



Risk Assessment and Risk Management Evaluations

The New Chapter II Evaluation: RARM

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RISK ASSESSMENT AND RISK MANAGEMENT EVALUATION (RARM)

Background

The What and How

The How Often and When

For many years, evaluation of state programs related to risk assessment and illness response has focused on managing *Vibrio parahaemolyticus* or *Vibrio vulnificus*.

RARM: Background

The concentration on Vibrio specific evaluations has resulted in states implementing robust Vibrio management control strategies and control plans (VMPs) to prevent illnesses during periods of identified risk and has improved the rate of illnesses associated with molluscan shellfish consumption and Vp.

The FDA's concentration on Vibrio specific evaluations has created a systemic unbalanced approach in evaluating states' non-Vibrio illness risk management controls.

RARM: Background

Issues with compliance and understanding of Chapter II requirements, resulted in states requesting clarification, interpretations and more training on NSSP Illness Outbreak Response requirements.

Discussions regarding a change of evaluation format began in earnest in 2018, with announcements being made during regional meetings and last years ISSC Informational Meeting.

RARM: Background

This evaluation will allow for a broad scope evaluation, covering all the items listed in Chapter II of the Model Ordinance.

It pulls all references to Chapter II requirements from the other Program Element Evaluations and puts them in the same report

RARM: Background

B. Status of Current Evaluation

1. Current Findings

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| <p>a. Administration [Chapter I @.01 A.]</p> <p>b. State Laws and Regulations [Chapter I @.01 B.]</p> <p>c. Record Keeping [Chapter I @.01 C.]</p> <p>d. Shared Responsibilities [Chapter I @.01 D.]</p> <p>e. Administrative Procedures [Chapter I @.01 E.]</p> | <p>f. Procedures for investigating incidents of shellfish borne disease. [Chapter I @.01 F.]</p> <p>g. Outbreaks of Shellfish-Related Illness [Chapter II @.01] Record Keeping [Chapter I @.01 C.]</p> <p>h. Shellfish Related Illnesses Associated with <i>Vibrio parahaemolyticus</i> (V.p.) [Chapter II @.02]</p> <p>i. Annual Assessment of <i>Vibrio vulnificus</i> and <i>Vibrio parahaemolyticus</i> Illnesses and Shellfish Production [Chapter II @.03]</p> <p>j. Presence of Human Pathogens in Shellfish Meats [Chapter II @.04]</p> | <p>k. Presence of Toxic Substances in Shellfish Meats [Chapter II @.05]</p> <p>l. <i>Vibrio vulnificus</i> Control Plan [Chapter II @.06]</p> <p>m. <i>Vibrio parahaemolyticus</i> Control Plan [Chapter II @.07]</p> <p>n. Laboratory Element [Chapter III @01 and @02]</p> <p>o. In-field Compliance Evaluation</p> |
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RARM: The What and How.
What will the evaluation cover?

B. Status of Current Evaluation (Cont.)

o. In-field Compliance Evaluation

- i. Were points of landing visited to verify compliance with required harvester records and time-temperature requirements? How many? How is the state verifying compliance? Where applicable, were internal oyster and/or clam temperatures measured? Provide compliance results (are the harvesters following the Vibrio Control Plan and in compliance with the requirements of the plan) of landing site visits.
- ii. Were processing plants, including PHP plants, visited? How many? Were records and labeling reviewed for verification and compliance with HACCP plans and NSSP-MO? Results of internal product temperature checks for compliance with HACCP/NSSP-MO? Provide compliance results of plant visits, including state actions where issues of non-compliance are encountered.
- iii. What were the State activities for verifying industry compliance? What were the State's actions regarding industry noncompliance?

RARM: What will the evaluation cover?

The concept of combining all Chapter II requirements into one program element evaluation was Beta tested during the 2020 program evaluation of the Mexican Shellfish Sanitation Program (PMSMB).

RARM: Implementation

FREQUENCY OF RARM EVALUATION:

- Every other year, UNLESS:
- The state has an illness outbreak with an implicated growing area

Program will be evaluated annually until three (3) consecutive years have passed without an outbreak associated with any growing area

- If an evaluation finds that the state is not meeting Chapter II requirements, the state may have a follow-up evaluation in the off year
- Non-producing states will be evaluated every other year.

RARM: How often will my state be evaluated?

Non-producing states are currently evaluated for the Plant Processing and Shipping Element only.

Since the RARM evaluation covers all aspects of risk assessment and illness response, non-producing states WILL receive a separate RARM evaluation.

Non-producing states will only be evaluated on portions of the RARM that apply to them.

Results will be provided to the Authority utilizing the RARM PEER template.

RARM: How often will my state be evaluated?

RARM Evaluations begin this year: FY22, October 2021 – September 2022

Your state will have a RARM evaluation THIS YEAR if:

- ❖ You are a producing state and due for your routine Vibrio evaluation**
- ❖ You are a producing state and had your routine Vibrio evaluation last year, but had an outbreak associated with a growing area**
- ❖ You are a non-producing state and due for your routine P&S evaluation**

RARM: When will my state have a RARM Evaluation?

The RARM Evaluation:

- *Replaces the Vibrio evaluation*
- *Combines all NSSP Model Ordinance Chapter II requirements for risk assessment and illness response into one focused evaluation*
- *Will be conducted every other year (even for non-producing states) unless you have an outbreak and then it will be conducted annually for 3 years*
- *Will be reported on the RARM PEER template*
- *Is new for all of us!*

RARM: Summing it Up

RARM: THANK YOU and QUESTIONS!

Thanks to the FDA RARM workgroup and big thanks to the conference for allowing me to provide a presentation on this topic.

**If you would rather submit a question, please feel free to email:
melissa.Farrell@fda.hhs.gov**

