR DRY VOLUME MAV'S FOR INDIVIDUAL PACKAGES LABELED IN INCH-POUND UNITS.

| Inch-pound units | | | |
|---|---|---|---|
| Labeled volume (fluid ounces) | Liquid MAV (fluid ounce) | Labeled volume (cubic inches) | Dry MAV (cubic inches) |
| 0.50 or less | ([1]) | 0.18 or less | 0.03 |
| More than 0.50 to 0.75 | 0.06 | 0.18 to 0.49 | 0.06 |
| More than 0.75 to 2.25 | 0.13 | 0.49 to 0.92 | 0.09 |
| More than 2.25 to 4.25 | 0.19 | 0.92 to 1.35 | 0.11 |
| More than 4.25 to 5.75 | 0.25 | 1.35 to 4.06 | 0.23 |
| More than 5.75 to 7.5 | 0.31 | 4.06 to 7.67 | 0.34 |
| More than 7.5 to 11.75 | 0.38 | 7.67 to 10.38 | 0.45 |
| More than 11.75 to 17 | 0.50 | 10.38 to 13.54 | 0.56 |
| More than 17 to 21 | 0.63 | 13.54 to 21.21 | 0.68 |
| More than 21 to 27 | 0.75 | 21.21 to 30.68 | 0.90 |
| More than 27 to 31 | 0.88 | 30.68 to 37.90 | 1.13 |
| More than 31 to 39 | 1.00 | 37.90 to 48.73 | 1.35 |
| More than 39 to 55 | 1.25 | 48.73 to 55.95 | 1.58 |
| More than 55 to 69 | 1.50 | 55.95 to 70.38 | 1.80 |
| More than 69 to 85 | 1.75 | 70.38 to 99.26 | 2.26 |
| More than 85 to 103 | 2.0 | 99.26 to 124.5 | 2.71 |
| More than 103 to 160 | 2.5 | 124.5 to 153.4 | 3.2 |
| More than 160 to 185.6 | 3.0 | 153.4 to 185.9 | 3.6 |
| More than 185.6 to 240 | 3.5 | 185.9 to 288.8 | 4.5 |
| More than 240 to 272 | 4.0 | 288.8 to 335.0 | 5.4 |
| More than 272 to 344 | 4.5 | 335.0 to 443.1 | 6.3 |
| More than 344 to 392 | 5.0 | 443.1 to 490.9 | 7.2 |
| More than 392 to 560 | 6.0 | 490.9 to 620.8 | 8.1 |
| More than 560 to 640 | 7.0 | 620.8 to 707.4 | 9.0 |
| More than 640 to 800 | 8.0 | 707.4 to 1,011 | 10.8 |
| More than 800 to 904 | 9.0 | 1,011 to 1,155 | 12.6 |
| More than 904 | 1 percent of labeled quantity. | 1,155 to 1,444 | 14.4 |
| | | 1,444 to 1,631 | 16.2 |
| | | More than 1,631 | 1 percent of labeled quantity. |

[1] Convert to metric units and use laboratory glassware.

TABLE 5.—COUNT MAV'S FOR INDIVIDUAL PACKAGES LABELED BY COUNT

| Labeled count | MAV |
|---|---|
| 51 to 83 | 2. |
| 84 to 116 | 3. |
| 117 to 150 | 4. |
| 151 to 200 | 5. |
| 201 to 240 | 6. |
| 241 to 290 | 7. |
| 291 to 345 | 8. |
| 346 to 400 | 9. |
| 401 to 465 | 10. |
| 466 to 540 | 11. |

TABLE 5.—COUNT MAV'S FOR INDIVIDUAL PACKAGES LABELED BY COUNT—Continued

| Labeled count | MAV |
|---|---|
| 541 to 625 | 12. |
| 626 to 725 | 13. |
| 726 to 815 | 14. |
| 816 to 900 | 15. |
| 901 to 990 | 16. |
| 991 to 1,075 | 17. |
| 1,076 to 1,165 | 18. |
| 1,166 to 1,250 | 19. |
| 1,251 to 1,333 | 20. |
| More than 1,333 | 1.5 percent of labeled count rounded off to the nearest whole number. |

**§ 101.250 Maximum allowances for moisture loss.**

Reasonable variations caused by the loss or gain of moisture in packaged foods are permitted as specified in this section. The following maximum allowances for moisture loss, expressed as a percentage of the labeled net quantity of contents, are permitted:

(a) No allowance for moisture loss will be made if:

(1) A food, other than a fresh bakery product, is weighed within 7 days following the end of the day of pack, except where the packer provides documentation of moisture loss during this time period, and the documentation has been produced in a manner that complies with paragraph (d) of this section; or

(2) A fresh bakery product is weighed within 1 day following the end of the day of pack, except where the packer provides documentation of moisture loss during this time period, and the documentation has been produced in a manner that complies with paragraph (d) of this section; or

(3) The food is not listed in paragraphs (b) or (c) of this section and thus is not subject to moisture loss; or

(4) The food is packaged in an air tight container (e.g., cans, glass bottles, enclosed in paraffin);

(b) One percent for the following foods: Frozen fruit and frozen vegetables more than 7 days following the end of the day of pack and fresh baked breads, buns, rolls, and muffins more than 1 day, but less than 7 days, following the end of the day of pack;

(c) Three percent for the following foods more than 7 days following the day of pack: Flour, 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; and

(d) A percent based on data that, upon request, is provided to an agency investigator to establish the moisture loss; provided that, the data are gathered through an approach that includes, but is not limited to, all of the following features:

(1) The data are based on 3 control lots with each lot consisting of at least 12 randomly selected individual packages that are collected on the same day, and the total number of randomly selected individual packages in the 3 lots is at least 48;

(2) Each of the individual packages in the control lots is identified and weighed at the time of collection;

(3) All control lots are stored at various locations in the storage site under the same conditions, which are typical for storage of the product (e.g., if the product is typically placed in a sealed case on a pallet and shrink wrapped, the control lots must be stored under those conditions, rather than under laboratory conditions);

(4) All individual packages in the control lots are weighed daily throughout the entire duration of the study;

(5) The maximum allowance for moisture loss is the average percent moisture loss that would be expected with a 97-percent level of confidence for the number of days of storage in view of the individual package weighings in all control lots for those days; and

(6) Where moisture loss varies with climatic changes in environmental conditions, the data are collected at an appropriate time to justify the moisture loss. For example, where an inspection is made of current production at a food processing plant in the middle of July, and moisture loss varies significantly from winter to summer, data collected in January cannot be used to document moisture loss during the inspection.

## PART 161—FISH AND SHELLFISH

3. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

4. Section 161.130 is amended by revising paragraph (c)(1) and adding new paragraph (d) to read as follows:

**§ 161.130 Oysters.**

* * * * *

(c) * * *

(1) ''Shell oysters'' means live oysters of any of the species, *Crassostrea gigas*, *Crassostrea virginica*, and *Ostrea conchaphila*, in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions that result in the addition of water.

(2) [Reserved]

(d) The oysters shall not have more than 15-percent liquid by weight after packing.

## PART 501—ANIMAL FOOD LABELING

5. The authority citation for 21 CFR Part 501 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

6. Section 501.105 is amended by revising paragraphs (a),(b), and (g) and by adding new paragraph (u) to read as follows:

**§ 501.105 Declaration of net quantity of contents.**

(a) The principal display panel of a food in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. If the food is liquid the declaration shall be in terms of fluid measure. If the food is solid, semisolid, or viscous, or a mixture of solid and liquid the declaration shall be expressed in terms of weight. If the food is a fresh fruit, fresh vegetable, or

other dry commodity that is customarily sold by dry measure the declaration statement may be expressed in terms of dry measure. If the food is packaged in a self-pressurized container, the statement shall be in terms of the mass or weight of the food and the propellant that will be expelled when the instructions for use as shown on the container are followed. If there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid, or viscous product by fluid measure, it may be used. Whenever the Food and Drug Administration determines that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination in the case of a specific packaged food does not facilitate value comparisons by consumers and offers opportunity for consumer confusion, it will by regulation designate the appropriate term or terms to be used for such commodity.

(b)(1) Statements of weight shall be in terms of avoirdupois pound and ounce.

(2) Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall:

(i) In the case of frozen food that is sold and consumed in a frozen state, express the volume at -18 °C (0 °F);

(ii) In the case of refrigerated food that is sold in the refrigerated state, express the volume at 4 °C (40 °F);

(iii) In the case of other foods, express the volume at 20 °C (68 °F);

(3) Statements of dry measure shall be in terms of the U.S. bushel of 2,150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof.

* * * * *

(g) The declaration of net quantity of contents shall provide an accurate statement of the quantity of contents of the package. For purposes of this section, an accurate statement is one that conforms to all requirements for the declaration set forth under part 101 of this chapter except for §§ 101.200 and 101.201. Sections 101.240, 101.245, and 101.250 of this chapter identify what constitutes a reasonable variation in net content declarations that is the result of loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice. Maximum allowance for moisture loss as permitted under § 101.250(c) applies to dry animal food. All net contents measurements shall be made in accordance with the procedures and methodology set forth in part 101 of this chapter. Any net quantity of contents declarations that overstate the amount of product in the container by an amount that is more than that can be attributed to a reasonable variation under these regulations will misbrand the product under section 403(e) of the Federal Food, Drug, and Cosmetic Act.

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(u) ''Dry animal food'' means animal food packaged in paperboard boxes or kraft paper bags that has 13 percent or less moisture at time of pack.

Dated: January 30, 1997.

William B. Schultz,

*Deputy Commissioner for Policy.*

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