Managing Positive Pathogen Results

Safe Food California
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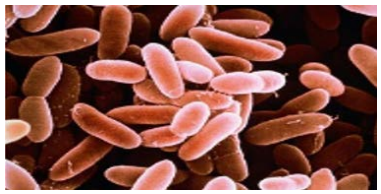
Post Consumer Brands

Managing Positive Pathogen Results



Requires immediate and effective response

- Establish in advance a notification protocol for lab to report results
  - presumptive results, confirmed positive results
  - email, telephone

- Have written response plan in place before it happens
  - Determine responsibilities of specific personnel
  - Training

Managing Positive Pathogen Results

Positive pathogen result occurrence

- During routine environmental monitoring
  - No known cause of the positive pathogen result

- During finished product testing
  - Routine or non-routine verification

- During risk assessment or verification of hygienic condition for an existing event
  - Known likely cause of the positive pathogen result (have a head start on understanding the situation)

Positive Pathogen Result – Routine Environmental Monitoring

Use organized approach

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

Positive Pathogen Result – Routine Environmental Monitoring

1. **Initial Response**
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Notification
  - Notify responsible people

- Isolation
  - Prevent further potential for spread of pathogens from the positive site

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. **Evaluation Actions**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Assemble the Environmental Pathogen Response Team

- Gather the facts
  - Location of positive sample
  - Time of sampling
  - Time of cleaning and sanitizing events
  - Any product stream in the area since the last sanitizing event

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. **Evaluation Actions, continued**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Determine potential sources of the pathogen – contaminated sites
  - Changes in area
  - Ingredients in the area
  - Dust in the area
  - Water (pooled, condensate, cracks/spaces) in the area
  - Potential for microbial harborage or niche in the area
  - Potential for harborage or niche within equipment (break down and inspect)
  - Recent changes to cleaning or sanitizing practices, or sanitation personnel
  - Consider previous environmental sampling results
  - Determine extent of the contamination by swabbing the facility area and equipment (“vector swabbing” 3 dimensions)

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. **Evaluation Actions, continued**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Determine potential sources of the pathogen – modes of transfer
  - Changes, new personnel
  - Contamination tracked in by human or equipment traffic
  - Product handling practices
  - Unusual recent events (example: leakage, drain backup, construction)
  - Consider root cause of previous pathogen positive incidents
  - Root cause analysis

Modes of Transfer

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. **Evaluation Actions, continued**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

Determine product disposition based on risk to product safety

- Likelihood of product stream contamination
  - Hygienic zone of positive site (relative to product steam)
    - Physical and procedural barriers that protect product stream
  - Product zone of positive site (relative to product stream)
    - Proximity to product stream
    - Product stream coverage
    - Air movement
  - Handling
- Effectiveness of downstream thermal process steps

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. **Evaluation Actions, continued**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

Determine Corrective Measures

Determine Verification Plan

Determine Preventive Measures

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. Evaluation Actions
3. **Corrective Actions**
4. Verification Actions
5. Preventive Actions
6. Records

- Examples of additional corrective actions:
  - Fix or contain any unsanitizable unsanitary locations
  - Fix or contain any leaks discovered
  - Maintain traffic restrictions until the area is verified hygienically acceptable

- Clean and sanitize the positive site, all surfaces in the surrounding area that are potentially contaminated, and all sites identified as potentially contributing to the positive finding

Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. **Verification Actions**
5. Preventive Actions
6. Records

- After cleaning and sanitizing, sample surfaces to verify hygienic condition
- If location is again positive evaluate sanitizing method and sanitizability, reclean, and verify
- After any positive pathogen result, 3 consecutive environmental testing events are required before containment is removed
- Implement elevated level of sampling for the positive site(s) and surrounding area during routine PEM (at least next weekly sampling events)

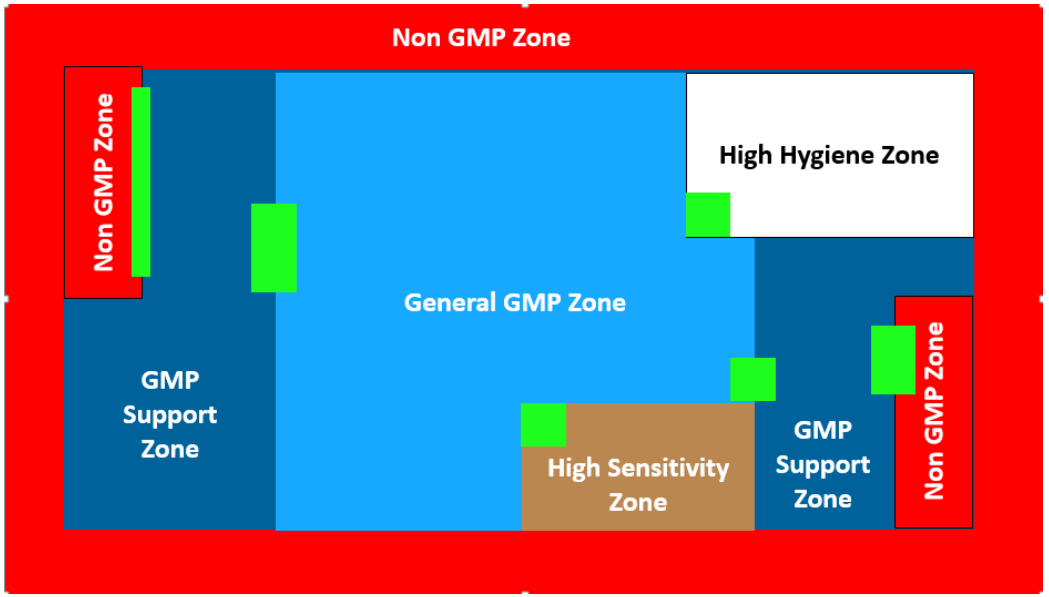
Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. **Preventive Actions**
6. Records

- Examples of preventive actions:
  - Repair damaged facility or equipment
  - Enhance sanitary design of facility or equipment
  - Reduce water presence
  - Implement more effective cleaning or sanitizing procedures
  - Enhance hygienic zone barriers (physical and/or procedural)
  - Change traffic pathways
  - Permanently fix leaks
  - Prevent drain backups
  - Implement procedures for more effective construction containment
  - Training

Preventive Actions

Hygienic Zoning



Positive Pathogen Result – Routine Environmental Monitoring

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. **Records**

Include:
Circumstances, evaluation results, corrective actions, verification results, preventive actions

Purpose:
To provide strong evidence of proper and effective actions assuring environmental pathogens are under control and that food is safe

Positive Pathogen Result – After Hygienically Adverse Event

Examples of Hygienically Adverse Events

- Leakage event (examples: roof leak, flour blowout)
- Drain back-up
- Hygienic zoning breach or GMP failure (example: tracking high sensitivity material into high hygiene zone)
- Construction (during containment, after containment breach, or after completion)
- Emergency access to facility (example: fire department footwear, hoses, water)
- Thermal process deviation (example: underprocessing – oven and divert failure)
- Contaminated ingredient (example: nonfat dry milk post-cook ingredient)

Positive Pathogen Result – After Hygienically Adverse Event

Response to adverse events has similar elements as that of receiving positive pathogen results during environmental monitoring:

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

Pre-clean micro results are used to evaluate risk and extent of contamination (evaluation action)

Post-sanitize micro results are used to verify hygienic condition (verification action)

Positive Pathogen Result – After Hygienically Adverse Event

1. **Initial Response**
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

At the time micro results are received

- Containment is already in place to prevent spread of any contamination potentially present
- Production may already be stopped
- Product may already be on hold

Notify the Environmental Pathogen Response Team working with the Event

Positive Pathogen Result – After Hygienically Adverse Event

1. Initial Response
2. **Evaluation Actions**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Pre-clean micro results are use to help evaluate the situation
  - Indicate less likelihood of pathogen presence, or confirm presence of pathogens
  - Identify locations of pathogen harborage
  - Indicate widespread contamination and need to widen area of concern

Positive Pathogen Result – After Hygienically Adverse Event

1. Initial Response
2. Evaluation Actions
3. **Corrective Actions**
4. Verification Actions
5. Preventive Actions
6. Records

- Fix or contain the source of contamination
  - Fix or contain leak (or install temporary containment)
  - Unclog drain
  - Enhance construction containment
  - Maintain traffic restrictions until the area is verified hygienically acceptable

- Clean and sanitize the positive site, all surfaces in the surrounding area that are potentially contaminated, and all sites identified as potentially contributing to the positive finding

Positive Pathogen Result – After Hygienically Adverse Event

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. **Verification Actions**
5. Preventive Actions
6. Records

- After implementing corrective actions, sample surfaces to verify hygienic condition. Post-sanitize micro results may
  - Verify hygienic condition, or indicate the area is not acceptable
  - Identify locations where sanitizing was not effective
  - Indicate corrective or preventive measures were not effective
- Followup
  - If location is again positive evaluate sanitizing method and sanitizability, reclean, and verify
  - After a positive pathogen result, three consecutive environmental testing events are required before containment is removed
  - Implement elevated level of sampling for the positive site(s) and surrounding area during routine PEM (at least next three weekly sampling events)

Positive Pathogen Result – After Hygienically Adverse Event

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. **Preventive Actions**
6. Records

- Examples of preventive actions:
  - Fix leak permanently
  - Replace inefficient processing equipment
  - Replace drains
  - Implement or strengthen hygienic zoning program
  - Change traffic pathways (construction)
  - Implement program to reduce water presence

Positive Pathogen Result – After Hygienically Adverse Event

1. Initial Response
2. Evaluation Actions
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. **Records**

Purpose:

To provide evidence of proper and effective actions assuring environmental pathogens are under control and that food is safe

Include:

Circumstances, evaluation results, corrective actions, verification results, preventive actions

Positive Pathogen Result – During Finished Product Testing

- Routine Finished Product Microbiology Verification Testing
  - Product is on quarantine, generally lot has microbiological lot separation
  - No known cause of the positive pathogen result

- Risk assessment or verification after a hygienically adverse event
  - Product is on quarantine
  - Known potential cause of the positive pathogen result

Generally finished product testing is not an effective method by itself to assure product safety because low level or sporadic contamination is not likely to be detected. Finished product testing usually contributes only a small amount of food safety assurance.

Positive Pathogen Result – During Finished Product Testing

1. **Initial Response**
2. **Evaluation Actions**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Notify according to predetermined response plan
- Shut down line(s)
- Keep product on hold
- Assemble Product Risk Assessment Team
- Gather the facts
  - Identity of product and lot for the positive sample
  - Production time of positive sample(s)
  - Time of cleaning and sanitizing events

Positive Pathogen Result – During Finished Product Testing

1. **Initial Response**
2. **Evaluation Actions**
3. Corrective Actions
4. Verification Actions
5. Preventive Actions
6. Records

- Confirm micro lab controls
- Retesting will not negate a previously positive result, but may be helpful for determining extent of the contamination
- If pathogen-positive product lot has been shipped, FDA Reportable Food Registry may need to be notified. A product recall may be needed.
- Investigate and determine root cause using immediate, organized, and thorough approach
  - Consider ingredients, processing records, environmental pathogen monitoring, hygienically adverse events, construction containment, emergency situations, downtime, sanitizing methods, new personnel, interview for anything unusual
- Determine corrective action plan, verification plan, preventive action plan

Positive Pathogen Result – During Finished Product Testing

1. Initial Response
2. Evaluation Actions
3. **Corrective Actions**
4. **Verification Actions**
5. **Preventive Actions**
6. **Records**

- Corrective action examples:
  - Product disposal
  - Equipment sanitizing
- Preventive action examples
  - Enhanced supplier controls
  - Enhanced process controls
  - Enhanced environmental controls
  - Enhanced GMPs
  - Training
- Verification
  - Controls
  - Test and hold product for several production runs
- Record

Regulations – Preventive Controls for Human Food

21CFR 117.150(a)(1) "You must establish and implement written corrective action procedures…..to address….."

(i) "The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing…..

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring….."

117.150(a)(2) "The corrective action procedures must describe the steps to be taken to ensure that:"

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated….."

FDA Regulations – Preventive Controls for Human Food

21CFR 117.150(d) “All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with 21CFR 117.155(a)(3) and records review in accordance with 21CFR 117.165(a)(4)(i).”

21CFR 117.155(a)(3) “Verification activities must include…..verification that appropriate decisions about corrective actions are being made…..”

21CFR 117.165(a)(4)(i) “You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include…..review of monitoring and corrective action records within 7 days after the records are created or within a reasonable timeframe…..by (or under the oversight of) a preventive controls qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.”

FDA Regulations – Preventive Controls for Human Food

21CFR 117.305 “Records must: Be kept as original records, true copies….or as electronic records…..”

21CFR 117.315(a)(1) “All records…..must be retained at the plant or facility for at least 2 years after the date they were prepared.

21CFR 117.315(c) “Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review…..Electronic records are considered to be onsite if they are accessible from on onsite location.”

21CFR 117.320 “All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.”

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Questions?
Comments to share?