Workflow: Product Quality

Toolkit 5.5
Change Control

target audience

Leadership, quality contractors, service providers, supervisors, product agents, and strategic partners.

what it is

Change control is the process through which all requests to changing an existing configuration, standard, or specification are captured, evaluated, and then approved, rejected, or deferred. A single change required by the Global G.A.P. could impact multiple operating and safety standards, data collection and document control systems, and employee training.

Any change introduced comes with an element of risk and changes cannot be avoided in a real-world operation. The focus of this toolkit is on managing these changes to reduce or eliminate risks associated with change. Changes in the workplace that may require a formal change control process can typically be grouped into one or more of the following categories:

➢ **Product Specifications** – Refers to changes required by existing customer groupings or changes required by new markets. Any change impact on food safety should be subject to formal change control.

➢ **Equipment or Process** – Refers to both simple and complex process changes as well as the installation or purchase of new equipment. Any change that impacts on health and safety should be included. Refer to Toolkit 6.1 - Embedding Safety Culture and Practice.

➢ **Operating Procedures and Conditions** – Refers to new standards for operating or maintaining the process that requires revising operating procedures or operating conditions. Refer to Toolkit 2.5 - Standard Work and Workflow 3 - Production: Basic Farming Standards.

➢ **Production Supplements (Fertiliser, herbicides, etc.)** – Introducing new or substitute ingredients which may impact process performance or finished product characteristics.

➢ **Staffing** – The loss of skilled, experienced employees due to turnover or any change in the number of employees, e.g., shift or team changes due to Covid-19 risk management measures.

Small changes will not require a rigorous change control process but should not be under-estimated. They should still be considered at the appropriate level and the impact escalated if necessary, i.e., where there are any safety concerns.

The change process refers to the policies and procedures that are enacted proactively to ensure the continued safe operation and maintenance before, during, and after one of the changes described above.

why it is important

Change is likely to occur in any operation. Being able to recognise the change and then develop and implement proactive change control actions will reduce the impact or risk that could be negative. Replacing an irrigation pump system without considering the impact on water pressure and irrigation infrastructure (filters, water lines, valves) could not only result in damage to equipment, but also (potentially) put trees under stress (lack of water).

Change control refers mainly to known or expected changes. Unexpected changes would require a thorough analysis to determine root causes (Refer to Toolkit 12 - Structured Problem Solving), the outcome of which could be taken through a formal change process.

Anticipated or planned changes will lead to unexpected outcomes and a material increase in safety risk if these changes are not planned and managed properly. A well-designed change process minimizes the safety risk and increases the chance that the change will achieve the desired results.

success factors

➢ Understand and describe what situations requires formal change control.

➢ Develop a formal change control procedure including change control steps, responsibilities (ensuring the involvement of management as well as specialists) and timelines for sign-off.

➢ Define an escalation procedure for non-routine decisions.

➢ Develop a Risk Management Plan, formally identifying and analysing potential hazards. Refer to the Basic Risk Assessment Template.

➢ A clear link to Project Management. Refer to Toolkit 13.3 - Managing Focused Improvement. The replacement or modification of equipment and, similarly, changes to the treatment of product would usually be executed through a formal project management process. Change control should be a standard activity in the project plan.

➢ For example, if the farm decides to reroute the path through which product flows in the operation then it should almost certainly initiate a change control request because making the change would require shutting down the operation and afterward will affect product flow and farm layout, which potentially introduces new safety hazards. Furthermore, employees will likely need to be trained in how to safely interact with the new process flow. Conversely, if the farm decided to install a whiteboard on the wall in the main conference room in the administrative building, then a formal process would appear to be "overkill" since the change would have no impact on the operation, nor would it appear to pose a material safety risk.

execution steps

1. Clearly define the criteria for the types of changes in the operation that require a formal Change Control process. The criteria should consider the types of changes described previously:

   a) Product specifications.

   b) Equipment or process.

c) Operating procedures and conditions.

d) Product supplements (ingredients).

e) Staffing.

2. Establish a formal Change Control process and required forms to document the implementation of the change. Clearly distinguish between changes that would require a formal change process and smaller controlled changes that might only require a good communication plan. All staff should be sensitised to be aware of the impact of change and should be comfortable to challenge decisions if necessary.

3. Train the workforce on the Change Control process and reinforce the importance of following the process under all circumstances.

assessment questions

Please Note: There is no minimum / maximum amount of questions you can add

1.	Is there general awareness for the need to do change control?
2.	Are there guidelines for Change Control categories?
3.	Have the criteria for formal Change Control been defined?
4.	Is there a formal SOP in place to guide formal Change Control?

resources

1.	Basic Risk Assessment Template
2.	Management of Change Flowchart