FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Inspiring Trust, Assuring Safe & Nutritious Food
Ministry of Health and Family Welfare, Government of India

# Within-lot and between-lot sampling and statistics / supplier buyer relationships


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# When & Where to Test for Food Safety Management

- When there is good evidence that:
  - There is a microbiological problem
    - Food safety or quality
    - Historical or current

AND

  - Testing will help to verify the problem is under control

Or

  - Testing will help to investigate the extent /nature of the problem

# Statistical basis for sampling

Statistical basis is that:

- analyses performed on a sufficient number of samples from single lot to give *high degree of confidence* that lot does not contain an *unacceptable* level of microorganisms affecting
  - *quality*

  and
  - *safety*

  of a food

# Targeted Sampling and Testing

- Within-lot testing
  - Establishes the safety or quality of a specified lot
  - E.g., ingredient or port-of-entry sampling
- Between-lot testing
  - Verifies process and practices are being performed as intended
  - E.g., **process control testing** within a facility

# Key concept in understanding statistical basis of testing

Defect rates

- Portion of servings or containers that do not satisfy some attribute e.g. absence in a defined quantity

Or

- Below a specified concentration

As acceptable defect rate becomes smaller → increasing need for resources e.g.

- analysing more samples per lot

Or

- Increasing size of the analytical units

# Problems with low acceptable defect rates

Consider 2 lots of Ready-to-eat foods requiring absence of *Salmonella*:

- One has 50% of portions contaminated and another has 1% portions defective

  - In 1st lot, analysing only 3 servings has 87.5% probability of identifying lot as contaminated

  - 2nd lot, analysing 100 servings gives only 63% of identifying defective

# ICMSF Sampling Plans

- ICMSF sampling plans apply when:
  - Information indicates a potential for contamination

    OR
  - Production conditions and history are not known
- A “within-lot” testing approach

# Important concept of within-lot testing

Assumes

- Little or no knowledge about product, processes and conditions under which food is manufactured and distributed

  - No prior knowledge of lot assumed

  - Results from testing one lot cannot be considered predictive of other lots

# Supplier-Buyer Relationships

- Aim of supply chain should be to prevent or minimise contamination and/or introduction of pathogens with raw materials
- Suppliers contribute to food safety by reducing levels of specific pathogens in primary production/processing
- Prevention of product re-contamination or cross contamination after processing plays a critical role
- Inappropriate or unhygienic factory processing will lead to microbial survival, spread and cross contamination
- Measures specified to control variability of raw mat. must be realistic and operating targets offset (to safe side) based on knowledge of process, ingredient and supplier variability
  - **Requires careful selection of suppliers**
  - **Establishing partnerships rather than playing off one against another for cost**

# Supplier testing

- Suppliers of ‘sensitive’ raw materials with regard to microbiological safety or spoilage, may have to test their products against the buyer’s specification
- They provide buyer with a certificate of analysis for relevant parameters with each shipment to verify compliance.
- Buyer may also analyse some raw materials after they are received – CoA verification.
- Micro. tests typically performed may involve indicator organisms or pathogens, or both.

- ➢ Suppliers considered unacceptable are removed from list
- ➢ If you are aware your supplier has a problem, you need to act on that information and seek assurance that problem has been rectified

# Parameters that can be used to assess the acceptability of a supplier

| Component of the Food Control System | Expectation |
|---|---|
| Good Hygienic Practice | In place and consistent with best practice, *including verification testing e.g. pathogen environmental monitoring* |
| HACCP plan | In place and designed to control significant hazards based on an analysis of risk |
| FSO | Process is designed and validated to meet a FSO where established |
| PO | Process is designed and validated to meet a PO where established |
| Performance criteria | Validated process(es) that meet the performance criteria |
| Process criteria | Process criteria incorporated into HACCP plan as critical limits |
| Product criteria: Organoleptic, chemical, physical and biological specifications | Meets specifications |
| Records | Records are complete, accurate and facilitate validation and verification |

ICMSF Book 7, 2nd edition, chapter 4

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# When it goes wrong

## Lactalis to withdraw 12m boxes of baby milk in salmonella scandal

**Emmanuel Besnier, chief executive of French dairy giant, says all products from contaminated factory will be recalled**


▲ A French government official checks baby milk products in a pharmacy in Orleans. Photograph: Guillaume Souvant/AFP/Getty Images

# Persistent environmental contamination

- 2004 – *Salmonella* Agona isolated from milk powders – 23 cases of illness in infants where strong epidemiological links to contaminated product and manufacturing environment
- 2005 – outbreak with same serotype caused 146 infant illnesses + environmental isolates recovered
- 2017 – outbreak caused by same serotype linked to 41 cases of illness in infants, with 18 hospitalised. All products recalled and manufacturing suspended.
- 2018 – July – restarted production following cleaning, dismantling equipment and closure of spray drying tower

⇨ Demonstrates importance of effective pathogen environmental monitoring programmes and taking appropriate action with positive findings

# Sampling plans applied at different steps may reveal differing levels of control

- Drink mix contains nonfat dry (NFDM) milk for infants, with no kill step
- Ingredients tested –ve using Case 14 (*n*=30x25g)
- Finished product also tested using Case 14, found +ve
- NFDM used at 60% in finished product
  - Lot size of NFDM = 100,000 kg → 750g tested per 100,000 kg
  - Lot size of drink mix = 10,000 kg → 750g tested per 10,000 kg
  - total of 7,501.6 g analysed versus 750g

⇨ Need to understand supplier sampling plans

⇨ Tightened sampling required and/or change supplier

# Tightened and Investigational sampling

Generally applied to situations where increased level of concern:

- Process deviation has occurred;
- Performance criteria have not been met;
- Raw material or product has failed to meet microbiological criteria;
- Food is from an operation with a history of inconsistent control;
- Food is from a region where there has been a recent increase in illness involving the same or similar type of food;
- Environmental monitoring indicator has shown that the equipment used to produce or package the product did not meet acceptable hygienic criteria or pathogens are detected.

Tighter sampling warranted when there is insufficient knowledge about a particularly sensitive ingredient or a food is intended for a sensitive population e.g. shipment from a new supplier or from a country in which the hygienic and manufacturing practices are not known may warrant increased sampling

# Targeted sampling and testing

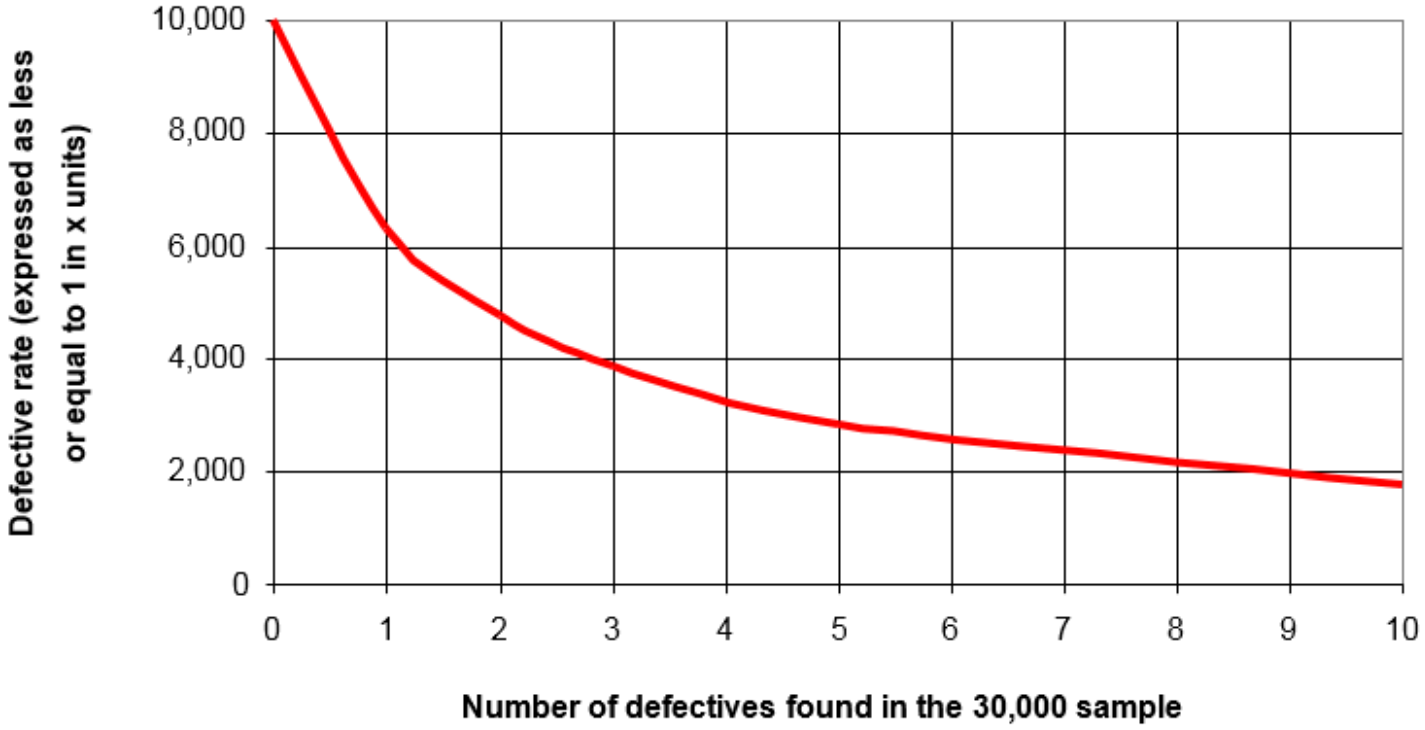
- May choose to use an investigational approach deliberately employing biased sampling.
- Targeted sampling of finished product often more efficient than random sampling when contamination associated with a time or sequence of production; such as the first product produced after a shut down, shift change, ingredient switch, mechanical repairs.
- Critical to identify affected lots (and associated sampling to establish this)

# Example of tightened sampling – aseptically-packed products

- Sampling elevated following particular events including failures after start-up, intervention stoppage, filling problems, seal integrity failures and commissioning new lines
- Target defective rate is normally <1 in 10,000 packs
- Initial sample size of 30,000, with 3 runs @10,000 with cleaning in between runs
  - Broth used as food matrix
  - pH reduction used to indicate microbial growth or turbidity
- When 1 or more +ves detected, possible to estimate defective rate

# New aseptic line commissioning

**Fig. 11.4: Estimation of the defective rate (95% confidence) when 30,000 units are sampled and when 0, 1… 10 defectives are found**



# Between-lot testing

Purpose

- *Not* to establish safety or quality of a specific lot
  - Safety and quality assumed to have been achieved by validating processes and practices controlling significant hazards
- *But* to verify that the process and practices are still performing as intended
  - Assumes detailed knowledge of how food is manufactured
  - Assumes actions have been taken to reduce variability between lots → allows loss of control to be readily identified

# Failure of within-lot and between-lot sampling & testing

- Failure of within-lot sampling indicates a potentially unacceptable lot
- Failure of between-lot sampling signals potential loss of control of a HACCP programme

# Conducting a process capability study

- Initial data collection must represent product manufactured when system is under control
- Ensure variability has been characterised properly
  - Need good reference level for ongoing performance assessment
- Requires usually >30 lots so that sampling error is acceptably small
  - Can do in phases or over longer period e.g. if raw material quality varies over a year, may need to extend over this period
- Perform initial analysis and set initial control limits
- Review and revise limits if necessary
- Intent is to detect loss of control *before* critical limit is exceeded
- Allows corrective actions to be taken proactively, before regulatory limits are exceeded

# Between Lot/Batch testing (cont.)

- The number of samples required becomes a limiting factor when the defect rate is small; e.g., Cases 13-15
- Cumulative data collected over many production lots will be useful to verify the value of across lot testing to verify compliance with Microbiological Criteria.

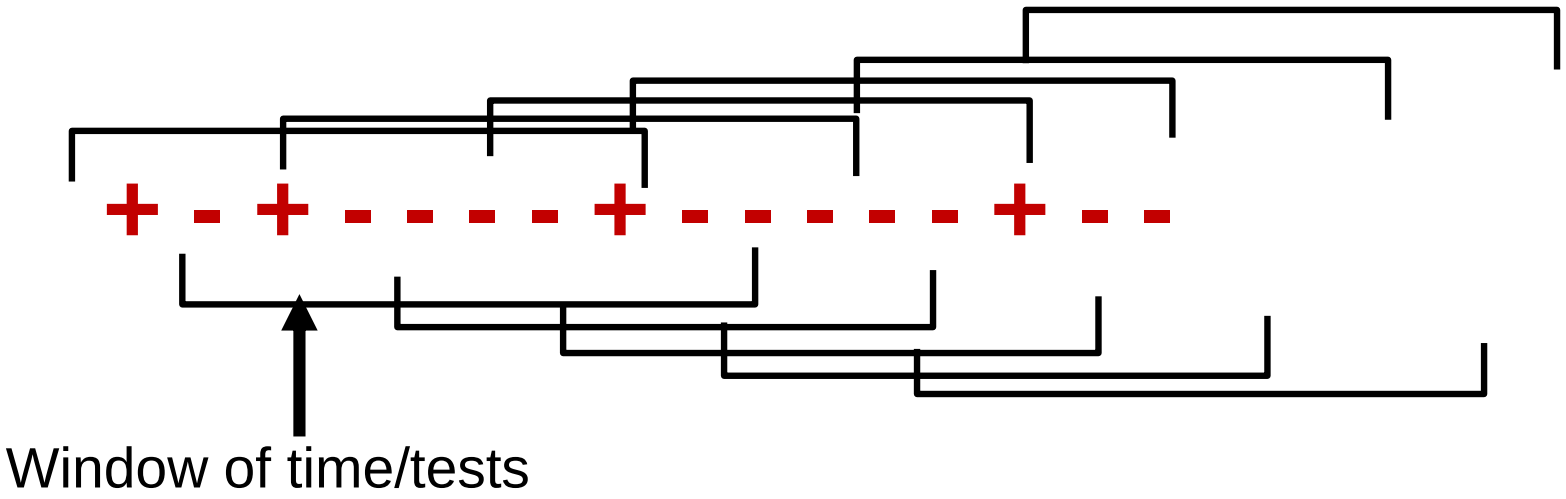
# Case and sampling plan performance, SD of 0.8

**Table 8.6** Cases and sampling plan performance assuming a standard deviation of 0.8. Lots having the calculated mean concentration or greater will be rejected with 95% probability

| | *Cases, sampling plans and calculation of their performance* | | |
|---|---|---|---|
| *Type of Hazard* | *Conditions reduce hazard* | *Conditions cause no change in hazard* | *Conditions may increase hazard* |
| Indirect | **Case 4** (three-class, $n = 5$, $c = 3$)<br>e.g. $m = 1000$/g, $M = 10000$/g<br>**Mean conc. = 5105/g (27849/g)** | **Case 5** (three-class, $n=5$, $c=2$)<br>e.g. $m=1000$, $M=10000$<br>**Mean conc. = 3282/g (17904/g)** | **Case 6** (three-class, $n=5$, $c=1$)<br>e.g. $m=1000$, $M=10000$<br>**Mean conc. = 1829/g (9976/g)** |
| Moderate | **Case 7** (three-class, $n=5$, $c=2$)<br>e.g. $m=1000$, $M=10000$<br>**Mean conc. = 3282/g (17904/g)** | **Case 8** (three-class, $n=5$, $c=1$)<br>e.g. $m=1000$, $M=10000$<br>**Mean conc. = 1829/g (9976/g)** | **Case 9** (three-class, $n=10$, $c=1$)<br>e.g. $m=1000$, $M=10000$<br>**Mean conc. = 577/g (3147/g)** |
| Serious | **Case 10** (two-class, $n=5$, $c=0$)<br>e.g. $m=0/25$g<br>**Mean conc. = 18/1000 g (100/1000g)**<br>**1cfu/55g (1 cfu/10g)** | **Case 11** (two-class, $n=10$, $c=0$)<br>e.g. $m=0/25$g<br>**Mean conc. = 5.6/1000g (31/1000g)**<br>**1 cfu/178g (1 cfu/33g)** | **Case 12** (two-class, $n=20$, c=0)<br>e.g. $m=0/25$g<br>**Mean conc. = 2.0/1000g (11/1000g)**<br>**1 cfu/495g (1 cfu/91 g)** |
| Severe | **Case 13** (two-class, $n=15$, $c=0$)<br>e.g. $m=0/25$g<br>**Mean conc. = 3.0/1000g (17/1000g)**<br>**1 cfu/328g (1cfu/60g)** | **Case 14** (two-class, $n=30$, $c=0$)<br>e.g. $m=0/25$g<br>**Mean conc. = 1.2/1000g (6.4/1000g)**<br>**1 cfu/854g (1 cfu/157g)** | **Case 15** (two-class, $n=60$, $c=0$)<br>e.g. $m=0/25$g<br>**Mean conc. = 0.5/1000g (2.7/1000g)**<br>**1 cfu/2034g (1 cfu/373g)** |

# Example: Moving Window Sum

An across lots attribute sampling plan



# Example of moving window

## Sampling scheme for broiler carcasses with n=5

| | Week number | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | Total positive pools after 10 weeks |
| Number of positive pools per week (out of 5) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 1 | | | | | | | | | | | 5 |
| | | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 1 | 1 | | | | | | | | | | **6** |
| | | | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 1 | 1 | 0 | | | | | | | | | **6** |
| | | | | 0 | 0 | 0 | 0 | 2 | 2 | 1 | 1 | 0 | 0 | | | | | | | | **6** |
| | | | | | 0 | 0 | 0 | 2 | 2 | 1 | 1 | 0 | 0 | 0 | | | | | | | **6** |
| | | | | | | 0 | 0 | 2 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | | | | | | **6** |
| | | | | | | | 0 | 2 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | | | | | **6** |
| | | | | | | | | 2 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | | | | **6** |
| | | | | | | | | | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | 5 |
| | | | | | | | | | | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 |
| | | | | | | | | | | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |

Bold figures circled indicate non-compliance

# Summary and Conclusions

- Between Lot/Batch testing may be useful:
  - To verify process control when levels of the target organisms are sufficient to allow control charting
  - To verify that a process can consistently produce product that will be in compliance with a microbiological criterion
  - Examination of cumulative data can be useful, even if each lot was sampled and tested for compliance to a microbiological criterion
- The statistics for between lot testing are essentially the same as within lot testing
- For Buyers, need to understand sampling plans used by suppliers, including stringency and methods used