# Appendix I

# Item 260-3: Handbook 133, Moisture Allowance for Pasta Products

Section 2.3.8. Moisture Allowance

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### Warfield, Lisa

From:

Hermida, Maile G. [maile.hermida@hoganlovells.com]

Sent:

Thursday, June 23, 2011 2:08 PM

To:

John.Albert@mda.mo.gov

Cc:

Gaccione, John; Don Onwiler; Warfield, Lisa; Sefcik, David; Steinborn, Steven B.

Subject:

NCWM Agenda Item 260-3

Attachments:

L&R 260-3 - Letter and Additional Information from NPA.pdf; NDSU Study Protocol.PDF;

Background Information on NDSU Study.pdf; Quantitiative Values.pdf

John.

Please find attached a letter from the National Pasta Association providing additional information regarding NCWM Agenda Item 260-3. We are sharing this supplemental information in response to requests received during the Laws & Regulations Committee's open hearing at CWMA's annual meeting. Specifically, we are providing three background documents regarding the published study about moisture loss conducted by North Dakota State University.

We are copying NCWM and NIST so that this information also may be shared with the NCWM Laws & Regulations Committee and other interested members of the Conference. Please feel free to forward this information to other members of CWMA and the CWMA Laws & Regulations Committee.

If you have any questions or if you would like to discuss this issue further, please contact either Steve Steinborn or me.

Thank you.

Maile

### Maile Gradison Hermida

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June 23, 2011

### By Electronic Mail

John Albert
Chair, Laws and Regulations Committee
Central Weights and Measures Association
c/o Missouri Department of Agriculture
PO Box 630
1616 Missouri Boulevard
Jefferson City, Missouri 65102

Re: Laws & Regulations Committee Agenda Item 260-3

Dear Mr. Albert:

The National Pasta Association (NPA) appreciated the opportunity to present information about Laws & Regulations Committee Agenda Item 260-3 at the Central Weights and Measures Association's annual meeting last month. As we discussed at the meeting, the proposed 3% gray area for moisture loss in pasta is well-supported by both published and industry data. In response to CWMA's request for additional information in advance of NCWM's annual meeting, we are providing three documents regarding the published study about moisture loss in pasta conducted by North Dakota State University.

First, we are providing a detailed listing of the specific quantitative values captured by the North Dakota State University study. This data shows the net weight for the pasta samples during each month of the study. While the NDSU study included graphs illustrating these data, we thought it may be helpful for the Conference to see the specific quantitative data points. The study found that pasta packaged in paperboard lost a maximum 5.02% of its weight at retail and that pasta packaged in flexible polyethylene bags lost a maximum of 3.18% of its net weight at retail.

Second, enclosed is the protocol for the study, which explains the survey design, methodology, and specifications. This information shows that the study was the result of a carefully considered process and underscores the validity and significance of the study's results.

Finally, we are providing a background document prepared at the time the study was published that explains the purpose of the study and provides context for the study's findings. We believe this document may be helpful in considering the weight of the study's results. The document explains that the parameters selected for the study were not "worst case" situations for net weight variation.

As we have previously presented, the nature of pasta, the packaging necessary to allow for gain or loss of moisture to ensure product quality, and the pasta distribution cycle are unchanged since the

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North Dakota State University study was conducted. NPA's petition also provided more recent company-specific data that validates the relevance of the original study to today's marketplace.

Given the interest in this information by the attendees at the CWMA meeting, we are copying the NCWM so that these documents also may be made available to other interested members of the Conference. We appreciate CWMA's interest in Agenda Item 260-3. NPA is hopeful that with support of the Central region and the Conference as a whole, this modest but important change to Handbook 133 will be adopted this year. If you would like to discuss this issue further, you can reach Steve Steinborn at (202) 637-5969 or <a href="mailto:steven.steinborn@hoganlovells.com">steven.steinborn@hoganlovells.com</a> and Maile Hermida at (202) 637-5428 or <a href="mailto:mai

Sincerely,

Steve Steinborn

Partner, Hogan Lovells

Counsel to National Pasta Association

Maile Gradison Hermida Associate, Hogan Lovells

Counsel to National Pasta Association

cc: Don Onwiler, Executive Director, NCWM

John Gaccione, Chair, NCWM Laws & Regulations Committee

Lisa Warfield, NIST David Sefcik, NIST

EXHIBIT [II

### PROTOCOL-

# NATIONAL PASTA ASSOCIATION (NPA) SURVEY OF NET WEIGHT VARIATIONS IN PASTA PRODUCTS

### A. INTRODUCTION

On August 8, 1980, The Food and Drug Administration (FDA) proposed amendments in the <u>Federal Register</u> for net weight labeling regulations which would quantitatively define permissible variations from stated net weights for several food categories, including foods subject to moisture loss. While recognizing that macaroni and noodle products have been reported to lose moisture during storage, FDA proposed no moisture loss tolerance for pasta products.

### 1. Purpose of Survey

The purpose of this survey is to provide data in support of NPA's request that a specific tolerance be established that recognizes, as reasonable and permissible, variations between the stated net weight and actual net weight of pasta products, such variations being due to the loss of moisture in pasta products during product distribution.

### 2. Background

The proposed NPA survey is based on (a) FDA survey of moisture loss in flour packaged in Kraft paper bags. (b) FDA guidelines for moisture loss surveys. (c) guidance offered NPA by FDA

(Exhibit I), and (e) Foremost-McKesson's R&D study (Exhibit II).

The R&D study shows the influence of various storage conditions on net weight variations of different pasta products (macaroni, noodle, etc.) and package sizes.

### Survey Design

Commercially produced and packaged pasta will be examined for net weight and moisture variations under environmental conditions normally encountered in the U.S. grocery product distribution system.

Single case quantities of test product produced by two different manufacturers and packaged in the industry's most common package size and types will be randomly selected at the manufacturing locations and shipped to selected storage locations. Each test production shipment will be accompanied by ten empty packages to be used for determining tare weight.

Sample packages and empty packages will be weighed at appropriate intervals throughout the survey. Product moisture will be determined only at the beginning of the survey. Moisture assays will be done in duplicate from a single sample package taken adjacent to the sample cases.

Moisture determinations and the collection, interpretation, and presentation of data will be under the direction of Dr. Joel W. Dick of the North Dakota State University.

The survey design is summarized in Table 1.

### D. SUKVEY CUMPONENTS

### 1. Product

Enriched spaghetti (21 CFR 139.115(c)) will be used as the test product in the present survey. The use of a single product is justified by the fact that spaghetti (a) responds to environmental conditions in a manner typical of other pasta products, shapes, and sizes (Exhibit II) and (b) is the industry's leading product in terms of per capita consumption (SAMI data FYE 1981, nearly one half retail sale was spaghetti).

### 2. Packaging Materials

The two most popular consumer packages will be studied in this survey: paperboard cartons and flexible bags. Construction and moisture vapor transmission data along with closure, and sealing methods are presented in Exhibit I.

### Package Size

Because net weight variation during storage has been found to be independent of package size (Exhibit II), the survey will be limited to the most popular package size -- 16 ounce.

### 4. Manufacturers

Product packaged in flexible bags (24 per case) will be supplied by the Skinner Macaroni Company.

Product packaged in paperboard cartons (20 per case) will be supplied by the C. F. Mueller Company.

### Storage Facilities and Test Locations

Two warehouse and one retail facility will be used throughout the survey.

The storage facilities will be located in the Minneapolis and New York City Metropolitan areas.

### 6. Duration of Survey

The survey will encompass all seasonal cycles over a 12-month period for each warehouse and retail location.

### C. METHODOLOGY

### 1. Identification Codes

A sample code will be affixed to each individual retail package by a pressure-sensitive label. Label information will include:

Manufacturing facility location

Sample code number

Manufacturing date

Statement - "TEST SAMPLE - NOT FOR SALE"

Each manufacturer will be assigned an identification code number. The shipping case will have labels containing the above information attached to all six sides.

### 2. Net Weight Determination

### a. Tare Weight

The total weight of ten empty packages (including any coupons, etc.) will be divided by a factor of ten to determine the average tare weight.

### b. Gross Weight

The total weight to the nearest 0.1g of each sample package will be recorded as the gross weight.

### c. Net Weight

The tare weight will be subtracted from the gross weight to obtain the net weight of the product.

### d. Frequency

Gross weights and tare weights are to be determined immediately after selecting and labeling sample units at the manufacturing plant, upon receipt at the storage facility, and bi-monthly for a period of 12 consecutive months at each warehouse and retail location.

### e. Weighing Scale

All test locations will use the same type of scale: Ohaus model 750-S, Triple Beam Balance with Stainless Steel Plate (6"), 610 gram (21.52 oz.) metric capacity, sensitivity O.lg.

### f. Calibration Check

Prior to each set of weighings, scales will be calibrated using a 500 g Class M2 (or C) brass weight.

### 3. Moisture Determination

a. Moisture Assays

Will be conducted in duplicate for each sample unit according to the AOAC Official Method (14.04 Cereal Lab/Flour-Oven Method) within 24 hours of receipt.

b. Sample Containers

Special widemouth, rubber lined screw cap, mason-type 8 ounce glass jars will be used.

c. Frequency

Product samples will be analyzed for moisture at the beginning of the study.

d. Sample Units

Each product will be sampled in duplicate. One sample will be submitted to the North Dakota State University for assay. The duplicate sample will be retained pending confirmation of sample receipt and analysis.

### 4. Environmental Readings

a. Measurements of the ambient temperature (<sup>O</sup>F) and the relative humidity will be recorded in the record-log each time samples are weighed.

- b. Method of environmental system control (heat or air conditioning by gas, electricity, etc.) for each storage area will be noted in the record-log.
- c. Weather conditions and unusual conditions of handling, storage, etc., will be noted in the record-log.

### 5. Record Keeping

- All test locations will be provided with appropriate forms to record data.
- b. Manufacturing sites will record sample identification, tare weights, gross weights, temperature, relative humidity, and any unusual conditions.
- c. Storage locations will record identification, tare weights, gross weights, temperature, relative humidity, and any umusual conditions.
- d. Copies of all records and data are to be mailed to: Dr. Joel W. Dick at the North Dakota State University.

### D. CONCLUSION

### Data Tabulation

The North Dakota State University will tabulate the data accumulated over the 12 month period.

### 2. Report

Final data will be assembled, interpreted, and presented in appropriate report form by the North Dakota State University to the NPA Standards Committee.

### FDA Presentation

NPA will present the results of this survey to the Food and Drug Administration as evidence supporting a request for an allowance for moisture loss for pasta products during commercial distribution.

May 14, 1982

L&R Committee 2011 Final Report Appendix I – Item 260-3: Moisture Allowance for Pasta Products

NPA NET WEIGHT SURVEY DESIGN

PRODUCT	SPAGHETTI						
MANUFACTURER	C. F. MUELLER			SKINNER			
PACKAGE	PAPERBOARD CARTON, 16 OZ.			FLEXIBLE BAG, 16 OZ.			
SAMPLE SIZE	ONE CASE OF 20 PACKAGES AT EACH STORAGE LOCATION			ONE CASE OF 24 PACKAGES AT EACH STORAGE LOCATION			
STORAGE FACILITY	WAREHO	USE	RETAIL	WAREHO	WAREHOUSE		
TEST LOCATIONS	MPLS. AREA	NYC AREA	NYC AREA	MPLS. AREA	NYC AREA	NYC AREA	
GROSS WEIGHT	EACH SAMPLE PACKAGE WEIGHED AT MANUFACTURING PLANT, UPON RECEIPT  AT STORAGE FACILITY, AND ★★★MONTHLY FOR ONE YEAR						
TARE WEIGHT	AVERAGE OF TEN EMPTY PACKAGES WEIGHED AT MANUFACTURING PLANT, UPON RECEIPT AT STORAGE FACILITY, AND #2-MONTHLY FOR ONE YEAR						
MOISTURE	PRODUCT MOISTURE TO BE DETERMINED AT BEGINNING OF THE SURVEY						
CONTROL	DATA COLLECTION, INTERPRETATION, AND PRESENTATION TO BE DIRECTED BY DR. JOEL W. DICK, NORTH DAKOTA STATE UNIVERSITY						

MPLS. = Minneapolis - St. Paul Metropolitan Area

NYC = New York City - New Jersey Metropolitan Area

# L&R Agenda Item 260-3: Moisture Loss in Pasta Frequently Asked Questions

1) Why do inspectors need to consider moisture loss?

A lawful inspection must take account of moisture loss for any product where moisture loss occurs, such as pasta. Federal (and corresponding state) requirements mandate that "reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice" must be recognized before the jurisdiction can determine the accuracy of the net weight statement.

The U.S. Supreme Court in the case of *Jones v. Rath Packing Company* held that the Federal Food, Drug, and Cosmetic Act "permits variations from stated weight caused by gain or loss of moisture" and therefore a manufacturer of food "is not subject to enforcement action for violation of the net weight labeling requirements if the label accurately states the net weight, with allowance for the specified reasonable variations" such as moisture loss.

2) When must an inspector consider moisture loss when checking packaged pasta products?

Inspectors always must account for moisture loss for pasta because the product will always have the potential to lose moisture. Failure to account for moisture loss for hygroscopic products like pasta renders an inspection invalid. Federal and state law do not permit inspectors to issue a citation, order pasta products off-sale, or issue a civil penalty unless moisture loss has been accounted for by the inspector. This is a well-settled matter of law.

3) Why should Handbook 133 be amended to address moisture loss for pasta?

The modest amendment to Handbook 133 would provide inspectors with critical guidance to ensure that pasta product package checking is done properly and lawfully. The industry petition was brought to the Conference because inspectors have mistakenly interpreted the lack of express guidance in Handbook 133 about moisture loss in pasta to mean that they are not required to consider moisture loss for these products. Of course, that is not the case.

4) Why should the Conference create a special allowance for pasta? Will passage of this proposal open the door to a flood of similar amendments to Handbook 133?

The pasta industry is not seeking special treatment. The proposal would merely memorialize a well-established moisture loss allowance and assist inspectors in accounting for moisture loss among pasta products, as is the case for flour, dry pet food, meat, and poultry. Indeed, both NIST and FDA have proposed 3% as the appropriate gray area for pasta.

Only a finite number of products are subject to moisture loss and the vast majority of packaged foods do not gain or lose moisture. The Conference should consider proposals from other industries that are able to amass appropriate data that supports a moisture allowance gray area.

5) How does a moisture allowance work? Why should pasta manufacturers be given a 3% "break" instead of just overpacking?

Although referred to in shorthand as a "moisture allowance," it is important to recognize that the proposal before the Conference would establish a 3% "gray area." It is not a tolerance. If a sample is found to be less than the labeled weight but within the 3% threshold, the lot is in the "gray" or "no decision" area. This is an indication for inspectors that more information must be collected before lot compliance or noncompliance can be decided. In such situations, inspectors can elect to conduct further investigation to determine whether moisture loss is the basis for the product being short weight. This same method of inspection already exists for flour and pet food, and the modest amendment to Handbook 133 does not introduce a new concept or loophole that favors pasta products.

The Supreme Court's ruling in *Jones v. Rath Packing Company* and subsequent legal precedent, affirms a uniform net weight compliance standard that regulates a manufacturer's conduct at the point-of-pack. *Rath Packing* recognizes that in a national marketplace companies are not required (nor is it feasible) to target package weights by region and climate.

Inherent in the Court's ruling is an understanding that companies are not required to over-pack to address moisture loss that may occur as the result of good distribution practices. The law does not sanction a requirement to target distribution regionally, nor would this approach be practicable for manufacturers to implement.

6) Is moisture loss really unavoidable for pasta? Why can't you just change your packaging to prevent moisture loss?

Pasta is hygroscopic, which means that its moisture content does not remain constant after the product is manufactured. Depending on the relative humidity of the atmosphere, pasta will frequently gain or lose moisture even when good manufacturing and distribution practices are followed. The amount of moisture loss depends upon many factors including the shape of the noodles, the packaging material, the length of time it is in distribution, the retail sales environment, and environmental conditions.

Pasta needs "breathability" throughout its life cycle in order to maintain quality because of its hygroscopic nature. Without flexible packaging, dissipating moisture would remain caught in the package. This could result in pasta that fails to cook properly or even could cause it to spoil if subject to extreme temperature changes.

7) Why is 3% an appropriate level for the gray area?

The proposed value of 3% has consistently been recognized as an appropriate gray area for pasta products. The FDA and NIST each previously recognized 3% as an appropriate level for moisture loss in pasta. Additionally, the 3% level is supported by a published study conducted by North Dakota State University, commissioned by NPA, which was conducted in 1988 following the guidelines and input from FDA and NIST. More recent company-specific data also validates the findings of the North Dakota State University study and supports the 3% threshold. (Note that some of our data suggests the need for a higher threshold.) This value also is consistent with the gray areas already established in Handbook 133 for flour and pet food, which are similar in their formulations to pasta. The North Dakota State University study and confirming industry data have been presented to the Conference for its review and consideration.



# Proposal: Handbook 133, Section 2.3, would be amended to incorporate a 3% ("gray area") moisture allowance for pasta products, as with flour and dry pet food products. A majority of the Conference voted in support of the proposal at the July 2010 Annual Meeting. The proposal received favorable treatment by L&R Committee at January 2011 meeting. The National Pasta Association appreciates the opportunity to survey the merits of the proposed amendment and appreciates the Conference's consideration of this item.



- Federal Food, Drug and Cosmetic Act: Foods in package form must bear "an accurate statement of the quantity of the contents in terms of weights . . . except that . . . reasonable variations shall be permitted." (21 U.S.C. 343(e))
- FDA Regulations: "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." (21 C.F.R. 101.105(q))
- State laws parallel the federal requirement. A unified legal framework guides inspectors' actions when checking pasta products.

# Legal Framework

- U.S. Supreme Court in <u>Jones v. Rath Packing Co.</u> (1977):
  - "The federal net-weight labeling standard permits variations from stated weight caused by this gain or loss of moisture."
  - "Over 60 years ago, Congress concluded that variations must be allowed because of the nature of certain foods and the impossibility of developing completely accurate means of packing. Since 1914, regulations under the food and drug laws have permitted reasonable variations from stated net weight resulting from packing deviations or gain or loss of moisture occurring despite good commercial practice. ... We can only conclude that under the [Fair Packaging and Labeling Act], as under the [Federal Food, Drug, and Cosmetic Act], a manufacturer is not subject to enforcement action for violation of the net-weight labeling requirements if the label accurately states the net weight, with allowance for the specified reasonable variations."



- Jones v. Rath Packing Co., continued:
  - "The moisture content of flour does not remain constant after milling is completed. If the relative humidity of the atmosphere in which it is stored is greater than 60%, flour will gain moisture, and if the humidity is less than 60%, it will lose moisture."
  - "Weight fluctuations of 3% to 4% resulting from changes in moisture content are not uncommon during good distribution practice within the continental United States."
  - "If flour were packed in airtight packages in order to prevent weight fluctuations resulting from changes in moisture content, it would spoil."

### Slide 6



# FDA Proposal – 1980:

- FDA proposed to quantitatively define permissible "reasonable variations" from stated net weights for several food categories, including food subject to moisture loss.
- FDA encouraged industry to submit data on moisture loss so that reasonable variations could be established for more food categories.
- FDA reviewed and accepted protocol for NPA moisture loss study.
- **FDA Proposal 1997:** 3% "gray area" for pasta.
- NIST Informal Guidance: Recognize 3% for pasta, rice and like products not formally included in Handbook 133.
- NCWM Working Group: Teaching inspectors how to account for moisture loss has proven challenging. Call for industry to address the issue.



- Goal: A moisture loss gray area facilitates retail inspections but does not excuse or sanction unlawful short weight packages on store shelves.
- An inspector cannot order product off-sale (nor can a jurisdiction issue a citation or impose a penalty) for pasta products unless adequate account is made for moisture loss.
- Adoption of a validated 3% "gray area" for moisture loss for pasta allows inspectors to effectively remove impermissibly short weight packages found on store shelves.
- This is not a "free pass." Inspectors can elect to conduct further investigation to determine whether moisture loss is the basis for the product being short weight and whether 3% is the appropriate amount of moisture loss to apply.
- The pasta industry views retail inspections as important to equity in the marketplace for consumers and competitors.

### Slide 8

# **Benefits of Agenda Item 260-3**

- Enhances the ability of inspectors to evaluate moisture loss for pasta products.
- Enables jurisdictions to meet their legal obligation to account for moisture loss.
- Prevents confusion about the need to consider moisture loss or how to account for moisture loss.
- Educates inspectors about the requirements for moisture loss consideration under Handbook 133.
- Encourages rigorous inspection of pasta products.
- Demonstrates the Conference's commitment to addressing issues of common concern in a timely and reasoned fashion.

## **Moisture Loss in Pasta**

- Manufacturing Overview: Pasta is hygroscopic. Its moisture content does not remain constant after manufacture. Pasta eventually reaches a moisture equilibrium with its surrounding atmosphere. This balance does not occur until long after the packaging and distribution of product.
- **Data:** Studies indicate that pasta exhibits moisture loss in all environments and packaging types. Data shows 3% to be an appropriate gray area.

Slide 10

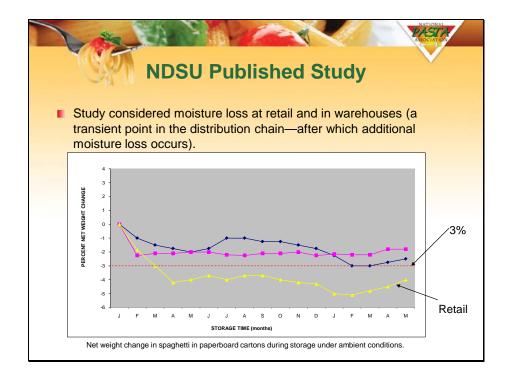
# Pasta – Manufacturing Overview

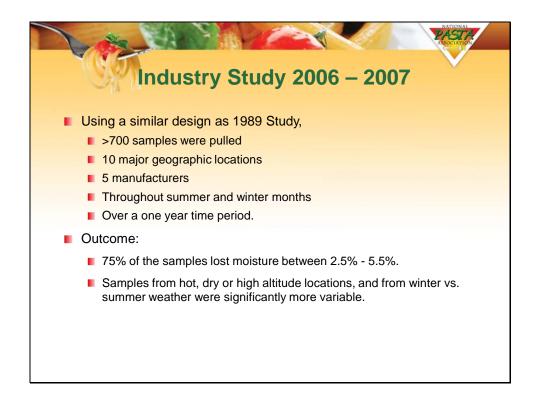
- Pasta is a basic recipe of flour and water.
- Pasta is produced in accord with the moisture and quality requirements as defined by FDA regulations.
- Pasta is packed and documented at or above label weight in "breathable" film or paperboard cartons. Pasta must "breathe" to prevent substandard quality or mold issues.
- Pasta is hygroscopic; It will seek to equilibrate with the surrounding atmosphere.
  - Hot, dry, arid and air conditioned store environments that have less humidity will pull moisture from the pasta into the environment.
  - Tropical, wet, high humidity environments, seldom seen in U.S. stores, will pull moisture from the environment, into the pasta.
- Pasta is produced regionally, but distributed nationally, subject to various climatology and environmental conditions.



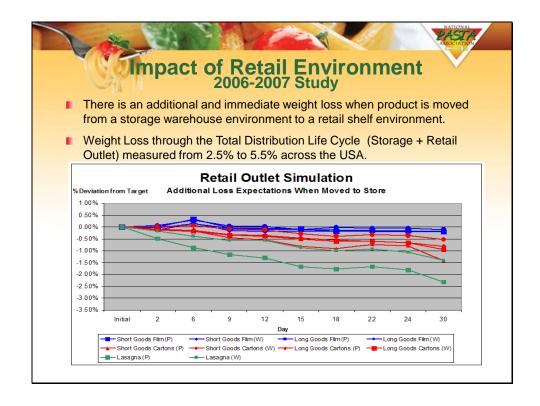
- North Dakota State University designed a controlled study in 1989 in accordance with previous FDA study on moisture loss in flour.
- Packaged pasta loses or gains moisture dependent upon environmental temperature and humidity during storage and distribution.
- At retail, pasta packaged in paperboard lost up to 5.02% of its weight. Pasta packaged in flexible polyethylene bags lost up to 3.18% of its weight.
- Neither product size, shape, composition or source of manufacture showed a significant effect on weight gain or loss. All products met the FDA regulations for pasta moisture at time of pack.

Slide 12





Slide 14



# Moisture Loss in Distribution -

- Total Loss in Distribution Environment; (up to 5.5%)
  - Climatology Temperature, Seasons and Humidity
  - Humid vs. Dry or High Altitude Areas of Country
  - Air Conditioned Store Environments
  - Length of Time in Distribution
  - Regional Production Locations with National Distribution
- Warehousing of Closed Palletized Cases of Product; (up to 2.5%)
  - Slowest Rate of Decline
  - Individual Packages are Not Exposed
- Cased to Uncased, Displayed Product; (Additional 1.0 3.0%)
  - Quickest Rate of Decline
  - Exposure of Individual Packages to Direct Environmental Conditions

Slide 16

# In Summary

- Federal and state law require consideration of moisture loss.
- Pasta is a hygroscopic product whereby moisture loss or gain occurs.
- Substantial data, including a peer-reviewed published article (and other data submitted by NPA to the Conference), demonstrates the known amounts of moisture loss.
- Regulatory officials have recognized 3% as a validated and reasonable "gray area."
- NPA appreciates the Conference's interest in and support of Agenda Item 260-3.