

Appendix F

NCWM BOD Item 101-14 – Protocol for Conduct of National Studies Updated following NCWM 7/99 Annual Meeting

1.0 PURPOSE and SCOPE

This protocol defines the formal structure for the conduct of national weights and measures product studies. This protocol will serve as the model for the identification, conduct, evaluation, and reporting of national product studies. Local Weights and Measures (W & M) officials asked to participate in a national product study should verify that the study will be conducted according to this protocol. A national product study is a geographically broad evaluation of two or more manufacturers' products within one or more product categories conducted by numerous states and local jurisdictions and designed to be representative of nationwide production. The scope of this protocol is intended to cover data gathering for informational purposes, such as product evaluation, in accordance with the practices and procedures of the National Conference on Weights and Measures, a non-profit weights and measures standards setting organization. This protocol supports the involvement and participation of industry as early as possible, when an issue is identified. The objective is to resolve issues at the lowest level, and as quickly as possible. Enforcement actions based on the individual inspections shall be left to the determination of the participating jurisdictions.

2.0 REFERENCES

National Conference on Weights and Measures (NCWM)
Executive Committee-1998 Pub 16, Agenda Item 101-15
Associate Membership Committee
NIST Handbook 44 (HB 44), Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices
NIST Handbook 130 (HB 130), Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality
NIST Handbook 133 (HB 133), Checking the Net Contents of Packaged Goods
State, Local, and Federal regulations, as applicable

3.0 DEFINITIONS

Jurisdictional Resources: Any agency either at the local or state level which has the authority to exercise regulatory actions.

Local: State, county, townships or city under local jurisdiction.

NCWM: National Conference on Weights and Measures

NIST: National Institute of Standards and Technology

Regional Association: One of the four Regional Conferences (Northeastern, Southern, Central, Western) affiliated with the NCWM.

TEAM (NCWM Board of Directors Subteam): Comprised of NCWM Chairperson, NCWM Chairperson-elect and 3 other non-industry NCWM Board Members.

4.0 PROTOCOL

4.1 Roles and Responsibilities Relevant to National Studies

- 4.1.1 NCWM: Promotes uniformity and encourages compliance in weights and measures laws, standards and practices. Ensures Local has contacted the appropriate company representatives of the issue.
- 4.1.2 Local: Develop and maintain trained personnel to conduct testing, work with regional or adjacent jurisdictions to pursue appropriate procedures to bring about compliance.

- 4.1.3 NIST: Promote national uniformity in weights and measures standards, laws, and practices. Issue NIST references; act as technical resource.
- 4.1.4 TEAM: Evaluate and determine need for national studies, define study scope and develop protocol, specify who will analyze and report study results, decide when to share data with affected companies.
- 4.1.5 Study Originator: Weights and Measures jurisdiction, Federal agency or other appropriate organization requesting TEAM approval to conduct a national study.
- 4.2 National Product Study Identification, Conduct, Evaluation, and Reporting Process through NCWM
- 4.2.1 National Study Origination:
National product studies can be requested by a number of various parties including federal agencies, regional associations, local jurisdictions, the NCWM and industry. The request should be submitted to the NCWM chairperson. The TEAM is responsible for making decisions on whether a study is warranted, the scope of the study, developing and approving the study protocol, establishing appropriate study evaluation methodology, designating who will conduct study analysis, and reporting of study results.
- National studies conducted for enforcement-related reasons should be considered when a diagnostic marketplace analysis is needed to confirm if a perceived marketplace problem exists that other enforcement options have not satisfactorily resolved. Federal regulatory agencies (FDA, FTC, DOA, etc.) and other federal agencies (NIST) can also recommend national studies to the TEAM. Requests for national studies should be assessed on a case-by-case basis to determine the need for the requested information.
- 4.2.2 The recommendation to proceed with the conduct of a national study must be approved by the majority of TEAM members. This group will assess if appropriate local, state, and regional actions have first been taken to attempt reaching resolution. Among the actions the TEAM will consider are:
- ≠# Review inspection and test reports to ensure the jurisdiction conducted the tests in full accord with NIST Handbook 133 and applicable federal law.
 - ≠# Determine that an appropriately large enough sampling of product has been made to suggest a national study is worthwhile.
 - ≠# Determine if this is an industry or company problem
 - ≠# The local jurisdiction has contacted affected companies
 - ≠# Review related industry correspondence to determine compliance issue communication, awareness, and related responsive actions.
 - ≠# Confirm that the Local has made reasonable effort towards issue resolution.
- 4.2.3 Based on its findings and judgment, the TEAM can either: 1) decline to take further action, 2) recommend the local, State, or regional enforcement actions that still must be taken before reconsidering the request, or 3) recommend pursuing the national study process. To insure impartiality and to prevent possible conflicts of interest, no industry representative (whether on the NCWM Board of Directors, the Associate Membership Committee, etc.) should participate in the discussion/vote on whether the TEAM should pursue a national study.
- 4.2.4 Since the objective of the W&M jurisdictions is to achieve marketplace equity, the TEAM shall determine if direct formal notification of the affected company(ies) and industry is appropriate before undertaking a national study. Correspondence should be signed by the NCWM Chairperson and be directed to affected firm(s) and trade associations where appropriate. Copies should be sent to all non-industry members of the NCWM Board of Directors, the study originator, and the director of each local jurisdiction of the affected companies.

The TEAM can determine a time frame for good faith response and demonstrated action by the affected companies or industry which will determine if they satisfactorily address the issue. Based on the response, the TEAM can elect to take no further action, to postpone taking further action to

allow deployment and an effectiveness assessment of the trade action plan, or to proceed into conducting a national study.

The TEAM will work with the study originator to track industry resolution progress and can authorize a national study when appropriate without further notice. The TEAM can authorize a national study without issuing a letter when the degree of a presumed problem are judged to be significant and trade cooperation has been minimal.

- 4.2.5 TEAM shall be responsible for designing the study protocol insuring study scope and methods are appropriate for the purpose of the study. Among the parameters the TEAM shall define (where appropriate) in the protocol are:

- ⊘ Purpose of the study
- ⊘ Relevant Background
- ⊘ Jurisdictions who will participate
- ⊘ Products/product sizes to be tested
- ⊘ Statistically sound design consistent with product characteristics
- ⊘ Preferred sampling locations
- ⊘ Time frame
- ⊘ Test methodology
- ⊘ Minimum lot and sample sizes
- ⊘ Who will collect and analyze the data
- ⊘ How data will be analyzed
- ⊘ How errors will be handled
- ⊘ How data will be reported

- 4.2.6 TEAM and the study originator shall approve the protocol for national studies and request concurrence of the federal agency(ies) having jurisdiction over the affected packaging plants. The person or organization analyzing the study should not be the study originator.

- 4.2.7 Study report content is recommended to include the analyses shown below. Circumstances relevant to each particular study may require modification to ensure results are accurate and non-misleading.

- ⊘ Overall Number of Participating Jurisdictions
- ⊘ Number of Jurisdictions from each region (NE, Central, South, West)
- ⊘ Number of Inspections Conducted
- ⊘ Number of Inspections Conducted in Accordance with Handbook 133
- ⊘ Percent of Inspections Conducted in Accordance with Handbook 133
- ⊘ Number of Products Represented in Conducted Inspections
- ⊘ Number of Inspection Lots Passed Using Handbook 133 Procedures
- ⊘ Percent of Inspection Lots Passed Using Handbook 133 Procedures
- ⊘ Number of Inspection Lots Failed Using Handbook 133 Procedures
- ⊘ Percent of Inspection Lots Failed Using Handbook 133 Procedures
- ⊘ Number of Handbook133 Lot Failures Due to MAVs
- ⊘ Percent of Handbook133 Lot Failures Due to MAVs
- ⊘ Number of Handbook133 Lot Failures Due to Average Requirements
- ⊘ Percent of Handbook133 Lot Failures Due to Average Requirements
- ⊘ Number of Products Passed Using Handbook 133 Procedures
- ⊘ Percent of Products Passed Using Handbook 133 Procedures
- ⊘ Number of Products Failed Using Handbook 133 Procedures
- ⊘ Percent of Products Failed Using Handbook 133 Procedures
- ⊘ Average Amount Overpack/Underpack in Products Passed
- ⊘ Average Amount Underpack in Products Failed
- ⊘ Economic Value of Overpack/Underpack in Products Passed

- €# Economic Value of Underpack in Products Failed
- €# Supplemental analyses where relevant

4.2.8 The TEAM shall approve the final report and decide when to affirmatively share data and the final report with affected companies and industries involved in the study. The TEAM will also determine if and when the study report will be published.