



*Funding for this statement, publication, press release, etc. was made possible, in part, by the Food and Drug Administration through grant 5U18FD005964-03; views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.

IFPTI Fellowship Cohort VII: Research Presentation

Ashlee-Rose Ferguson, RS

Refrigerated and Frozen Pet Food: Estimating Risk Factors and Analyzing Regulatory Authority

Ashlee-Rose Ferguson, RS

IFPTI 2018-2019 Fellow

Washington State Department of Agriculture

Background



2007 Massive Pet Food Recall

Melamine and
cyanuric acid



Over 150
brands
affected

100k+ tons
recalled from
the shelves



Estimated:
3,500 deaths
39,000 illnesses

FDA received
over 13,000
complaints



Special
Hearings
before
U.S. Senate
&
House of
Representatives



100s of Class
Action
Lawsuits

Claims from
the
consolidated
U.S. Class
Action:
13,242 deaths
9,001 illnesses

Background:



Background

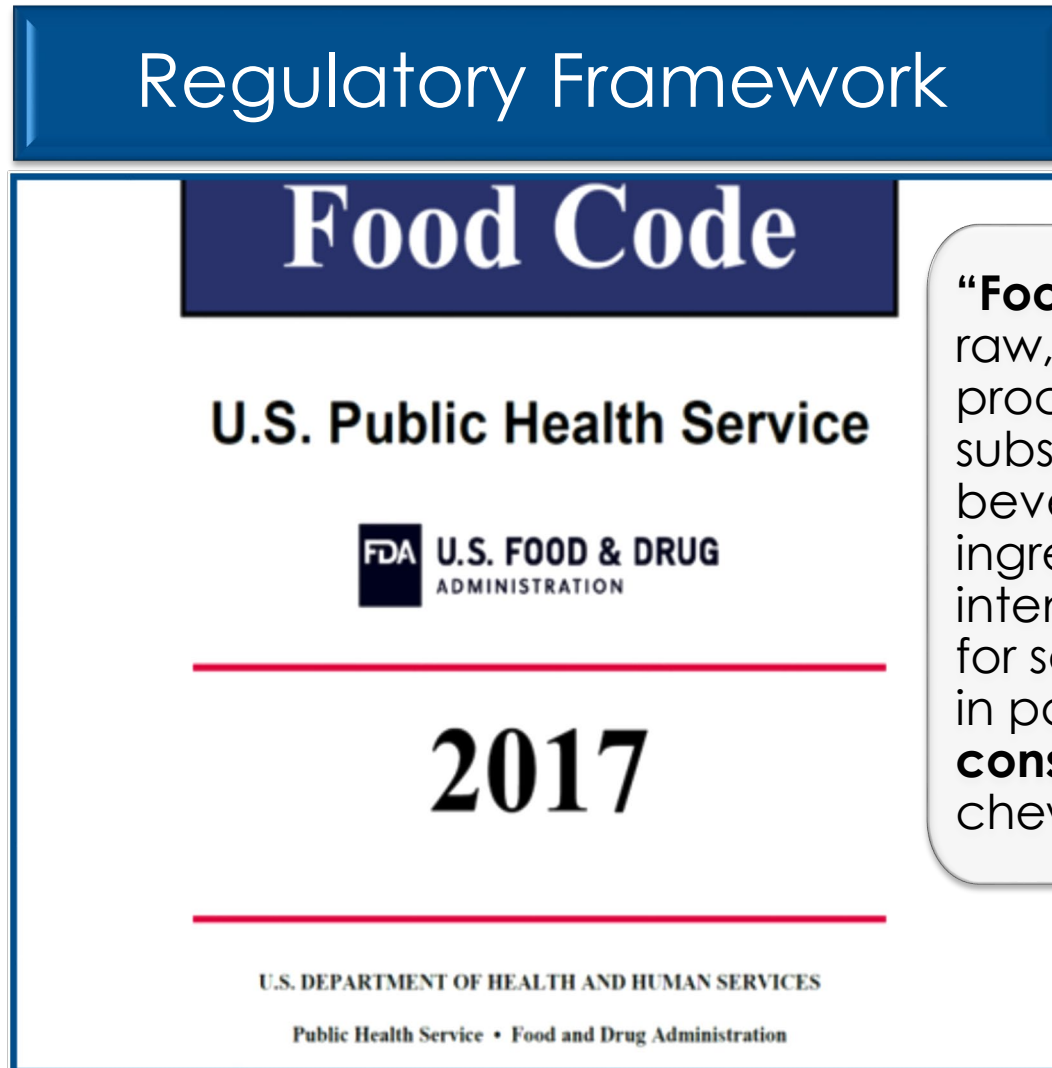
- Risks to human and animal health

ANTIMICROBIAL RESISTANT BACTERIA FOUND		
	Raw	Cooked
# (and %) of fecal samples	37 of 57 (89.5%)	3 of 51 (5.9%)
# (and %) of products	14 of 18 (77.8%)	0 of 35 (0%)

Millions of Americans with Dirty Hands are Spreading Dangerous Bacteria

97% of attempts to wash hands failed

Background



“Food” means a raw, cooked, or processed edible substance, ice beverage, or ingredient used or intended for use or for sale in whole or in part **for human consumption**, or chewing gum.

Background

Regulatory Framework

June 25, 1938
[S. 5]
[Public, No. 717]

Federal Food, Drug,
and Cosmetic Act.

Chapter I—Short
title.

Chapter II—Defini-
tions.

“Territory.”

“Interstate com-
merce.”

“Department.”

“Secretary.”

“Person.”

“Food.”

[CHAPTER 675]

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term “Territory” means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means the Department of Agriculture of the United States.


(d) The term “Secretary” means the Secretary of Agriculture.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

June 25, 1938
[S. 5]
[Public, No. 717]

Federal Food, Drug,
and Cosmetic Act.



Background

FIFTY-NINTH CONGRESS. SESS. I. CH. 3915. 1906.

769

rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated:

Scope.

Chemical examinations.

Notice of result.

Hearings.

Certificate of violations to district attorney.

Legal proceedings.

Terms defined.
"Drugs."

"Food."

Adulterations defined.

Drugs.

Regulatory Framework

1906 Pure Food & Drug Act

Problem Statement

The degree of regulation and proper controls of refrigerated and frozen pet food is relatively unknown.

Research Questions

1. Do regulatory agencies have the authority to inspect retail establishments that hold refrigerated or frozen pet food?
2. Do regulatory agencies have the authority to enforce corrective actions for facility violations at retail establishments?
3. How well do pet food establishments that hold refrigerated or frozen pet food control the risks associated with the product?

Methodology

Surveys on:

1. Regulatory Authority
2. Certain Risk Factors

Surveys were piloted and distributed through AAFCO

Results submitted via email and analyzed for:

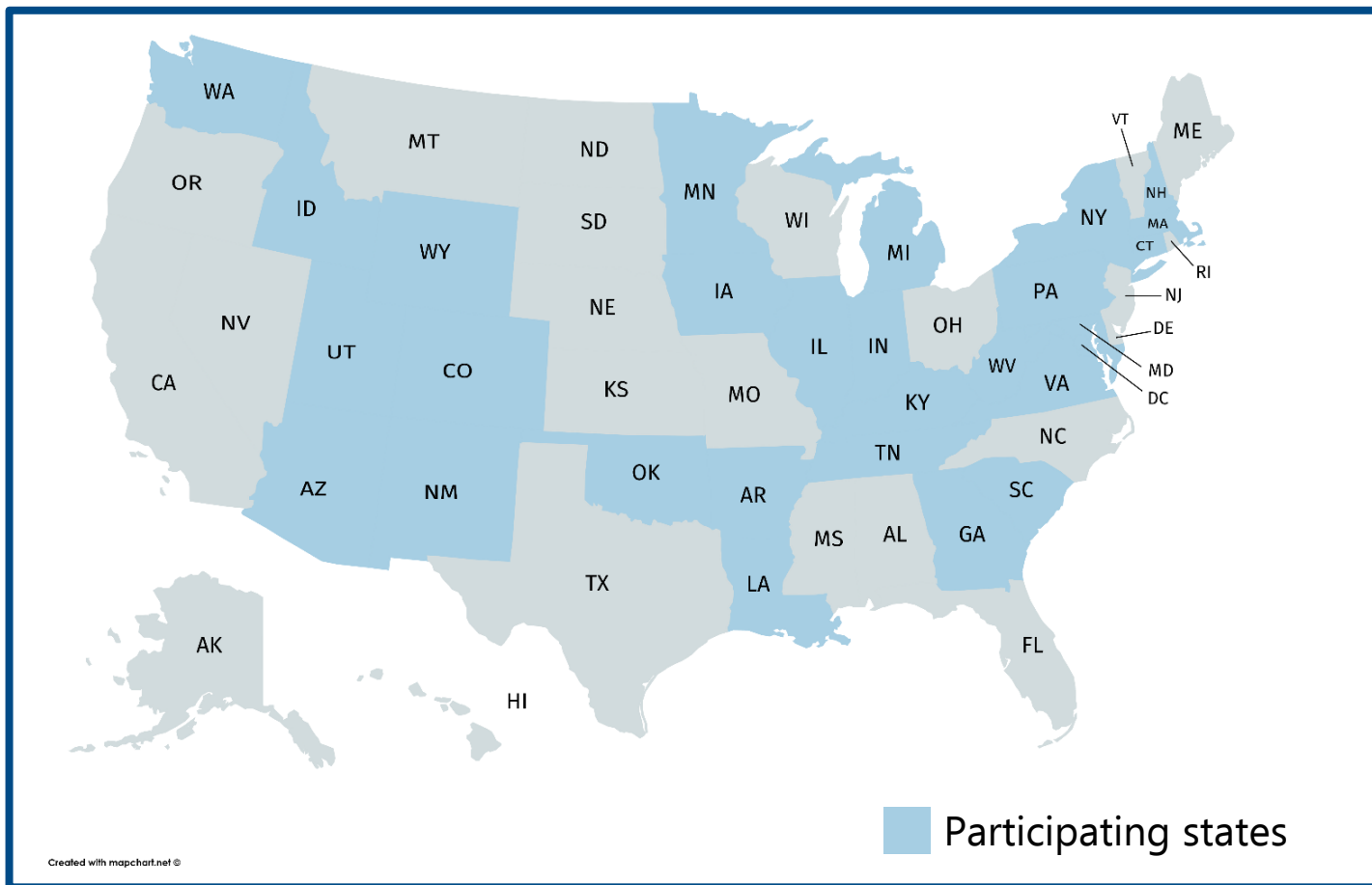
- Statistical conclusions
- Prevalence of answers

Study Population

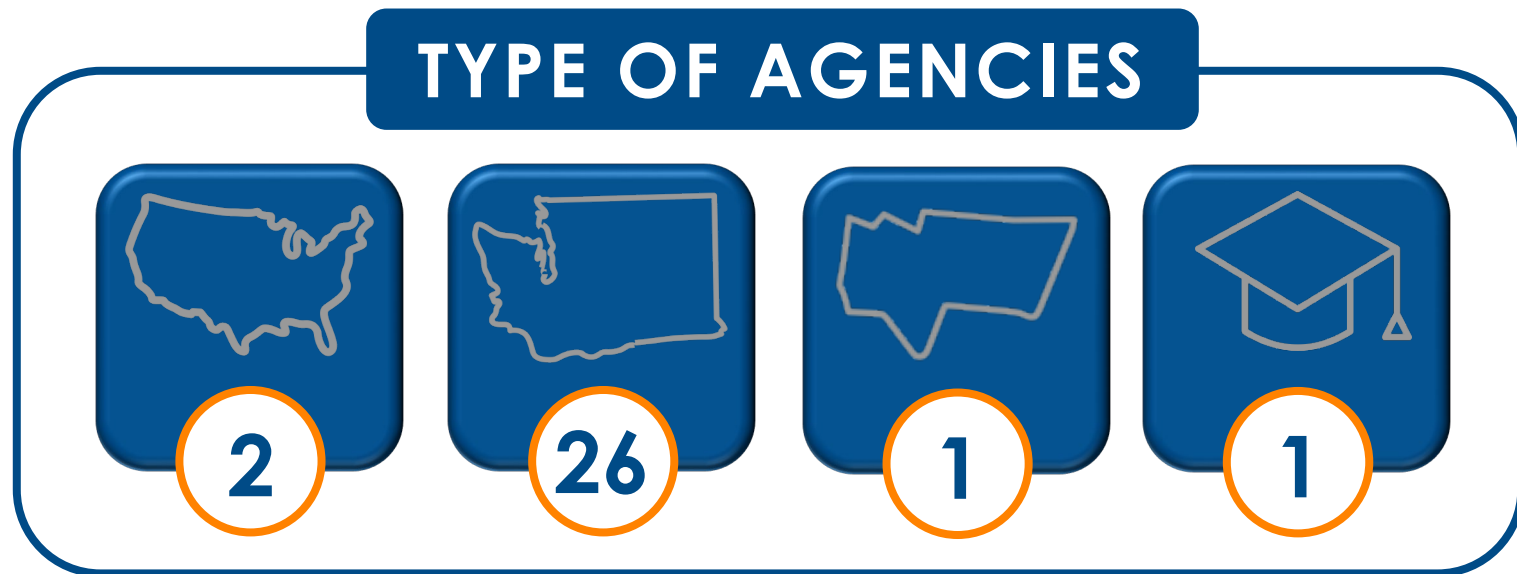
1. State and local agencies, their program managers and inspectors that have regulatory authority of refrigerated or frozen pet food.
2. Establishments that manufacture, process, hold, or distribute refrigerated or frozen pet food.

Regulatory Authority Surveys

received 30 from the following locations



Results - Regulatory Authority Survey



100% of those received have the authority to regulate pet food

Results - Regulatory Authority Survey

ENFORCEMENT AUTHORITY OF PET FOOD RETAIL ESTABLISHMENTS



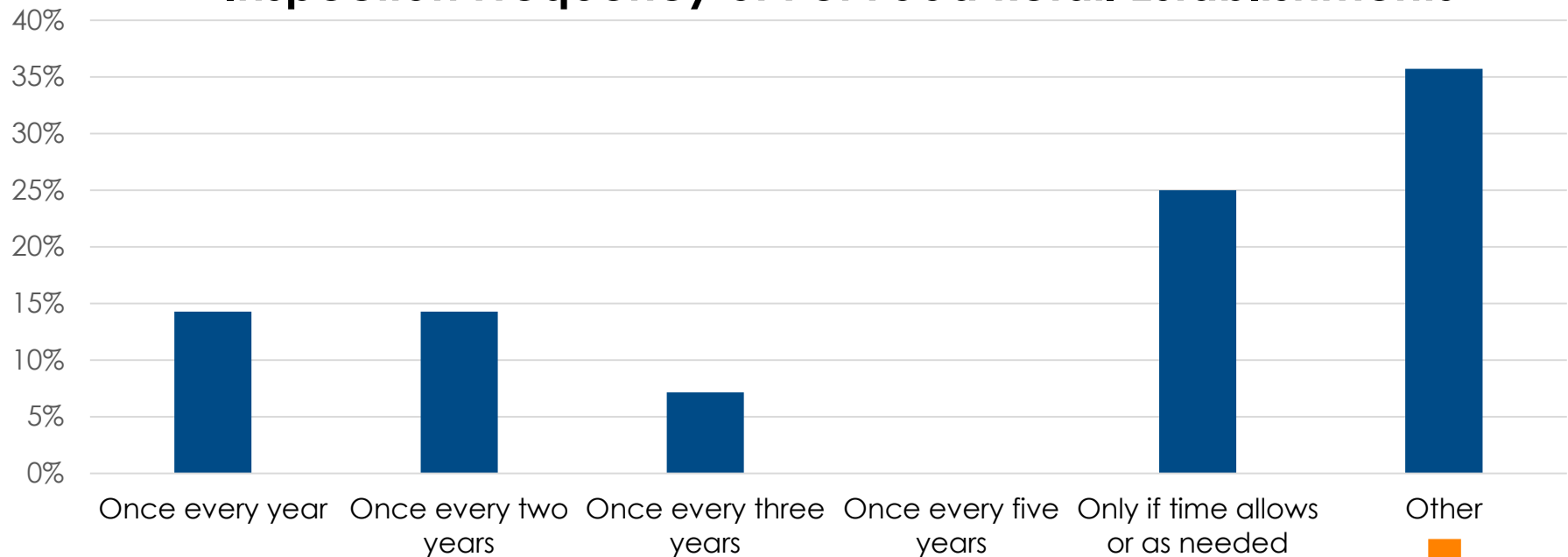
Stop Sale/Embargo	
Federal (n=2)	None
State (n=26)	All
Local (n=1)	All
University (n=1)	All



CA on Facility Violations	
Federal (n=2)	None
State (n=26)	Few
Local (n=1)	All
University (n=1)	None

Results - Regulatory Authority Survey

Inspection Frequency of Pet Food Retail Establishments

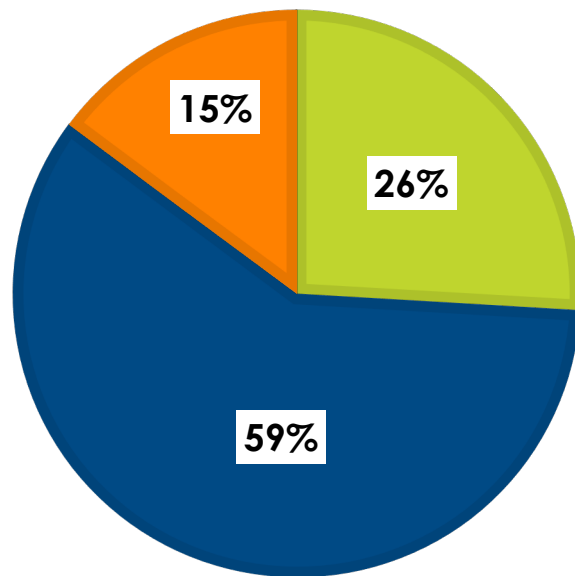


"Retail locations are visited on a seasonal basis for sample."

"We inspect the products multiple times throughout the year as part of our Regulatory program, but we do not inspect the retail location unless they manufacture pet food or animal feed."

Results - Regulatory Authority Survey

THERMOMETERS ISSUED?



■ Yes ■ No ■ Other

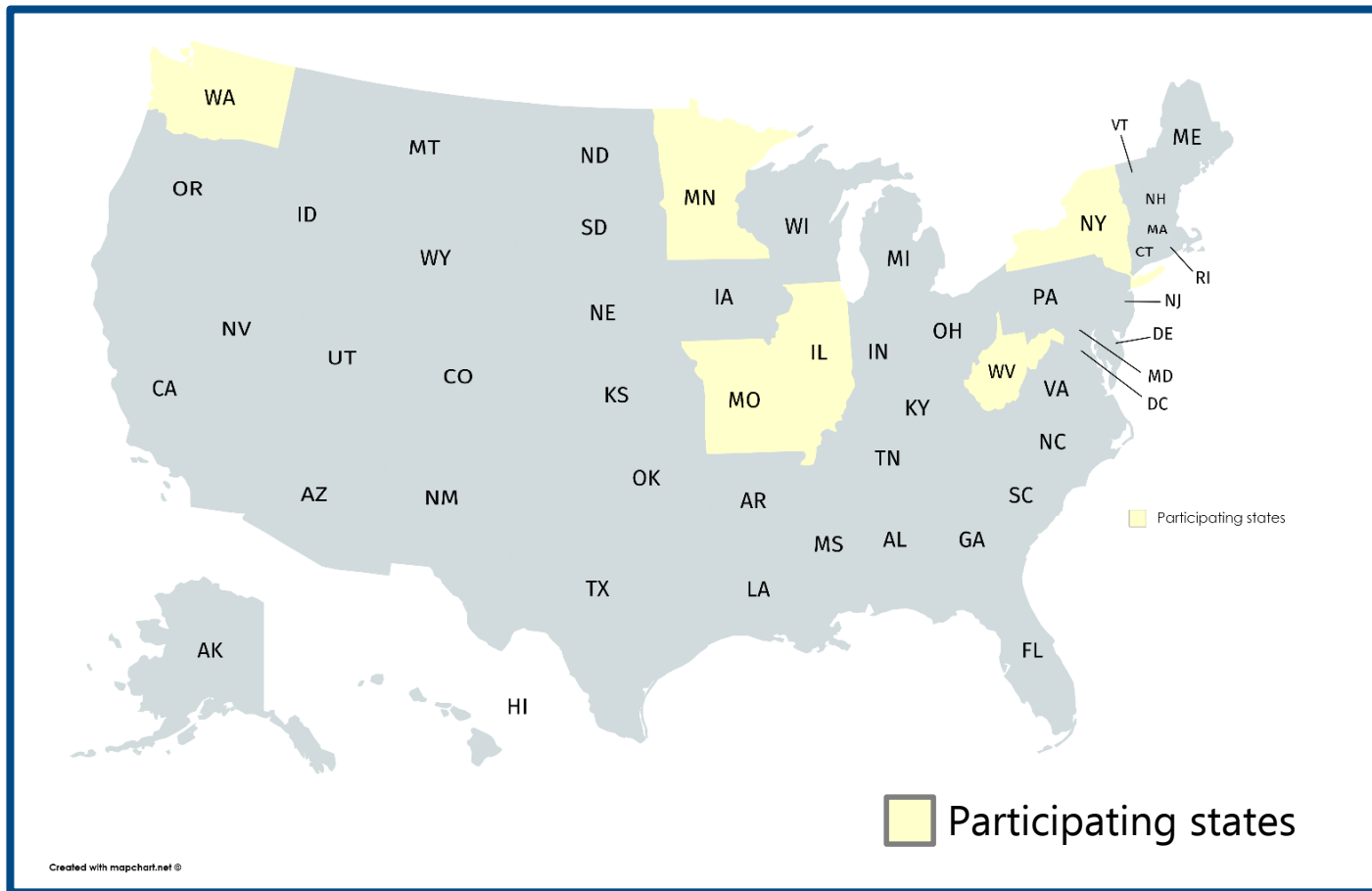


"We are currently researching NIST traceable thermometers."

"Our inspectors will be getting infrared thermometers which will be calibrated based on the thermometer's recommendations."

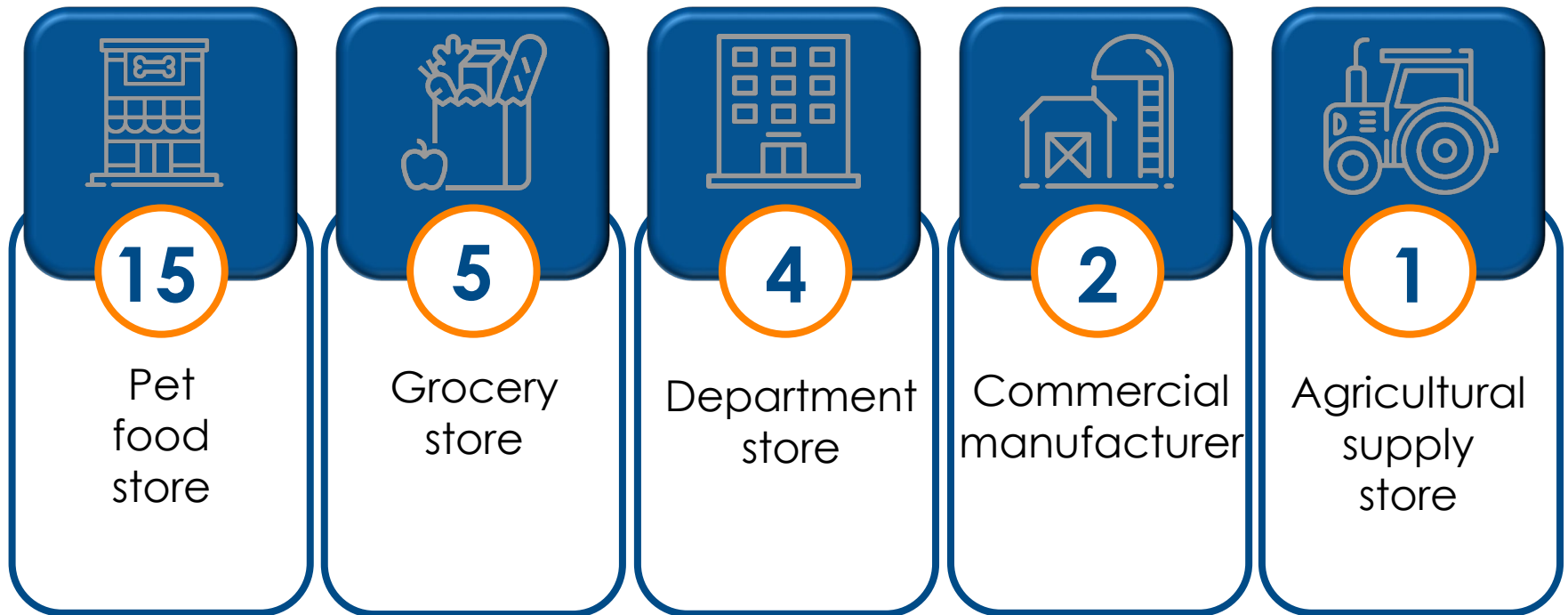
"They will be assigned certified thermometers in the future, for sampling purposes."

Risk surveys: received 28 from the following locations



Results - Risk Survey

TYPE OF ESTABLISHMENT WHERE RISK SURVEY WAS PERFORMED



Results - Risk Survey



58 units,
temperatures
documented

Mostly using
the unit's TMD



3 freezers
above 0°F but
were within 2°F

1 cooler above
41°F at 50°

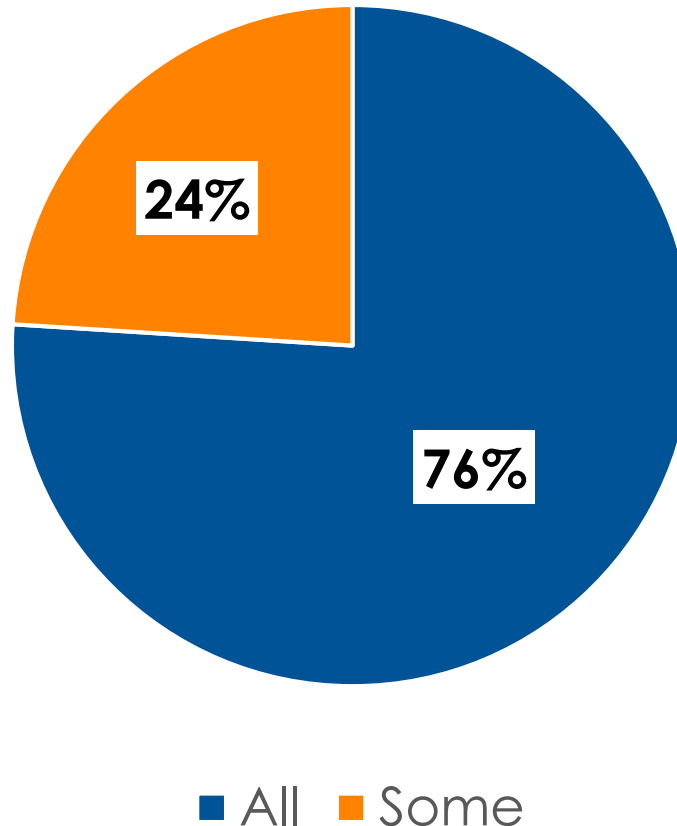


2 other units
did not have
TMDs

Storage hierarchy and separation was
conducted properly 100% of the time.

Results - Risk Survey

SAFE HANDLING ON LABELS?



Conclusions

- **Research question #1** – Do regulatory agencies have the authority to inspect retail establishments that hold refrigerated or frozen pet food?
 - Most surveyed agencies have authority to inspect nearly all establishments that handle refrigerated or frozen pet food, including retail.
 - Retail establishments low priority with infrequent inspections.
 - When retail establishments are visited, it is mainly for sampling or label checks.
 - Small percentage of animal food inspectors carry thermometers.

Conclusions (continued)

- **Research question #2** – Do regulatory agencies have the authority to enforce corrective actions for facility violations at retail establishments?
 - Most surveyed agencies have enforcement authority over the products themselves.
 - Very few agencies can enforce corrective actions at retail establishments.
 - Therefore, no effective means to resolve potential contributing factors or root cause of a problem.
 - Refrigerated and frozen pet food products are in a wide variety of establishments indicates this trend will be here for the long term.

Conclusions (continued)

- **Research question #3** – How well do pet food establishments that hold refrigerated or frozen pet food control the risks associated with the product?
 - In the small amount of cooler and freezer units observed, issues were still identified.
 - Study conducted in the winter months which makes mechanical stresses of higher external temperatures less likely.
 - Product packages were in good condition and had proper storage hierarchy.
 - Inconsistent or not complete safe handling instructions provided on product labels.

Recommendations

- **Education**

1. Consumer education
2. Educational campaigns and materials

- **Training**

1. Manufacturers and retailers
2. Regulators

Recommendations (continued)

- **Regulatory Actions**

1. Proactive measures
2. Voluntary inspection program
3. Match definition of “food” in Model Food Code to U.S. Code
4. Epidemiology foodborne illness questionnaires

Acknowledgements

- WSDA Animal Feed Program
- AAFCO
- IFPTI, mentors and cohort
- Every agency that submitted a regulatory authority survey
- Every agency and inspector that participated in the field risk surveys

Questions?

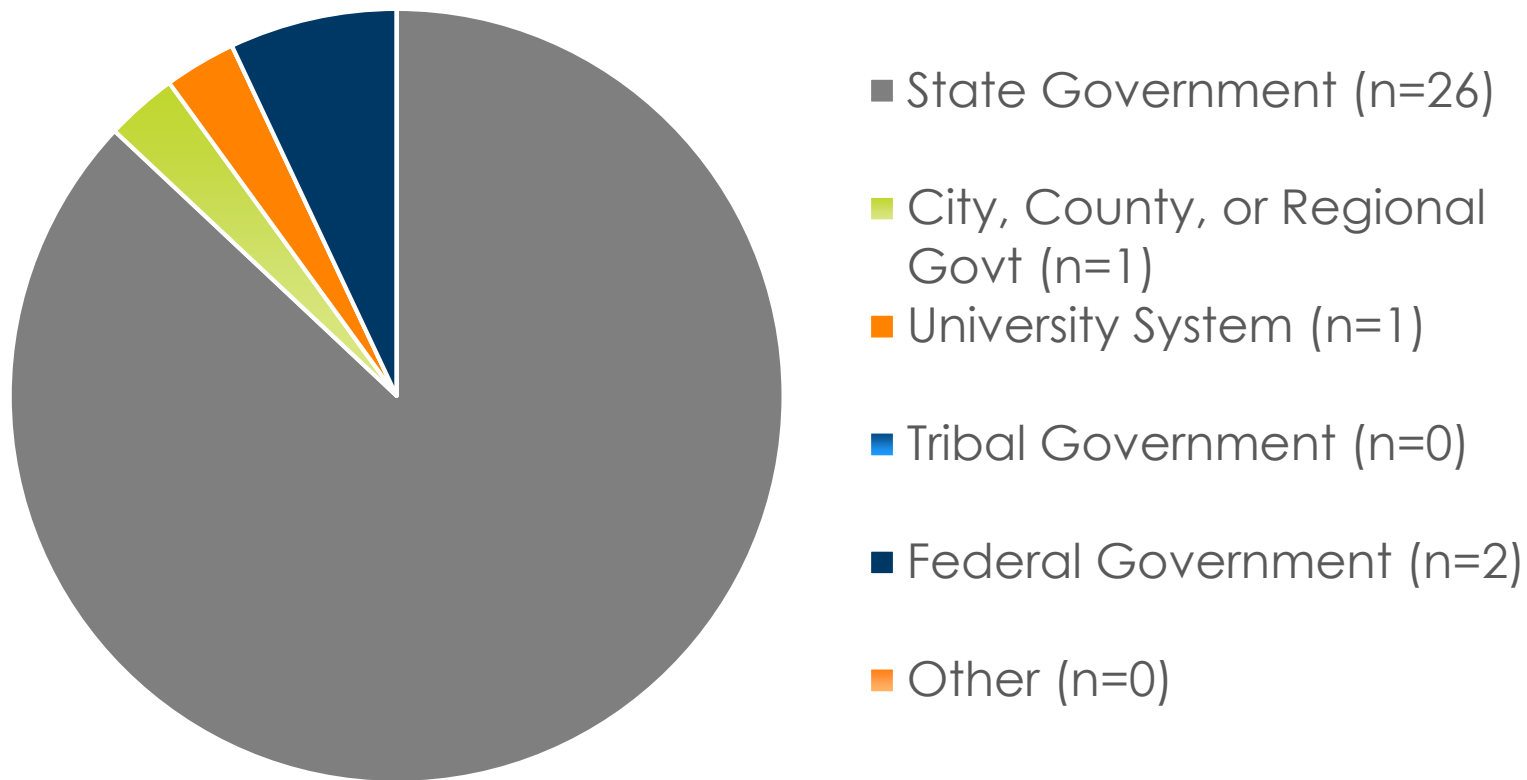
Ashlee-Rose Ferguson, RS
aferguson@agr.wa.gov
360-902-1905

Background (continued)

- 66 total animal food recalls since 2016
 - 46% raw pet food

Results - Regulatory Authority Survey

Type of Agency

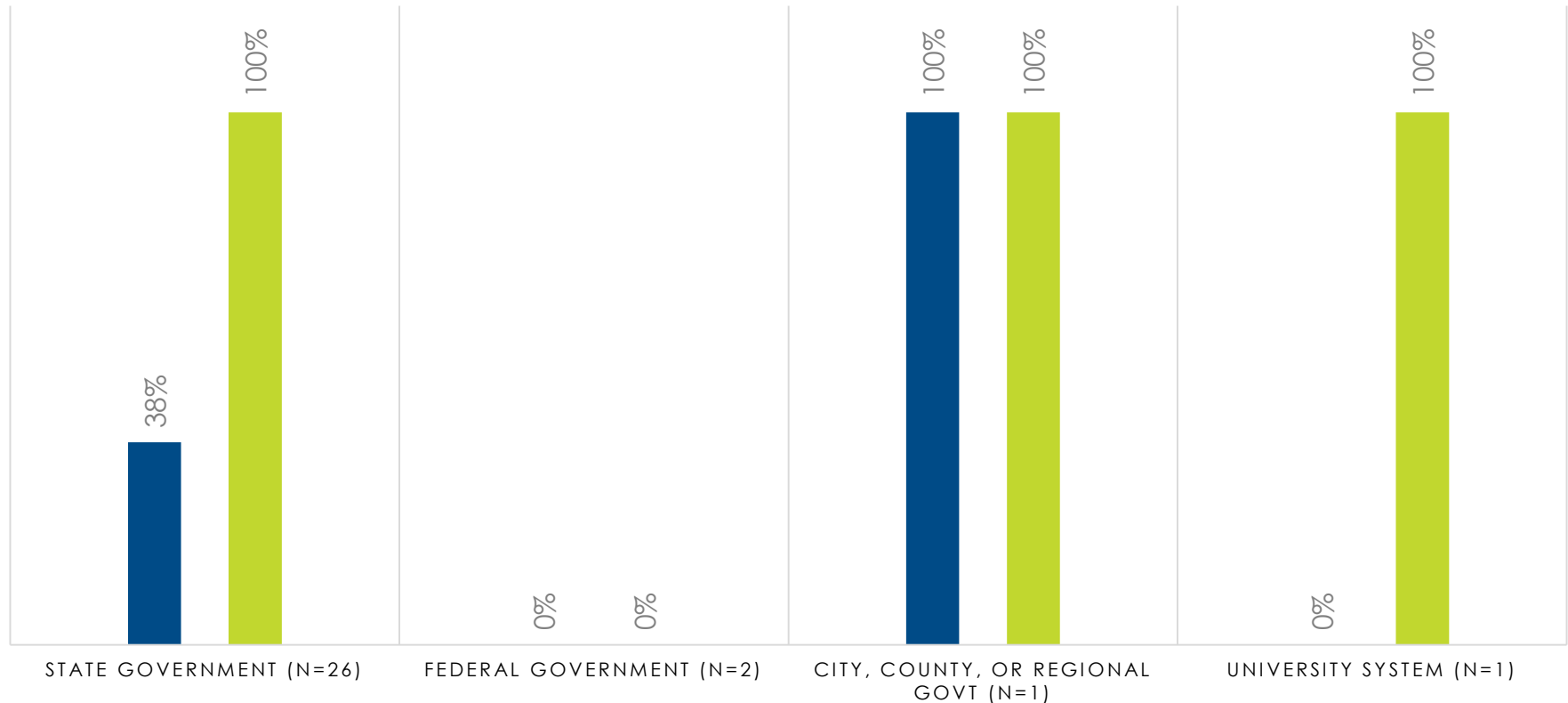


100% of those received have the authority to regulate pet food

Results - Regulatory Authority Survey

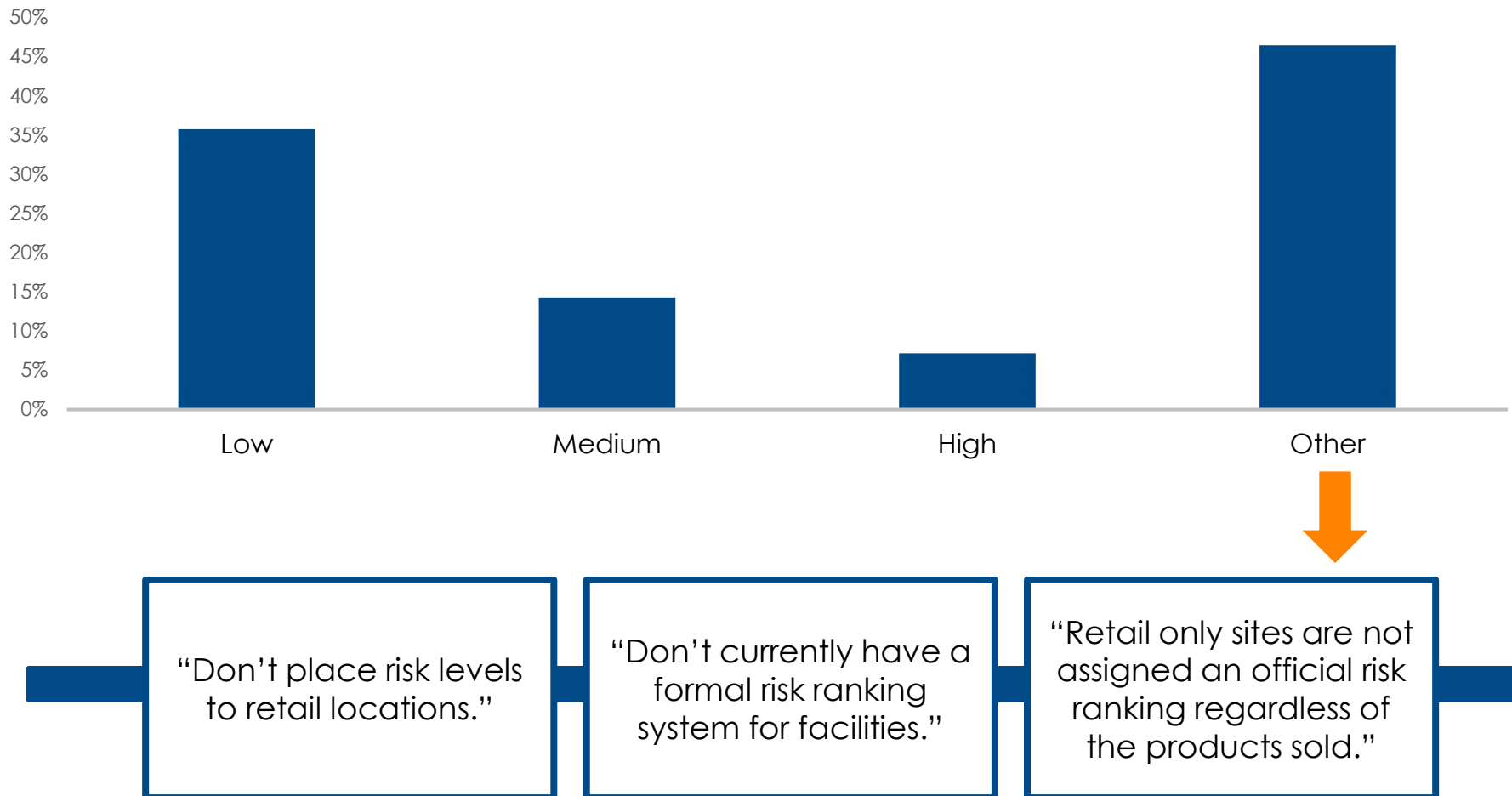
ENFORCEMENT AUTHORITY ON PET FOOD RETAIL ESTABLISHMENTS

■ Corrective Actions on facility violations ■ Embargo/Stop Sale adulterated product



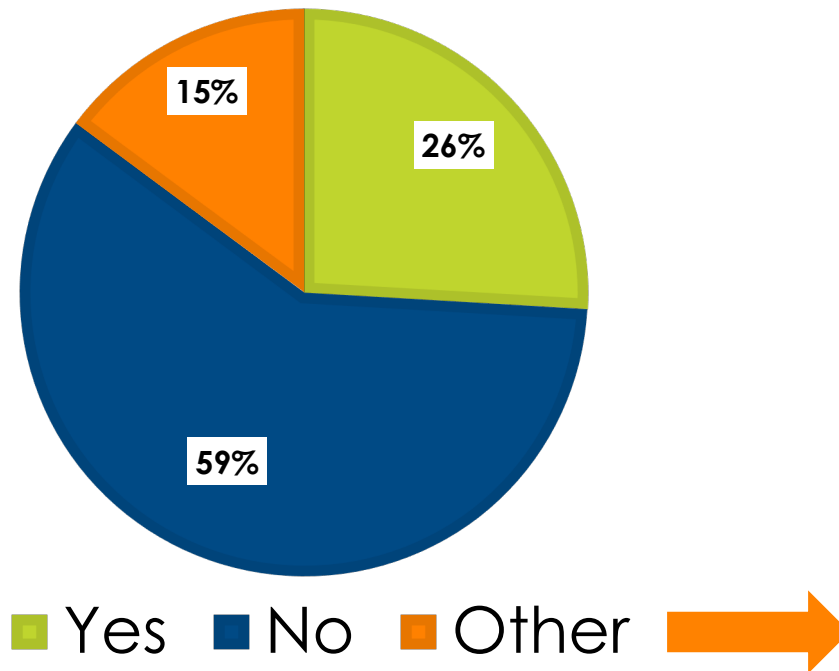
Results - Regulatory Authority Survey

RISK CATEGORY ASSIGNED TO PET FOOD RETAIL ESTABLISHMENTS



Results - Regulatory Authority Survey

% OF AGENCIES THAT ISSUE THERMOMETERS TO INSPECTORS



"They will be assigned certified thermometers in the future, for sampling purposes."

"Our inspectors will be getting infrared thermometers which will be calibrated based on the thermometer's recommendations."

"We are currently researching NIST traceable thermometers."

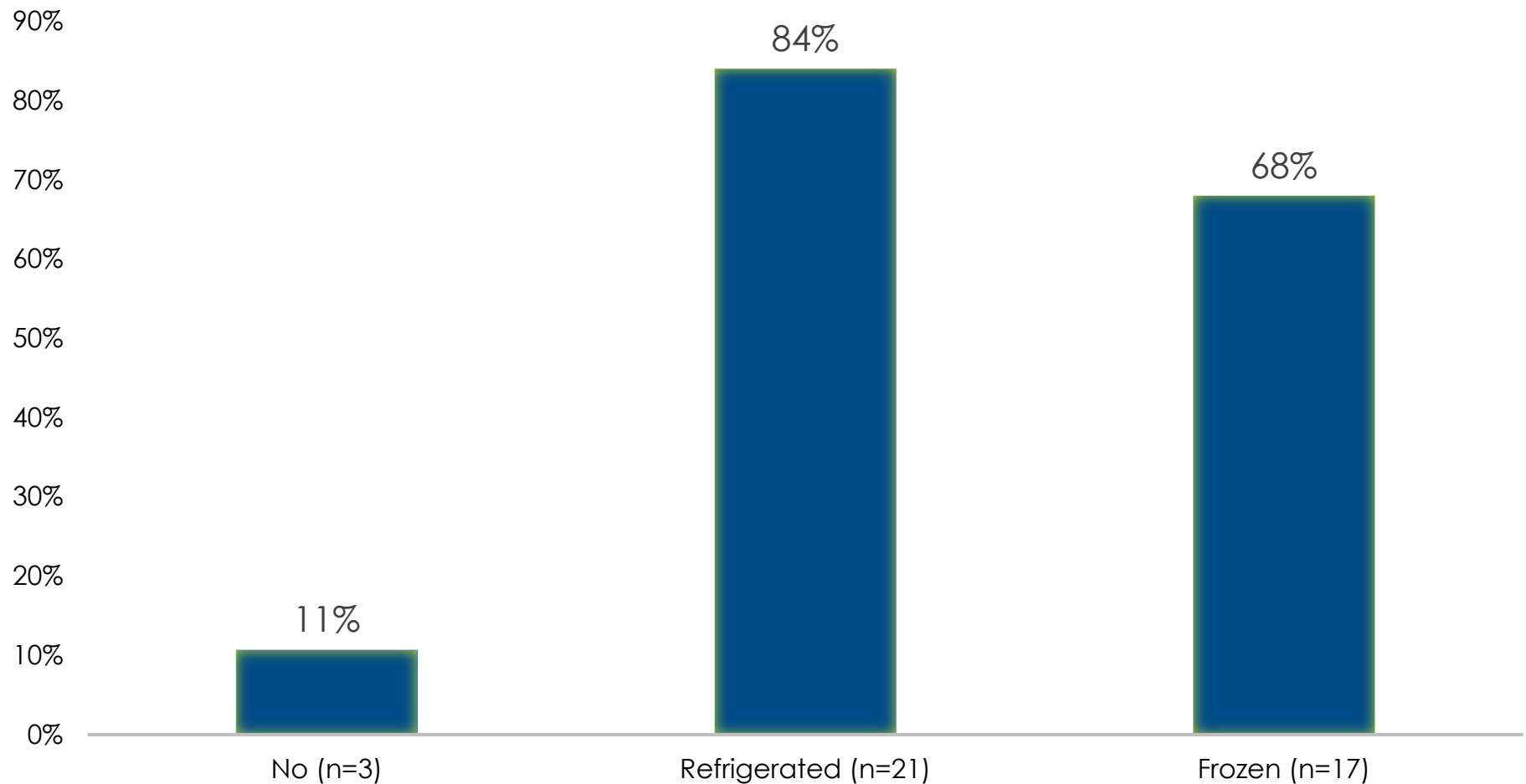
Results - Risk Survey

TYPE OF ESTABLISHMENT WHERE RISK SURVEY WAS PERFORMED



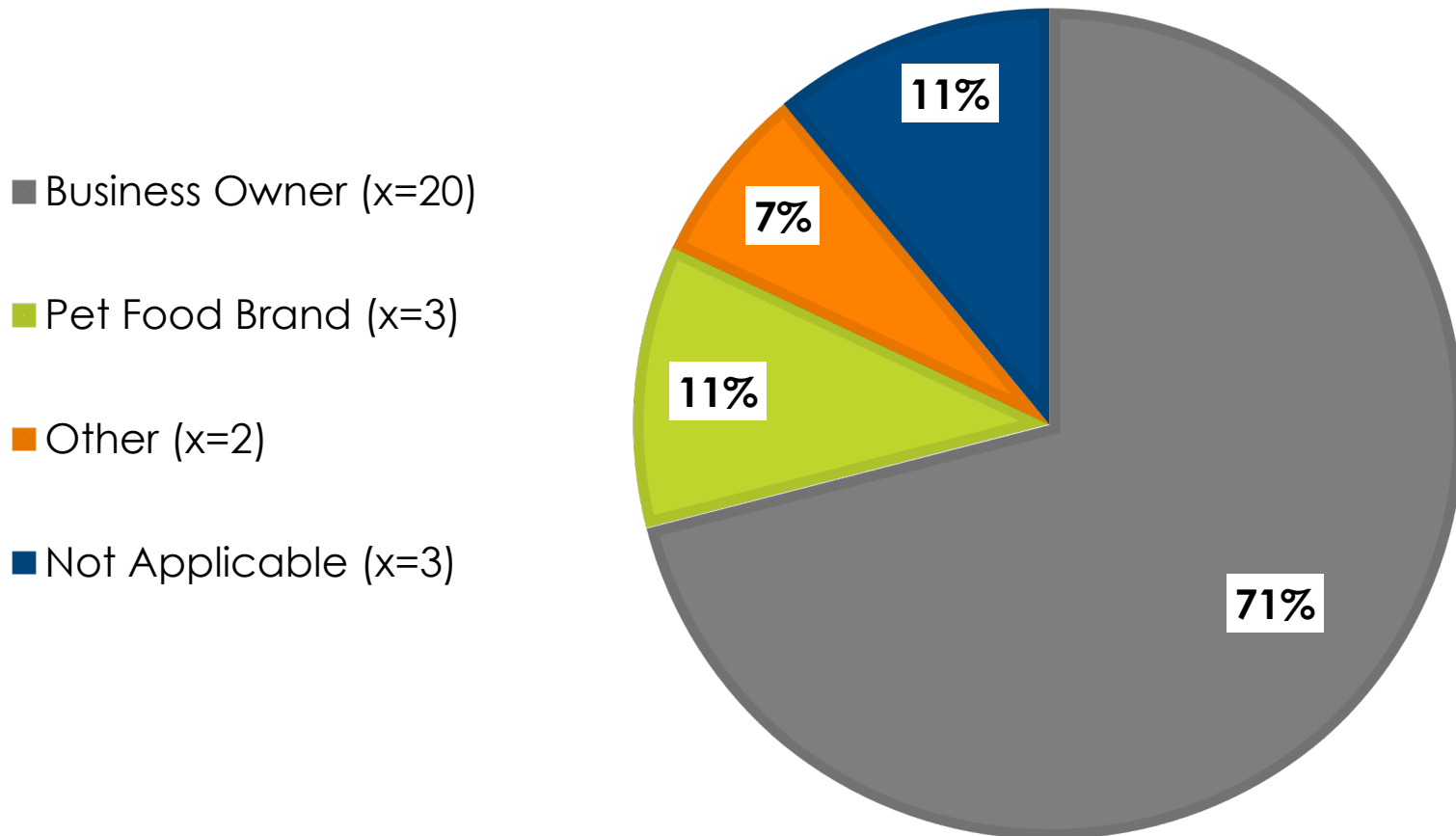
Results - Risk Survey

% OF ESTABLISHMENTS THAT HELD REFRIGERATED AND FROZEN PET FOOD



Results - Risk Survey

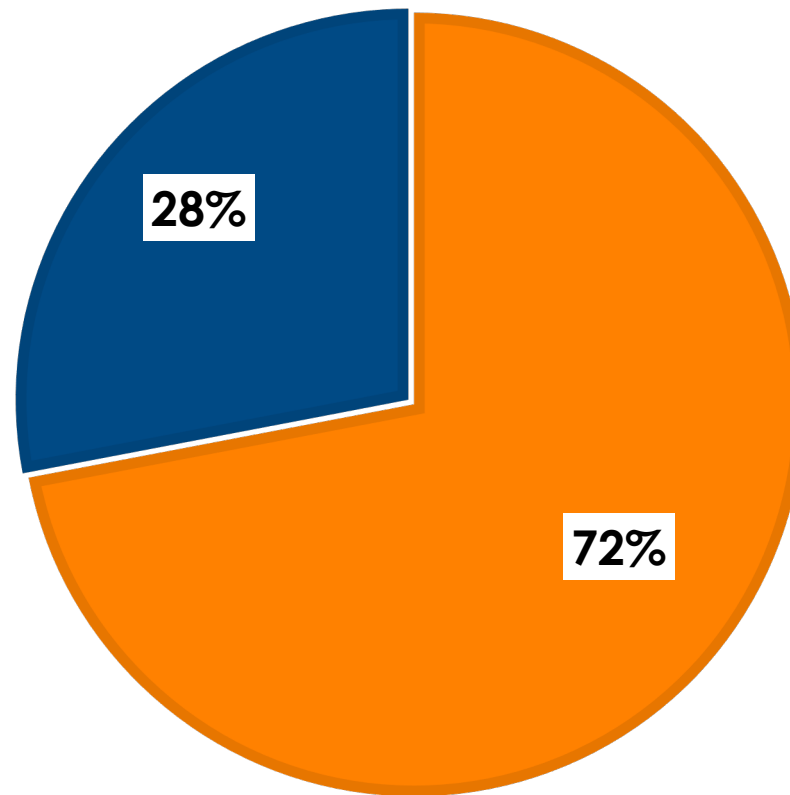
% OF WHO IS RESPONSIBLE FOR COOLERS/FREEZERS?



Results - Risk Survey

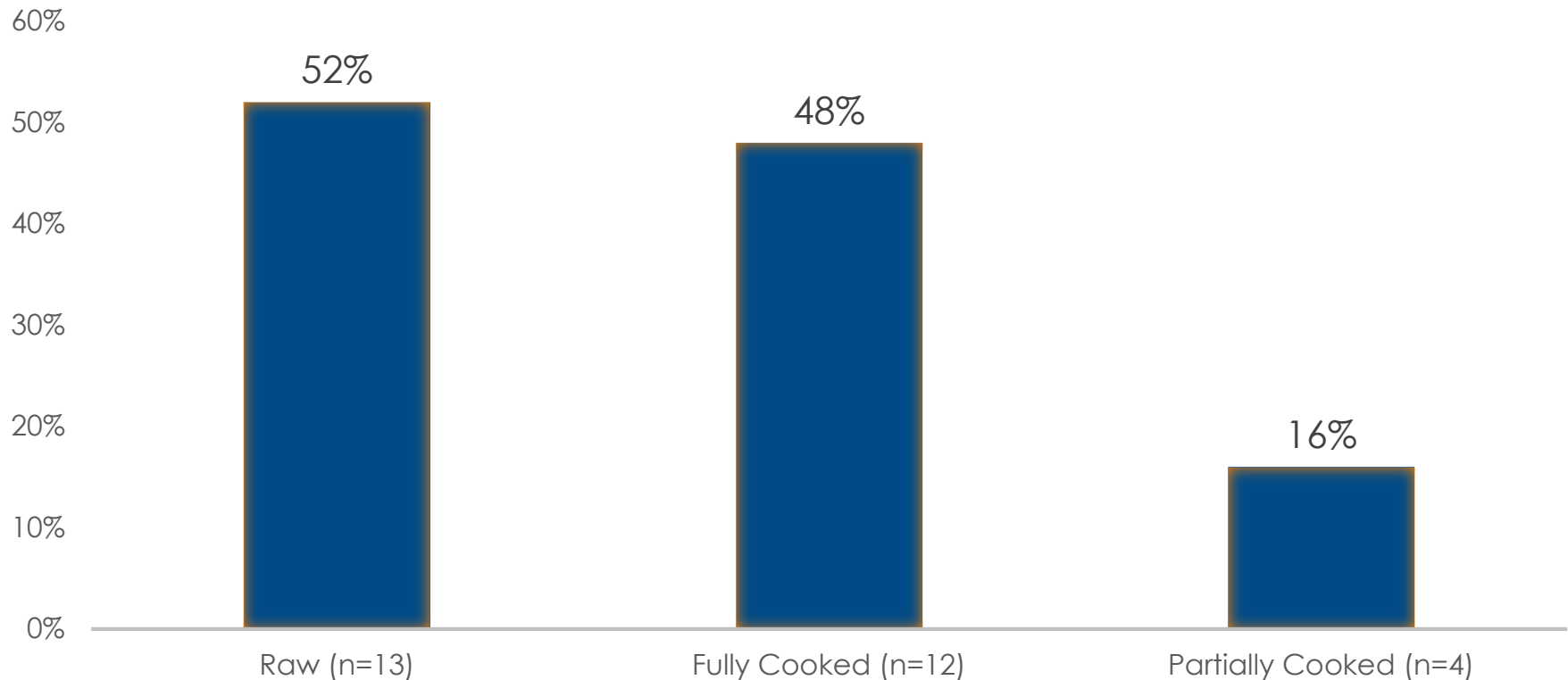
% OF ESTABLISHMENTS THAT KEEP TEMPERATURE LOGS

■ No ■ Yes



Results - Risk Survey

% OF TYPE OF REFRIGERATED OR FROZEN HELD

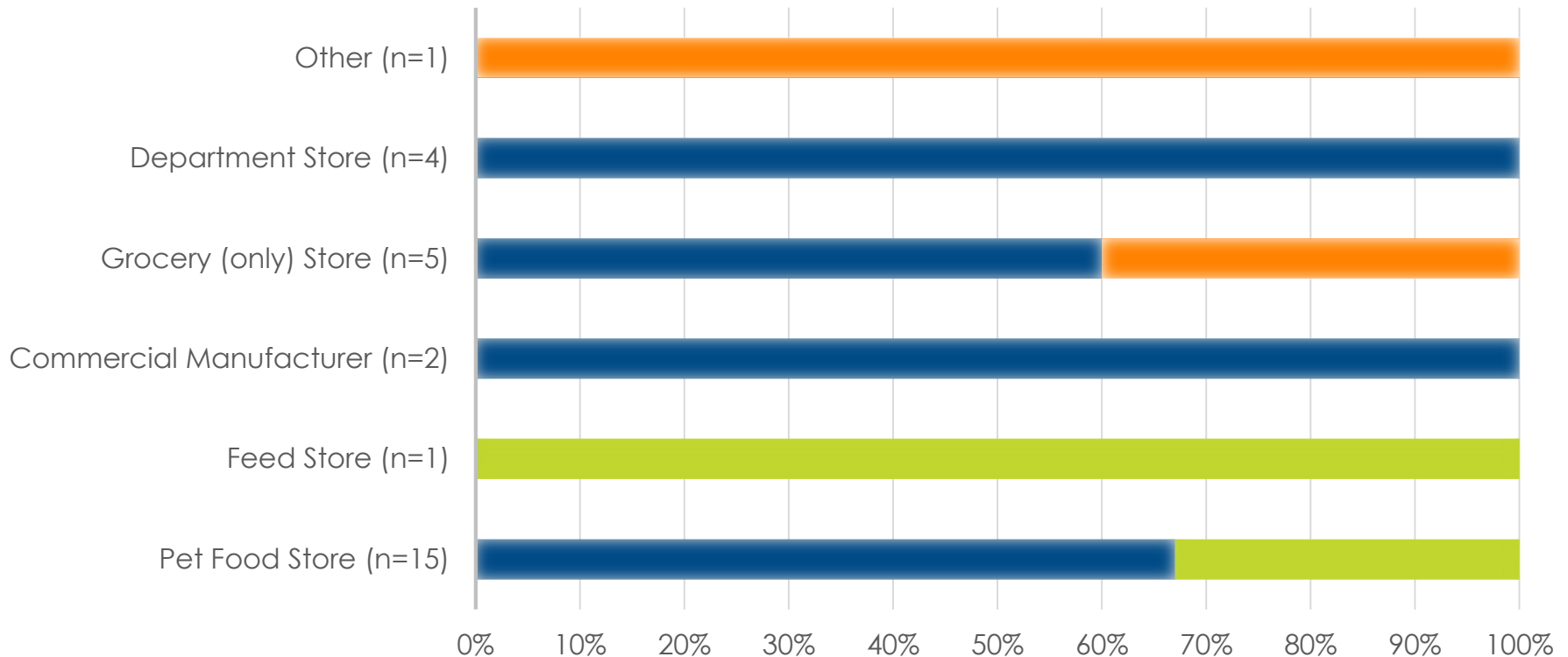


100% of establishments that held raw pet food stored it properly

Results - Risk Survey

% OF PRODUCTS OBSERVED WITH SAFE HANDLING INSTRUCTIONS

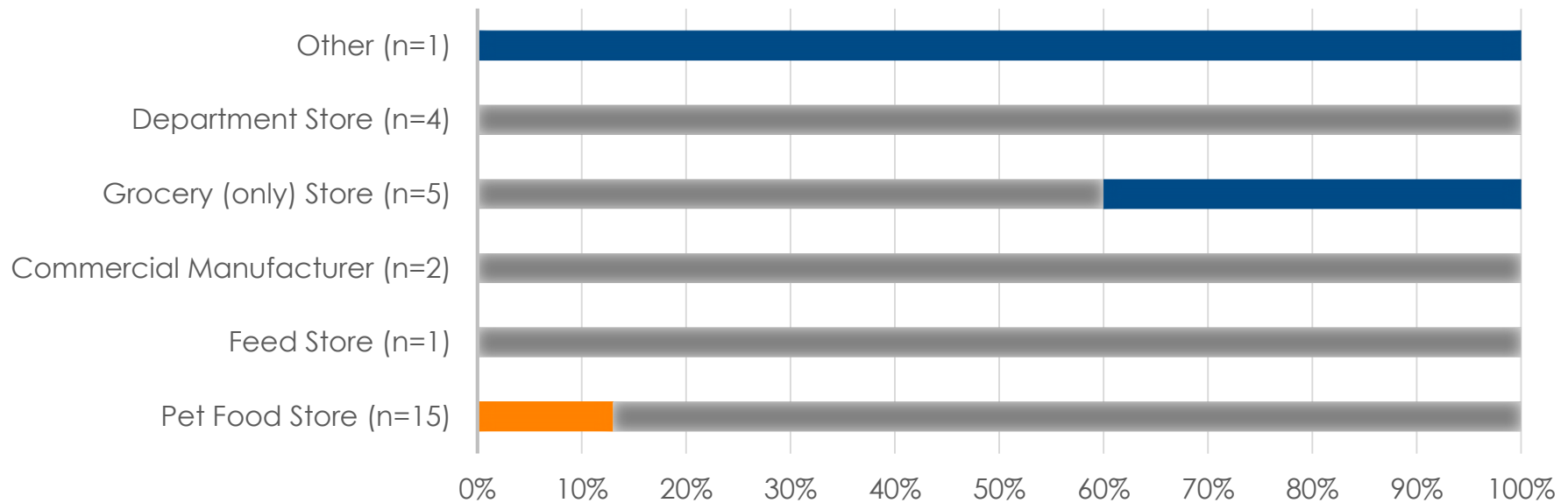
■ All ■ Some ■ N/A



Results - Risk Survey

% OF EXPIRED PRODUCTS OBSERVED, BY ESTABLISHMENT TYPE

Yes No N/A



100% of products observed were not leaking or have past evidence of leaking