



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Food Labeling: Net Quantity of Contents; Compliance
21 C.F.R. Parts 101, 161, and 50

Docket No. 92P-0441

COMMENTS OF THE STAFF OF FEDERAL TRADE COMMISSION [\(1\)](#)

INTRODUCTION

The staff of the Federal Trade Commission ("FTC") submits this comment regarding the proposed revisions to the Food and Drug Administration's ("FDA") human and animal food labeling regulations about declarations of net quantity of contents.

The FTC is a law enforcement agency charged by Congress to protect the public against deceptive or unfair practices and anticompetitive behavior. The FTC, through its Bureau of Consumer Protection, has been involved in issues concerning packaging and labeling for many years. The FTC has been responsible for enforcement of the Fair Packaging and Labeling Act ("FPLA"), adopted in 1966, with respect to consumer commodities, excluding food, drugs, devices and cosmetics. 15 U.S.C. § 1456(b). Under Section 5 of the FTC Act, the FTC also has authority to take action against inaccurate net content statements on all commodities as deceptive practices. 15 U.S.C. § 45(a).

The FTC's interest in labeling accuracy stems from its role in protecting consumers from deceptive practices. Recently, staff of the FTC's Bureaus of Consumer Protection and Economics worked closely with federal and state officials in coordinating a study of the accuracy of net content labeling on milk and other products. A report of this study, *Milk: Does it Measure Up?*, was released on July 17, 1997 (the "milk study"). This FTC staff comment is based in part on data from this milk study, as well as information obtained from industry members and other government agencies.

PROPOSED REVISION TO FDA REGULATIONS

The FDA states that the proposed revisions to the Food and Drug Administration's human and animal food labeling regulations about declarations of net quantity of contents "would establish specific procedures for checking conformance to net contents labeling requirements nationwide, and would provide consumers with information that accurately reflects the actual contents of the package."⁽²⁾ Pursuant to a 1990 amendment of the Federal Food, Drug, and Cosmetic Act ("the FDA Act"), FDA regulations that pertain to net contents declarations of human and animal food,

which are issued under authority of Section 403(e) of the FDA Act, preempt corresponding state and local laws and regulations.⁽³⁾ The FDA notes that, in amending the FDA Act, "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."⁽⁴⁾

Current FDA regulations pertaining to net contents declarations on food are very general and do not provide specific guidance to state and local regulatory agencies regarding enforcement criteria. The proposed revisions to FDA regulations would create a well-defined compliance standard that is readily understood by both enforcement officials and industry members. At the state and local level, decisions regarding frequency of inspections and appropriate remedies would still be made by state and local officials. The proposed rule would incorporate much of NIST Handbook 133, *Checking the Net Contents of Packaged Goods* ("NIST Handbook 133") into FDA regulations and would result in the uniform labeling requirements sought by manufacturers.⁽⁵⁾ Adoption of the proposed rule would also lead to consistency with the treatment of meat and poultry labeling, which is regulated by the U.S. Department of Agriculture (USDA),⁽⁶⁾ and of non-food consumer product labeling, which is regulated by the Federal Trade Commission.⁽⁷⁾

In evaluating the proposed rule, the FDA should consider the potential costs and benefits. Adoption of the proposed rule would not lead to significant costs being imposed on manufacturers who are currently attempting to keep their average fill at the labeled content level. Under the proposed rule, manufacturers would not have to bear the costs of purchasing new filling equipment. As explained below, in the section titled "Impact of Proposed Rule on Manufacturers," the proposed rule takes into account the fact that manufacturers that have older, less accurate packing equipment will be more likely to produce packages with a greater range of measured contents from one package to another and automatically allows lots with this greater content variation a larger margin of average sample underfill before being found to be out of compliance.⁽⁸⁾ In addition, under the revised regulations, the manufacturers that previously had been intentionally overfilling (that is, aiming their average fill above the labeled content) could elect to reduce their average amount of overfill, and thereby reduce their costs, while keeping their risk of non-compliance constant, by investing in more accurate filling equipment or improving their quantity control practices.

To the extent that the proposed rule facilitates a higher level of enforcement, there would likely be some additional costs imposed on packers that had either aimed their average fill below the labeled content or had been underfilling due to poor quantity control practices. Faced with increased enforcement and a higher risk of being found out of compliance, some of these manufacturers may choose to aim closer to the labeled amount and improve their quantity control practices, thereby incurring some increase in production costs.⁽⁹⁾ The extent of these increased production costs cannot be determined because the overall extent of underfilling of food packages is not known.

DAIRY INDUSTRY'S COMPLIANCE WITH PROPOSED RULE

The recently conducted milk study suggested benefits from retail-level oversight of the accuracy of net content declarations. This study was undertaken after federal officials received scattered reports from state and local officials of possible short-filling of milk sold in retail stores and served in schools. Some states had periodically checked milk and other dairy products sold in retail stores, but few states had regularly inspected milk or juice served in schools, universities or other institutions. The milk study was coordinated by staff of the FTC, USDA and National Institute of Standards and Technology ("NIST"), in cooperation with the Office of Food Labeling at FDA. (A copy of the report is attached hereto.)

For the milk study, weights and measures inspectors in twenty states used the procedures in NIST Handbook 133 to conduct 1638 inspections of milk, other dairy products and juice at 512 schools, retail stores, state and federal institutions, and dairies. Just over 40 percent of all inspected lots failed. Of the 858 lots of milk and juice inspected at schools, universities and hospitals, almost half, 411, failed inspection. Of the 340 lots inspected at dairies, one-third, 113, failed inspection. Of the 440 lots of milk and other products inspected in retail stores, almost a third, 142, failed inspection.

Most of the dairies included in the study were able to fill their containers with a high level of consistency and precision. The net content of individual packages in many of the measured samples varied little. This high measured precision shows that some inspection lots from some dairies failed because the dairies were targeting their fill level just a little too low.⁽¹⁰⁾

Modern dairy filling equipment does not appear to be the cause of a significant number of underfilling problems because it can be very precisely calibrated. (And as discussed below in the section titled "Impact of Proposed Rule on Manufacturers," the proposed rule allows more leeway for manufacturers with older, less accurate packing equipment.) Rather, most dairy underfilling problems likely result from inadequate quantity control measures in the packing process. For example, a dairy may be using incorrect target weights, incorrect tare weights, incorrect metric declarations, plastic jugs that have shrunk too much, or improperly calibrated filling equipment. It thus appears that increased compliance with net content labeling requirements, as set forth in NIST Handbook 133, could be achieved in the dairy industry through the implementation of more effective quantity control procedures.

INSPECTION LOT VERSUS PRODUCTION LOT

Some have argued that the only correct statistical population to use for inspection sampling is an entire production lot, rather than an inspection lot.⁽¹¹⁾ A key concept in the NIST Handbook 133 methodology is the "inspection lot." The proposed rule, at § 101.205(e), defines an inspection lot as "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." An inspection lot is found in one location because all packages in the lot must be available for sampling at the time of inspection. On the other hand, a production lot does not have a standard definition but is usually understood to be a large amount of packaged product designated by the manufacturer as belonging to the same production lot.⁽¹²⁾ A complete production lot does not necessarily ever exist at the same

location at the same time. For example, a packer may continuously ship packages as they come off the production line.

Impact of production lot requirement. Any requirement that enforcement procedures must somehow relate the result of an inspection lot to the originating production lot would severely limit the ability of state and local officials to protect consumers in their jurisdictions from inaccurate net content declarations. Such a requirement would most affect regulation of products shipped from another state or imported from another country. For these products, the receiving state would likely have to rely on the state or the country where the plant is located to conduct plant inspections. Not even the originating state or country could define and inspect production lots at plants that continuously ship packages as the packages come off the line. Moreover, the sheer number and variety of food products and sources makes it impracticable for concerned officials to make all necessary plant inspections.

In the absence of plant inspections, there are, in theory, other ways to determine whether the production lot complies with net content labeling requirements. In some cases, a company's production records might help determine whether a production lot (assuming it could be defined well enough) contained the proper amount of product. According to weights and measures officials, however, many companies whose lots failed inspection did not keep production records for the lots in question, and other companies kept unreliable records.⁽¹³⁾ In addition, states may not have the authority to subpoena out-of-state, or foreign, companies to turn over such records. In many instances, particularly for foreign manufacturers, it may be very difficult to contact the companies.

It would also be impractical and unrealistic to require state and local officials to find enough product to sample so that the inspected packages are representative of the production lot. First, parts of a production lot may be shipped into several different states or dispersed among numerous warehouses and retail stores. Second, a large proportion of the production lot may already have been sold to consumers and thus would not be available for inspection. Third, products in storage areas may not be available for inspectors' examination, on the grounds that the products are not being offered for sale.

Furthermore, the process of trying to identify a production lot may require unacceptable and impracticable delays or other obstructions to normal business. An inspecting state may lack power to require retailers or wholesalers to take underfilled inspection lots off-sale while the state seeks more information about the originating production lot. Underfilled packages might then continue to be sold to consumers until the state determines that the production lot was not in compliance. On the other hand, removal of product from sale pending a determination on the compliance of the production lot could impose serious financial burdens on wholesalers and retailers.

Efficient enforcement. Adoption of the proposed procedures would enable inspections to be performed with statistical validity in an unbiased fashion relatively simply and inexpensively. An inspection lot, as defined in the proposed rule, can feasibly and properly be used as the statistical population about which quantitative content compliance inferences can be made in the many different situations where sets of packaged product are located. An inspection lot is well-

delineated and available to be sampled from in a random and unbiased manner. By contrast, production lots are usually neither well-defined nor readily available for inspection. Some plants, for example, operate for many hours at a time, so identifying when one production lot ends and another lot begins could be entirely arbitrary. Specifying a standard procedure that would ensure valid statistical sampling from, and inferences about, production lots would be virtually impossible. Moreover, insisting that the only correct statistical population to use for inspection sampling is an entire production lot would have the effect of disabling almost all possible enforcement of quantitative labeling standards.

Under the proposed rule, inspection lots can be tested at any point in the food manufacturing and distribution cycle, from the packer through the wholesaler and distributor to the retailer. A random inspection sample is taken from the inspection lot and is used to draw a statistical inference about the average quantitative content of items in the inspection lot (§§ 101.210 and 101.240). The proposed rule protects against using compliance testing of small inspection lots to make improper enforcement decisions about the compliance of larger production lots. Under the proposed rule, the inspection lot cannot be used to make statistical inferences about a larger production lot from which it comes unless the inspection lot is a representative random sample of the production lot.

Furthermore, sampling from the inspection lot, rather than some larger production lot, would not cause the statistical finding to be biased against the manufacturer. Of course, it is possible that an inspection lot is significantly more underfilled, on average, than some larger set of packages of which it is part. But it should be just as likely that an inspection lot is significantly more overfilled, on average, than the larger production lot. Data from the milk study support the conclusion that inspections of packages in retail stores will not result in any bias against the dairy industry. Overall, the rate of failures of inspection lots at dairies equaled the rate of failures of inspection lots at retail stores. Approximately one-third of the inspection lots failed in both locations. There was no disproportionate number of failures in retail store inspections as compared to dairy inspections.⁽¹⁴⁾

The proposed rule's use of the inspection lot would facilitate state and local enforcement of net content labeling requirements and thereby help ensure that consumers get what they pay for. The milk study provides a telling example of how consistent monitoring and inspection of packages at the retail level can result in higher levels of compliance with net content labeling requirements. In spring 1997, weights and measures officials in Wisconsin inspected sixteen lots of eight ounce cartons of milk in the schools and found that 50 percent of the inspected lots failed. In a follow-up survey in the fall, they inspected 150 lots of the same kinds of packages in the same kinds of locations, but only 4.6 percent failed. This marked improvement demonstrates the effectiveness of inspections at the retail level.

By incorporating procedures that would enable inspections to be performed relatively simply and inexpensively, the proposed rule would help discourage packers from manipulating their packing practices in a violative manner. With modern filling equipment, many packers can control package content in their filling process extremely accurately. These packers could underfill packages for shipment to areas where there is little chance of inspection and overfill packages for

shipment to areas where inspections are more likely. Such violative practices would be less likely to occur with increased enforcement.

In addition, the use of inspection lots as defined in the proposed rule is the only effective means of monitoring how net contents are affected by distribution practices. The proposed rule, at § 101.201, recognizes that net contents will vary after packages are filled and allows for "reasonable variation in net content declaration that are the result of loss or gain of moisture during the course of good distribution practice." Variations may result from weather and seasonal changes, time and distance, transportation, and warehousing conditions. The negative impact of these factors can be controlled by maintaining good storage and rotation practices. Many manufacturers specify safe temperature ranges for storage, and others use "open" dating on packages (meaning that date information can be read by anyone without use of deciphering codes) to ensure that distributors and retailers rotate products. Products most affected by distribution practices represent a broad cross-section of retail food products, including most baked goods, flours, animal foods, and even soft drinks and ketchup packaged in PET plastics. Compliance testing of inspection lots makes it possible to monitor these effects. That, in turn, would encourage manufacturers, distributors and retailers to implement good distribution practices that maintain the accuracy of content declarations.

IMPACT OF PROPOSED RULE ON MANUFACTURERS

The proposed rule creates a compliance testing method that focuses on detecting inspection lots that are significantly underfilled on average, and includes mechanisms that are designed to reduce the risk that an accurately filled inspection lot will be incorrectly rejected. Under this approach, the manufacturer that underfills just a little will often be found in compliance. And the manufacturer that fills to an average exactly equal to the labeled content will rarely be found out of compliance. The proposed rule also takes into account the variations in precision in production technology and makes allowances for the fact that older, less accurate filling equipment is going to result in greater variations in content. Thus, manufacturers will enjoy the "benefit of the doubt" on several points under the proposed rule.

Type I versus Type II errors. Some industry members assert that the proposed rule may, in effect, require minimum content labeling, rather than filling to an average.⁽¹⁵⁾ In fact, the proposed rule reaches the opposite result. The compliance procedures set forth at § 101.240 include mechanisms designed to reduce the risk that an accurately filled inspection lot will be incorrectly rejected. The proposed rule balances two types of possible errors that can result from the use of a sampling procedure.⁽¹⁶⁾ On the one hand, the use of a sampling procedure can lead to rejecting some inspection lots that are actually correctly filled. This is referred to as a Type I error. On the other hand, the use of a sampling procedure can lead to accepting some inspection lots that are actually incorrectly filled. This is called a Type II error. An increase in the probability of a Type I error will automatically result in a decrease in the probability of a Type II error, and vice versa.

Under the proposed rule, an inspection lot is deemed out of compliance when the measured sample average is below the labeled content by more than two times the estimated standard deviation for the sample mean. There are two strong reasons for inspectors in the field to use this particular compliance criterion. First, the criterion is well-defined and easy to use, thus greatly

limiting the potential for mistakes. Second, the criterion gives manufacturers very strong protection against having inspection lots incorrectly found to be mislabeled (a Type I error), especially where the inspection lot is very small.⁽¹⁷⁾ Use of the compliance criterion thus would help keep inspection lots from being incorrectly found to be mislabeled and provide an efficient means of detecting lots that are significantly underfilled on average.

Under the proposed compliance procedures, the probability of a Type I error will never be larger than 3.5 percent.⁽¹⁸⁾ By ensuring that the probability of a Type I error is very low, the proposed procedures allow the probability of a Type II error to be quite large in some circumstances. The probability of Type II errors is highest when the inspection sample is only slightly underfilled. In other words, for inspection lots that are very close to compliance, the proposed procedures are more likely to result in acceptance of incorrectly filled inspection lots. This is why some inspection lots will still pass inspection under the proposed rule even though the inspection sample is slightly underfilled on average.

For example, if the average contents for an inspection lot were actually below the label amount by exactly one standard deviation of the sample mean, the lot will incorrectly be found in compliance about 84 percent of the time. This is a fairly large Type II error probability to allow in this situation, but it illustrates the proposed procedure's approach of placing more emphasis on avoiding incorrect decisions that a lot is underfilled than on avoiding incorrect decisions that a lot is adequately filled.

Variations in filling process. Some industry members have asserted that packers may have to overfill significantly to avoid problems caused by retail-level enforcement.⁽¹⁹⁾ On the contrary, the proposed rule would enable manufacturers to reduce overfilling and the extra costs to manufacturers and consumers associated with overfilling. While the current extent of overfilling and underfilling is not known, the FDA noted, in a 1980 rulemaking, that a nationwide survey had revealed that consumers routinely received a 4 percent overfill for the average of all packaged foods purchased.⁽²⁰⁾

The proposed rule recognizes that there will be some amount of randomness in the filling process. No manufacturer can be expected to fill every package perfectly. In particular, the procedures take into account the fact that manufacturers that have older, less accurate packing equipment will be more likely to produce packages with a greater range of measured contents from one package to another. Thus, when groups of packages from these manufacturers are sampled for inspection, there will be more measured content variation and, therefore, a greater likelihood that the inspected sample will, on average, be underfilled by a given amount.⁽²¹⁾ Taking this fact into account, the proposed compliance procedures at § 101.240 automatically allow a greater margin of underfill in an inspection sample with greater content variation before declaring the corresponding inspection lot to be out of compliance.⁽²²⁾

Making this type of allowance for quantitative inaccuracy in packing raises the possibility that some manufacturers will have insufficient incentive to invest in or maintain high accuracy in their packing process. However, as explained below, such incentives will be greatly affected by the level of enforcement manufacturers are faced with. Under the proposed method, manufacturers that have substantial incentives to comply will slightly overfill on average and

will have a positive incentive to keep packing error variation low.⁽²³⁾ Manufacturers that lack substantial incentives to comply may elect to slightly underfill on average and may have little incentive to reduce the error variation.

Under the proposed rule, improvements in the accuracy of quantity control would enable those who are overfilling to overfill by a smaller amount in order to maintain the same probability that an inspection lot of their product will be found out of compliance. On the other hand, improvements in quantity control accuracy would require those who are underfilling to reduce the amount by which they are underfilling in order to keep the risk of being found out of compliance constant. Thus, manufacturers that wish to maintain a low noncompliance risk will gain from improved packing accuracy by saving the costs associated with unnecessary overfilling. In contrast, those manufacturers that prefer a strategy that maintains a relatively high level of noncompliance risk associated with underfilling on average will lose from improved packing accuracy and will have little incentive to invest in greater accuracy.⁽²⁴⁾

Enforcement level. The strength of manufacturers' desire to avoid noncompliance with net content labeling requirements is likely to be directly related to the level of enforcement of these requirements by federal, state and local authorities. If inspections are infrequent, the expected loss (or risk) from maintaining an average underfill target is low even if the target is well below the labeled content. The manufacturer's expected cost savings from underfilling are then much greater than the expected loss from having some inspection lots found to be out of compliance. Data from the milk study reveal that the frequency and amount of underfilling was higher in inspection lots at schools, universities and hospitals, where net content compliance testing has been sporadic, compared to inspection lots at retail stores and dairies, where compliance testing has been more frequent.

CONCLUSION

The staff of the FTC believes that significant benefits are likely to accrue from the proposed revisions to FDA's human and animal food labeling regulations, particularly from a federal requirement to use inspection lots instead of production lots and from a uniform standard for measuring compliance that allows for variations in the accuracy of filling equipment. The proposed rule would enhance the ability of federal, state, and local officials to maintain a level of enforcement that would provide greater incentives for all manufacturers to increase their compliance with net content labeling requirements. The staff of the FTC has not identified any significant costs that the proposed rule might impose upon industry. To the extent, however, that comments filed by other parties document the source or magnitude of any such costs, they should be evaluated in light of the benefits likely to accrue from adoption of the proposed rule.

Endnotes:

1. The views expressed in these comments represent the views of the staff of Bureau of Consumer Protection and Economics of the Federal Trade Commission and do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner. Inquiries regarding this comment should be directed to Louise Jung (202-326-2989) and Russell Porter (202-326-3460).

2. 62 F.R. 9826.

3. The Nutrition Labeling and Education Act of 1990 has preempted state and local laws that are not "identical" to certain corresponding FDA labeling requirements. 21 U.S.C. § 343-1(a)(2).
4. 62 F.R. 9828.
5. 62 F.R. 9829.
6. In 1995, the USDA adopted the procedures in NIST Handbook 133 for the inspection of net content declarations on packages of meat and poultry. *See* 60 F.R. 12883 (March 8, 1995).
7. In 1986, the FTC issued a policy statement that the procedures in NBS Handbook 133 (predecessor to NIST Handbook 133) for checking the net contents of packaged consumer commodities "are not in conflict with existing Federal Trade Commission requirements." *See* 51 F.R. 10264 (March 25, 1986).
8. Thus, the proposed rule provides incentives to packers to keep average filled content near the labeled content, but does not penalize packers that choose not to invest in more accurate filling equipment. This is in contrast to either a minimum content standard (where every package has to include at least a certain amount) or a standard that specifies a fixed percentage average underfill allowance (where the average of inspected packages could, for example, be 1 percent underfilled and still pass inspection). Implementation of either of these approaches would likely have the greatest impact on packers with less accurate filling equipment that produce packages with greater variations in content.
9. The costs of such adjustments would not be treated as a net social cost in a properly done cost-benefit analysis inasmuch as they are pure transfers. Here, for example, the costs saved by a manufacturer that, on average, underfills packages are an average loss to consumers. When the manufacturer raises average package content up to the labeled amount, the cost of doing that is transferred as value directly to consumers. It is possible that the proposed rule might result in other costs that would be treated as a net social cost in a properly done cost-benefit analysis. While such costs should be considered, no discussion of such costs, or the scope or magnitude of such costs, appears in the rulemaking record.
10. The milk study found that the average amount of underfill in failed inspection lots was greater than the average amount of overfill in passed inspection lots. Overall, the average amount of underfill in failed lots of milk was 0.76 percent, whereas the average amount of overfill in passed lots of milk was 0.45 percent. In retail stores, the average underfill for failed lots of milk was 0.51 percent, and the average overfill in passed lots of milk was 0.25 percent. Similarly, in dairies, the average underfill in failed lots of milk was 0.70 percent, and the average overfill in passed lots of milk was 0.41 percent.
11. *See, e.g.*, request for extension of comment period submitted by the International Dairy Foods Association (letter dated Aug. 13, 1997, p.2), and comments submitted by the National Fisheries Institute (letter dated Aug. 28, 1997, p.1), American Bakers Association (letter dated Sept. 18, 1997, pp. 1-3), The Quaker Oats Company of Canada Limited (letter dated Sept. 24, 1997, pp. 1-2), and the American Frozen Food Institute (letter dated Sept. 26, 1997, pp. 1-2).
12. Thus, the manufacturer controls the definition of the production lot and often marks packages from the same production lot with the same identifying lot code.
13. *See* comment submitted by the NIST Handbook 133 Working Group of the National Conference on Weights and Measures (letter dated, July 9, 1997, p. 15).
14. There was a higher rate of inspection lot failure at schools and institutions than at dairies: 48 percent versus 33 percent. These rates are difficult to compare because most of the packages inspected in schools and institutions were 8 ounce containers, but very few 8 ounce containers were inspected at dairies. Data from the milk study show that inspection lots consisting of 8 ounce containers were the most likely to fail inspection: 52 percent failures for 8

ounce containers, compared to 41 percent for 16 ounce containers, 49 percent for 32 ounce containers, 40 percent for 64 ounce containers, and 21 percent for 128 ounce containers.

15. *See, e.g.*, request for extension of comment period submitted by the International Dairy Foods Association (letter dated Aug. 13, 1997, p. 2), and comment submitted by Multinational Business Services, Inc. (letter dated Aug. 28, 1997, p. 3). Minimum content labeling would require that every package in an inspection lot contain at least the amount stated on the label. Under a minimum content standard, no Type II errors would be allowed. In other words, any underfill in any inspected package would result in failure of the inspection lot.

16. The sampling procedure, set forth at § 101.210, specifies the size of the sample to be drawn from inspection lots of different sizes.

17. For inspection lots of 12 or fewer packages, sampling is not used. Rather, every package in the lot is examined. For larger lots, the probability of a Type I error decreases as the size of the lot increases. *See infra* note 18.

18. The procedures specify that the sample size increases in steps as the inspection lot size becomes larger. For lots smaller than 13, the sample is the entire lot. Between lot size 13 and 250, the sample size is 12. For lot sizes between 251 and 3,200, the sample size is 24; and, for lot sizes greater than 3,200, the sample size is 48. Under this specification, the probability of a Type I error is zero when the lot size is less than 13 because the entire lot is sampled and after that increases monotonically with the lot size until reaching a maximum value of approximately 3.5 percent at lot size 250. At lot size 251, the probability of a Type I error drops to 2.9 percent (because the sample size steps to 24) and stays fairly flat until lot size 3,201, where it drops to 2.56 percent (because the sample size steps to 48). For the lot sizes 250 and greater, the probability of a Type I error can be approximated as the probability that a T-statistic (having degrees of freedom equal to the sample size minus one) is less than minus 2.

19. *See, e.g.*, comments submitted by The Quaker Oats Company of Canada Limited (letter dated Sept. 24, 1997, p. 1), and the Food and Consumer Products Manufacturers of Canada (letter dated Sept. 26, 1997, p. 1).

20. 62 F.R. 9829. In contrast, the milk study found, overall, slight underfilling of milk on average--.13 percent. For inspection lots of milk that passed, the milk study found an average overfill of .45 percent. It should be noted that the milk study data cannot be statistically projected to the entire country because the inspection sites were not randomly selected and the 20 states participating in the study are not necessarily representative of all 50 states.

21. For example, consider a situation where samples of 24 packages are randomly drawn from two inspection lots of 2000 packages that are both, on average, correctly filled. Further, for purposes of this analysis, assume that the given amount of underfill is 0.4 ounces. Then, if one inspection lot has the content accuracy indicated by a lot standard deviation of 1.0 ounce, the sample average will be underfilled by the given amount of 0.4 ounces approximately 2 percent of the time. But, if the second inspection lot has a lower accuracy indicated by a lot standard deviation of 2.0 ounces, the sample average will be underfilled by the given amount of 0.4 ounces approximately 15 percent of the time. This example illustrates the fact that, if a fixed percentage amount of underfill were used as the noncompliance threshold, the lot with lower accuracy would be found out of compliance much more often than the lot with the higher accuracy even though both lots are, on average, correctly filled.

22. This automatic adjustment is accomplished by using the estimated sample variance as a measure of the inaccuracy of the filling process and setting the threshold for compliance at a point where, depending on the inspection lot size, correctly labeled inspection lots having this level of measured inaccuracy will be found out of compliance (a Type I error) from zero to 3.5 percent of the time.

23. Under the proposed rule, manufacturers that fill their packages to an average exactly equal to the labeled content will have up to 3.5 percent of inspection lots incorrectly rejected depending on the size of the inspection lot (a Type I error).

24. For example, a packer that wishes to maintain a probability of 0.1 percent that a random inspection lot of its product will be found mislabeled must overfill on average by 1.08 times the standard deviation of the sample mean

(that is, 3.08 standard deviations above the noncompliance threshold). Therefore, when the manufacturer improves accuracy by reducing the standard deviation by 90 percent, the amount of average overfill can be reduced by 90 percent without a change in noncompliance risk. However, for the manufacturer that has chosen a strategy of underfilling on average, a 90 percent reduction in the standard deviation of the fill process will lead to a 90 percent reduction in the amount the manufacturer can underfill and maintain the same violation risk.