What is 'Validation'?

22 September 2017

Guidance Document

Purpose

This Guidance Document has been developed by the Ministry for Primary Industries (MPI) to help food operators understand the concept of validation. It should be used by businesses operating a Risk Management Programme (RMP) under the Animal Products Act 1999 (APA) and could be useful for businesses operating a Food Control Plan (FCP) under the Food Act 2014.

This guide is not intended to provide technical detail. You should refer to the Risk Management Programme (RMP) Manual or seek assistance from food safety consultants.

What is Validation?

Validation is the process of collecting evidence (e.g. scientific technical information or records) to show that your RMP is capable of consistently producing the desired outcome. Validation can be simple to very complex depending on the product or process to be validated.

Why do I need to Validate?

You are required to validate the effectiveness of your RMP to ensure it can consistently produce product that is fit for its intended purpose and meet relevant regulatory and operator-defined limits. A RMP that is not properly validated cannot provide assurance that hazards are effectively managed.

What do I need to show?

Validation includes measuring product or process performance against the desired outcome. The following table lists some examples of evidence that can be used to demonstrate that you have achieved the desired outcomes.

Table 1: Example of desired outcomes to be achieved and possible evidence

Examples of desired outcomes	Examples of evidence
Setting regulatory limits and operator-defined limits (e.g. product characteristics, acceptable level of hazards in a product is achieved, process parameters).	New Zealand food legislation: • APA Notices • Food Standards Code Operator-defined limits: • Codes of Practice • internationally recognised standards • published scientific literature • industry agreed criteria • own validation research and trials
Product characteristic related to food safety and shelf stability (e.g. pH, moisture content, water activity). This can be an acceptable level of hazard in a product, e.g. microbiological criteria, maximum levels of chemical residues or metal contaminants.	• data from previous or current validation studies (including experiments such as challenge trials) • monitoring records of a control point (CP)

Examples of desired outcomes	Examples of evidence
Process parameters (e.g. pasteurisation time and temperature, thermal process lethality such as a 6-log reduction in *Listeria monocytogenes*, or cooling rate)	• equipment commissioning reports • equipment calibration reports or certificates Existing businesses and processes (provided no changes have been made to the process): • data from previous or current validation studies (including experiments such as challenge trials) • monitoring records of a control point (CP) New businesses or processes: • microbial modelling • lethality calculations • data from validation studies (including experiments such as challenge trials) • trials to show process parameters (e.g. time and temperature) are met during commercial operation
Good Operating Practices (GOP) are effectively implemented	• records generated for each GOP (e.g. training and cleaning records)

Note that validation is often not simply running trials in your process. It involves designing a robust experiment to show the data you have collected is statistically valid (i.e. good sample collection) and how you will analyse your data to determine if the desired outcomes have been achieved.

The use of manufacturer specifications or claims about performance is unlikely to be sufficient to validate the performance of new processing equipment (especially equipment that is used to deliver a critical processing step, e.g. thermal processing or high pressure processing). You will need to obtain evidence from experimental trials to validate that new machinery is functioning as intended.

What is the difference between validation, operator verification and monitoring?

There is often confusion between validation, operator verification and monitoring. Validation confirms that product is fit for its intended purpose. Monitoring and verification both take place after the validation has been completed. They are tools to check that procedures are being followed, or that equipment is operating as intended, i.e. confirming you are doing what you planned to do.

Operator verification can be observing personnel as they monitor control points, or reviewing records to show the limits have been met. Monitoring of control measures is an on-going activity to make sure the process is functioning as intended, e.g. collecting 'real-time' measurements such as temperature data.

Stepping through a Validation process

Figure 2: Flowchart of steps to validation guides you through the steps recommended for validation. You should develop a clear purpose, and plan how the evidence will be collected and analysed (a protocol). Perform trials and carry out the relevant data analysis. When you have the evidence to show your process can achieve the desired outcome, it is recommended that you write a validation report. The suggested contents of the validation report are shown in Table 2.

Validation can be either completed before you register your RMP (you will need to give your full RMP and the validation report/evidence to your evaluator to be evaluated) or after the RMP has been registered (provided a protocol was developed and evaluated). In that case, validation must be carried out within the specified timeframe after the RMP is registered.

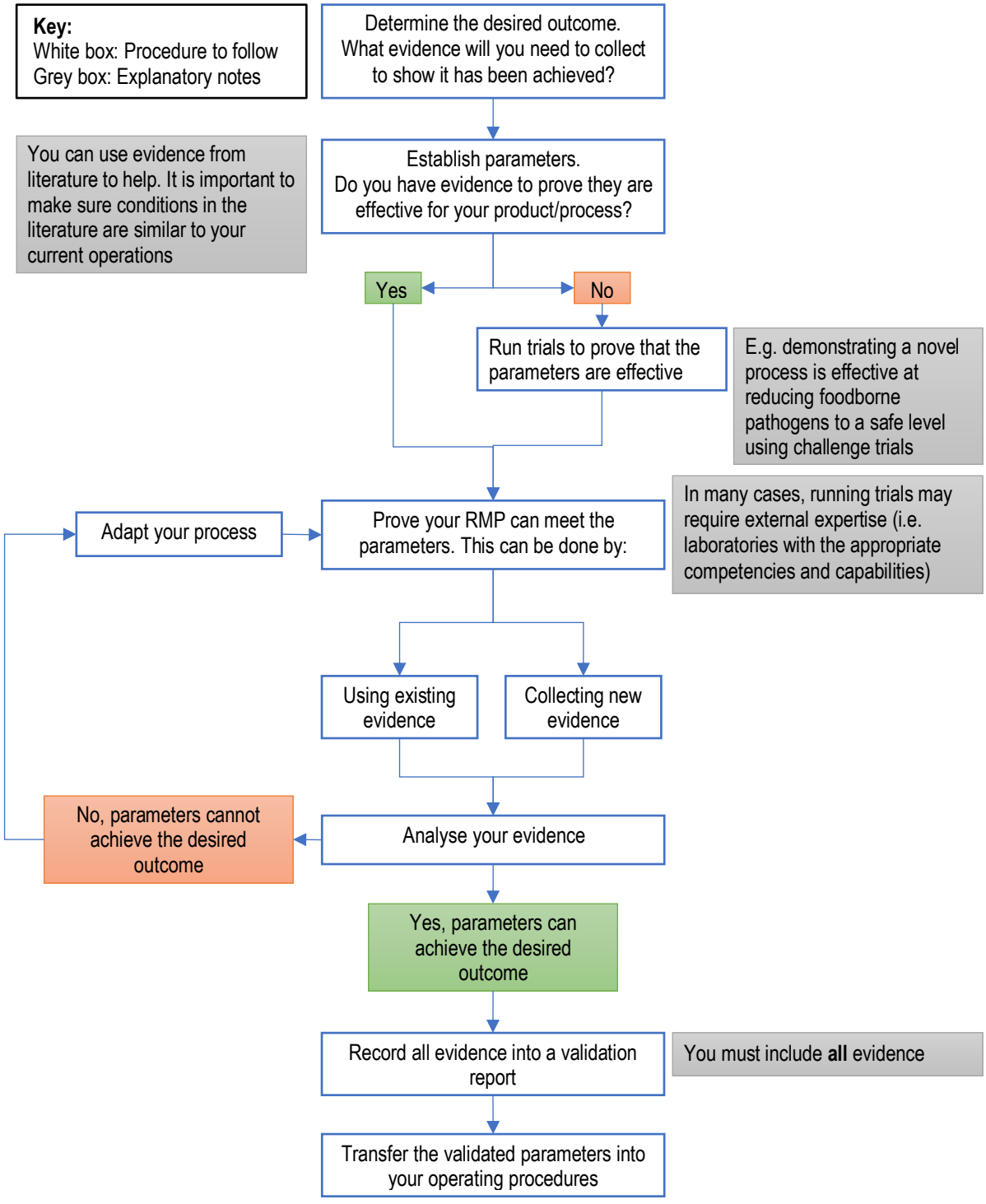
You may need to revalidate whenever there is a change that could affect the control of hazards (e.g. new equipment, raw materials or control measures), or if new scientific or regulatory information becomes available.

You may also need to revalidate when there is a system failure, or if non-conformances indicate the current control measures are ineffective.

Table 2: Suggested content of a validation report

Sections	Suggested Headings	Examples of what to include
1	**Scope and Purpose of the validation** What am I trying to validate?	• what is the desired outcome? Are you trying to show that a product or process parameter is being met, or that GOP is effective? (refer to Table 1) • what are the regulatory or operator-defined limits to be met? • any product characteristics (e.g. water activity, formulation, pH) • the process (e.g. pasteurisation, Ultra High Temperature (UHT), high pressure processing) and any process parameters • GOP(s) to be validated (e.g. cleaning)
2	**Competencies**	• person responsible for validation and any required competencies • any training for personnel working on the process line (e.g. plant personnel, plant managers) prior to starting validation? • are you relying on external or in-house technical expertise?
3	**Equipment**	• identify the equipment to be validated • commissioning reports • calibration reports or certificates • maintenance schedule
4	**Criteria against which effectiveness will be determined**	• regulatory or operator-defined limits (e.g. product characteristics, acceptable level of hazards in a product or process parameters) • GOP requirements, e.g. water testing, effectiveness of cleaning and sanitation
5	**Trial Design**	Either: • do you have any previous data, records or reports to demonstrate what you are trying to validate is effective? Make sure the data is collected under your current processing conditions. Or: • trial design: – equipment set-up – any specific trial conditions you need to meet – worst-case operating conditions, (e.g. maximum loading, throughput, essential services, seasonal variations, shifts) – what data will be collected – any other variables that need to be considered • sampling design: – types of sample – number of samples to be collected, how often, any replicates? **Your sampling plan should be statistically valid.** – location of sampling sites – sensitivity of your method, repeatability and consistency • method of analysis: in-house, external (accredited or non-accredited method)?
6	**Product disposition**	• how the product resulting from the trials is to be disposed, (e.g. test and release, rework, downgrading or dumping)
7	**Results**	• overview of the data collected (raw data should be included in the appendices) • analysis or interpretation of the data (**outliers should not be discarded** without good justification) • repeated testing of the same product until desired results are obtained is not acceptable • confirmation product disposition has occurred as planned
8	**Conclusion**	• have the desired outcomes been met? Does the evidence support the conclusions made? If not, you will need to adapt your trial design • have validated parameters been transferred to operating procedures?

Figure 1: Flowchart of steps to validation



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