AN OVERVIEW OF HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

"An ounce of prevention is worth a pound of cure"

INTRODUCTION

HACCP was originally developed as a microbiological safety system in the early days of the US manned space programme in order to guarantee the safety of astronauts' food. Up until that time most food safety systems were based on end product testing and could not fully assure safe products as 100% testing was impossible. A pro-active, process-focused system was needed and the HACCP concept was born.

The original system was designed by the Pilsbury Company working alongside NASA and the US army laboratories at Natick. It was based on the engineering system Failure, Mode and Effect Analysis (FMEA) which looked at what could potentially go wrong at each stage in the operation along with possible causes and the likely effect, before applying effective control mechanisms.

HACCP is a system that identifies, evaluates and controls hazards which are significant for food safety. It is a structured, systematic approach for the control of food safety throughout the commodity system, from the plough to the plate. It requires a good understanding of the relationship between cause and effect in order to be more pro-active and it is a key element in Total Quality Management (TQM). HACCP builds on the foundations of well established quality management systems such as Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Agricultural Practice (GAP), and Good Storage Practice (GSP). The HACCP concept has been successfully applied in the control of quality as well as safety in low-acid canned foods in the USA, and many food companies in Europe and the USA have adopted the approach. Increasingly, regulatory bodies have recognised the usefulness of this tool and its 'principles' have has been incorporated into legislative requirements by both the EU (in the General Hygiene regulations for managing food safety (93/43/EEC)), and the United States Federal Department of Agriculture (CPR - 123). The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) provided guidelines on HACCP including generic

plans and decision trees in 1992, and the Codex Alimentarius Commission adopted the HACCP system at its twentieth session in 1993. HACCP systems can be incorporated into other quality assurance systems such as the ISO 9000 series (Figure 7).

Although conceived as a food safety system for both the agricultural and processing systems, it is in the latter that HACCP has found most application hitherto. This is primarily because it is much easier to apply a HACCP system in a factory where there is a single management or 'owner', and where it is possible to completely prevent a food safety hazard, or eliminate, or reduce it to an acceptable level. In the commodity system there are often many disparate 'owners' of the commodity as it passes from the farm to the consumer, and complete control may be unobtainable. This Manual aims to address this subject, basing the approach as closely as possible on the Codex Code of General Principles on Food Hygiene (1997), which emphasises the importance of GMP/GAP/GHP as sound foundations to incorporate the HACCP approach and develop a user friendly Food Safety Management System.

PRE-REQUISITE PROGRAMMES

Pre-requisite programmes such as GAP, GMP and GHP must be working effectively within a commodity system before HACCP is applied . If these pre-requisite programmes are not functioning effectively then the introduction of HACCP will be complicated, resulting in a cumbersome, over-documented system.

Good Agricultural Practices

Primary Production

Primary food production should be managed to ensure that food is safe and wholesome for the consumer. Production will start on the farm, in the sea or lake or even within a forest. It is essential that certain ground rules are followed. Land used for crop or horticulture production should be fit for purpose and should not have previously been contaminated with heavy metals, industrial chemicals or environmental waste. Such hazards will be transferred into the food chain rendering the commodity unfit for human consumption. Farmers should control production so that contamination of the crop, proliferation of pests, and diseases of animals and plants, do not compromise food safety. Good Agricultural Practices (GAP), including Good Hygienic Practices (GHP) where appropriate, should be adopted to make sure that the harvested commodity will not present a food hazard to the consumer.

Good Storage Practices (GSP) should be followed when the commodity is stored on the farm. As well as being covered in Food Hygiene Basic Texts (CODEX) there are also four ISO procedures that cover the storage of cereal s and pulses (ISO 6322 series). GSP should also be followed for storage throughout the commodity system.

Good Manufacturing Practices

Establishment Design and Facilities

The structure and location of a processing plant needs to be considered in relation to the nature of operations and risks associated with them.

- Food premises should be designed to minimise possibilities of contamination of commodity or product.
- Design and layout should permit maintenance, cleaning and disinfection of the site to minimise airborne contamination.
- All surfaces that come into contact with food should be non toxic, as well as being easy to maintain and clean in order to prevent any additional contamination .
- Suitable facilities should exist for temperature and humidity control, when required.
- Effective measures should exist to prevent access by pests

Control of Operation

Effective control measures should be in place to reduce the risk of contamination of the commodity or food supply such that it is safe and fit for purpose:

- Adequate time, temperature or humidity controls
- Food grade packaging
- Potable water supplies
- Maintenance of equipment

Maintenance and Sanitation

Procedures and work instructions should exist to demonstrate an adequate level of maintenance of an establishment as well as efficient practices for cleaning, waste management, and pest control. Overall, these operations will support the ongoing control of potential food hazards that may contaminate food.

Personnel Hygiene

Measures need to be in place to ensure that food handlers do not contaminate food. This objective can be attained by maintaining an appropriate level of personal cleanliness and following guidelines for personal hygiene.

Transportation

The method of transportation should be such that measures are taken to prevent any contamination or deterioration of the commodity. Commodities or product that need to be transported in certain environments should be appropriately controlled, e.g. chilled, frozen, or stored under specific humidity levels.

Containers and conveyors used for transporting food need to be maintained in good condition and be easy to clean.

Containers used for bulk transfer should be designated and marked specifically for food use only.

Training

All food handlers should be trained in personal hygiene, as well as in the specific operation with which they are working, to a level commensurate with their duties. Food handlers should also be supervised by trained supervisors.

An ongoing training programme for food handlers is paramount to the success of a Food Safety Management System

Product Information and Consumer Awareness

The end product should be accompanied by adequate information to ensure that personnel at the next stage in the food chain will handle, store, process, prepare and display the product safely. Since the consumer may be responsible for performing the ulitimate control measure, the cooking of raw meat or fish, they should have all the relevant information required to carry out this step effectively.

All batches of food should be easily identified, by a batch or lot number, to allow traceability of the commodity if required.

BASIC PRINCIPLES OF HACCP

There are seven discrete activities that are necessary to establish, implement and maintain a HACCP plan, and these are referred to as the 'seven principles' in the Codex Guideline (1997).

The seven principles are[1]:

Principle 1

Conduct a hazard analysis.

Identify hazards and assess the risks associated with them at each step in the commodity system. Describe possible control measures.

Principle 2

Determine the Critical Control Points (CCPs)

A critical control point is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level. The determination of a CCP can be facilitated by the application of a decision tree, such as the one given in Appendix IV.

Principle 3

Establish critical limits.

Each control measure associated with a CCP must have an associated critical limit which separates the acceptable from the unacceptable control parameter.

Principle 4

Establish a monitoring system

Monitoring is the scheduled measurement or observation at a CCP to assess whether the step is under control, i.e. within the critical limit(s) specified in Principle 3.

Principle 5

Establish a procedure for corrective action, when monitoring at a CCP indicates a deviation from an established critical limit.

Principle 6

[1] please refer to Appendix 1 for a definition of the terms used in this section

Establish procedures for verification to confirm the effectiveness of the HACCP plan.

Such procedures include auditing of the HACCP plan to review deviations and product dispositions, and random sampling and checking to validate the whole plan.

Principle 7

Establish documentation concerning all procedures and records appropriate to these principles and their application

DEVELOPING A HACCP PLAN

There are twelve tasks required to develop a HACCP plan and these are designed to ensure that the seven principles are applied correctly. Principle 1, which is to conduct a hazard analysis, requires that the first five tasks have all been addressed in a logical and honest manner so that all real hazards associated with the commodity have been identified. The twelve tasks are discussed briefly below, and listed in Appendix II.

TASK 1 – Establish a HACCP team

To fully understand the commodity system and be able to identify all likely hazards and CCPs, it is important that the HACCP team is made up of people from a wide range of disciplines. The team should include:

- A team leader to convene the group and to direct the work of the team ensuring that the concept is properly applied. This person must be familiar with the technique, be a good listener and allow all participants to contribute.

- A specialist with a detailed knowledge of the commodity system is required. This specialist will have a major role in the production of the commodity flow diagrams.

- Several specialists, each with an understanding of particular hazards and associated risks, e.g. a microbiologist, a chemist, a mycotoxicologist, a toxicologist, a QC manager, a process engineer.

- People, such as packaging specialists, raw material buyers, distribution staff or production staff, farmers, brokers, who are involved with the process, and have working knowledge of it, may be brought into the team temporarily in order to provide relevant expertise.

- The team's progress and results of the analysis should be recorded by a technical secretary.

If any changes are made to composition or operational procedures, it will be necessary to re-assess the HACCP plan in the light of the changes.

The first activity of the HACCP team is to identify the scope of the study. For example, will the whole commodity system be covered, or only selected components? This will make the task more manageable and specialists can be added to the team as and when they are required.

TASK 2 - Describe the product

To start a hazard analysis, a full description of the product, including customer specification, should be prepared using a form such as that given in Appendix III. This should include information relevant to safety, e.g. mycotoxin regulation/ target level, composition, physical/chemical properties of the raw materials and the final product, the amount of water available for microbial growth (a_w), the amount of acid or alkali in the product (pH). Also information regarding how the product is to be packaged, stored and transported should also be considered together with facts regarding its' shelf life and recommended storage temperatures. Where appropriate, labelling information and an example of the label should be included. This information will help the HACCP team to identify 'real' hazards associated with the process.

TASK 3 - Identify the product's intended use

How the product is intended to be used is an important consideration. Information on whether the product will be consumed directly, or be cooked, or be further processed, will all have a bearing on the hazard analysis , see task 6). The nature of the target group for the product may also be relevant, particularly if it includes susceptible groups such as infants, the elderly, and the malnourished. The likelihood of misuse of a product should also be considered, such as the use of pet food as a human food, either by accident or design. This information can be recorded on the same form as the product description, see Appendix III.

TASK 4 – Draw up the commodity flow diagram

The first function of the team is to draw up a detailed commodity flow diagram (CFD) of the commodity system, or that part of it which is relevant. The expertise of the commodity specialist is important at this stage. Commodity systems will differ in detail in different parts of the world, and even within one country there may be a number of variants. Secondary processing will need to be detailed for each factory, using generic flows only as a guide. Examples of commodity flow diagrams are included in the case studies presented in Chapter 3.

TASK 5 - On site confirmation of flow diagram

Upon completion of the CFD, members of the team should visit the commodity system (e.g. farm, store or manufacturing area) to compare the information present on the CFD with what actually happens in practice. This is known as "walking the line", a step by step practice to check that all information regarding materials, practices, controls etc. have been taken into consideration by the team during the preparation of the CFD. Information such as time of harvest, drying procedures, storage conditions, the marketing chain, socio-economic factors, grading systems and any incentive for improved quality or safety, and processing systems, should be collected and included in the CFD as appropriate. The site for which the HACCP plan is being designed should be visited as many times as possible to ensure that all relevant information has been collected.

TASK 6 – Identify and analyse hazard(s) - (Principle 1)

Effective hazard identification and hazard analysis are the keys to a successful HACCP Plan. All real or potential hazards that may occur in each ingredient and at each stage of the commodity system should be considered. Food safety hazards for HACCP programmes have been classified into three types of hazards:

- Biological: typically foodborne bacterial pathogens such as *Salmonella*, *Listeria* and *E. coli,* also viruses, algae, parasites and fungi.
- Chemical: There are three principle types of chemical toxins found in foods: naturally occurring chemicals, e.g. cyanides in some root crops, and allergenic compounds in peanuts; toxins produced by micro-organisms, e.g. mycotoxins, and algal toxins; and chemicals added to the commodity by man to control an identified problem, e.g fungicides or insecticides.
- Physical: contaminants such as broken glass, metal fragments, insects or stones.

The probability that a hazard will occur is called a risk. The risk may take a value from zero to one depending on the degree of certainty that the hazard will be absent or that it will be present. After hazard identification, a hazard analysis must be conducted to understand the relative health risk to man or animal posed by the hazard. It is a way of organizing and analyzing the available scientific information on the nature and size of the health risk associated with the hazard. The risk may have to be assessed subjectively and simply classified as low, medium, or high. Only those hazards considered by the HACCP team to present an unacceptable risk of being present are taken forward to Stage 7, Principle 2.

Once a food safety hazard has been identified, then appropriate control measures should be considered. These are any action or activity that can be used to control the identified hazard, such that it is prevented, eliminated, or reduced to an acceptable level. The control measure may also include training of personnel for a particular operation, covered by GAP, GMP, and GHP.

TASK 7 - Determine the critical control points (ccps) - (Principle 2).

Each step in the commodity flow diagram, within the scope of the HACCP study, should be taken in turn and the relevance of each identified hazard should be considered. It is also important to remember the stated scope of the HACCP analysis at this stage. The team must determine whether the hazard can occur at this step, and if so whether control measures exist. If the hazard can be controlled adequately, and is not best controlled at another step, ans is essential for food safety, then this step is a CCP for the specified hazard. A decision tree can be used to determine CCPs, and an example of the Codex decision tree is included in Appendix IV. However, the HACCP team's judgement, expertise and knowledge of the process are the major factors in establishing CCPs.

If a step is identified where a food safety hazard exists, but no adequate control measures can be put in place either at this step or subsequently, then the product is unsafe for human consumption. Production should cease until control measures are available and a CCP can be introduced.

TASK 8 - Establish critical limits for each ccp - (Principle 3)

Critical limits must be specified and validated for each CCP. Criteria often used include measurements of temperature, time, moisture level, pH, water activity, and sensory parameters such as visual appearance. In the case of mycotoxins for example, they may include the moisture

content or the temperature of the commodity. All critical limits, and the associated permissible tolerances, must be documented in the HACCP Plan Worksheet, and included as specifications in operating procedures and work instructions.

TASK 9 - Establish a monitoring procedure - (Principle 4)

Monitoring is the mechanism for confirming that critical limits at each CCP are being met. The method chosen for monitoring must be sensitive and produce a rapid result so that trained operatives are able to detect any loss of control of the step. This is imperative so that corrective action can be taken as quickly as possible so that loss of product will be avoided or minimised.

Monitoring can be carried out by observation or by measurement, on samples taken in accordance with a statistically based sampling plan. Monitoring by visual observation is basic but gives rapid results, and can therefore be acted upon quickly. The most common measurements taken are time, temperature and moisture content.

TASK 10 - Establish corrective action - (Principle 5)

If monitoring indicates that critical limits are not being met, thus demonstrating that the process is out of control, corrective action must be taken immediately. The corrective action should take into account the worst case scenario, but must also be based on the assessment of hazards, risk and severity, and on the final use of the product. Operatives responsible for monitoring CCPs should be familiar with and have received comprehensive training in how to effect a corrective action.

Corrective actions must ensure that the CCP has been brought back under control. They must also include appropriate disposition of any affected commodity or product. Whenever possible an alarm system should be introduced which will activate when monitoring indicates that the critical limit is being approached. Corrective action can then be applied to pre-empt a deviation and prevent the need for any product disposition.

TASK 11 - Verify the HACCP plan - (Principle 6)

Once the HACCP plan has been drawn up, and all of the CCPs have been validated, then the complete plan must be verified. Once the HACCP plan is in routine operation, it must be verified and reviewed at regular intervals. This should be a task of the person charged with the

responsibility for that particular component of the commodity system The appropriateness of CCPs and control measures can thus be determined, and the extent and effectiveness of monitoring can be verified. Microbiological and/ or alternative chemical tests can be used to confirm that the plan is in control and the product is meeting customer specifications. A formal internal auditing plan of the system will also demonstrate an ongoing commitment to keep the HACCP plan up to date, as well as representing an essential verification activity.

Ways in which the system can be verified include:

- collecting samples for analysis by a method different from the monitoring procedure
- asking questions of staff , especially CCP monitors
- observing operations at CCPs
- formal audit by independent person

It is important to remember that the HACCP system is set up for a particular formulation of product handled and processed in a given way.

TASK 12 – Keep record - (Principle 7)

Record keeping is an essential part of the HACCP process. It demonstrates that the correct procedures have been followed from the start to the end of the process, offering product traceability. It provides a record of compliance with the critical limits set, and can be used to identify problem areas. Furthermore, the documentation can be used by a company as evidence of 'Due Diligence Defence' as required, for instance, by the Food Safety Act 1990 (HMSO), in the UK.

Records that should be kept include: all processes and procedures linked to GMP, GHP, CCP monitoring, deviations, and corrective actions.

Documents should also include those that recorded the original HACCP study, e.g. hazard identification and selection of critical limits, but the bulk of the documentation will be records concerned with the monitoring of CCPs and corrective actions taken. Record keeping can be carried out in a number of ways, ranging from simple check-lists, to records and control charts. Manual and computer records are equally acceptable, but a documentation method should be designed that is appropriate for the size and nature of the enterprise. A template of a form to document product description and intended use is given in Appendix III, and a template of a

HACCP Plan Worksheet is given in Appendix V. Examples of the use of these forms are provided in the case studies presented in Chapter 3.

APPLICATION OF HACCP TO MYCOTOXIN CONTROL

Once tasks 1 to 5 have been completed the following will be in place: a HACCP team, a Description and Intended Use table, and a verified Commodity Flow Diagram. This will provide information on a specific commodity from a unique source, and this information is required to complete the hazard analysis. See the case studies in Chapter 3 for examples of implementation, including that of stages 1 to 5.

Task 6 - Mycotoxin hazard analysis and identification of possible control measures

Hazard Analysis

a). Identification of mycotoxin hazard

For a given commodity system in a particular location, the HACCP team need to first consider which, if any, of the mycotoxins known to constitute a food safety hazard are likely to be present.

Over 300 mycotoxins are known, but only a relatively few of these are widely accepted as presenting a significant food or animal feed safety risk. These hazardous mycotoxins are listed in Tables 1 and 2 in Chapter 1. Of these only the following mycotoxins have regulatory limits set by one or more countries: the aflatoxins (including aflatoxin $M_{1)}$, ochratoxin A, zearalenone, patulin, ergot alkaloids, and deoxynivalenol. Guideline limits exist for fumonisin B_1 and regulatory limits are likely to be set in the near future. The regulatory limits are taken as the target levels and should be included in the Product Description table. Mycotoxin limits can also be set by the customer in specific contracts and it is possible that these may include mycotoxins not subject to regulatory limits.

The risk of a particular mycotoxin hazard should be estimated using well established data on the relative susceptibilities of commodities to given mycotoxins and the climatic conditions required for the mycotoxins to be produced. The EU has identified the following animal feed ingredients, and their products, as being highly susceptible to aflatoxin contamination: maize, groundnut cake, cottonseed cake, babassu, palm kernel cake and copra cake. The EU has also identified the

following foodstuffs as highly susceptible to aflatoxin contamination: dried figs and other dried fruit, groundnuts, pistachios and other edible nuts and cereals. These commodities are specified in the respective EC regulations (1525/98 amending regulation 194/97). Maize grown in temperate climates would be less likely to be contaminated with aflatoxin, but could be contaminated with trichothecene mycotoxins or fumonisin B_1. Although published mycotoxin survey data exists for many commodities, it is important that surveillance studies are performed if mycotoxin data is lacking for a particular commodity, or for production in a particular climatic zone.

b). Identification of steps in the Commodity Flow Diagram (CFD) where mycotoxin contamination is most likely to occur

Once the mycotoxin hazard(s) has been identified, each step in the CFD must be considered in turn and the likelihood of mycotoxin contamination occurring must be assessed. Usually published scientific data will be available to act as a guide, but it may be necessary to commission a study to determine, or confirm that the correct steps have been identified. The situation may change from year to year, and season to season, so there will need to be an element of mycotoxin surveillance in the HACCP plan.

An important fact to establish is whether pre-harvest contamination with mycotoxins is likely or whether contamination occurs primarily post-harvest. Mycotoxins produced by *Fusarium* spp , such as fumonisin B_1 are invariably produced pre-harvest, but climatic conditions effect the degree of blight and the resultant level of mycotoxin contamination. Aflatoxins can be produced both pre-harvest and post-harvest and climatic conditions can have a significant bearing: drought stress favours pre-harvest contamination, whereas post-harvest handling during the rainy season favours post-harvest aflatoxin contamination.

It is rarely possible to be certain that pre-harvest mycotoxin levels are below regulatory or target levels in the commodity system, so post-harvest mycotoxin control measures can often only prevent or reduce ADDITIONAL contamination, rather than prevent the hazard completely. Consequently it is often necessary to introduce a segregation step to remove any batches containing an unacceptable level of mycotoxin.

c). Possible Mycotoxin Control Measures

The most effective mycotoxin control measures is to dry the commodity such that the water activity (a_w) is too low to support mould growth and/ or prevent mycotoxin production. To prevent the growth of most moulds the a_w needs to be ≤ 0.70, which translates to a moisture content of approximately 14% for maize and 7.0% for groundnuts at 20°C (the corresponding moisture content decreases as the temperature increases). Each toxigenic mould has its own minimum water activity for growth and mycotoxin production and these translate into moisture contents for each commodity. These moisture contents are termed 'safe' and would be the critical limit for the control measure.

It is important to specify a target 'safe' moisture content with a maximum as well as an average value, e.g. 14% no part exceeding 15%. If only an average value is specified it may conceal a large range of moisture contents within the batch and the commodity would not be safe from mould growth and mycotoxin contamination. A drying process is required which dries evenly and the critical limits must be set bearing this in mind. Validation of such a CCP must involve moisture determination of multiple samples.

If the commodity is at an 'unsafe' moisture content for longer than 48 hours, then mould can grow and mycotoxins be produced. Hence limiting the time that the commodity spends in the 'unsafe' moisture content window to less than 48 hours is a control measure. This explains why timely sun-drying can sometimes be safer than delayed mechanical drying. Two days on a drying floor with occasional turning can often achieve the target 'safe' moisture content, whereas a back-log at the mechanical drier can result in the critical limit of 48 hours not being met.

Once produced, it is not usually possible to remove mycotoxins, other than by physical separation (grading) techniques. To apply this type of control measure, representative samples of batches of commodity are collected and tested for selected mycotoxins. Only those batches containing less than the critical limit of mycotoxin, as specified in official regulations, are accepted. For some commodities, such as blanched groundnuts, colour sorters may be effective in rejecting individual high-aflatoxin nuts and accumulating low-aflatoxin nuts, and may be classified as a control measure.

There are a few examples where effective chemical detoxification is possible, such as ammoniation of certain animal feed ingredients and refining of vegetable oils. These are control measures that would also be suitable for application at a critical control point for aflatoxin, but only for the specified commodities.

It is essential that GAP, GSP, and GMP pre-requisites are in place, and simply ensuring that this is the case can significantly reduce the risk of the mycotoxin hazard. Examples of procedures which fall within the scope of these pre-requisites include: irrigation, insect control, use of resistant varieties, and use of pallets in store.

Task 7 - Determine Critical Control Points (CCPs)

Determination of CCPs can be achieved using a well designed decision tree, if necessary, to supplement the knowledge and experience of the HACCP team (see Appendix IV). Each step in the CFD is considered in turn, and the questions answered in sequence. It should be noted that it is necessary to be able to answer Yes to Question 1 (Do preventative control measures exist?) before a CCP can be established. The Codex 1997 definition of a control measure is any action and activity that can be used to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

There are commodity systems, such as the production of apple juice (Case study 5), where control measures are possible at a number of steps, and each is capable of achieving a known percentage reduction in the level of mycotoxin. It is possible, therefore, to calculate the acceptable level of patulin at each step and perform validation. If the risk of the acceptable level of mycotoxin being exceeded is considered to be sufficiently low, then the HACCP team may determine each of the steps as CCPs.

Task 8 - Establish critical limits for each CCP

When the control measure is segregation based on mycotoxin analysis, then the critical limit will often be set at the acceptable level, which in turn will be set at, or below, the regulatory mycotoxin limit. Acceptable levels, and any associated critical limits, can sometimes be set higher than a regulatory limit, provided that a subsequent step can guarantee to attain the acceptable level of hazard in the final product.

For control measures that involve drying to a ‘safe’ moisture content, the parameter that will be measured, and for which critical limits will be set, will usually be parameters such as the temperature of the drier and the dwell time, e.g. for a continuous flow drier the critical limit for temperature could be 80 +/- 2°C and the critical limit for dwell time could be 20 +/- 1 minute.

Critical limits for chemical detoxification could be the temperature and pressure of the reaction vessel and the dwell time.

Task 9 - Establish a monitoring system for each CCP

The monitoring system must be a scheduled measurement, usually of a basic parameter such as temperature or time, to detect any deviation from the critical limits.

When segregation of acceptable and unacceptable batches is required in the agricultural system, for example at a secondary trader, then rapid testing procedures are needed to test incoming batches.

A number of semi-quantitative immunoaffinity rapid test kits are available which work to a stated target level, eg 5 or 20 µk/kg of the appropriate mycotoxin. Here the critical limit would normally be the presence or absence of a coloured derivative. More traditional mini-column and TLC dilution to extinction techniques can still be useful for segregation of batches at the factory gate, and for these the presence or absence of a blue fluorescent band or spot is the critical limit.

Task 10 - Establish a corrective action

There are two sorts of corrective action. The first is action to regain control. For instance if a critical limit for a moisture content is not attained, then the corrective action could be to check the specification of the drier and effect repairs, or perhaps to increase the temperature setting or the dwell time. The second type of corrective action is to isolate the product produced whilst the CCP was out of control and amend the product disposition, by either discarding or down-grading it, or re-processing it if this is appropriate.

Task 11 - Establish verification procedures

At regular, specified, intervals the complete HACCP plan should be verified by checking that the levels of mycotoxin in the final product are within acceptable levels. If this is found not to be the case, then immediately trouble-shooting should be carried out to identify the step at which the hazard has become out of control. Critical limits may need to be amended, or a new control measure may need to be validated and introduced. Similarly, if a review of deviations and product dispositions indicated an unacceptable degree of control at a particular CCP, then revisions will need to be made.

Task 12 - Establish documentation and record keeping

Standard HACCP documentation and record keeping is appropriate, but the complexity of the records should reflect the sophistication of the step in the commodity system.

CONCLUSIONS

1. HACCP is a powerful tool with application to the control of mycotoxins in the commodity system.

2. Undertaking a HACCP study focuses the thinking of everyone involved with the product on the details of the process, and promotes a greater awareness of safety issues.

3. Implementation of a HACCP system is not an end in itself. The ongoing maintenance of the HACCP plan is where the benefit really lies.

Appendix II

Tasks involved in developing HACCP system

(Based on Codex 1997)

Task 1.	Assemble an HACCP team
	⇓
Task 2.	Describe product
	⇓
Task 3.	Define essential characteristics of the product and intended use
	⇓
Task 4.	Construct a Commodity Flow Diagram
	⇓
Task 5.	On-site Confirmation of Flow Diagram
	⇓
Task 6.	List all Potential Hazards Conduct a Hazard Analysis Identify Control Measures
	⇓
Task 7.	Determine CCPs
	⇓
Task 8.	Establish Critical Limit for each CCP
	⇓
Task 9.	Establish a Monitoring System for each CCP
	⇓
Task 10.	Establish Corrective Action for deviations that may occur
	⇓
Task 11.	Establish Verification procedures
	⇓
Task 12.	Establish Documentation and Record Keeping

Appendix III

Example of Form – Description and identified use of product

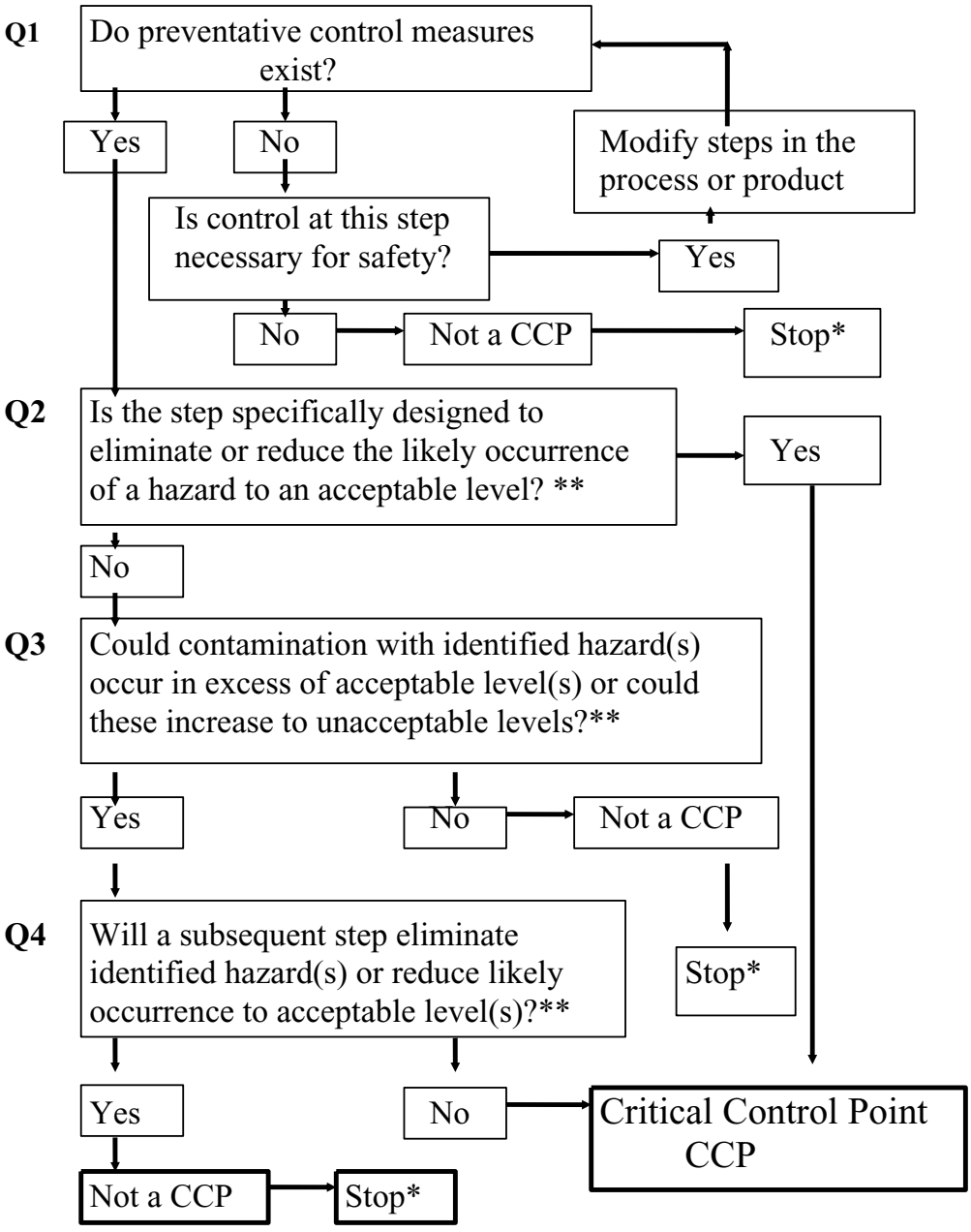
Name of product	
Full description of product including structure/variety, processing parameters, additive concentrations, storage instructions, pH/Aw/moisture levels, *and any mycotoxin target levels (regulatory or to customer specification).*	
Customer specification	
Conditions of storage and distribution	
Shelf Life	
Packaging	
Instructions on the label	
Target Consumer	
Recommendation for further processing required before consumption	
Intended use, e.g. will the end product be cooked before consumption?	

Appendix IV

An example of decision tree to identify CCPs

(The definition of control measure in Codex 1997 has been modified slightly for application to the production chain. The definition now includes activities used to prevent further contamination)

Answer questions in sequence



*Proceed to next hazard **Acceptable levels needs to be defined

Appendix V

An Example of a HACCP Worksheet

1. **Describe Product**

2. **Commodity Flow Diagram**

3. **HACCP Analysis Plan**

Step	Hazard(s)	Control Measures	Control	Critical Limits	Monitoring Procedure	Corrective Actions	Records

4. **Verification**

(Inssert Table 6 – available in hard copy only – one page)

Table 8. HACCP Plan Worksheet, Copra By-Product in Southeast Asia

Process Step	Description of hazard	Possible Control Measures	Control Step?	Critical Limits	
1 Farm Harvest/ de-husking	Mould	Select sound nuts only	CCP1	No visible crack	Inspect
2 Farm Splitting		Avoid soil contamination	GAP	No visible soil on flesh	Inspect
3 Farm Drying	Mould	Dry to 'safe' m.c. within 48 hrs of splitting nut a) Smoke drying to <=16% m.c. no part >17% or b) Hot-air drying to <=12% m.c. no part >13%	 CCP2a CCP2b	Into drier within 12 hours of splitting nuts Dry for >=24 hours Turn copra every 8 hours Dry for >=30 hours Change position on bed every 10 hours	Time pe Time dr Schedu Time dr Schedu
4 Primary Trader Procurement/ Drying	Mould	National grading system Procure Grade 1 copra		GMP/ GSP	
5 Secondary traders Procurement/ Storage	Mould	National grading system Procure Grade 1 copra		GMP/ GSP	
6 Oil Mill Procurement/		National grading system Procure Grade 1 copra		GMP/ GSP	
7 Oil Mill expelling/ pelleting	AFLATOXIN CONTAMINATION	Control moisture of pelleted product during cooling and aeration	CCP3	Final moisture content <=12%	Moistur represe
8 Shipment Export	AFLATOXIN CONTAMINATION	Prevent re-wetting during shipment		GMP/ GSP	

Task 11: Establish verification procedures

Validation procedures are required for each of the CCPs and overall verification of the HACCP Plan is provided by aflatoxin results on representative samples of batches of feed leaving the feed mill.

Complaints from farmers or traders would be logged and followed-up, especially if a pattern developed which was consistent with an outbreak of aflatoxicosis. This could indicate that the HACCP plan has failed and needs to be amended.

The HACCP Plan would be audited quarterly and amended as necessary.

Task 12: Establish documentation and record keeping

The HACCP Plan is fully documented, and records kept of the CCP monitoring data, deviations and corrective actions.

Example 5: Apple juice (Apple drink) - South America

Introduction

There is a significant risk that levels of patulin in apple juice produced in South America will exceed a 50 µg/kg target level. A survey carried out on apple juice in Chile (Canas, P. 1996) found a 28% incidence of samples of apple juice and apple concentrate exceeding this limit.

Apple juice produced in Latin America is different to that produced in Europe in that it has added sucrose and water, as well as the preservative sodium metabisulphite.

Task 1 - The HACCP team

An appropriate HACCP team will be composed of: a HACCP consultant, a mycotoxicologist, a mycologist, a quality assurance manager at the processing plant, a process engineer, representatives of the farmers and the Department of Agriculture, and a scientific secretary. A specialist in the area of fruit juice production and legislative matters will be consulted as and when necessary.

Tasks 2 and 3. - Product Description and Intended Use, Verified.

This information is given in Table 11, below.

Table 11. Description and Intended Use of End Product

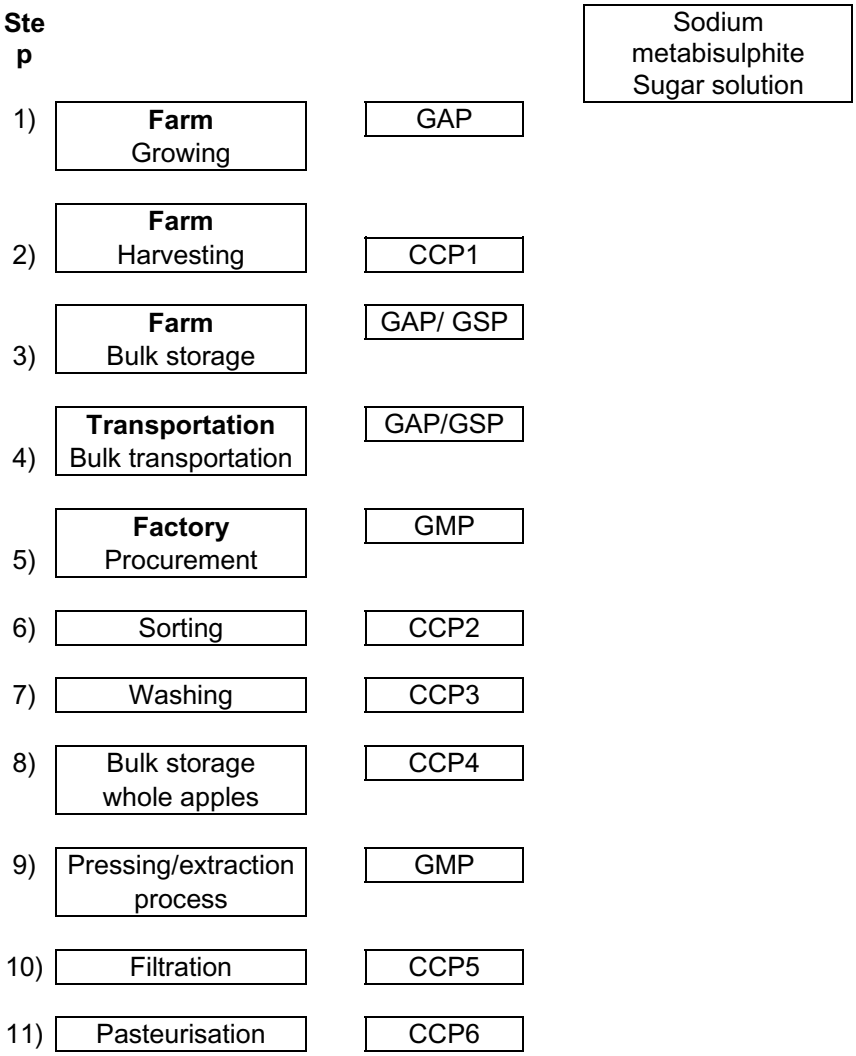
Name of Product	Apple juice
Description	13° Brix apple juice with added sugar, preservative (sodium metabisulphite) and water. Filtered through 5 micron filter, pasteurised at 90°C for 2 minutes
Conditions of storage	Bulk tank at reduced temperature until processed. Ambient temperature when processed
Shelf Life	Six month at ambient. Chilled and consumed within 4 days once opened
Intended use	Consumed without further heating.
Packaging	Glass bottle or tetrapack - 1 litre

Customer specification	Acid level important to product taste. Within microbiological and mycotoxin guidelines
Target Consumer	Local consumption and export. All age groups

Tasks 4 and 5 - The Commodity Flow Diagram (CFD), Verified (Figure 12)

The CFD will be prepared and verified by a series of visits to the orchards and processing plant. A typical CFD is presented in Figure 12.

Fig. 12. HACCP Process Flow-diagram: Apple juice



12)	Aseptic filling	GMP
13)	Storage and dispatch	GMP

Task 6 - Mycotoxin hazard analysis and identification of control measures

a) Identification of mycotoxin hazard

Patulin was the only mycotoxin hazard identified in this product. A number of European countries including Switzerland, Belgium, Austria and France have a 50 µg/Litre limit. The lowest limit is 30 µg/kg, in Romania.

b) Identification of steps in the CFD where mycotoxin contamination is most likely to occur.

Each step in the CFD will be considered in turn.

Patulin contamintion is likely to be produced in the orchard during growing (Step 1) and during bulk storage (Step 3). There is little risk of further contamination during transportation, but damage to apples at this stage can increase the risk of subsequent contamination.

At the factory, patulin contamination is most likely to increase during storage at Step 8.

There is likely to be patulin contamination present in the apples, or the resultant apple juice, at every step in the commodity chain. Hence it is important to both minimise contamination, and reduce levels of contamination to the acceptable level.

c. Possible Patulin Control Measures

Contamination of the juice can be prevented at steps where rotten or rotting apples can be rejected from the process, either in the orchard when the fruit is harvested, or during sorting in the factory.

Post-harvest patulin contamination can be eliminated, or significantly reduced, by storage at <10°C, and by minimising storage times.

Washing, and in particularly pressure spraying, has been shown to be effective in removing patulin from apples.

Patulin can also be removed from apple juice by filtration, when patulin bound to solid particles of apple flesh are removed.

Inactivation of *Penicillium expansum* spores during pasteurisation at Step 11 will reduce the risk of patulin production in the finished juice.

Tasks 7 to 10: Development of a HACCP Plan

A spreadsheet summarising the HACCP plan for patulin in apple juice is given in Table 12. The development of the plan at each step in the CFD is given below.

Step 1: Farm, growing in the orchard - GAP

Growth of the mould *Penicillium expansum*, and subsequent patulin contamination, can occur pre-harvest, where it is associated with damaged and over-ripe fruit. Good Agricultural Practice (GAP) will minimise insect and bird damage.

Step 2: Farm, at harvest – CCP1

The control measure at this step is to efficiently reject rotten and damaged apples during harvesting. Rotten apples are much more likely to contain high levels of patulin than sound looking apples. In one study (Sydenham, E. W., 1995), as much as 70% of patulin present in a batch of over-ripe apples was removed by sorting and removing visually mouldy apples. Application of this control measure at Step 2 is considered a CCP because it will reduce mould contamination to an acceptable level.

The effect of this CCP on levels of patulin in the system should not be considered in

Table 12. HACCP Plan Worksheet, Apple Juice, S. America

Process Step	Description of hazard	Control Measures	Control	Critical limits	Monitoring Procedures	Corrective actions	Records
1 Orchard growing	Mould / Pests	Minimise damage caused by birds and insects	GAP				
2 Orchard Harvest	Mould	Remove mouldy and damaged apples Avoid trash and soil contamination	CCP1 GAP	<1% visibly mouldy apples	Visual observation	Discard	Farm records
3 Farm Cooling and bulk storage	Mould	Reduce risk factors Handling and storage at <10°C to minimise mould growth	GAP/ GHP[2]	All staff to be trained	Check training records Automated readout	Discard Adjust temperature Check monit. system Inspect fruit	Farm records
4 Transportation	Mould	Avoid damage and mould contamination	GAP / GHP				
5 Factory Procurement	Mould	Inspect and reject low-grade apples with >10% mould apples	GMP	<10% damaged fruit	Quality check on representative sample	Reject batch	Factory records
6 Factory Sorting	Mould / Patulin	Remove mouldy apples	CCP2	<1% visibly mouldy apples	Visual observation of samples	Discard or re-sort Adjust inspection procedure	Operator log % reject

[2] GHP = Good Horticultural Practice

Process Step	Description of hazard	Control Measures	Control	Critical limits	Monitoring Procedures	Corrective actions	Records
7 Factory Washing	Mould / Patulin	Leach patulin from apples. Remove rotten parts of fruit containing patulin with pressure spraying	CCP3	Critical soaking time and pressure of spray system	Time of soaking step; regular check of water spray pressure	Repeat the washing step	Factory records
8 Factory Bulk storage	Mould / Patulin	Temperature control to <10°C in store, and minimise time in store	CCP4	<10°C temperature or <48 hours in store	Thermometer reading Storage time	Check monitoring system Inspect fruit	Factory records
9 Factory Pressing/extract.	Mould / Patulin	Cleaning Batch segregation	GMP GMP				
10 Factory Filtration	Patulin Mould	Remove patulin in particles	CCP5	Size and quality of particles remaining	Laboratory test	Un-block/replace filter Re-filter juice	Factory records
11 Factory Pasteurisation	Mould	Destroy *Penicillium expansum* spores	CCP6	Correct time/Temp.	Automated readout	Re-pasteurise?	Factory records
12 Factory Aseptic filling			GMP				
13 Factory Storage &			GMP				

Process Step	Description of hazard	Control Measures	Control	Critical limits	Monitoring Procedures	Corrective actions	Records
dispat							

isolation. The HACCP team will consider the cumulative effects of subsequent CCPs and will judge whether levels of patulin in the final product are likely to exceed acceptable levels. The HACCP team will also consider the fact that removal of mouldy apples at this step will reduce the risk of subsequent patulin production, especially during on-farm storage. There is a subsequent sorting step at Step 6, so it could be argued that sorting is not required here. However, there are strong arguments to support sorting at both steps. Failure to sort at Step 1 will result in greatly increased patulin production at Steps 3, and unnecessary transportation of rotten fruit. There is little doubt that application of this sorting control measure at Step 1 is important for the production of apple juice containing acceptable levels of patulin.

The critical limit for this CCP will relate to the percentage of visibly mouldy apples remaining after sorting, and will be determined by the sorting efficiency which can reasonably be expected at this stage. For this example, the HACCP team considered that 99 per cent of mouldy apples should be removed at this step. The procedure will be monitored by trained supervisors and verified by a grading check on representative samples.

Step 3: Farm, bulk storage - GAP

Application of GAP and GSP is necessary to minimise rotting of fruit and subsequent patulin production during bulk storage. Storage of sound apples is important and the length of storage should be minimised, unless refrigerated storage facilities are used.

Step 4: Transportation – GAP

There is little risk of patulin contamination during short duration journeys, but any physical damage sustained during transportation, including loading and unloading, will predispose the fruit to subsequent mould attack and possible patulin contamination. The correct handling of fruit is therefore required.

Step 5: Factory procurement – GMP

Procurement of batches of low-grade apples, with a high percentage of damaged and rotten fruit, are to be avoided. It could be argued that, with a sorting step to follow, the procurement of low-grade apples would be permissible. However, batches containing >10% rotten fruit, say, will be extremely difficult to sort manually, and the levels of patulin likely to be present will make it difficult to attain an acceptable level of patulin in the finished product.

Step 6: Factory sorting – CCP2

The control measure is sorting to remove visibly mouldy apples. This CCP will reduce the level of mould to an acceptable level, and make a major contribution towards achieving an acceptable level of patulin in the final product. Sorting will both remove mouldy apples missed during sorting at Step 2, and remove apples that have subsequently become mouldy at Steps 3 and 4.

As for Step 1, the critical limit for this CCP will be the acceptable percentage of mouldy apples remaining after the sorting procedure, and monitoring will be by use of a trained supervisor.

Step 7: Factory, washing – CCP3

The control measure is washing the apples using high-pressure water spraying to remove rotten apple flesh, and patulin, from the fruit. Studies (Acar, J., 1998, & Sydenham, E.W., 1995) have shown that washing in this way can remove more than half of the patulin present in the fruit. The critical limits for this CCP will be related to the pressure of the sprays and the duration of the washing step. The water pressure will be monitored using pressure gauges and the washing step will be timed.

Patulin levels will be reduced at this step, but spores will be suspended in the water. This inoculum will increase the risk of mould growth during bulk storage.

Step 8: Bulk storage of whole apples – CCP4

The control measure is to prevent mould growth and patulin production by storing at reduced temperature. If refrigerated storage is not available, then storage time must be minimised. The critical limits are either a storage temperature of <=10°C or a maximum storage time at ambient temperature of 48 hours. These critical limits for temperature are monitored by means of a calibrated thermometer, preferably with a continuous chart read-out, and the storage period is monitored by a timing device.

Step 9: Pressing/ extraction process – GMP

Good Manufacturing Practice will ensure that the presses are cleaned regularly to prevent a build-up of mouldy apple waste which could be a source of patulin contamination.

Step 10: Filtration – CCP5

The control measure is the removal of fine, patulin-rich particles held in suspension in the crude juice. Research has shown (Acar, J., 1998) that a significant reduction in levels of patulin can be achieved using filtration. Conventional clarification by means of a rotary vacuum precoat filter resulted in a 39% reduction in levels of patulin, and ultrafiltration resulted in a 25% reduction. Critical limits are set for the size and quantity of particles remaining in the apple juice after filtration. These critical limits are monitored by microscopic examination of samples of apple juice.

Step 11: Pasteurisation – CCP

This step is a CCP for the control of bacterial hazards. However, it can also be considered as a CCP for control of the patulin hazard since pasteurisation will destroy spores of *Penicillium expansum*, and therefore prevent any subsequent mould growth, and patulin production, in submerged culture in the apple juice.

Although patulin levels are unlikely to be reduced significantly during pasteurisation, mould spores will be destroyed and the risk of patulin being produced subsequently in the apple juice will be reduced.

Step 12: Asceptic packaging process - GMP

Following pasteurisation, it is important to prevent the re-introduction of micro-organisms, including mould spores, during packaging. These procedures are covered by GMP.

Packaging is selected which will protect the juice from contamination by micro-organisms, e.g. tetra packs, or glass bottles with air-tight seals for the lid.

Step 13: Storage and dispatch - GMP

No subsequent contamination with patulin is likely.

Tasks 11: Establish verification procedures

The HACCP plan will be audited quarterly, and amended as necessary.

Tasks 12: Establish documentation and record keeping

The HACCP Plan will be fully documented, and appropriate records kept at each CCP.

References

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