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,

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 faild l
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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

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.

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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 overrnd(t)-2(i)r(

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 Bureaus 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.

(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