USDA Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

EIAO and IPP

Examine similarities and differences

1

HACCP Regulations

9 CFR 417

Regulation	
§ 417.1	Definitions.
§ 417.2	Hazard Analysis and HACCP Plan.
§ 417.3	Corrective actions.
§ 417.4	Validation, Verification, Reassessment.
§ 417.5	Records.
§ 417.6	Inadequate HACCP Systems.
§ 417.7	Training.
§ 417.8	Agency verification.

SSOP Regulations

9 CFR 416

Regulation	
§ 416.11	General rules.
§ 416.12	Development of Sanitation SOP's.
§ 416.13	Implementation of SOP's.
§ 416.14	Maintenance of Sanitation SOP's.
§ 416.15	Corrective Actions.
§ 416.16	Recordkeeping requirements.
§ 416.17	Agency verification.

2

9 CFR 416.1 – 6 Sanitation Performance Standards

§ 416.1	General rules.
§ 416.2	Establishment grounds and facilities.
§ 416.3	Equipment and utensils.
§ 416.4	Sanitary operations.
§ 416.5	Employee hygiene.
§ 416.6	Tagging insanitary equipment, utensils, rooms or compartments.

3

IPP

Directive 5000.1

Verifying an Establishment's Food Safety System

NOTE: In this directive, the term IPP refers to consumer safety inspectors (CSIs) and public health veterinarians (PHVs).

EIAO

Directive 5100.1

Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology

4

Inspection Program Personnel (IPP)

Directive 5000.1

From Chapter VII, General PHIS Verification thought process:

1. **Gather** all available information;
2. **Assess** the significance and meaning of the information gathered;
3. **Determine** whether the information supports a finding of regulatory compliance; and
4. Put it all together and document "findings," in PHIS.

5

Inspection Program Personnel (IPP) 1

Directive 5000.1

From Chapter VII, General PHIS Verification Process:
GATHER

1. Review establishment programs and supporting documentation;
2. Review establishment records documenting implementation of its programs;
3. Observe establishment employees implementing the establishment's programs and procedures;
4. Observe the conditions in the establishment; and
5. Observe product and occasionally take measurements as specified in the establishment programs

6

Inspection Program Personnel (IPP) 2

Directive 5000.1

From Chapter VII, General PHIS Verification Process:

Assess

1. Are conditions in the establishment getting worse over time?
2. Are the same or similar problems occurring repeatedly or consistently occurring on a seasonal basis?
3. Is the establishment responding effectively and in a timely manner to problems that do arise?

7

Inspection Program Personnel (IPP) 3

Directive 5000.1

From Chapter VII, General PHIS Verification Process:

Determine

1. That the establishment is not maintaining sanitary conditions;
2. That the establishment has produced or shipped adulterated products;
3. That the establishment's food safety system is not effectively controlling the relevant food safety hazard; and
4. That the establishment is not meeting the requirements in one or more regulations.

8

Inspection Program Personnel (IPP) 3

HACCP Regulations

9 CFR 417

HACCP Verification Tasks

1) Hazard Analysis Verification (HAV) Task *(Design)*
2) HACCP Verification Task *(Implementation)*

SOP regulations

9 CFR 416.11 - 17

SSOP Verification Tasks

1) Pre-Op Record Review Task
2) Pre-Op Review & Observation Task
3) Operational Record Review Task
4) Operational Review & Observation Task

9

Food Safety Assessment EIAO

Directive 5100.1

From Chapter I General : IV FSA Overview

The EIAO is to use FSA tools to record findings and to determine whether:

1. The HACCP system is designed to prevent, reduce, or eliminate the hazards identified in the hazard analysis;
2. The establishment's decisions in its hazard analysis are appropriately supported, including by the establishment's validation documents; and
3. The establishment's sampling and testing programs are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.

10

Food Safety Assessment
EIAO 1

Directive 5100.1

FSA Tools:
1. General Tool
2. Meat Tool
3. Poultry Tool
4. Ready-to-Eat Tool
5. Not Ready-to-eat Tool
6. Thermal Processing Tool
7. Fish Tool
8. Egg Tool

The purpose of the FSA tools (in PHIS) is to provide the EIAO with a structured framework for conducting the FSA

11

Food Safety Assessment
EIAO 2

General Tool plus one other Tool

- Tool Summary
- Decision Making Analysis (only in General Tool)
- Executive Summary (only in General Tool)

12

Food Safety Assessment
EIAO 3

FSA Tool

- EIAO is to focus on documenting **noncompliance** and **vulnerabilities**
- A **vulnerability** is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could contribute to the establishment's ability to produce safe and wholesome meat or poultry products.

13

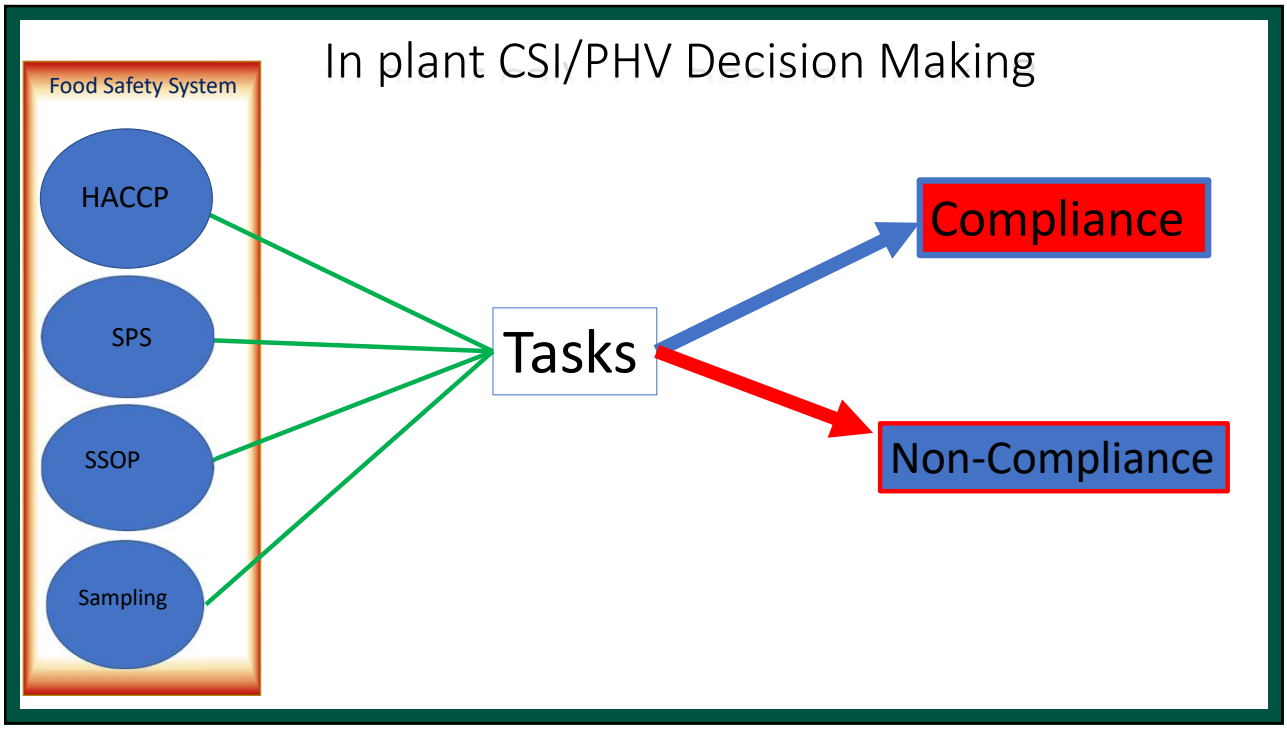
IPP

When there is regulatory non-compliance the IPP will reference the regulations. Documented on a Non-compliance Record (NR).

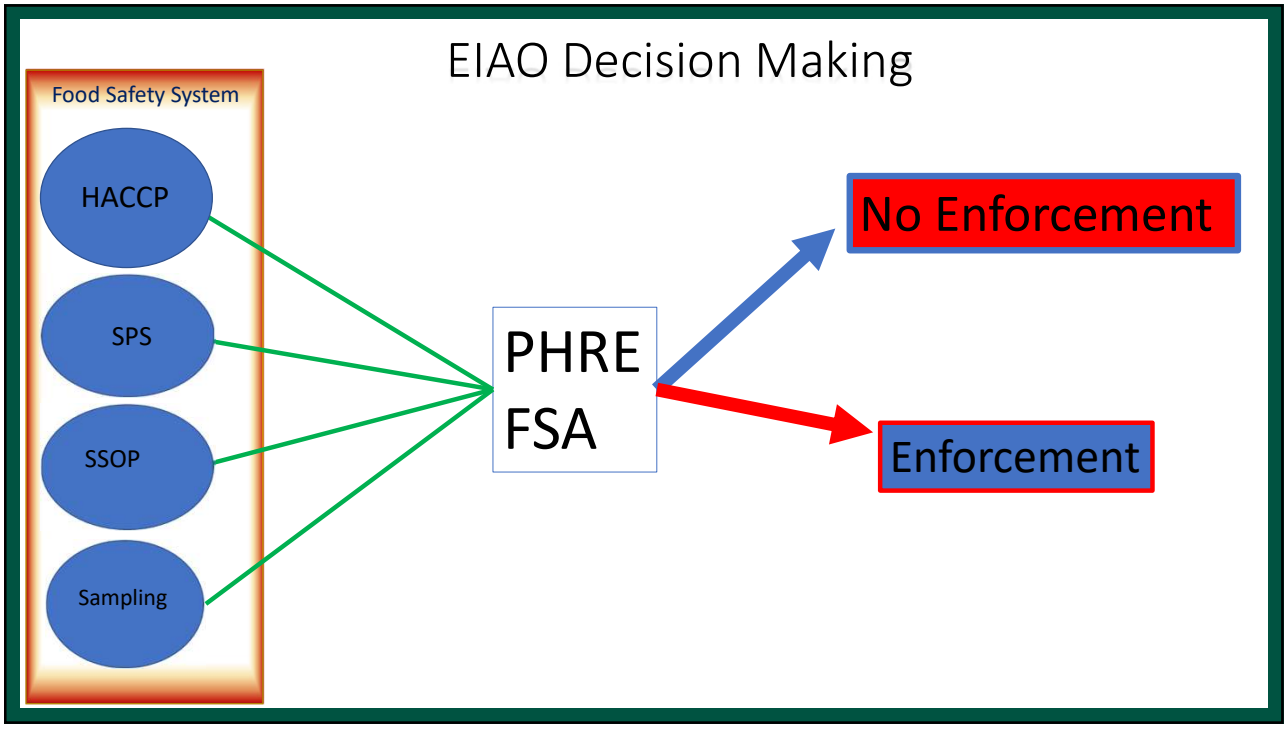
EIAO

- **When there is regulatory noncompliance the EIAO will recommend a supportable level of an enforcement action.**
- **This could be NRs , Notice of Intended Enforcement (NOIE), or Notice of Suspension (NOS).**

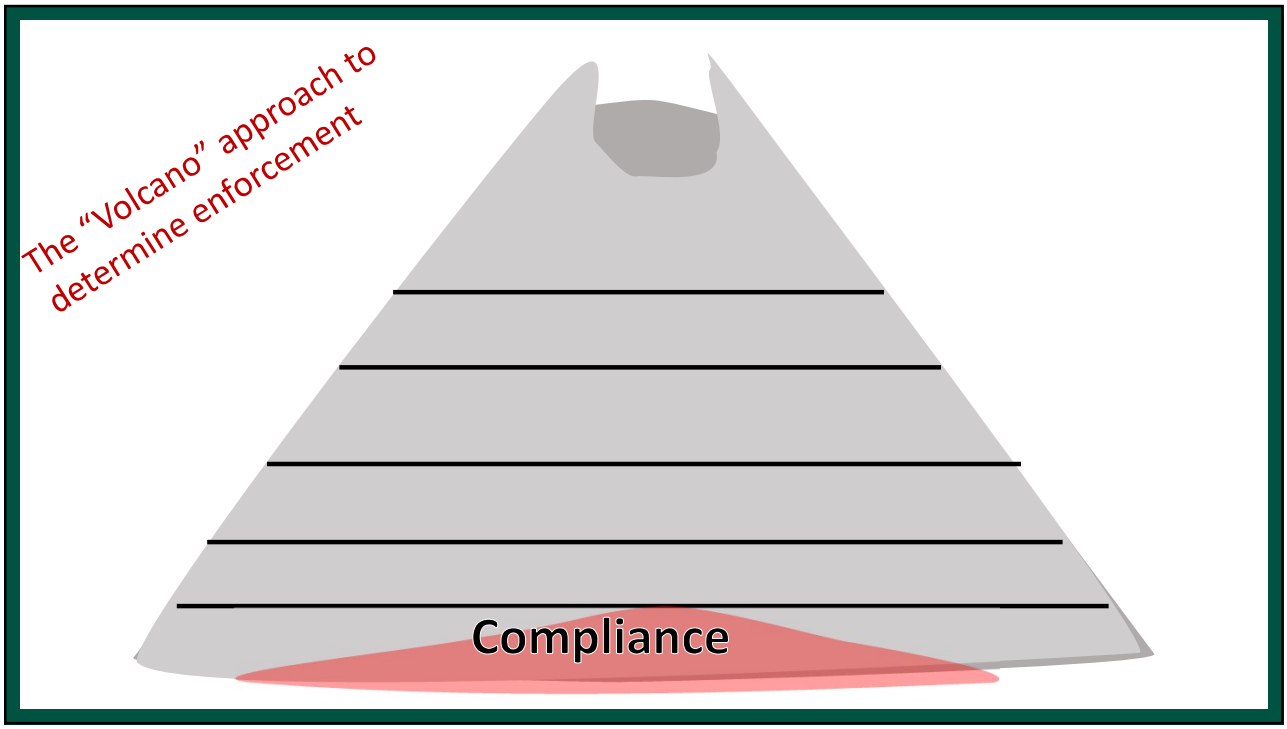
14


In plant CSI/PHV Decision Making
Food Safety System
HACCP
SPS
SSOP
Sampling
Tasks
Compliance
Non-Compliance

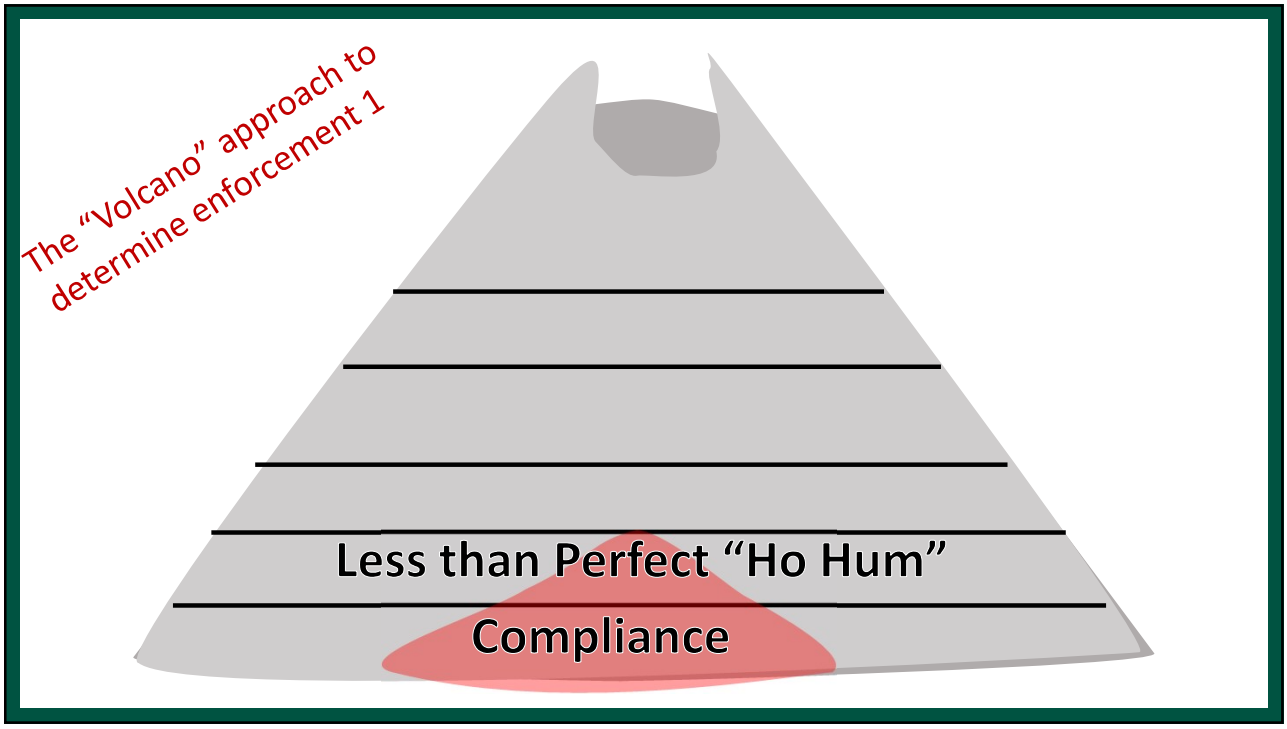
15


EIAO Decision Making
Food Safety System
HACCP
SPS
SSOP
Sampling
PHRE
FSA
No Enforcement
Enforcement

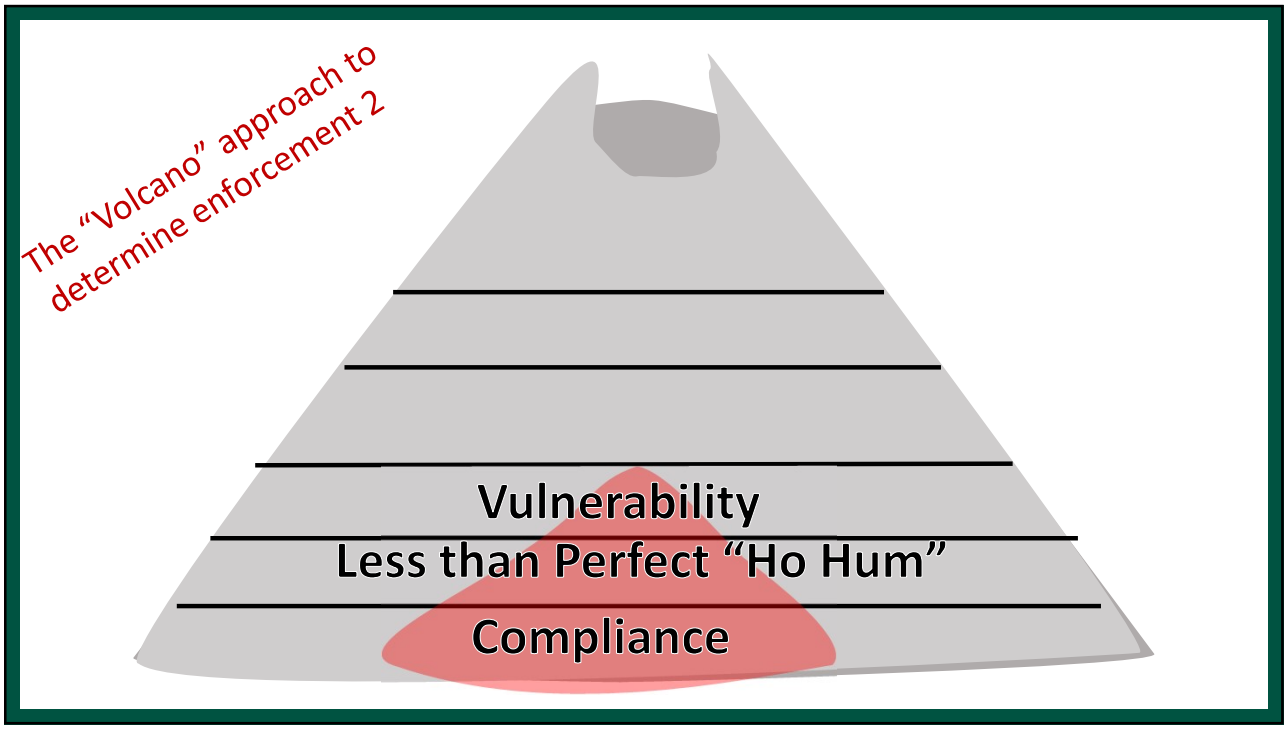
16


The "Volcano" approach to determine enforcement
Compliance

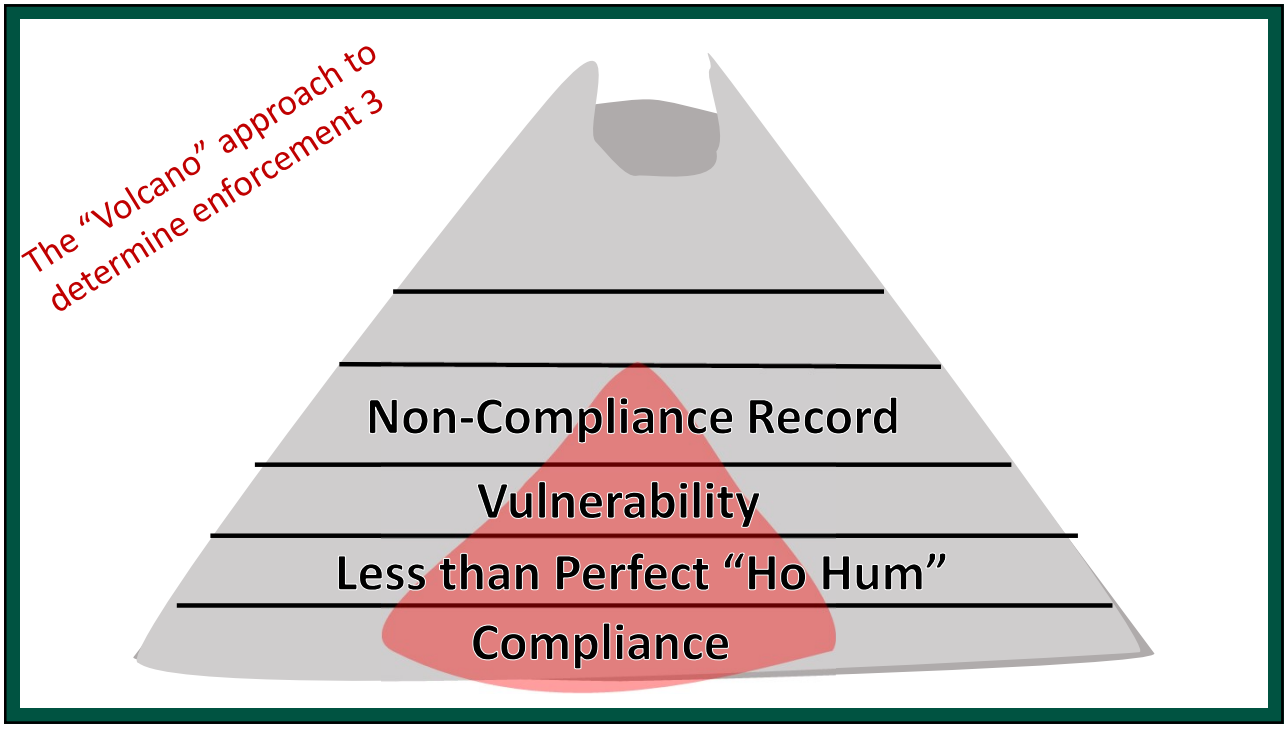
17


The "Volcano" approach to determine enforcement 1
Less than Perfect "Ho Hum"
Compliance

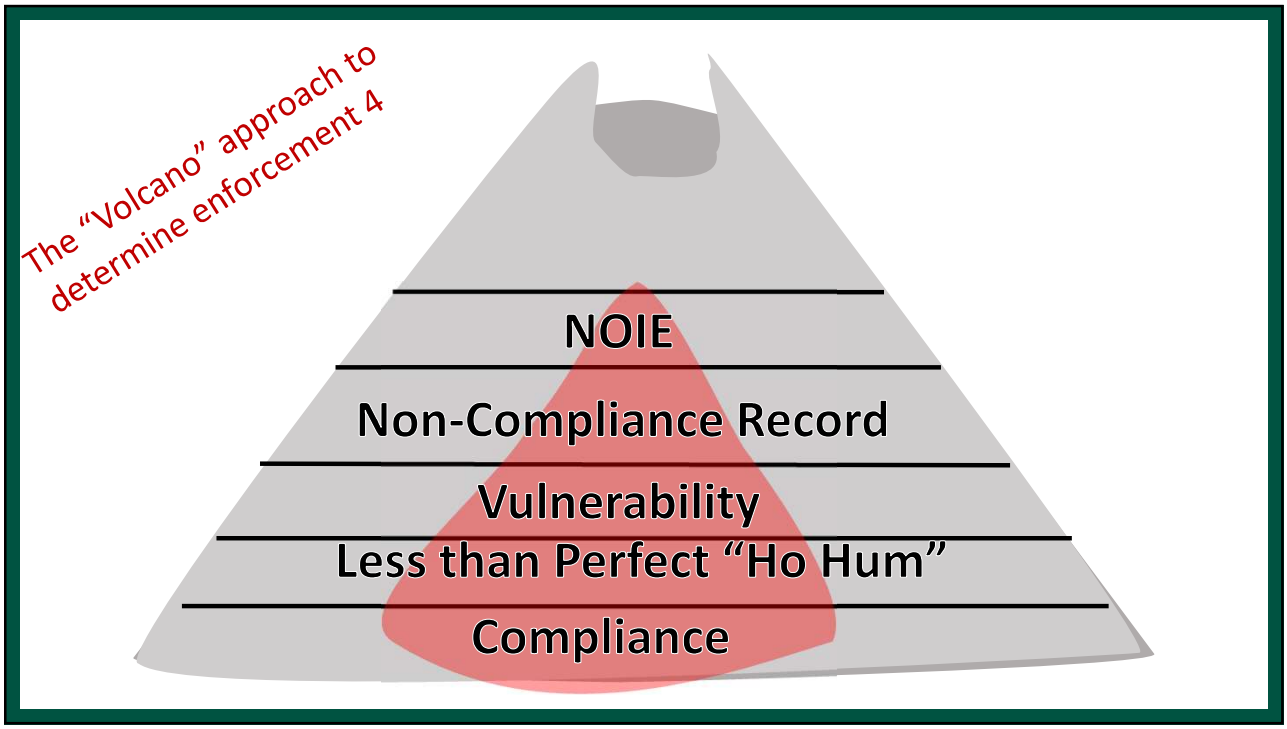
18


The "Volcano" approach to determine enforcement 2
Vulnerability
Less than Perfect "Ho Hum"
Compliance

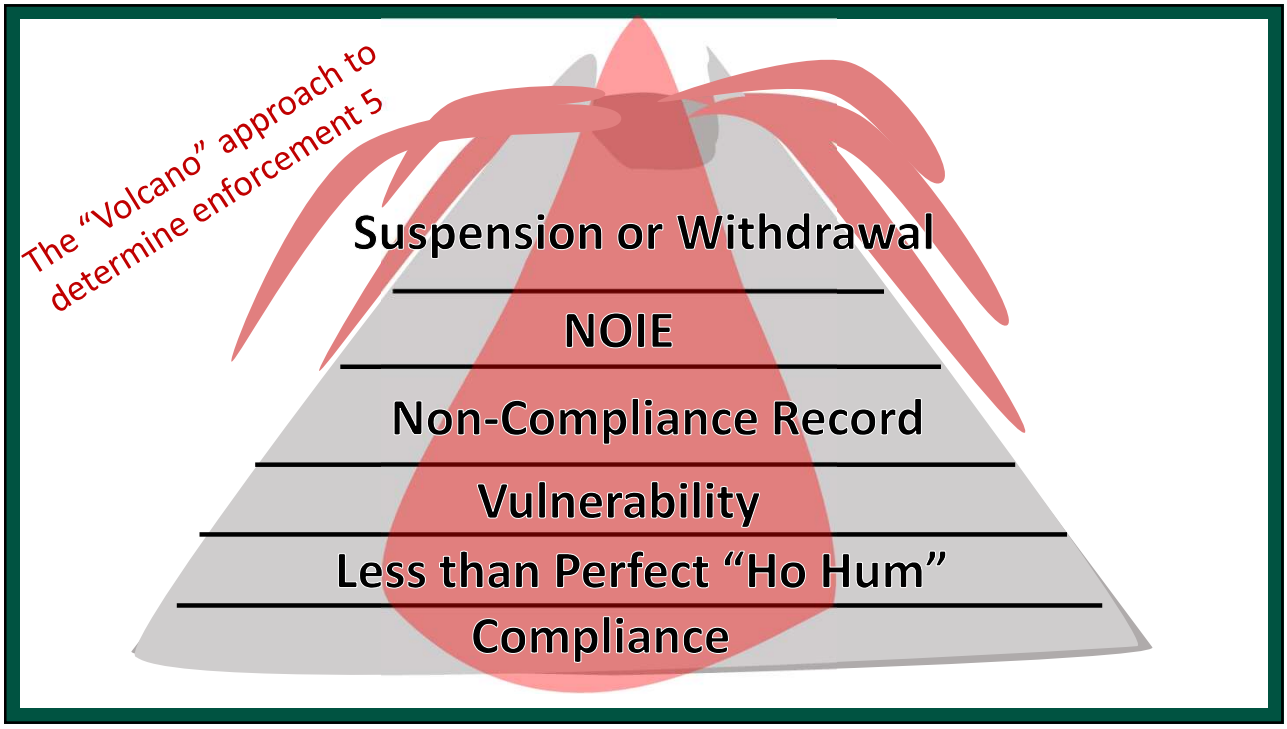
19


The "Volcano" approach to determine enforcement 3
Non-Compliance Record
Vulnerability
Less than Perfect "Ho Hum"
Compliance

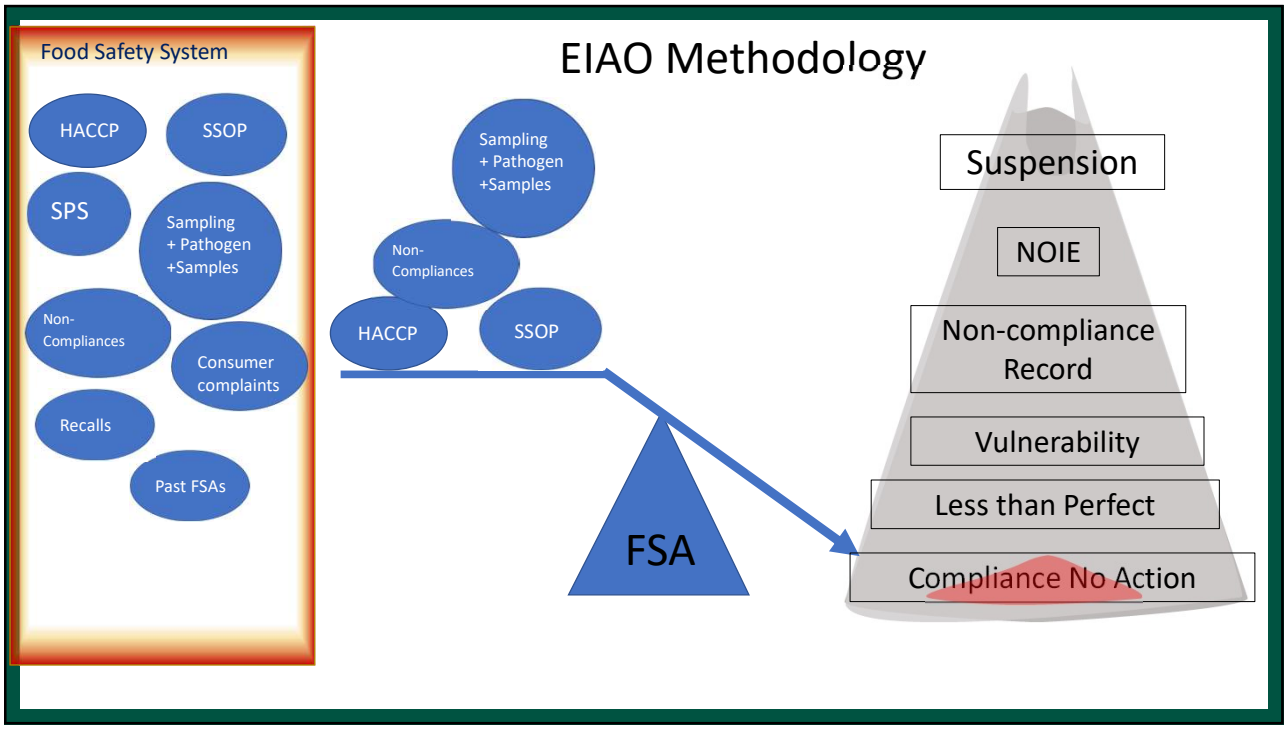
20


The "Volcano" approach to determine enforcement 4
NOIE
Non-Compliance Record
Vulnerability
Less than Perfect "Ho Hum"
Compliance

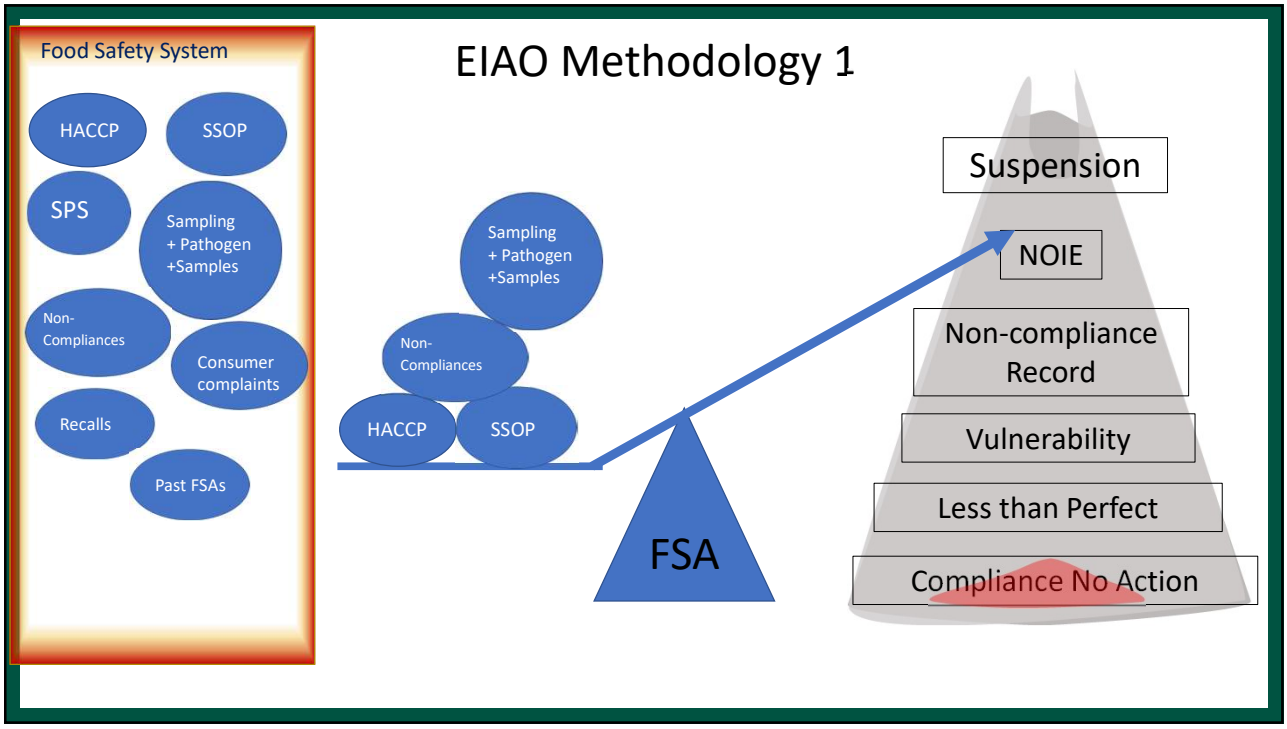
21


The "Volcano" approach to determine enforcement 5
Suspension or Withdrawal
NOIE
Non-Compliance Record
Vulnerability
Less than Perfect "Ho Hum"
Compliance

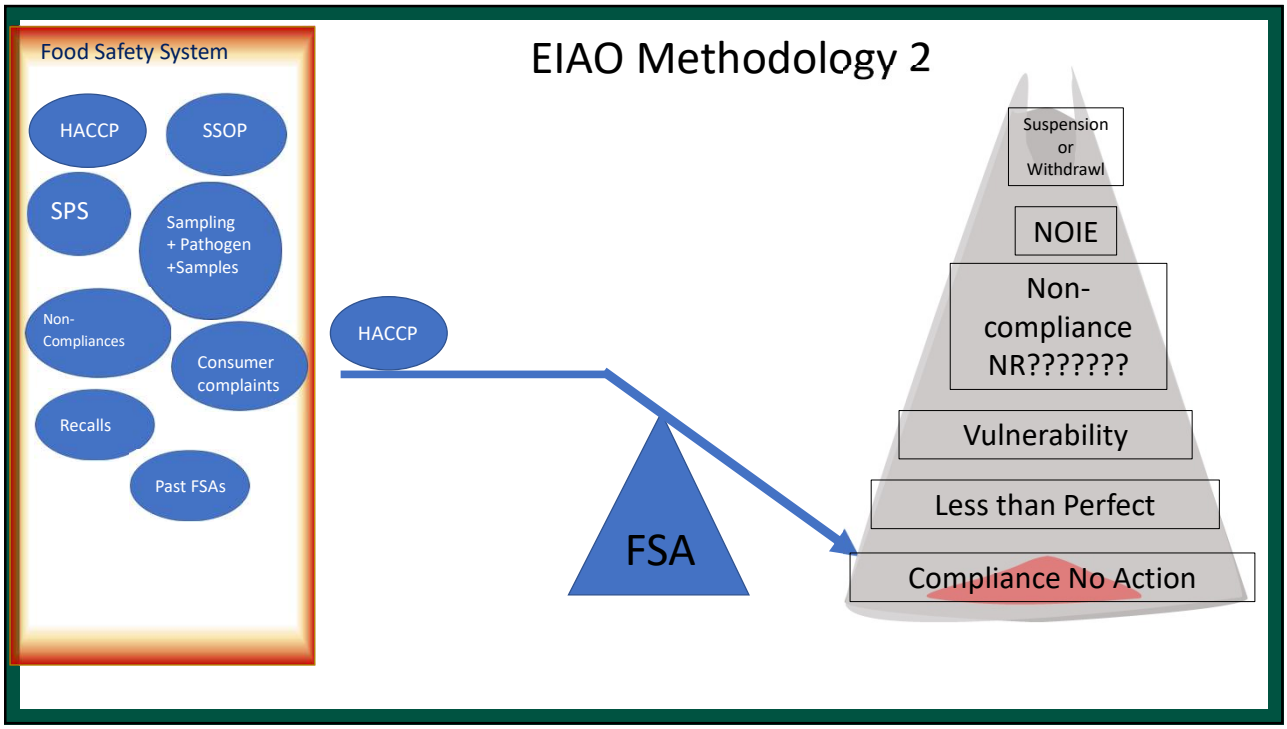
22


Food Safety System
HACCP
SSOP
SPS
Sampling + Pathogen +Samples
Non-Compliances
Consumer complaints
Recalls
Past FSAs
EIAO Methodology
Sampling + Pathogen +Samples
Non-Compliances
HACCP
SSOP
FSA
Suspension
NOIE
Non-compliance Record
Vulnerability
Less than Perfect
Compliance No Action

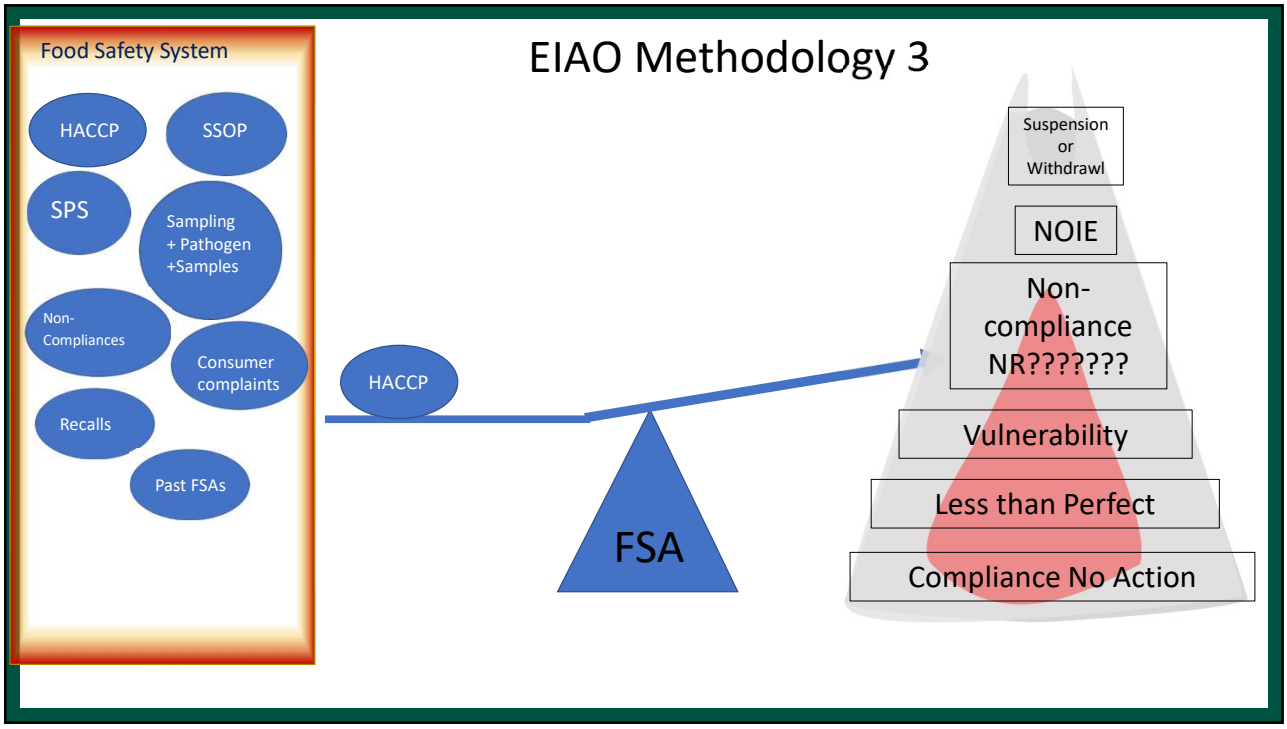
23


Food Safety System
HACCP
SSOP
SPS
Sampling + Pathogen +Samples
Non-Compliances
Consumer complaints
Recalls
Past FSAs
EIAO Methodology 1
Sampling + Pathogen +Samples
Non-Compliances
HACCP
SSOP
FSA
Suspension
NOIE
Non-compliance Record
Vulnerability
Less than Perfect
Compliance No Action

24


Food Safety System
HACCP
SSOP
SPS
Sampling + Pathogen +Samples
Non-Compliances
Consumer complaints
Recalls
Past FSAs
EIAO Methodology 2
HACCP
FSA
Suspension or Withdrawl
NOIE
Non-compliance NR???????
Vulnerability
Less than Perfect
Compliance No Action

25


Food Safety System
HACCP
SSOP
SPS
Sampling + Pathogen +Samples
Non-Compliances
Consumer complaints
Recalls
Past FSAs
EIAO Methodology 3
HACCP
FSA
Suspension or Withdrawl
NOIE
Non-compliance NR???????
Vulnerability
Less than Perfect
Compliance No Action

26

Thought Exercise

- Scenario
  - While review the establishments HACCP records, you observe that on one day of production a CCP monitoring check was missed.

IPP action	EIAO action

27

Thought Exercise

- Scenario
  - While review the establishment's pre-requsite program for receiving beef trim, you observe that a COA is missing from one load of product. A COA is required for each load of product as written in the establishments receiving beef trim program.

IPP action	EIAO action

28

Questions?

29