
The Regulatory Cascade

But first, a word from our sponsors HACCP Collapsers of America.

What is the Regulatory Cascade?

- The Regulatory Cascade is a sequence of noncompliant events that leads to the collapse of a food safety system and enforcement action that is supportable by 9 CFR Part 500.
  - It involves an inadequate HACCP system.
  - It always involves documenting that product **is** or **may be** adulterated.

Describing the Regulatory Cascade

- A description of the regulatory cascade will adequately depict
  - What happened
    - The sequence of events that led to the collapse of the food safety system.
  - Why, when, and how it happened
    - How that sequence of events was precipitated due to noncompliance.
  - How those two things are related
    - This tells the story.

Noncompliance associated with the Regulatory Cascade

- For a trickle or stream of noncompliance to turn into a torrent and regulatory cascade of noncompliance it must be…
- Widespread and not localized
  - Affects the majority of the system
  - Or
  - Affects the majority of the regulations within or across chapters. 416 → 417

Noncompliance associated with the Regulatory Cascade

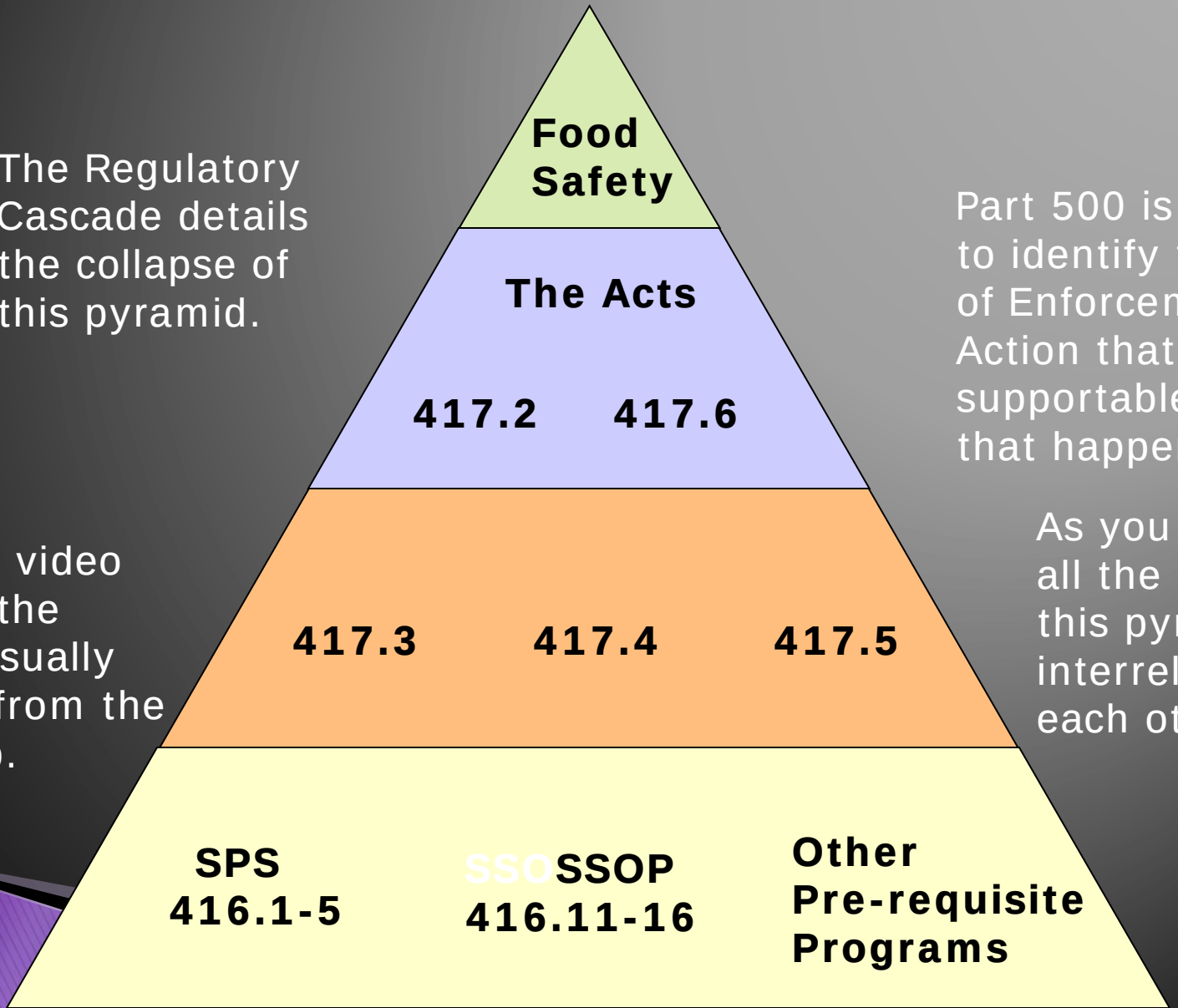
- For a trickle or stream of noncompliance to turn into a torrent and regulatory cascade of noncompliance it must be…
- Serious in nature or leading to serious noncompliance
  - Capable of undermining the system and producing contaminated or adulterated product.

Noncompliance associated with the Regulatory Cascade

- For a trickle or stream of noncompliance to turn into a torrent and regulatory cascade of noncompliance it must be…
- Repetitive and/or uncorrected
  - Recurrent and ongoing
  - Preventive measures have been ineffective or not implemented
  - May be documented in NRs or previously undiscovered

The Food Safety Pyramid

The Regulatory Cascade details the collapse of this pyramid.



Part 500 is used to identify the type of Enforcement Action that is supportable when that happens.

Unlike our video example, the pyramid usually collapses from the bottom up.

As you can see, all the parts of this pyramid are interrelated to each other.

Regulatory Interrelationships

- SPS, SSOP, and HACCP regulations are interrelated and parts of a whole, the food safety system.
  - SPS regulations are designed to prevent insanitary conditions, that if left uncorrected, might lead to product contamination.
  - SSOP regulations are designed to prevent direct product contamination/adulteration.

Regulatory Interrelationships

- SPS, SSOP, and HACCP regulations are interrelated and parts of a whole, the food safety system.
- HACCP regulations are designed to prevent food safety hazards from occurring.

Regulatory Interrelationships

- It is extremely important to recognize that both SPS programs and SSOP programs are pre-requisite to HACCP programs.
- That is why, together with other pre-requisite programs, they form the base of the food safety pyramid!

Regulatory Interrelationships

- Other pre-requisite programs help to provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.
  - They may support SPS, SSOP, or HACCP programs.
  - If not followed or implemented as designed, they may not provide support for the programs as intended.

Regulatory Interrelationships

- Other pre-requisite programs often cause confusion among both agency and industry personnel because they do not have specific regulations associated with them.
- None the less, if not followed they often result in regulatory noncompliance.

Regulatory Interrelationships

- When faced with no other pre-requisite program, an inadequate other pre-requisite program, or another pre-requisite program that is not being implemented as designed, ask…
- What is the result?
- That should guide us to the nature of the noncompliance.

Regulatory Interrelationships

- For instance…
  - The establishment has a pre-requisite program with a SOP for taking out the trash.
  - If not followed, not taking out the trash might result in the overflowing of trash cans.
  - If in a hallway, this results in an insanitary condition that doesn't affect product-SPS Noncompliance.

Regulatory Interrelationships

- For instance…
  - The establishment has a GMP calling for their employees to wash their hands after using the restroom.
  - If the employees fail to follow that GMP and then handled product with their bare hands, they may contaminate product resulting in SSOP noncompliance.

Regulatory Interrelationships

- For instance…
  - The establishment has a pre-requisite program for determining the age of cattle that are slaughtered using dentition.
  - The establishment's hazard analysis concludes that BSE is not a hazard reasonably likely to occur due, in part, to this program.
  - If not followed, what has occurred?

Regulatory Interrelationships

- Answer:
- There would be regulatory noncompliance with 9 CFR 417.5(a)(1), since, if not followed, the establishment's pre-requisite program does not support the decision they made in their hazard analysis.
- Similar situations-Allergens, Testing for STEC

Regulatory Interrelationships

- Programs that are pre-requisite to HACCP (SPS, SSOP, Other)…
  - Generally deal less directly with food safety issues.
  - Are more general and apply throughout the plant, crossing multiple product lines.
  - Failures to meet a pre-requisite program seldom result in a food safety hazard occurring, but when they do…

Regulatory Interrelationships

- HACCP plans, on the other hand…
- Deal solely with food safety issues;
- Are based on hazard analyses that are product and line specific;
- And when deviations occur from the critical limits within them typically result in action against the product.

Regulatory Interrelationships

- In describing the “regulatory cascade”, we describe the interrelationships between noncompliance with regulations as they pertain to the events that led to the collapse of the food safety system.
- That is why it is important to understand those interrelationships.

Hazard Analysis

- Many problems that EIAOs find ultimately involve decisions made in the hazard analysis.
- In all beef operations, the establishment should consider as potential hazards…
- The presence of *E. coli* O157:H7.
- The outgrowth of *E. coli* O157:H7.

Hazard Analysis

- Presence of a pathogen ≠ Outgrowth of a pathogen
- These are two different things.
- Presence of a pathogen means it is there and detectable.
- Outgrowth of a pathogen means it is possible that it may grow and multiply given the right conditions.

Hazard Analysis

- If, in the hazard analysis, the establishment concludes a hazard is reasonably likely to occur they must have…
- A CCP to control it.
- If they don’t, it’s a noncompliance with 9 CFR 417.2(c)(2)!

Hazard Analysis

- If, in the hazard analysis, the establishment concludes that a potential hazard is not reasonably likely to occur, they must have…
- Supporting documentation that supports that decision.
- If they don’t, it’s a noncompliance with 9 CFR 417.5(a)(1), at least!

Hazard Analysis

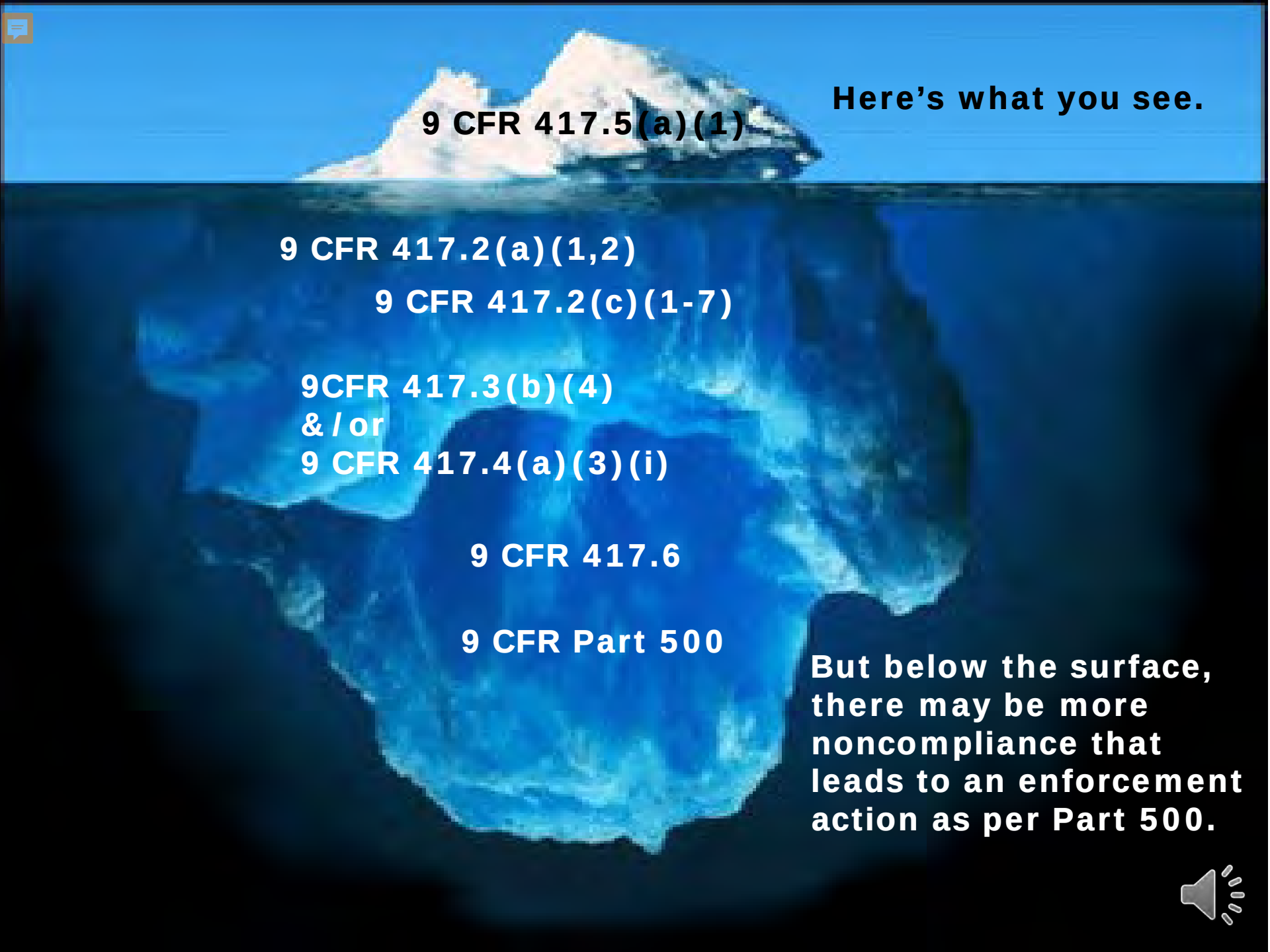
- The reason I say, “at least”, is because if the establishment can’t support a decision that a hazard is NOT reasonably likely to occur, they may not have listed all the food safety hazards that ARE reasonably likely to occur!
- That is a noncompliance with 9 CFR 417.2(c)(1)!

Hazard Analysis

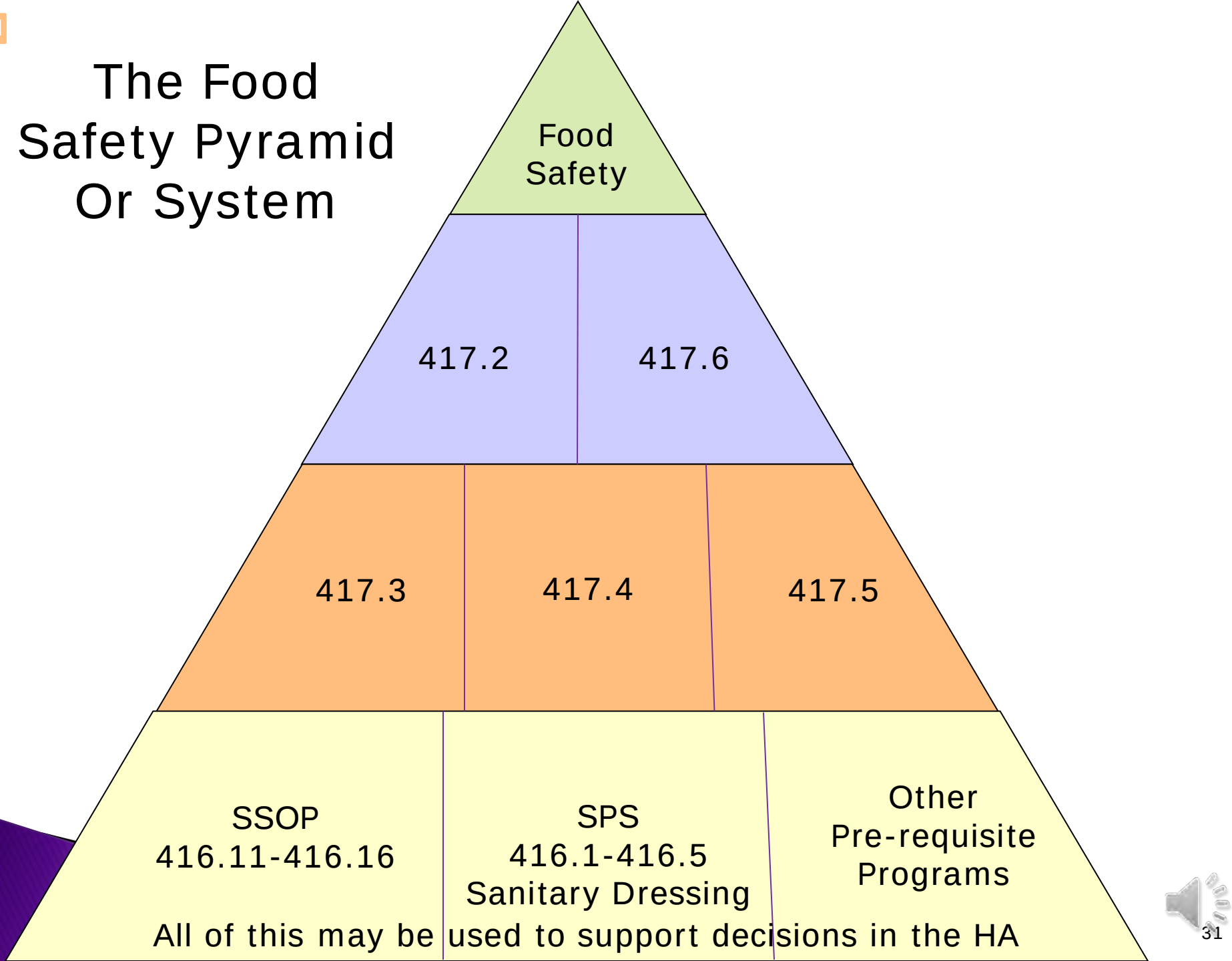
- In that case, the hazard analysis is inadequate and doesn't meet the regulatory requirements of 9 CFR 417.2(a)(1).
- Since all the rest of the HACCP system is designed to control identified hazards, an inadequate hazard analysis will almost certainly result in the system's collapse!

Some Examples

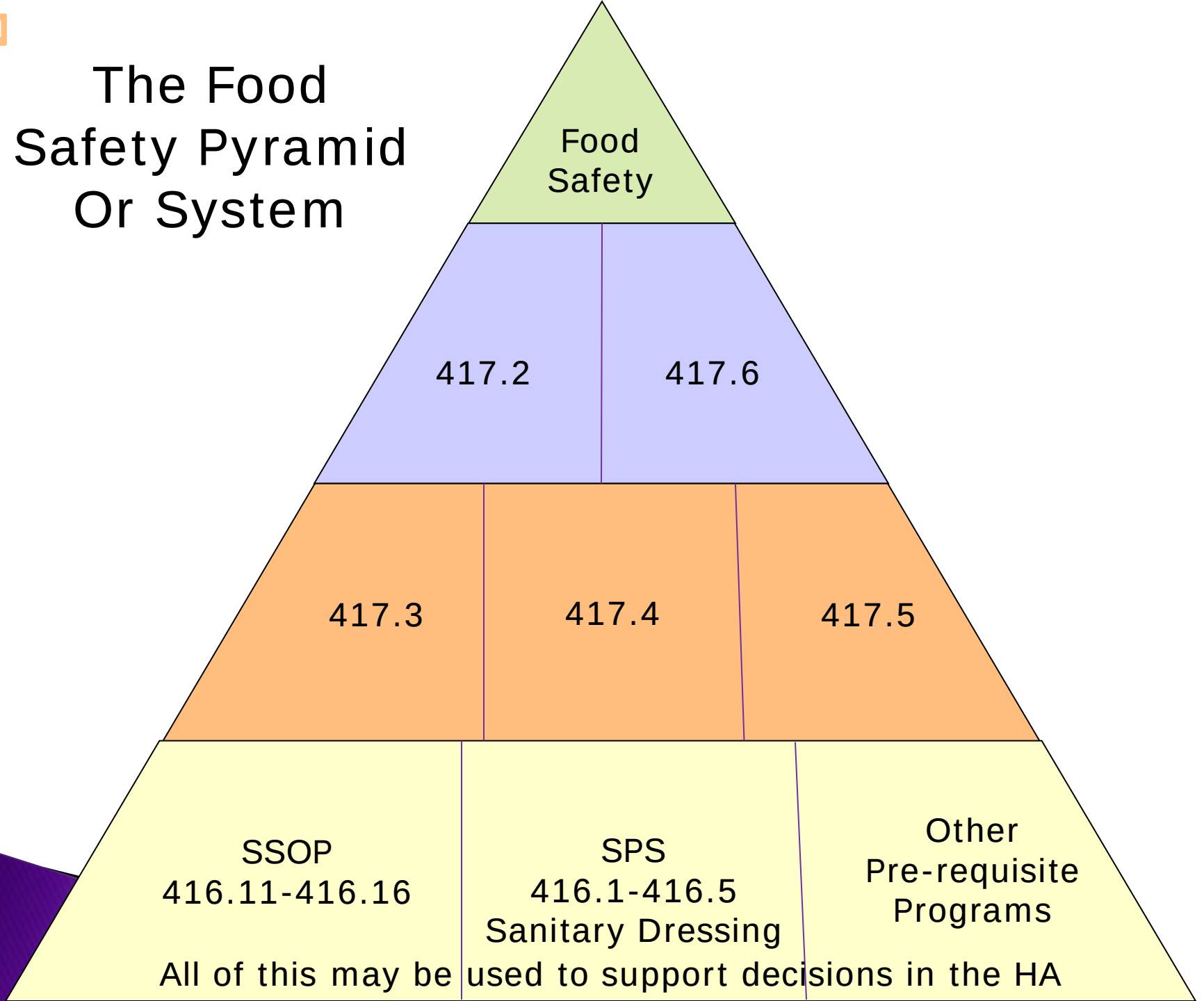
- So let's look at some scenarios
- Again, if pre-requisite programs don't continue to support the decision in the hazard analysis that a hazard is not reasonably likely to occur there is noncompliance with 417.5(a)(1).
- That could be just the tip of the iceberg!


Here's what you see.
9 CFR 417.5(a)(1)
9 CFR 417.2(a)(1,2)
9 CFR 417.2(c)(1-7)
9CFR 417.3(b)(4)
&/or
9 CFR 417.4(a)(3)(i)
9 CFR 417.6
9 CFR Part 500
But below the surface, there may be more noncompliance that leads to an enforcement action as per Part 500.

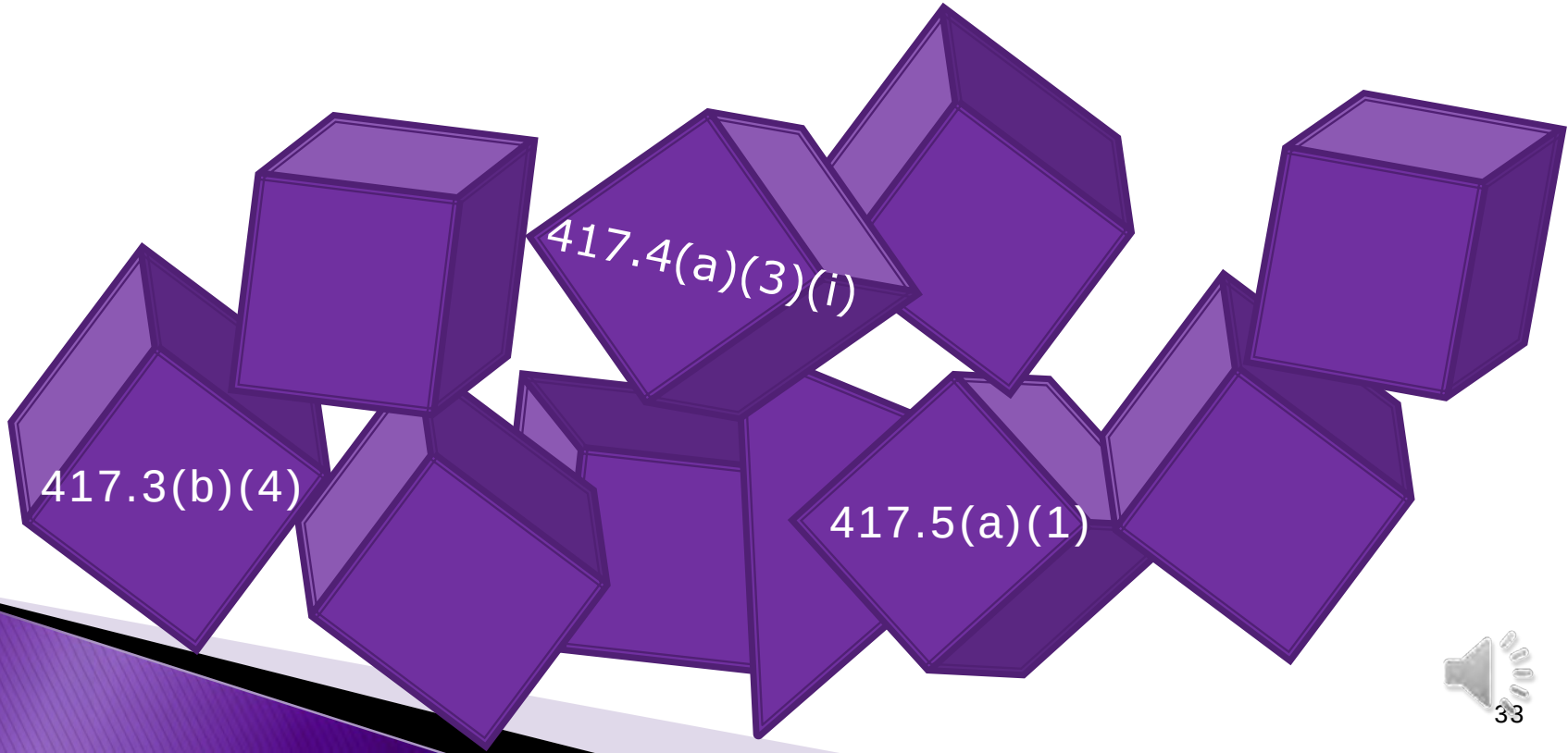
The Food Safety Pyramid Or System



The Food Safety Pyramid Or System



The Food Safety Pyramid or System With No Support or Reassessment



The Warm Heart Incident

The Warm Heart Incident

- An establishment used to have a CCP for 24-hour chilling but collected data over a two-year period from the cooler that showed that the Critical Limit of 44.6° F. was always met.
- In fact, after 24 hours in the cooler, carcasses/variety meats were colder than 44.6° F.

The Warm Heart Incident

- This then supported the fact that no pathogen growth was occurring on the carcasses or in the variety meats.
- This data was reviewed by an EIAO and found to be accurate, as was the conclusion that no pathogen outgrowth was reasonably likely to occur.
- The establishment developed a cooling GMP to capture this.

The Warm Heart Incident

- The cooling GMP involved monitoring cooler temperature twice daily which was correlated to the product temperature through the two years of data.
- Review of the GMP records showed that the cooler temperature was being monitored as per the GMP and that the cooler temperature never exceeded 39° F.

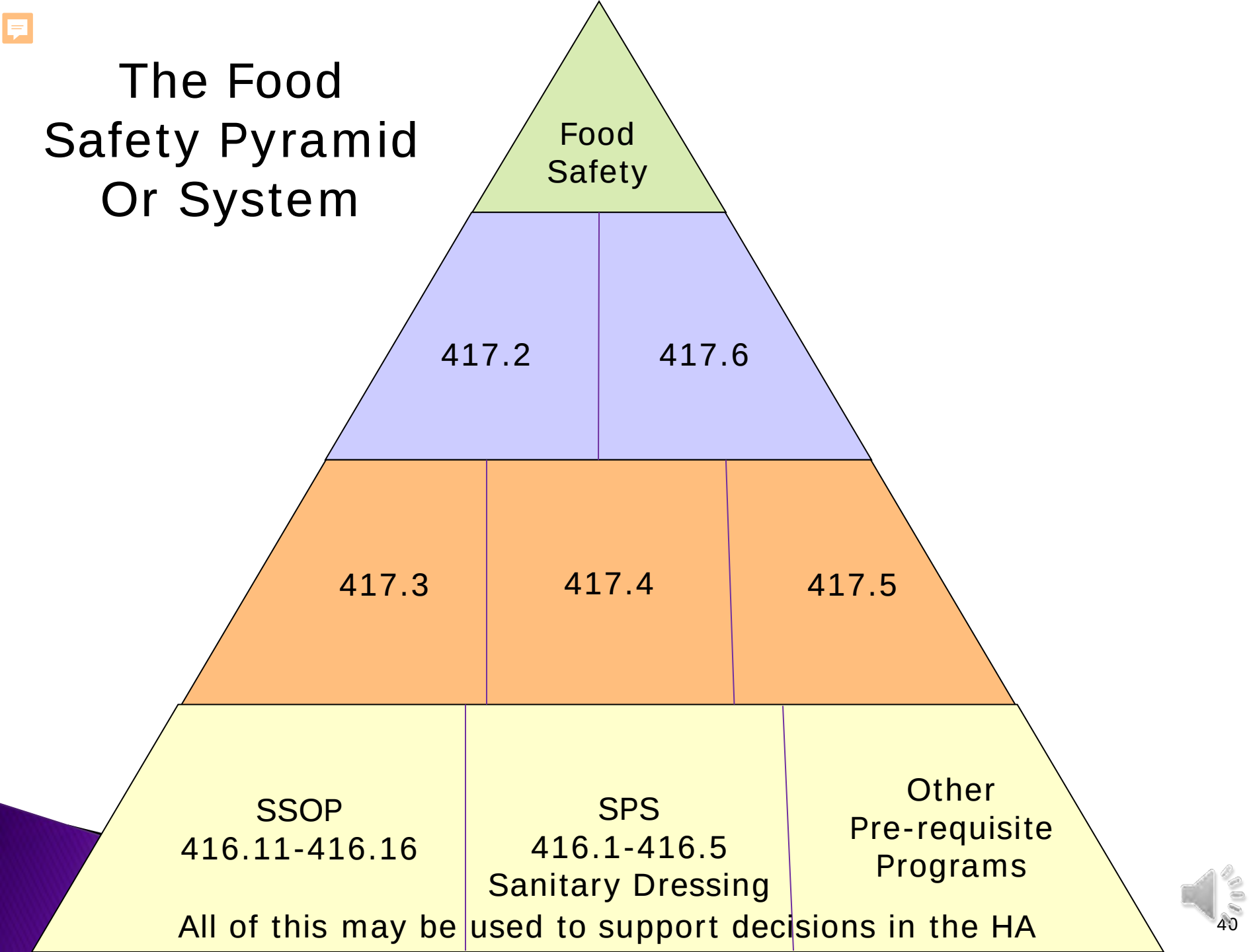
The Warm Heart Incident

- A CSI saw that a partial box of hearts from 30 month and older cattle from a previous day's production was on the kill floor in late morning.
- He took the temperature of the hearts and found it to be 54.6° F.
- Is there a noncompliance?

The Warm Heart Incident

- If so, with what regulation is there noncompliance?
- What else would you want to check on?
- Is there apt to be more noncompliance associated with this event?

The Food Safety Pyramid Or System



The Undeclared Allergen Incident

The Undeclared Allergen Incident

- An establishment changes the formula of a product and adds soy.
- It has an allergen control program in its SSOPs that says changes in ingredients will prompt labeling changes and that ingredients in the formula will be reviewed against the label at packaging.

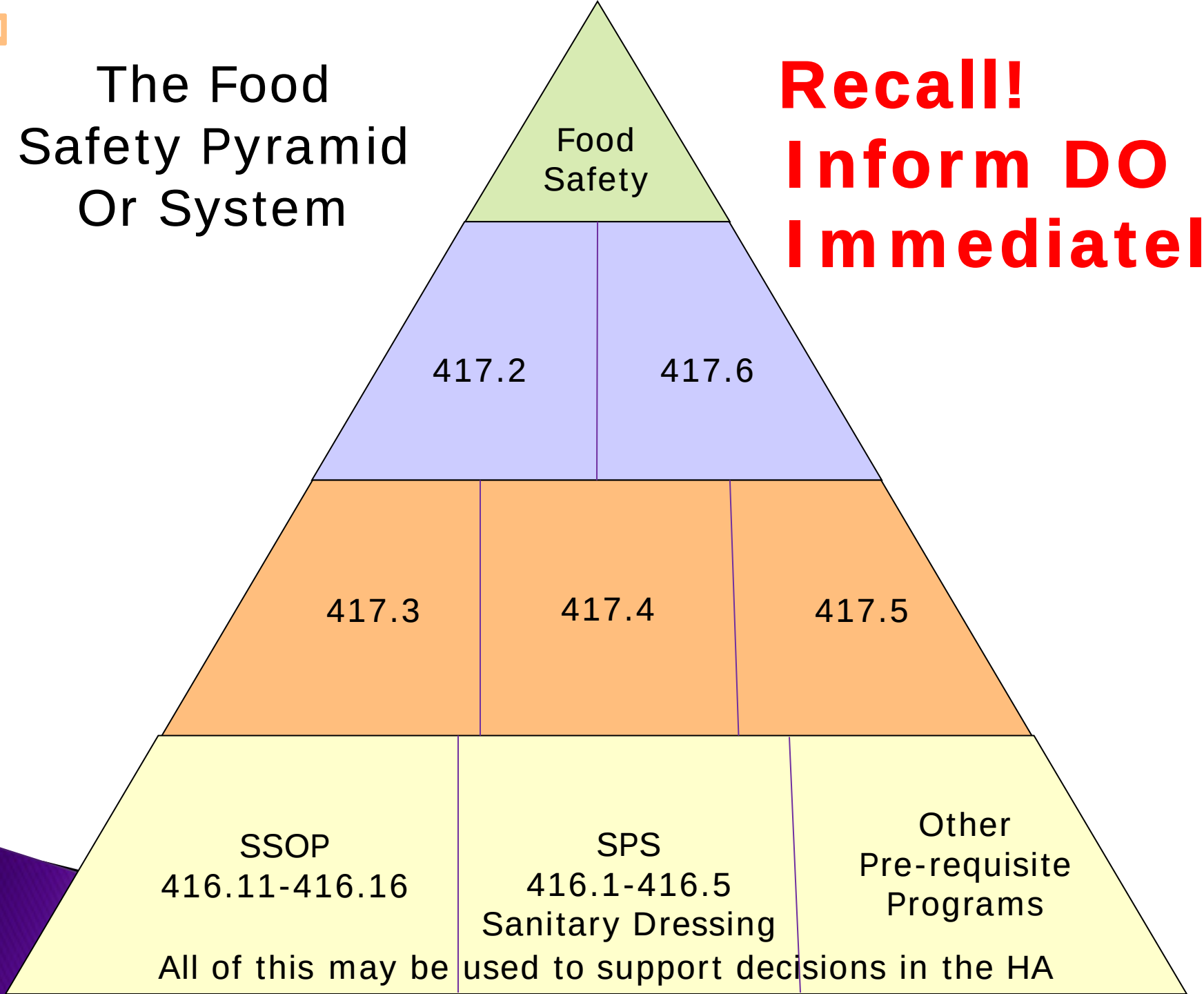
The Undeclared Allergen Incident

- Records indicate the establishment did not follow its SSOP.
- The establishment does not change the label, signs the pre-shipment review, and ships the product into commerce.
- Is there other noncompliance in addition to misbranding?

The Undeclared Allergen Incident

- If so, what is it?
- What else do you want to look at to help make this determination?
- What else should you do?

The Food Safety Pyramid Or System



Recall!
Inform DO
Immediately!

The Negative Test Incident

The Negative Test Incident

- You decide to verify that the establishment operating under their raw, intact plan, is testing the trim it produces as per their written pre-requisite program.
- Their other pre-requisite program (an SOP) states that they will use n=60 methodology and excise exterior surfaces of trim from trim on the top of the combos.

The Negative Test Incident

- The establishment has a zero rate of samples that test positive for *E. coli* O157:H7.
- Samples collected are sent to an independent lab located on-site that uses AOAC approved methodology.
- The establishment uses the PRP test results to support that STEC are not reasonably likely to occur.

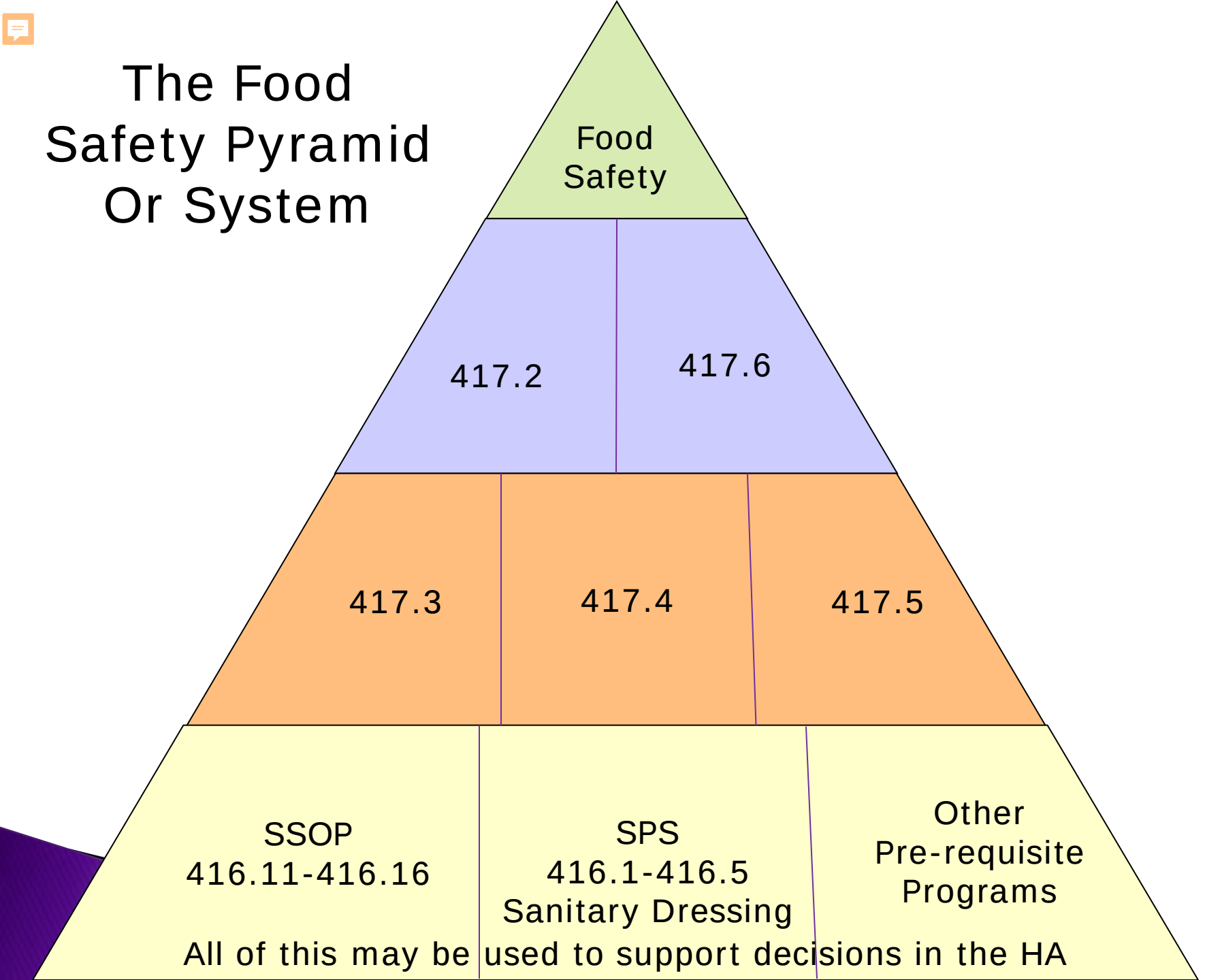
The Negative Test Incident

- In conducting this direct observation verification you observe that the QA is sampling a lot consisting of 3 combos.
- The QA sprays the top of the trim with a lactic acid solution, then excises 15 samples 3 inches long by 1 inch wide by 1/8-inch-thick from interior muscle surfaces on the top of the combos.

The Negative Test Incident

- Is the establishment following their written program?
- At this point, what else do you want to know or check on?
- Does this represent noncompliance?
- If so, with what regulation is this noncompliant?
- Is there apt to be more noncompliance?

The Food Safety Pyramid Or System



The Six-Shooter Incident

The Six-Shooter Incident

- You are doing a FSA a large high-speed beef slaughter/processing operation.
- You are on the processing side and are doing a direct observation verification of the establishment's sampling of combos of trim for O157:H7.

The Six-Shooter Incident

- The number of O157:H7 + lots of trim has been increasing over the last month.
- The establishment is investigating as part of a reassessment but has made no changes.
- You ask the QA in the area when sampling for O157:H7 will occur and are informed that all product in the area at this time is not destined for use in raw, non-intact product, but there will be some soon.

The Six-Shooter Incident

- While waiting, you observe that the establishment is also sampling all trim using a “six shooter” to core sample each combo of trim so that the percentage of lean and fat can be determined.
- You know that this same device is used to sample trim destined for raw, non-intact product.

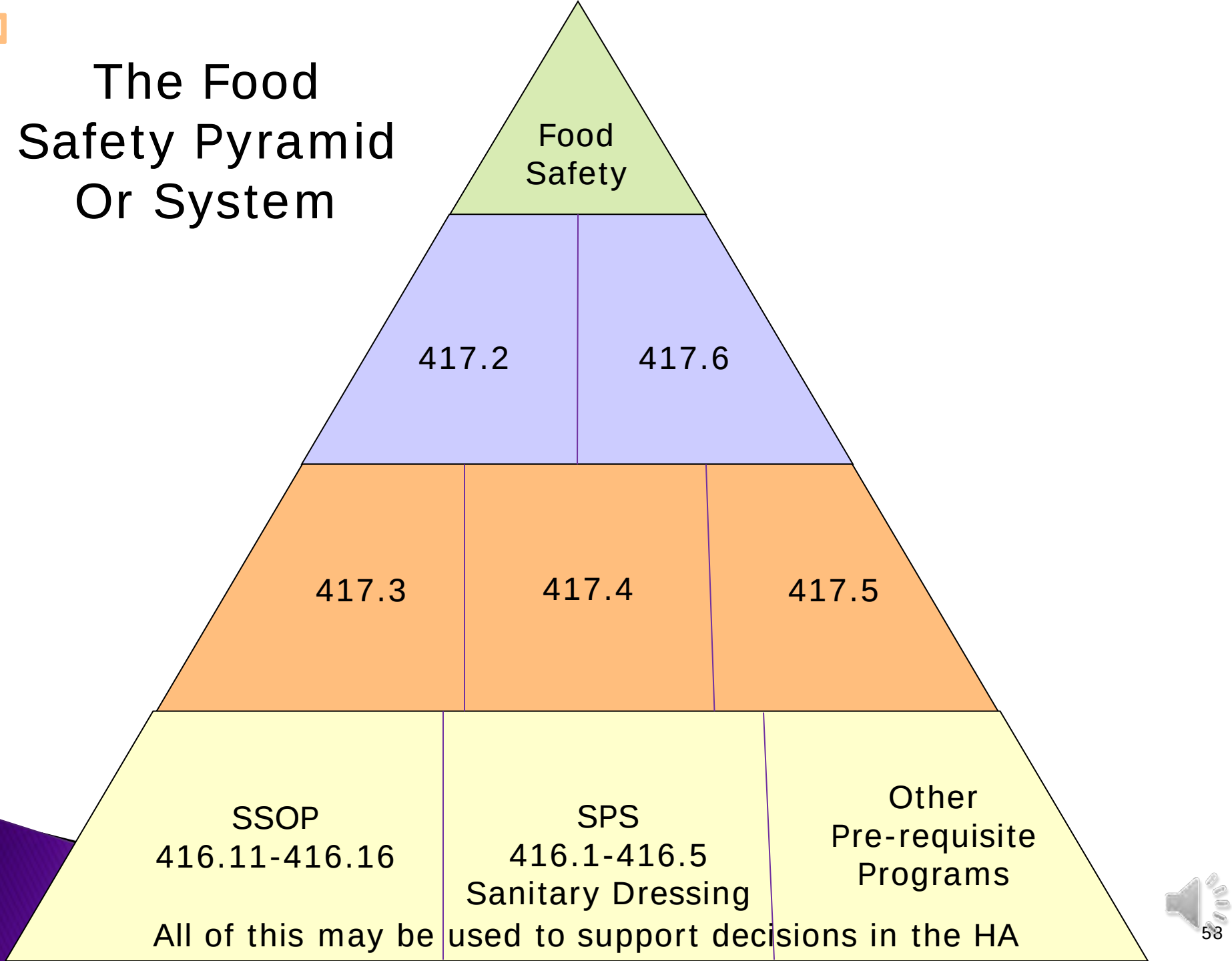
The Six-Shooter Incident

- You observe the six stainless steel tubes descend into the combo of trim destined for cooking, thus sampling the combo.
- The sample is then expelled into sample bags using air under pressure.
- The next combo is similarly sampled.

The Six-Shooter Incident

- Do you foresee any problems with this?
- Might this be a noncompliance?
- Is there potentially more noncompliance?
- What questions would you need answered to make that determination?

The Food Safety Pyramid Or System



The Stacked Combo Incident

The Stacked Combo Incident

- You are conducting an FSA at a high-speed beef slaughter/processing operation and are on the processing side.
- You want to verify the establishment's sampling of trim destined for grinding to be tested for O157:H7.
- There is a 0% STEC positive rate for trim.

The Stacked Combo Incident

- The establishment's written other pre-requisite procedure for sampling states that n=60 methodology will be used.
- "Samples from exterior surfaces of trim will be excised from the top of the combo **when available**".
- You observe several combos ½ to ¾ filled with trim having a large percentage of exterior trim.

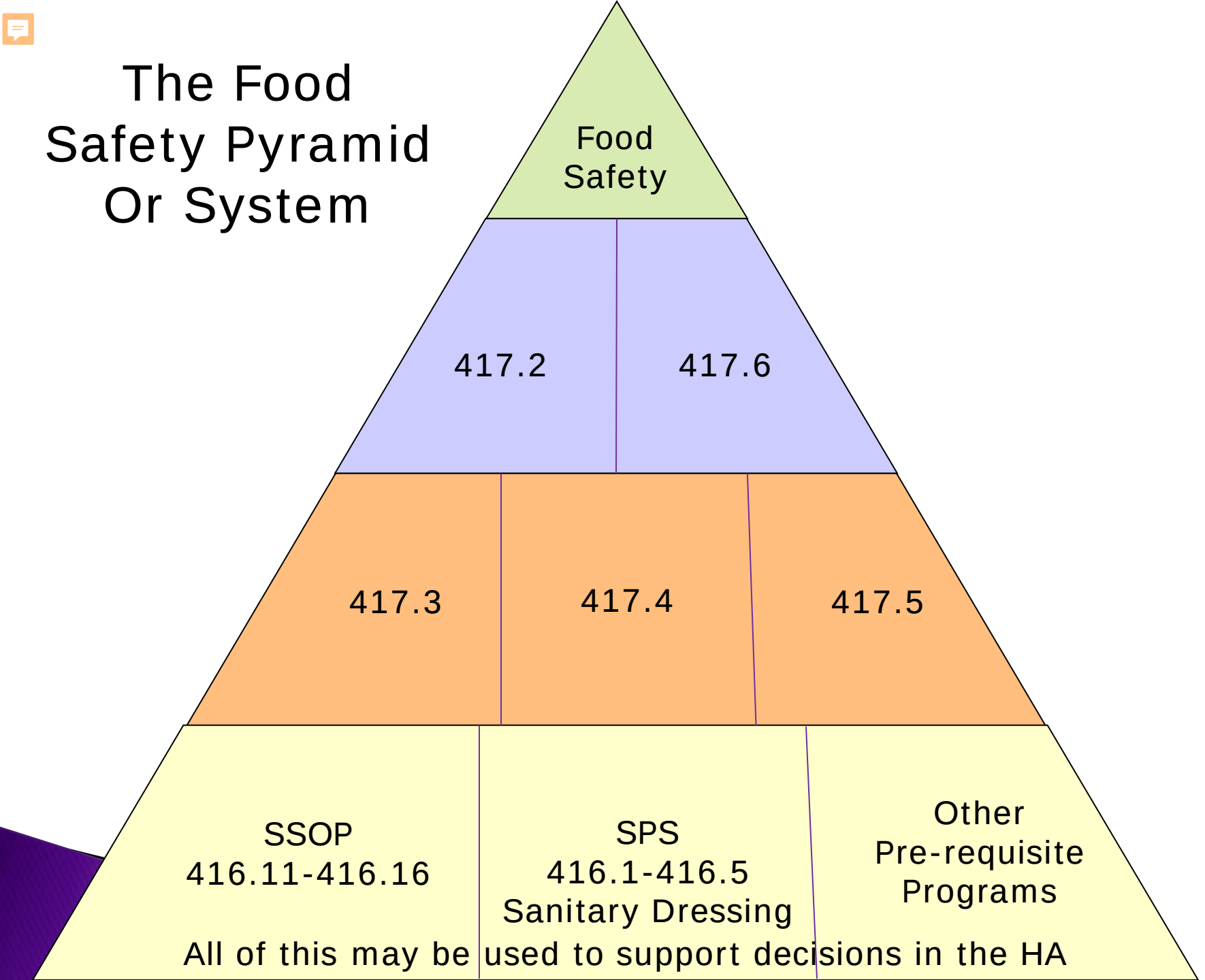
The Stacked Combo Incident

- You point this out to a QA and ask why they are only partially filled? “You know,” is the answer.
- Later, you observe that the partially filled combos are now completely filled, but the trim on top has only interior muscle surfaces
- Trim from the top is sampled according to the written procedure.

The Stacked Combo Incident

- Do you have any concerns?
- What would you ask?
- What other questions would you ask?
- Is there noncompliance associated with this event?
- If so, what regulation is associated with it?
- Might there be more noncompliance?

The Food Safety Pyramid Or System

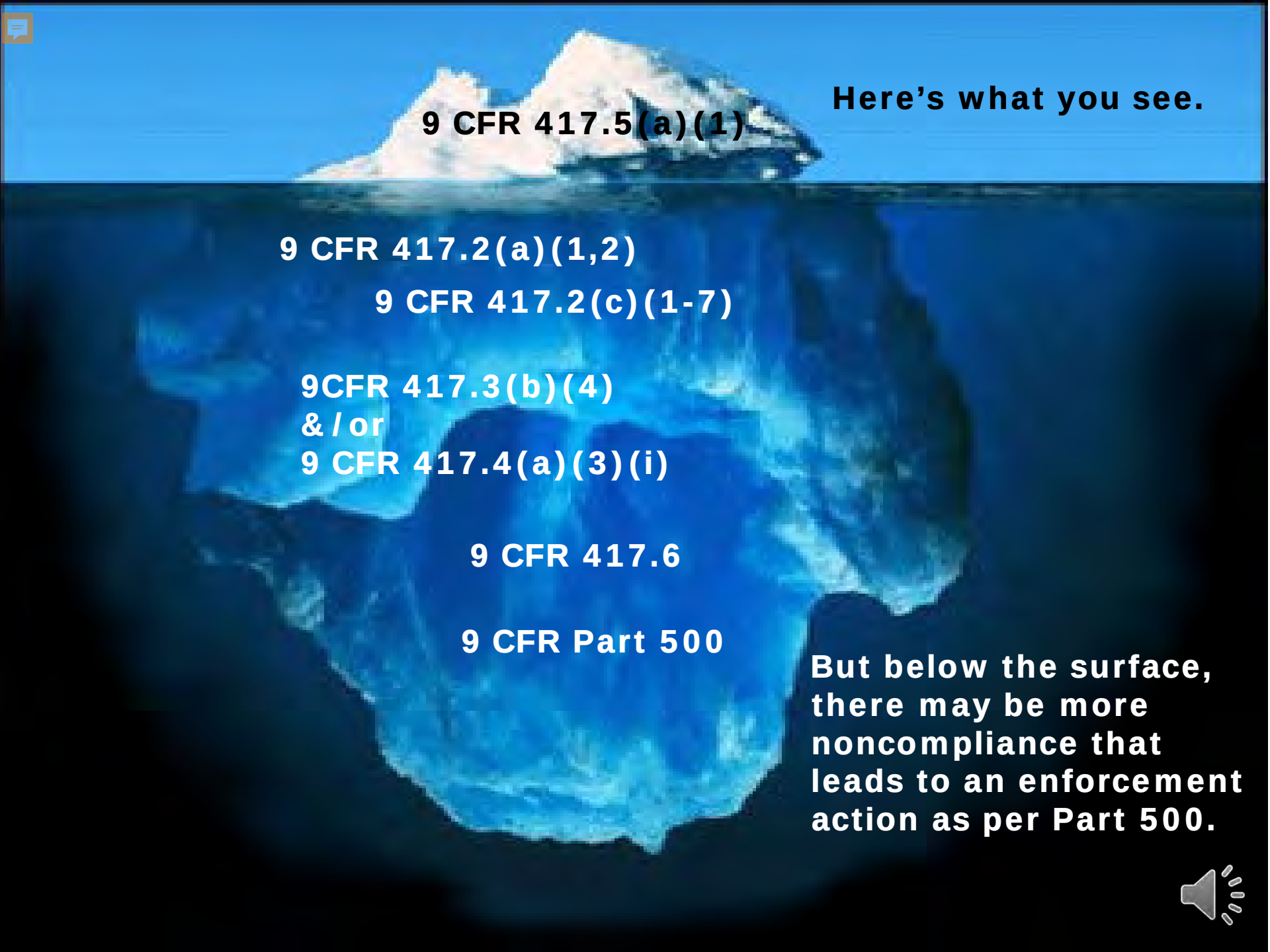


Scenario take home points

- All of these events involved noncompliance with 9 CFR 417.5(a)(1) at a minimum because the establishments could not support decisions made in their hazard analyses, because the establishment was not properly implementing a pre-requisite program, or the pre-requisite program was inadequate.
- Noncompliance with 417.5(a)(1) is not “just a recordkeeping” noncompliance!

Scenario take home points

It is important to document noncompliance with this regulation, since it's often just the tip of the iceberg!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&/or
9 CFR 417.4(a)(3)(i)
9 CFR 417.6
9 CFR Part 500
But below the surface, there may be more noncompliance that leads to an enforcement action as per Part 500.

And leads to…


Questions?


Thank You!
IT'S
5:00
SOMEWHERE