REPRESENTATIVE SAMPLING FOR MAP ANALYSIS & PACKAGE LEAK TESTING

A practical guide to planning representative tests across your production run.

One of the most common questions we are asked is:

> "How many packages should we test?"

Unfortunately, there is no single number that is correct for every food production line.

Testing five packs, ten packs or one pack every hour may sound like a sampling plan, but the number alone does not tell you whether those samples adequately represent your production.

A good sampling plan considers:

- what you are trying to verify
- the size and duration of the production run
- the consequences of a failure
- how consistent the process is
- the expected frequency of defects
- the number of packaging lines, lanes, sealing heads or filling stations
- changes occurring during production
- previous process performance
- the level of confidence required

The food manufacturer should determine and document its own sampling frequency as part of its quality or food-safety system.

Representative Sampling Matters

The objective is not simply to test a certain number of packs.

The objective is to take samples that are **representative of the production process.**

For example, taking ten consecutive packages from the same lane at 10:00 am may tell you something about production at 10:00 am, but very little about a six-hour production run involving several sealing heads, operators or product changeovers.

Where practical, samples should be distributed across the production run.

Consider sampling from:

- the beginning of production
- different times throughout the run
- different packaging lanes
- different sealing heads or cavities
- different operators or shifts
- immediately following changeovers
- after machine adjustments
- after film, tray or packaging-material changes
- after interruptions or maintenance
- towards the end of the production run

Within these groups, packages should be selected as randomly as practicable rather than always choosing the easiest package to reach.

First Define the Lot

Before deciding how many samples to take, determine what the sample is intended to represent.

A production lot might be defined by:

- one production batch
- one product run
- one shift
- one packaging-material batch
- one machine or packaging line
- a defined production period

If conditions change significantly during production, it may be more appropriate to treat the production as separate sampling groups rather than assuming one sample represents everything.

MAP Headspace Analysis

For Modified Atmosphere Packaging, headspace analysis may be used to verify parameters such as:

- residual oxygen
- carbon dioxide concentration
- balance gas
- consistency of gas flushing
- stability of the packaging process

A representative MAP sampling plan should account for sources of variation that could influence gas composition.

For example, if a tray sealer has four sealing positions, repeatedly testing product from only one position may fail to identify a problem affecting another position.

Rather than simply asking “How many packs should we test?”, consider asking:

> **“Are we testing enough packages, from enough points in the process, to detect a meaningful change?”**

Package Leak Testing

The same principle applies to package integrity testing.

Potential package defects may not occur evenly throughout production. Problems can be associated with:

- individual sealing heads
- contamination in the seal area
- incorrect sealing temperature or pressure
- damaged tooling
- folds or wrinkles in film
- packaging-material variation
- product trapped in the seal
- machine adjustment or start-up conditions

Sampling should therefore be distributed so that these potential sources of variation are represented.

Where package integrity is particularly critical, manufacturers may choose a higher testing frequency, automated inspection or, where practical, 100% package testing.

Sample Size and Probability

A small sample can identify an obvious widespread problem, but it is much less effective at detecting an occasional defect.

This is an important point when deciding whether a sampling plan is adequate.
As a simple statistical illustration, assume:

- packages are selected randomly
- defects occur independently
- the underlying defect rate is constant

The approximate number of packages that would need to be tested to have a 95% chance of finding at least one defective package would be:

ACTUAL DEFECT RATE IN PRODUCTION	SAMPLES REQUIRED FOR APPROXIMATELY 95% PROBABILITY OF DETECTING AT LEAST ONE DEFECT
20%	14
10%	29
5%	59
2%	149
1%	299

This does not mean that every manufacturer should test 299 packs.

It demonstrates why testing only a very small number of samples cannot provide strong statistical assurance that rare defects are absent.

For example, if approximately 5% of packages were defective, testing ten randomly selected packages would provide only around a 40% probability of encountering at least one defective pack. Sampling cannot prove that every untested package conforms.

Start With Risk

Testing frequency should generally increase where:

- the food-safety consequence of failure is greater
- MAP composition is important to product safety or shelf life
- package integrity is critical
- a new product or package is being introduced
- equipment has recently been commissioned
- process capability has not yet been established
- defects have previously been identified
- production conditions are changing
- maintenance or adjustments have been performed

Once a process is well understood and consistently controlled, historical data may support a different sampling frequency.

Any reduction should be based on evidence rather than convenience.

Consider Increased Testing After a Failure

A sampling plan should also specify what happens if a result is outside specification.

Depending on the manufacturer's procedure, this may include:

- immediate retesting
- increasing the number of samples
- checking other packaging lanes or sealing positions
- placing potentially affected production on hold
- identifying when the process was last known to be within specification
- investigating equipment and packaging conditions
- correcting the process
- verifying the correction before production continues

Finding one failed package should generally trigger investigation rather than simply testing another package until one passes.

Trend the Results

Individual measurements are useful.
Trends are more useful.

Recording MAP and leak-test results over time can help identify gradual changes before they become obvious failures.

Useful information to record may include:

- date and time
- product
- batch or lot
- packaging line
- sealing head or position
- operator
- O_2 result
- CO_2 result
- leak-test result
- specification limits
- corrective action where applicable

Consistent records can help manufacturers determine whether their existing sampling frequency is providing adequate process visibility.

A Practical Sampling Approach

A representative routine might therefore involve:

- **Start-up verification**
Confirm that the process is operating correctly before or shortly after normal production begins.
- **Samples throughout production**
Spread testing across the production period rather than taking all samples together.
- **Representative machine positions**
Rotate sampling between sealing heads, lanes or cavities where these could behave differently.
- **Event-based verification**
Perform additional testing following changeovers, adjustments, maintenance, stoppages or material changes.
- **End-of-run verification**
Where appropriate, confirm that the process remained stable through the end of production.
- **Escalation following failure**
Increase inspection and investigate when an abnormal result is identified.

The exact number and frequency should be determined by the manufacturer according to the product, process, risk and established quality or HACCP plan.

Can SGTA Help Me Determine Testing Parameters?

SGTA can assist with the measurement technology and practical testing methodology, including:

- MAP headspace gas analysis
- O_2 and CO_2 measurement
- package leak detection
- gas mixing and process control
- equipment calibration
- development of repeatable equipment test procedures

However, SGTA cannot prescribe the number of samples that a food manufacturer must test or determine whether a particular sampling plan satisfies that manufacturer's HACCP, regulatory or customer requirements.

Those decisions should be made by the manufacturer and its appropriately qualified food-safety or quality personnel.

Further Guidance

Organisations developing formal statistical sampling plans may wish to refer to:

Codex Alimentarius – CXG 50-2004
General Guidelines on Sampling

ISO 2859-1
Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit for lot-by-lot inspection

Other commodity-specific standards or customer requirements may also apply.

Specialised Gas Technologies Australia
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