## ANNEX 1: HACCP: THE METHOD AND EXAMPLES

(Hazard Analysis, Critical Control Points):

### ANNEX 1.1. General information and prerequisites

The HACCP is a method used to effectively identify the critical points for which control measures are essential to preventing or limiting identified hazards. It is implemented for a given product and process, step by step and hazard by hazard.

The success of its application relies on the shared commitment of the management and the will of all of the staff. Another essential prerequisite consists of adhering to the general hygiene rules established for the profession; these good hygiene practices determine the effectiveness of the control measures (refer to the good hygiene practice recommendations section contained in this Code).

The management (from the higher management to the lower management) must be committed to the implementation of the Guide in order to help ensure safety of products. The management must ensure that responsibilities and authorities are defined, documented and communicated within the organisation.

The measures that have been included in the Code can be integrated into one of the operator's management systems when it exists, and notably complete the documentation system. It should also be pointed out that the HACCP system, like the management system undergoes amendments aimed at improving the method, in the light of regulatory, standards, technical and scientific developments.

### ANNEX 1.2. The application in 12 stages

#### Annex 1.2.1 Creating and running the HACCP team

***1.2. Defining the scope of the study:***

Based on the current regulations and potentially a summary of the customers' requirements, the management must:

- identify the hazards to be considered (biological, chemical and physical),
- determine the places and productions concerned (number of sites, types of production).

***1.3. Creating the HACCP team:***

Create a group of 2 to 8 people who possess the necessary skills and know about the hazards from which the operator wants to protect itself. This team must contain at least one representative of the decision-making power, a coordinator who will guarantee the method and a storage representative, in order to group together all of the necessary skills in the different domains (storage, maintenance, regulations, food and feed safety, hygiene etc.).

***1.4. Planning the initiative:***

Specify the different stages, the managers, the time scales and the dates on which checks will be carried out on the study's progress.

***1.5. Training:***

The operator must train:

- all staff on food and feed safety hazards and good hygiene practices based on this CODE
- the team responsible for the study of the HACCP method in order to successfully complete the project
- the field staff (silo, maintenance, and drivers) on applying the HACCP system

### Annex 1.2.2. Describing the product

Describe the raw materials received and the products marketed (preparation and processing carried out, physicochemical characteristics, food and feed safety characteristics, packaging – packing, storage length, storage conditions).

### Annex 1.2.3. Identifying the intended use of the product

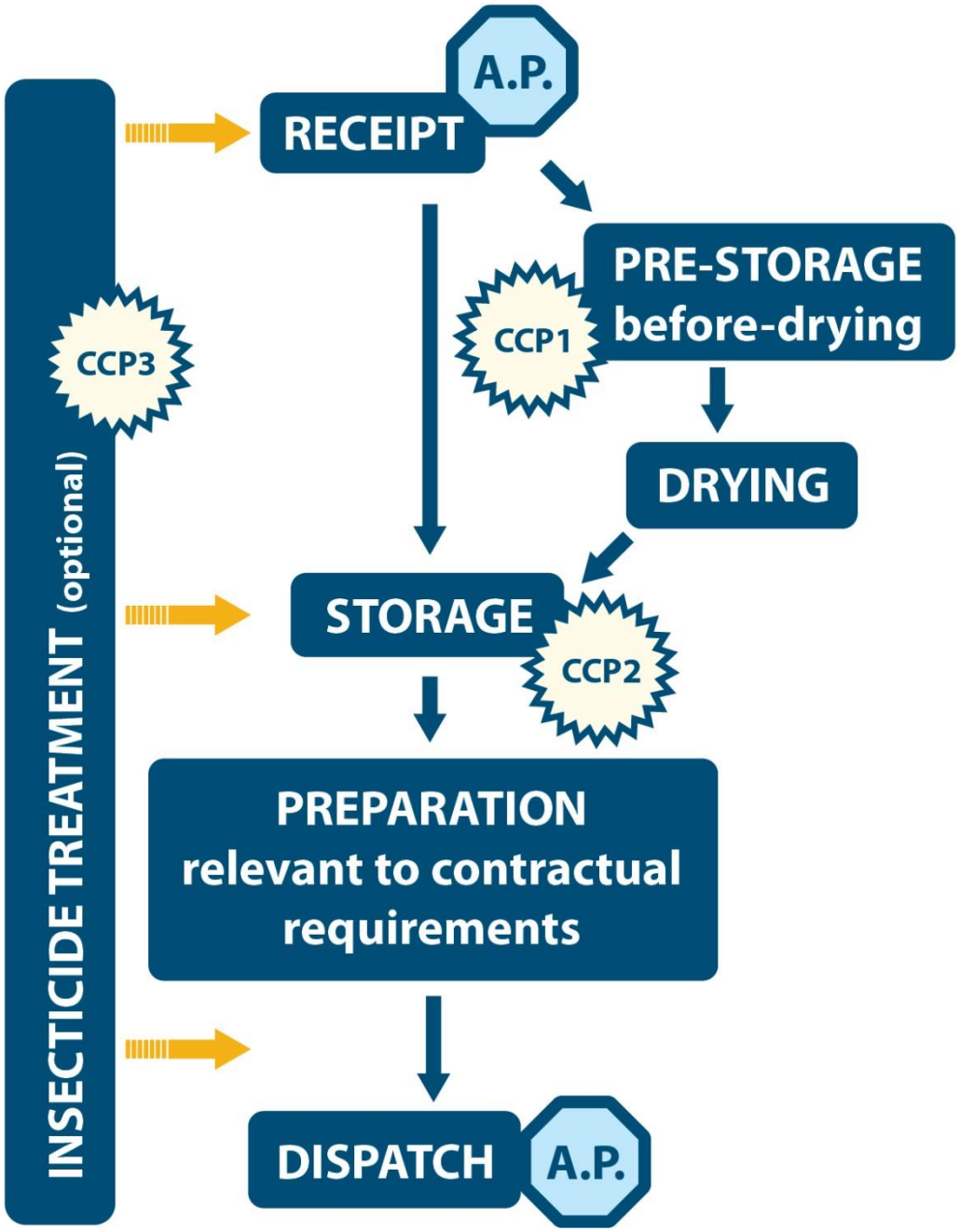
Determine the normal methods of use by the end user or the consumer (animal feed, flour trade, starch industry, semolina production, oilseeds-crushing industry etc.), and any particular methods. Identify the high-risk populations (children etc.).

Take into consideration any potential subsequent processing (grinding at the flour mill or semolina factory removes the bran and reduces the microbial or mycotoxins levels).

### Annex 1.2.4. Drawing up an operations diagram

Accurately describe all of the elementary stages of the diagram. The food and feed safety management parameters of the stage must be stated (temperature, humidity, duration etc.). Traditionally each stage is represented by a rectangle and the stages are linked together by arrows.

**Example:**
There are seven stages in the collection/storage of cereals, oilseeds and protein crops, which follow on from one another as shown below:




- cleaning is carried out, where necessary, during the drying, storage and preparation stages according to contractual requirements
- Between each stage, handling operations are carried out. These handling operations can also take place during an inter-bin transfer
- inter-bin transfers are carried out if necessary to optimise the storage plan or facilitate an intervention on the stored grain (aeration)

### Annex 1.2.5. Checking the operations diagram on site

Check that the operations diagram is accurate and complete in practice. The *Codex Alimentarius* stipulates that "the HACCP team must permanently compare the development of the activities with the operations diagram and, where appropriate, modify it". In practical terms, the HACCP team is present on site and assists in the development of the operations

from receipt of the goods from crops or transfers to dispatch or even delivery to the customer.

### Annex 1.2.6. Conducting an analysis of the hazards (Principle 1)

Make a list of all the possible hazards (known or conceivable) by brainstorming and by using the "5-Ms" method referring to this Code, scientific articles or works, customer requests etc. Only retain real hazards, that is, those likely to significantly affect the consumer's food and feed safety. For example, a dead insect in a batch of corn is not a significant hazard for the consumer.

List all of the causes of the hazards identified at each stage in the operations diagram.

At each stage, assess the relative risk of each hazard (evaluation of the severity, the frequency of its appearance and the likelihood of it not being detected).

Determine the control measures for the hazards identified.

**Example:**
The potential hazards which could arise during the collection and storage of cereals, protein crops and oilseeds are the following:

| Nature of the hazard | Example of hazard (non-exhaustive list) |
|---|---|
| **BIOLOGICAL OR MICRO-BIOLOGICAL** | **Flora**<br>Mould, bunt, *Bacillus cereus*, salmonella<br>**Mycotoxins**<br>Ochratoxin A, trichotecenes (including DON and $T_2$ / $HT_2$), zearalenone, fumonisin, aflatoxins.<br>**Pests**<br>Insects from cereals and oilseeds, fowl, rodents<br>**Ergot** |
| **CHEMICAL** | **Pesticide residues**<br>Storage pesticides<br>**Heavy metals**<br>Cadmium, lead<br>**Treated seeds**<br>**Dioxin** |
| **PHYSICAL** | **Foreign bodies**<br>Broken bulbs, bits of gravel, pieces of metal, transport residues etc. |
| **ALLERGENS** | **Allergenic products**<br>Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut or their hybrid strains) or Ambrosia seeds (e.g. destined to food) |

**Hazard analysis**

### *1.6. Description of the hazards*

To assess the hazards in cereals, protein crops and oilseeds during the different stages of the silo diagram, we have created hazard fact sheets which can be found in Annex 3. These sheets give a general description of the hazard, specify the origin, the conditions favourable to its persistence, proliferation or elimination and provide a reminder of the current regulations and recommendations.

### *1.7. List of the causes of the hazards*

At each stage in the operations diagram, the causes of the potential hazards are identified using the **"5 Ms method"**. This method is extremely thorough and therefore means that no potential cause of a hazard is omitted. See below the example applied to the storage of cereals, oilseeds and protein crops:

***The 5 Ms method:***

| | |
|---|---|
| Material | Cereals, oilseeds or protein crops |
| Environment | Atmosphere, surrounding areas |
| Labour | Hygiene |
| Method | Operating method |
| Equipment | Installations, transport equipment |

### *1.8. Evaluating the risk relating to each hazard*

The hazards are then prioritized for each cause, based on the following two criteria:

- Severity (S) which corresponds to the consequences of the hazard on the consumer's food and feed safety
- Frequency (F) of the hazard's appearance,

These indices are quantified using a scale of 0 to 9 as a result of the combination between severity and frequency and the multiplication of (very) low, medium and high scales. This evaluation is carried out according to latest technical and scientific experiments. The HACCP study also takes into consideration the impact of the agricultural raw materials and the role played by the storage/processes. The product's final destination and the data from monitoring plans are also considered.

| Risk Assessment | | Frequency (F) | | | |
|---|---|---|---|---|---|
| | | Very low (0) | Low (1) | Medium (2) | High (3) |
| Severity (S) | Low (1) | 0 | 1 | 2 | 3 |
| | Medium (2) | 0 | 2 | 4 | 6 |
| | High (3) | 0 | 3 | 6 | 9 |

As part of the hazard analysis, to quantify the severity index, contamination, survival and multiplication factors are also taken into account if necessary.

Refer to the HACCP plan in the following pages and the hazard analysis tables in Annex 2 and 3.

### *1.9. Determining the preventive control measures*

Preventive control measures were defined for each cause of an identified hazard: refer to the HACCP plan on the following pages and the hazard analysis tables in Annex 2 and 3.

## Annex 1.2.7. Determining the critical points for controlling the hazards: the C.C.P.s (Principle 2)

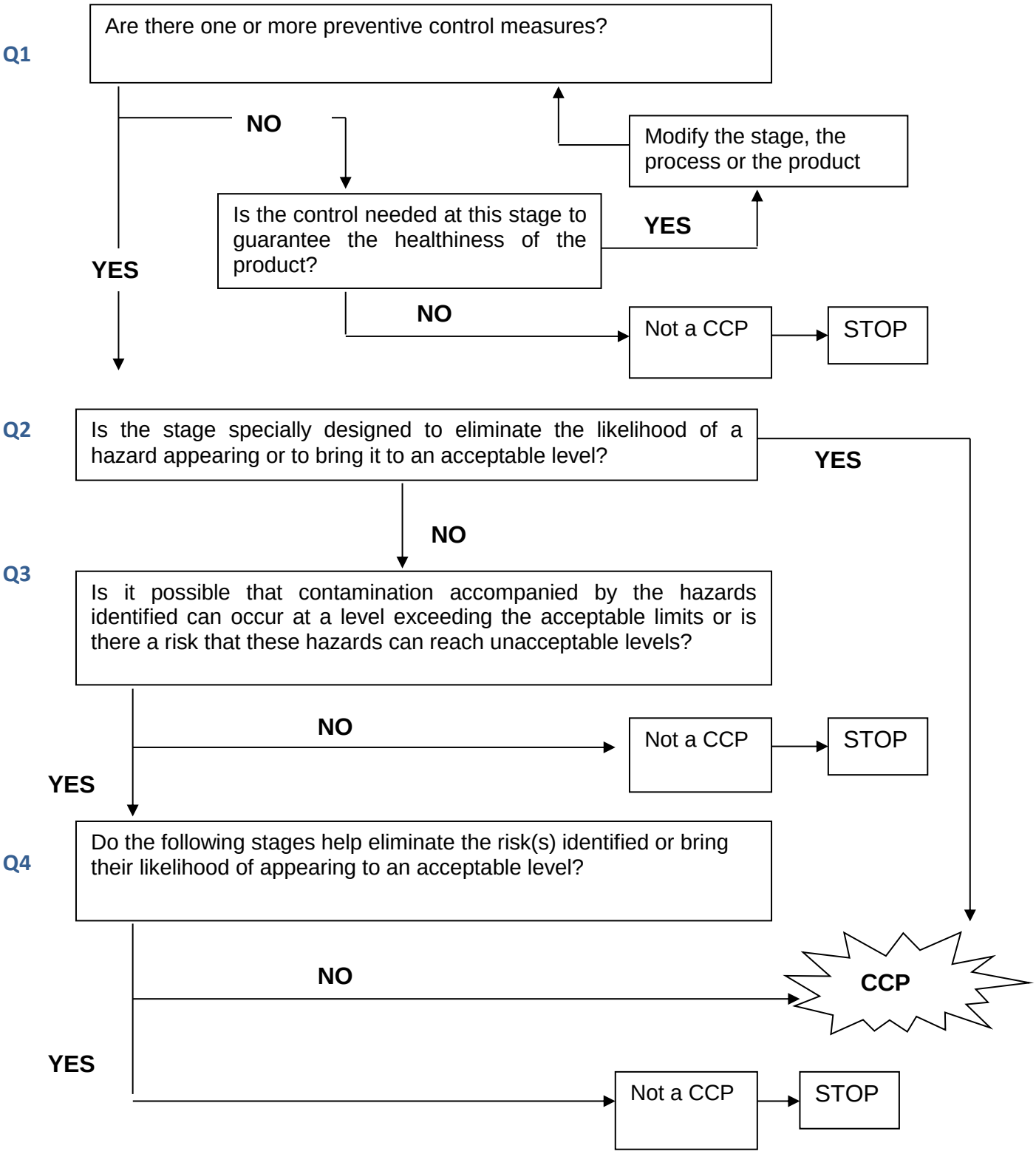
For each hazard, apply the decision-making tree or logic diagram (see page 54, Determining the critical control points) where appropriate.

This is only a tool and is not intended to replace the team's own expertise or thinking. There are several models. A C.C.P. should control a hazard, prevent it, or bring it to an acceptable level; if this is not the case, it is not a C.C.P. Monitoring actions carried out on the C.C.P.s ensure the control measures are implemented effectively.

For practical reasons, the C.C.P.s should be noted on the operations diagram (refer to the diagram on page 50) and a monitoring plan should be established based on the C.C.P.s identified.

**Determining the critical control points (CCP)**

Example of a decision tree for determining the CCPs (answer the questions in order)



**Example of answers according to the decision tree:** CCP 3

**Q1:** At the pesticide treatment stage, are there one or more preventive measures?

YES

⇩

**Q2:** Is the pesticide treatment stage specially designed to eliminate the likelihood of pesticide residues appearing or to bring it to an acceptable level?

NO

⇩

**Q3:** Is it possible that contamination accompanied by pesticide residues can occur at a level exceeding the acceptable limits or is there a risk that the quantity of residues can reach unacceptable levels?

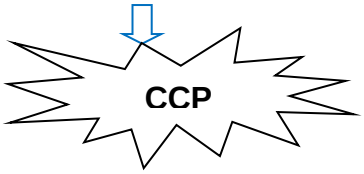
YES

⇩

**Q4:** Do the following stages help eliminate the risk(s) identified or bring their likelihood of appearing to an acceptable level?

NO

⇩




**Example of answers according to the decision tree:** case of drying

**Q1:** At the drying stage, are there one or more preventive measures?

YES

⇩

**Q2:** Is the drying stage specially designed to eliminate the likelihood of storage mycotoxins appearing or to bring it to an acceptable level?

NO

⇩

**Q3:** Is it possible that production of storage mycotoxins can occur at a level exceeding the acceptable limits or is there a risk that the quantity of storage mycotoxins can reach unacceptable levels?

YES

⇩

**Q4:** Do the following stages help eliminate the risk(s) identified or bring their likelihood of appearing to an acceptable level?

NO

(the storage/preservation by ventilation stage)

⇩

Not a CCP

Drying aims to reduce the grains' water content and prepare them for subsequent good storage. The drying activity is therefore an important stage in maintaining the grains' hygiene quality in the stores (silos, warehouses, cells, tanks, etc..). However, during the storage stage, storage mould and mycotoxins can develop from sound grains due to a practice fault, poor insulation or a condensation phenomenon. According to the decision diagram, the drying stage is therefore the last stage at which the mould and storage mycotoxins development can be controlled.

### Annex 1.2.8. Establishing the critical limits for each C.C.P. (Principle 3)

This involves defining the measures on which the C.C.P.s' controls will rely. Those most frequently used are: temperature, duration, humidity etc.

For each measure, quantifiable criteria are defined (and therefore critical limits) which separate a "compliant" product from a "non-compliant" product. These criteria ensure that for a given C.C.P. the corresponding control measure is correctly applied. For example, a critical limit may be the authorised pesticide dose.

For safety reasons it is important to also set a target limit or a tolerance zone. A controlled product can be "compliant", "acceptable" or "non-compliant".

It may be necessary to determine several quantifiable criteria and therefore several critical limits for a single C.C.P.

### Annex 1.2.9. Establishing a monitoring system for each C.C.P. (Principle 4)

The control operations need to be defined to ensure the critical limits are respected and therefore each C.C.P. is controlled. This involves answering the following questions: Who? does What? (which control) Where? When? How often? How?

These control methods can be formalized in the form of instructions or procedures and feature in the HACCP plan.

Keeping a record of these controls provides internal and external proof that the controls have really been carried out.

The controls are limited in their effectiveness by:

a. human capabilities with the risks of errors this can entail
b. the rarity of the hazard's occurrence: a hazard that appears very rarely will be more difficult to detect
c. the resources available: equipment, budget.

The HACCP team must optimise the frequency of the controls by first targeting the C.C.P.s linked to the most significant hazards and risks.

### Annex 1.2.10. Establishing the corrective actions for each C.C.P. (Principle 5)

The corrective actions are implemented as soon as a C.C.P. control is lost or absent. They define the future of the non-compliant product and enable the C.C.P. control to be re-established.

### Annex 1.2.11. Defining the verification methods (Principle 6)

Establish the methods used to check that the system is working correctly.

1. initial plan of analyses confirming that the hazard is controlled by applying the HACCP system
2. validation of the initial study by an expert opinion
3. final control (verification that all of the controls have been carried out)
4. annual plan of analyses
5. rate of “non-compliant” control results compared to “compliant” results (very interesting in the case of mycotoxin or pesticide analyses)
   internal or external audit etc.

The management must conduct a review at least once a year to verify the effectiveness of the H.A.C.C.P. system in place.

### Annex 1.2.12. Establishing a documentation system (Principle 7)

The documentation system contains:

- HACCP documents, referring to each of the stages (control plans, procedures, operating methods etc.) forming the HACCP plan
- the records cited in the HACCP plan.

Generally, all of the documents produced within the context of the HACCP system must be stored and archived (reports of verification actions etc.).