Food and Agriculture Organization
of the United Nations

HACCP – STEP 8, PRINCIPLE 3

ESTABLISH VALIDATED CRITICAL LIMITS

FAO Good Hygiene Practices (GHP) and
Hazard Analysis and Critical Control Point
(HACCP) Toolbox for Food Safety

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Food and Agriculture Organization of the United Nations
Rome, 2023

Required citation:

FAO. 2023. *Establish validated critical limits – Step 8, Principle 3.* FAO Good Hygiene Practices (GHP) and Hazard Analysis and Critical Control Point (HACCP) Toolbox for Food Safety. Rome. https://doi.org/10.4060/cc6263en

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Technical note for readers

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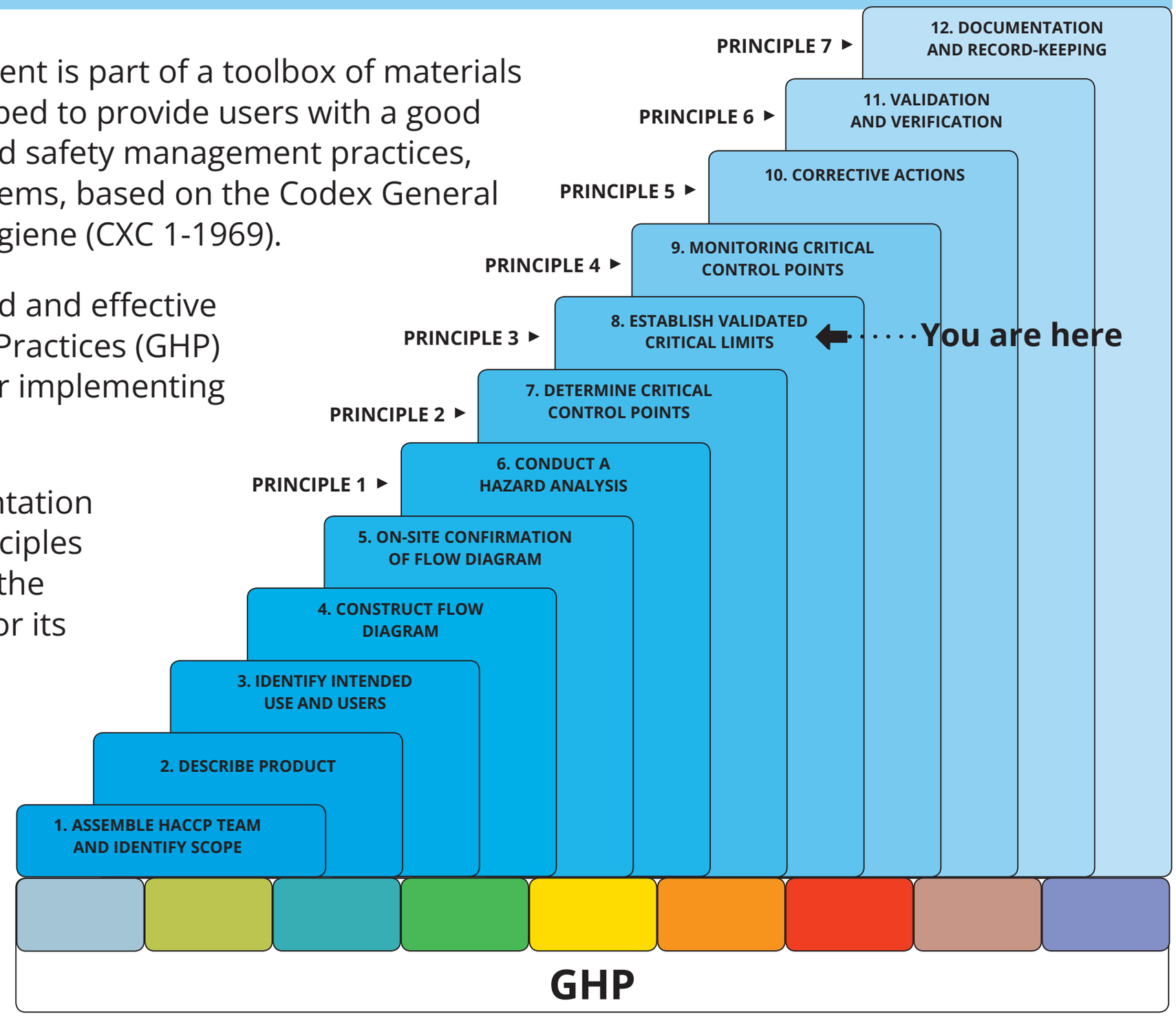
ESTABLISH VALIDATED CRITICAL LIMITS

INTRODUCTION

This guidance document is part of a toolbox of materials and has been developed to provide users with a good understanding of food safety management practices, including HACCP systems, based on the Codex General Principles of Food Hygiene (CXC 1-1969).

Well established and effective Good Hygiene Practices (GHP) set the foundation for implementing a HACCP system.

This graphic representation shows the seven principles of HACCP along with the 12 successive steps for its application.



ESTABLISH VALIDATED CRITICAL LIMITS

CONTEXT

Critical limits establish whether a critical control point (CCP) is in control, and can, therefore, be used to separate acceptable products from unacceptable ones. Critical limits should be measureable or observable and typically use minimum and/or maximum values or critical parameters, such as temperature, time, moisture level, pH, aw, conveyor belt speed, etc. Critical limits should be scientifically **validated** to ensure they are capable of controlling hazards to an acceptable level. In many cases, CCPs can be validated using available information and existing studies from credible sources.

Learning objectives

This document provides guidance on how to:

- establish critical limits that are measurable or observable;
- use critical limits to differentiate acceptable from unacceptable products;
- validate critical limits; and
- **document this step as part of the HACCP plan.**

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Principle 3: Establish validated critical limits

Codex definitions:

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/ are applied in a HACCP system.

Critical limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

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What are critical limits and why are they necessary?

Critical limits are:

- criteria that separate acceptable products from those that are unacceptable once the processing step/operation is completed;

- measurable or observable boundaries for CCPs that are used to judge whether an operation is producing a safe product (the product should move on to the next process step only if the criteria are met and the CCP was operated safely);

- indicators of how each CCP must be operated in order to prevent, eliminate or reduce to safe levels the most relevant hazards; and

- set for factors such as temperature, time, physical product dimensions, moisture levels, etc.

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Examples of critical limits

Hazard	CCP	Critical Limit
Bacterial pathogens (non-sporulating)	Pasteurization	72 °C for at least 15 seconds
Metal fragments	Metal detector	Metal fragments no larger than 0.5 mm
Bacterial pathogens	Drying oven	Aw <0.85 for controlling growth in dried food products
Excessive nitrites	Curing room/brining	Maximum 200 ppm sodium nitrite in finished product
Bacterial pathogens	Acidification	Maximum pH of 4.6 to control Clostridium botulinum in acidified food
Food allergens	Labelling	Label that is legible and contains an accurate list of ingredients
Histamine	Receiving	Maximum histamine level 25 ppm in evaluation of tuna for histamine*

*Regulatory action level is 50 ppm, but histamine levels may increase during production. Therefore, industry may want to set lower critical limits at receiving.

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Critical limits should:

- define how a CCP must be operated to achieve the intended hazard control;
- meet the requirements of government regulations and/or company standards and/or be supported by scientific data;
- be established once one or more CCPs have been identified; and
- be validated to ensure that the CCP controls the targeted hazards effectively and reliably.

By focusing on the safety and reliability of a process for effective hazard control a food business is able to guarantee much more reliable levels of product safety than through end-product testing because the process is:

- carried out according to defined safety criteria (critical limits);
- monitored in way that enables the operator to take action to prevent loss of control before critical limits are exceeded, ensuring that the operation stays within critical limits at all times; and
- stopped and corrected if there is any deviation from the critical limit as the food produced is likely unsafe.

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How to establish critical limits

- Establishing critical limits is a two-part process consisting of:
  - ➡ specifying the critical limits; and
  - ➡ validating the critical limits for each CCP.
- This requires both technological understanding of the process and scientific knowledge of the hazard.
- If the food business personnel do not possess the necessary understanding and knowledge, the food business should seek support and guidance from government, large retailers, consulting companies, etc.

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It is essential that the person(s) responsible for establishing critical limits know both the process and the legal and commercial standards required for the product. Sources of information on critical limits include:

- scientific publications and research data;
- regulatory requirements and guidelines;
- experts (such as thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians and academics); and
- experimental studies (including in-house experiments and contract laboratory studies).

If the information needed to establish critical limits is not available, a conservative value should be selected, or regulatory limits should be used.

The rationale and reference materials used should be documented and should be included in the supporting documentation of the HACCP plan.

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➡ Example: Ensuring the safety of hot foods at a buffet

A caterer who wants to ensure the safety of hot foods displayed at a buffet would have started with a hazard analysis and subsequent CCP determination. The logic flow of the thought process might be as follows:

- Food poisoning due to foods held at unsafe temperatures is a known problem because low concentrations of microorganisms can multiply to unsafe levels and produce toxins.
- To prevent this from happening, foods must be kept above 60 °C.
- Because temperature controls at this point can effectively prevent the described biological hazard, the process of holding foods is determined as a CCP.
- The caterer's HACCP team must now decide how to operate the CCP to ensure that the foods are always kept above 60 °C.
- The team will do this by defining critical limits (criteria that separate acceptability from unacceptability) for the process regarding keeping the foods at safe temperatures.

cont.

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Scenario I: use of a water bath with a heat source

In this case, the temperature of the water should be high enough to ensure that the foods are constantly above 60 °C.

The caterer must define how the heating process must be operated in order to achieve the food safety goal.

The critical limit would therefore be a defined temperature of the water bath, or (in the absence of a thermometer) an established number of fuel containers.

Scenario II: no special technology used to keep foods hot

In this case, the caterer must ensure that the foods are kept at a safe temperature when they leave the kitchen (for instance, ensuring that dishes are not left out at room temperature) and are consumed within a certain time after cooking to ensure they remain above 60 °C until they reach the customer.

The critical limit would therefore be a defined time frame within which foods must be served before they cool to unsafe temperatures.

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Challenges that may arise in specifying critical limits:

- Critical limits cannot be established because the CCP process cannot be adequately monitored. For example, if a plate pasteuriser does not include a thermometer, the temperature cannot be monitored.

- The CCP process cannot be operated according to critical limits because the design of equipment or facilities used in the process does not consider the food safety goal. Examples include a pasteurizing system that does not reach the temperature required to inactivate the targeted microorganisms and a storage facility for tree nuts that is too small for the quantity of nuts that is to be stored.

- There may be challenges in defining measurable critical limits for non-technological operations or processes, such as determining whether incoming raw materials are safe or not. In such cases, food businesses might opt to require documentation of raw materials that establish their safety. For instance, for temperature-sensitive raw materials, documents that prove that required temperatures where constantly maintained, or, for fish, documents that prove that fish were not caught in a danger zone.

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Validating critical limits

Because CCPs are unique to specific food processes, it is not possible to “copy and paste” critical limits from similar processes or foods, and assuming that this will result in the desired food safety outcome.

It is therefore necessary to obtain scientific evidence that the critical limits are effective in achieving the desired hazard control. This is referred to as validation.

To achieve this, the HACCP team must perform tests to demonstrate that the CCP is operating to the desired outcome.

Conditions under which tests are performed affect the outcome of the tests. As such, it is crucial that these conditions be considered when tests are performed. Ideally, the test conditions should reflect the actual conditions in which the food is stored or consumed.

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Conditions to consider when conducting tests to validate critical limits:

- date and time of day
- personnel performing the test
- ambient temperature
- serving size or quantity of food product
- type of product
- product storage

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Validating critical limits

It is not always necessary for food business operators to conduct or commission studies themselves in order to validate critical limits. Critical limits can be based on:

- existing literature;
- government regulations or guidance from competent authorities; and
- studies carried out by a third party, such as studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts.

For additional information on validating control measures, please consult the **Further reading** section accessible from the **SECTION LANDING PAGE**.

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Documenting critical limits

Once critical limits are established and validated, they should be documented and communicated, as follows:

- Critical limits must be documented in the HACCP plan and in the standard operating procedure (SOP) of the CCP.

- Critical limits must be communicated to the staff operating the CCP.

The HACCP team is responsible for documenting the critical limits. (See Supporting documents for templates and examples).

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Critical limit documentation format:

- Critical limits are commonly documented in the HACCP plan using a table format, however the HACCP team may choose any format they prefer.

- Key elements to be included in the documentation are:

  - name and number of the CCP (corresponding to the hazard analysis table)

  - critical limits

  - monitoring procedures

  - corrective actions

  - monitoring records

EXERCISE: FOOD SAFETY FOR THOUGHT

This is the little “game” we created. This will apply to all HACCP steps, except the intro.

8. ESTABLISH VALIDATED CRITICAL LIMITS

GHP are fundamental to the sucessful application of HACCP.

Think of a food operation that you are familiar with, and select those GHP elements that you feel are most relevant for the application of HACCP step 8.

GHP PROGRAMMES	✓
1. INTRODUCTION AND CONTROL OF FOOD HAZARDS	☐
2. PRIMARY PRODUCTION	☐
3. ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT	☐
4. TRAINING AND COMPETENCE	☐
5. ESTABLISHMENT MAINTENANCE, DISINFECTION, AND PEST CONTROL	☐
6. PERSONAL HYGIENE	☐
7. CONTROL OF OPERATION	☐
8. PRODUCT INFORMATION AND CONSUMER AWARENESS	☐
9. TRANSPORTATION	☐

Please explain your choices.

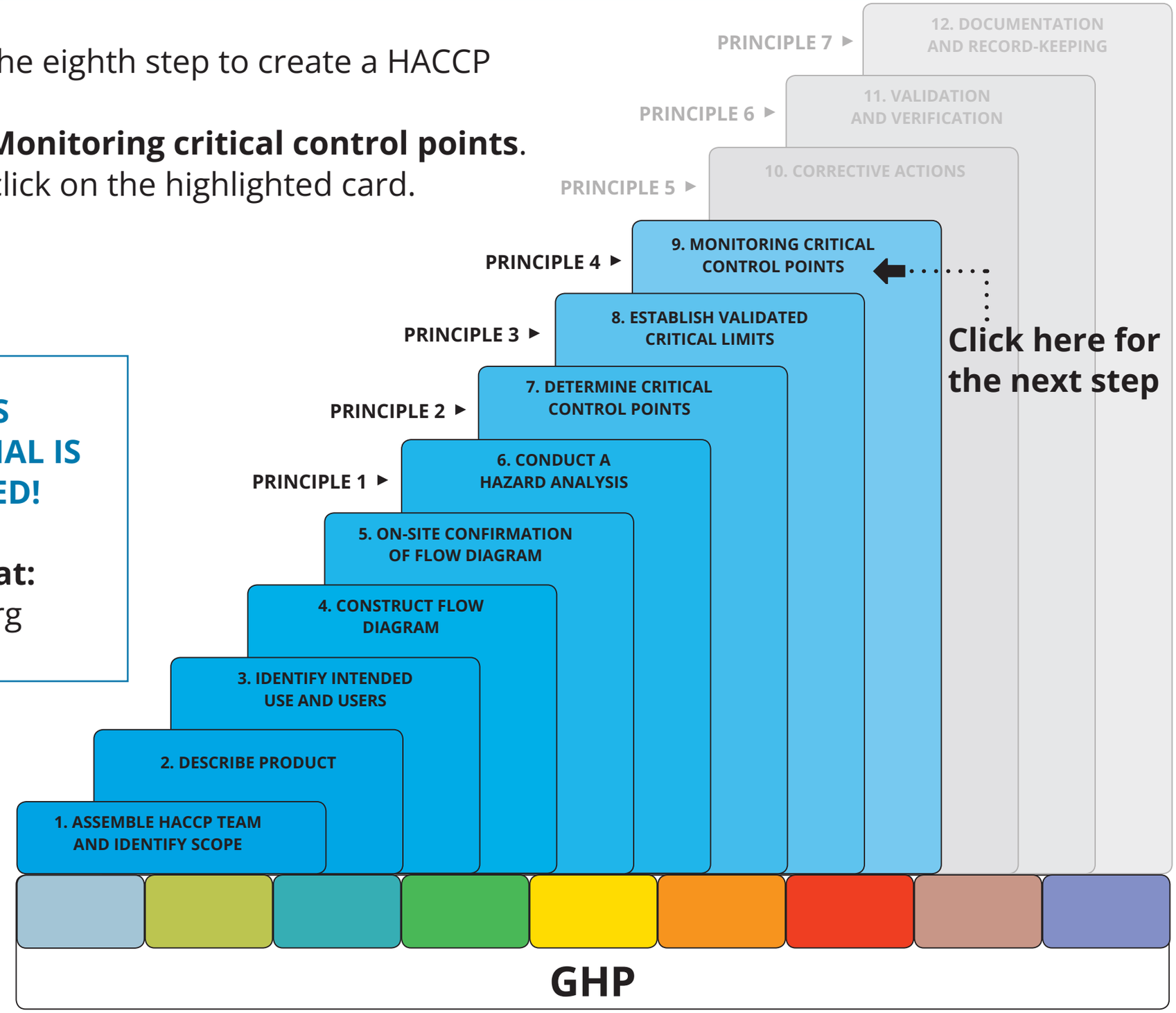
ESTABLISH VALIDATED CRITICAL LIMITS

KEEP READING

You have completed the eighth step to create a HACCP system.
The next step will be **Monitoring critical control points**.
To continue reading, click on the highlighted card.

FEEDBACK ON THIS GUIDANCE MATERIAL IS ALWAYS WELCOMED!

Please contact us at:
food-quality@fao.org



KEEP READING

GHP and HACCP Toolbox for Food Safety
www.fao.org/good-hygiene-practices-haccp-toolbox

FOOD SYSTEMS AND FOOD SAFETY –
ECONOMIC AND SOCIAL DEVELOPMENT
www.fao.org/food-safety

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CC6263EN/1/06.23