



The Application of HACCP Principles

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A Practical Guide for the Agri-Food
Supply Chain

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1 INTRODUCTION

Hazard Analysis and Critical Control Points (HACCP) is a system that was devised to identify, evaluate and control hazards that are significant for food safety. This Guide is designed to help the following operations use HACCP principles within their businesses although its use must be supported by thorough training by those experienced in the practical application of the principles:

Producers and processors of feed materials, additives and additive like substances (feed ingredients);

Those who trade, merchant, store, pack or deliver feed ingredients or compound feeds;

Producers of compound animal feeds;

Those who trade, merchant, store, pack or deliver combinable crops for human or animal consumption.

Hazard Analysis and Critical Control Points (HACCP) is a methodology jointly developed during the 1960s by the Pillsbury Company, the United States Army Laboratories and the National Aeronautics and Space Administration (NASA) to ensure that foodstuffs taken into space would not cause harm to astronauts. As product testing alone was not a practical solution for the identification of all potential hazards, the HACCP concept was created. Today HACCP is the most widely used method for assessing potential food safety hazards in the food industries right across the globe. HACCP is the recommended food safety methodology of the World Health Organisation and is a requirement of food and feed regulations and certification standards in Europe. Regardless of the legislative requirement for HACCP, food and feed companies are discovering that it can deliver real benefits, both financial and otherwise, to their businesses. In particular, the management of commercial risk is a significant benefit of an effective HACCP system.

In its purest form, HACCP is concerned solely with food safety and only with food intended for human consumption. The methodology behind HACCP is however suitable for much wider application and is already used by the feed industries of several countries in considering potential hazards to both human and animal health. With the introduction of the EU Feed Hygiene Regulation (EC) No. 1831/2003 feed may not be placed on the market or fed to any food producing animal if it is unsafe and adherence to HACCP principles is a legal obligation for all 'feed business operators'. The techniques associated with HACCP can also be used to consider additional issues that may not strictly be hazardous, but are of critical interest to the feed industry. This Guide is intended to optimise the benefits of developing HACCP systems into practical and beneficial tools for feed businesses. In so doing, the methodology used for HACCP is utilised to consider wider issues than would be the case in textbook HACCP studies. For this reason, references in this Guide to 'HACCP' should be interpreted as meaning 'HACCP principles' as described in Codex Alimentarius and 'HACCP methodology' rather than 'pure' HACCP.

This Guide is designed for use both by companies for whom HACCP may be a completely new concept and also for those companies with prior experience of HACCP. Companies already operating a HACCP system will find this Guide particularly useful if they are seeking certification against an accredited feed industry assurance scheme or have found that their existing HACCP system does not bring significant benefits to the business. HACCP systems can be effectively implemented to provide benefits to companies of all sizes, from one-man operations to multi-national corporations. This Guide is therefore intended for use by businesses both large and small.

2 THE AIM OF HACCP IN AGRIFOOD SUPPLY CHAIN BUSINESSES

It is important right at the outset to consider what is to be achieved by using HACCP principles and then to keep this in mind through the process of developing and maintaining a risk management system.

Many businesses will be familiar with ISO 9000, which focuses on systems and procedures, however HACCP is different – it focuses on the product. Systems, procedures and records will inevitably play a part in delivering the controls required by HACCP, but systems and procedures are only required by HACCP where they help to maintain the integrity of the product. ISO 9000 and similar standards are not an essential requirement for a successful HACCP.

By definition, HACCP is intended to control hazards, typically divided into physical, chemical and biological hazards.

In the context of the agri-food supply chain, the hazards to be considered fall into two main groups:

Hazards that have the potential to cause direct harm to animals eating feedingstuffs or humans consuming agricultural plant products.

These may be physical (e.g. stones are a choking hazard, wire may pierce the gut wall, glass may cut the gut, etc), chemical (e.g. mycotoxins produced from fungal activity, fertilizers or pesticides used in the growing of crops etc) or biological (e.g. various diseases, salmonellae or other pathogens).

Hazards that have potential to cause actual (or perceived) harm to humans consuming animal products.

The hazards most likely to affect humans through this route are of chemical or biological origin. For example, chemicals hazardous to humans include Aflatoxin B1 that may be present in certain feed materials, synthesised in the gut of dairy cows and excreted into milk as Aflatoxin M1. The most notorious biological hazards are probably the various types of salmonellae that can be present in feed materials and feed products, ingested by livestock and subsequently contaminate eggs or carcasses. In addition, it may be that regulations, the media or consumer regards an aspect of the feed product or feed material as 'hazardous' although there is no factual basis for concern. An example is the EU ban of meat fit for human consumption from any livestock feeds, where the legal framework assumes the feeding of meat is potentially hazardous and therefore the feed business operator must do the same. Control of these kinds of issues may need to be included in the HACCP Plan.

In the context of the agri-food supply chain, the aim of HACCP is to identify what hazards exist and the risk of them having a detrimental effect on both animals and humans, then to implement controls, so that any potential effect is prevented or reduced to an acceptable level.

It is important to remember that potential hazards may be inherent to the products themselves (e.g. mycotoxins in crops or heavy metals in minerals) or to the processes that produce them (e.g. by addition to growing crops as fertilizers or pesticides, through combustion gases from direct flame driers and solvent residues from oil extraction), or may be introduced subsequently during transport, storage and handling (e.g. through contamination, weather damage, pest damage or chemicals used in pest control).

In a business environment of finite financial and personnel resources, HACCP methodology helps to focus attention on the areas of the business that really matter if hazards and the risks of them occurring are to be controlled. There is consequently a business advantage in developing a HACCP system – it ensures both spending and time are targeted in the right places to assure the products.

2.1 HACCP in Feed Production

The distinction between 'quality' and 'food safety' is less clear in feed than it is with food, as a quality failure may quickly affect the health or performance of the animals being fed and consequently make the feed unsafe; particularly for livestock where only one source of feed is available. Some examples may illustrate this point:

Insufficient sodium will cause tail biting in pigs, navel sucking in cattle and reduced egg production in laying hens. Excessive sodium in feed will in contrast make all classes of livestock drink substantial quantities of water and cause diarrhoea.

A significant and uncontrolled drop in the fibre levels of a feedstuff can cause constipation in livestock and in worst case scenarios will result in collapsed guts or prolapse.

For humans, if we do not find food attractive we can usually replace it with something we do like. For intensive livestock species in particular, feed that is unpalatable or does not flow out of the feeders correctly may fairly quickly result in a loss of growth performance, a drop in milk yield or a reduction in the number of eggs produced, simply because the livestock have no other source of nutrition available and have starved.

Although the control of sodium, fibre, palatability and flow characteristics in feedstuffs are a matter of 'quality', the effects of getting it wrong can be hazardous to the well-being of the animals concerned. Whereas relatively minor adjustments in the nutrient levels of any given foodstuff will rarely have a severe effect on most humans (because human diets often offer a wide selection of items that balance each other), the same relatively small adjustments in the nutrient levels of animal feedstuffs may have severe effects on the animal. The relationship between quality and food safety in animal feed is therefore far less distinct than it is for human food and critical quality parameters are worthy of consideration when undertaking a HACCP study.

Although compound feeds are usually designed for specific species of animals, the same feed ingredients may be fed to many species of animals. The sensitivity and tolerance of different livestock species to nutrients or anti-nutrients is extremely variable. Any consideration of hazards therefore has to include the particular needs and sensitivities of all the species for which the feedstuff is intended.

3 THE PRINCIPLES OF HACCP

The *Codex Alimentarius Commission of the World Health Organisation* has issued a list of seven principles of HACCP (CAC/RCP 1 - 1969, rev.4 –2003), which have been adopted widely and form the basis of most HACCP guidelines

These principles are:

- ***Conduct a hazard analysis.***
- ***Determine the Critical Control Points (CCPs).***
- ***Establish critical limit(s).***
- ***Establish a system to monitor control of the CCP.***
- ***Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.***
- ***Establish procedures for verification to confirm that the HACCP system is working effectively.***
- ***Establish documentation concerning all procedures and records appropriate to these principles and their application.***

These principles will be used to lead us through the development of a HACCP system in the following sections of this Guide.

4 PREPARATION FOR THE HACCP STUDY

4.1 Selecting the HACCP Team

In a classic HACCP Team the following disciplines will be represented but not necessarily by different people in every case:

Team Leader. This may be one of the people identified below and ideally will have been trained in HACCP principles and have experience of applying them.

Quality Assurance/Quality Control/Technical. This will require someone who understands the products under consideration and the historical hazards and critical issues associated with them.

Production. This will require someone who is closely involved with the production process and has an intimate knowledge of what happens where in the process.

Engineering. This will require someone who understands the mechanics of the processing plant, where material may accumulate inside machinery, where heat or moisture may be applied and how to gain access to machinery.

Additional, Part-Time Expertise. This may require specialists who offer technical or specific expertise on purchasing, operational activities, distribution, microbiology, specific species requirements, etc.

It is essential that Team members are familiar with what actually happens in the business and are not too removed from day to day activities. They must be given the authority to carry the project forward, but may not necessarily themselves be amongst the most senior members of the company.

It is important to have a person available who is competent in HACCP techniques if no member of the Team has the necessary training and experience.

There will necessarily be a lot of documentation generated by the HACCP Study. The inclusion in the Team of someone with skills to record all this information will allow the Team to focus on the task.

For complex businesses the core HACCP Team should ideally be supplemented with:

A qualified HACCP expert (if no member of the core team is already qualified);
Secretarial/computing services.

Once the HACCP Team has been appointed, it can then move on to consider the HACCP study.

4.2 HACCP Study Documentation

It is important that all parts of the HACCP study are recorded and documented. This will provide information for the Project as it develops and references for future HACCP reviews.

4.3 Scope of the Hazard Analysis

The business can ultimately only exercise direct control over those areas where the product is owned by the business. Not all potential hazards may however be identified in this part of the supply chain and it is important for the study to consider all potential hazards, whether they are introduced in areas where the business has direct control or outside of these. This is particularly true of feed ingredients where it will be necessary to gain an understanding of how and where these are produced and what happens to them between the point of production and their being supplied to the business. Identifying the potential hazards in feed ingredients will play a significant part in determining specifications and contractual requirements imposed upon suppliers by the business.

4.4 Products to be included in the HACCP Study and Product Descriptions

The HACCP team must consider and document all products that are to be included in the study, as well as all locations and processes relevant to them. This should include different physical forms of product, products intended for different species and products produced by different processes. The HACCP team must also understand the intended use of the products by the customer.

Where product specifications already exist the HACCP team should refer to these. Where they do not already exist, the team must work with the relevant departments of the business to develop product specifications. It is possible that the HACCP risk assessment will uncover potential hazards that need to be included in the product specifications: for example limitations in the way products are used.

4.5 Prerequisite Programmes

Before undertaking a HACCP study a company should have in place basic operating procedures validated as effective by internal auditing systems. These procedures are referred to as 'prerequisites' (i.e. 'required as a prior condition') for the HACCP system.

Some examples of prerequisite programmes include:

- Smoking, eating and drinking policy
- Cleaning schedules and hygiene audits
- Pest control programme
- Supplier approval procedures
- Plant operating procedures and instructions
- Job descriptions and responsibilities
- Staff training

The establishment and validation of effective procedures to control potential hazards in these areas allows the HACCP to focus on those hazards not controlled by other means. Subsequent HACCP reviews must revisit prerequisites as well as the HACCP system itself to ensure that large areas with potential hazards are not ignored.

4.6 Producing Flow Diagrams

A flow diagram (or series of flow diagrams for ease of use) should be created dividing the business process into a series of numbered steps (for ease of reference), from the start of the operation, through processing (where applicable) and distribution to the customer, taking into account any storage, transport or handling involved.

For a manufacturing business, a current engineering flow diagram should be available to the HACCP team. The HACCP team should confirm the details of any engineering flow diagrams produced by physically checking them against the process being studied, prior to progressing to the next stage.

Flow diagrams should include (where relevant):

- All administrative processes such as order receipt and product formulation
- All relevant inputs to the process flow, including raw materials and any products purchased for re-sale
- All mechanical process steps
- Passive equipment (such as stone traps and magnets)
- Recycle and return loops where fractions are returned to the process
- Potential areas for cross-contamination
- All areas where product is not enclosed
- Storage, packing and transport steps
- Steps where fractions are removed from the process (and do not return)

(This list is not necessarily exhaustive)

The overview flow diagram will subsequently need to be broken down into smaller and more detailed sections for working purposes and the determination of potential hazards.

4.7 Description of the Business Process

It is useful to describe the business processes in simple terms. This ensures that all members of the HACCP team fully understand the process flow. Process descriptions are helpful for external auditors and enforcement officers with statutory authority.

5 THE HACCP STUDY

5.1 Hazard Analysis (Codex Principle 1)

‘Hazard - a biological, chemical or physical agent or condition with the potential to cause an adverse effect’

HACCP concerns the product. It is essential to bear in mind both the process of production and expected use of the product:

5.2 Identifying Hazards

At each step of the process, the HACCP Team should list all the potential hazards that might reasonably be expected to present a threat. At this stage all hazards should be listed and any that may be removed from the study as prerequisites can be identified at a later stage.

Key considerations are:

- Hazards inherent within the product
- Hazards that may be introduced at the process step in question
- Hazards that may increase at the process step in question

5.3 Risk Assessment

The HACCP Team should next undertake a risk analysis of all the hazards identified. The aim is to identify those that have the most impact on feed or food safety by assessing the likelihood of each occurring and the severity of its effect. Existing controls should be ignored in this exercise.

Some practitioners find it helpful to use a simple model for scoring hazards. A table that can be used to manage this is suggested in Appendix 2.

Whether or not a risk scoring method is used, it is necessary to ensure that the most significant risks receive the most attention.

5.4 Tabulating the HACCP Study

For ease of reference it is beneficial to use a HACCP table to summarise the data accumulated from the HACCP Study. When using such a table, it is important that the detail includes actions, responsibilities and timescales.

5.5 Creating Control Measures

Control Measure - 'A control measure is any action and/or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.'

It is important to apply a control measure or measures wherever there is a hazard with a high risk score (3 or above) to eliminate it or reduce it to an acceptable level. The control measure(s) can take several forms but must be practical and achievable. When determining control measures the following considerations apply:

- Can the hazard be eliminated?
- Can the hazard be removed by engineering design?
- Can the hazard be managed by automated process control systems?
- Can the hazard be managed by personnel action?

5.6 Validation

Any controls applied must be validated to ensure they are effective. For example, this means demonstrating by analytical or other means that a statement made about a control is true and the control works as intended. Records of this must be kept for future reference.

5.7 Determining the Critical Control Points (Codex Principle 2)

Critical Control Point - 'a step at which control can be applied and is essential to prevent or eliminate a hazard or to reduce it to an acceptable level.'

Critical controls points (CCPs) are those that are essential for excluding hazards or for maintaining them at acceptable levels and where no subsequent process or procedure will be able to control the hazard adequately in the event of a failure. Determining whether control points are 'critical' can be done using a decision tree. An example of a decision tree is shown in Appendix 1.

Having determined and confirmed the CCPs it is important to identify them clearly in all HACCP-related documentation. In the case of physical equipment these should be clearly labelled or otherwise identified.

5.8 Establishing the Critical Limits (Codex Principle 3)

Critical Limit - 'a criterion separating acceptability from unacceptability.'

Having determined all the CCPs in the process under study, the HACCP Team must detail the critical limits for the control measures at each of these. The critical limit is that which divides the acceptable from the unacceptable. Some critical limits will be determined by legislative requirements, while others will be determined by experience or scientific research.

5.9 Establishing a Monitoring System (Codex Principle 4)

Monitoring - 'the act of conducting a planned sequence of observations or measurements to assess whether a control measure is operating within specified parameters.'

Businesses must be aware when critical limits have been breached or where there is a trend indicating that they may be breached. Achieving this may require automatic recording, observation and/or testing. Whichever methodology is most appropriate, monitoring must be recorded.

Ideally, monitoring systems must be designed to identify as quickly as possible any controls that are becoming ineffective, prior to their failure. The frequency of any monitoring is therefore also important and should be specified as part of the HACCP System.

It is essential that properly qualified and authorised personnel undertake monitoring activities and those authorised to undertake monitoring must be specified in the HACCP System. For example, if testing forms part of the monitoring activity, the HACCP system must define how samples are taken, and by whom, as well as who monitors the test results. The monitoring frequency must also be specified in the HACCP system.

5.10 Establishing a Corrective Action Plan (Codex Principle 5)

Corrective Action - 'an action to be taken when monitoring indicates a loss of control.'

The HACCP Team must specify the actions to be taken in the event of a CCP going out of control. Responsibilities for implementing corrective actions must be clearly assigned and documented.

It is important to ensure procedures also consider action to be taken with regard to any product processed since controls were last confirmed as operating within acceptable limits. This may require bonding of stock or even recall of product from customers or intermediaries.

5.11 Verification (Codex Principle 6)

Verification - 'the application of methods, procedures, tests and other evaluations, in addition to monitoring, to ensure compliance with the HACCP plan'

Verification systems must be implemented by the HACCP Team to ensure not only that all personnel are complying with the requirements of the System, but also that the System is effective.

Verification systems must review the whole HACCP system and its associated records. There may be several CCP's in the HACCP Plan to control one hazard type each with its own appropriate monitoring, however the verification activity should cover the control of that hazard throughout the whole process. When establishing verification systems the following should be considered:

- Sampling & Testing
- Complaints Monitoring
- Internal Auditing Of The HACCP System
- External Auditing Of The HACCP System

6 ESTABLISHING DOCUMENTATION (Codex PRINCIPLE 7)

No HACCP System will work effectively unless the controls it identifies as necessary are properly implemented. In most circumstances this will require the establishment of procedures and records. Therefore a HACCP System must include two types of documentation.

THE HACCP Plan itself - this is all the detail described previously in this Guide.

Procedures and Records – these include written procedures detailing control measures and other aspects of the HACCP Plan, together with associated records. These may form part of a Quality System (such as ISO 9001/2), or may solely be connected to the HACCP Plan. For practical purposes, it is usually most effective to integrate HACCP procedures and records into the overall quality system of the business, wherever possible.

7 HACCP SYSTEM REVIEW AFTER IMPLEMENTATION

7.1 Immediate HACCP System Review

There are a number of circumstances under which sections of the HACCP System, or even the whole HACCP System, may need to be reviewed immediately. In particular, where any changes are being considered, the HACCP Review must always form part of the planning process. In such circumstances the HACCP Team must instigate an immediate review to ensure all identified hazards will still be under control and no new ones result from the changes. Minutes of Immediate Reviews must be kept for future reference and be considered as part of the Scheduled Review. Some examples of circumstances that may require an Immediate Review of part or all of the HACCP System are noted below (this list is not exhaustive):

- Changes in raw materials, suppliers or sources
- Changes in formulation
- Changes in factory equipment or layout
- Proposed modifications or replacement of process & handling equipment
- Changes in cleaning or maintenance practices
- Changes in packaging, transport or storage
- Changes in personnel, whether replacement or reduction in numbers
- Changes in product type or use
- Changes in customer base that may affect the hazard analysis
- Changes in legislation/other requirements
- A breach of HACCP critical limits
- Feedback/complaints from customers
- New knowledge regarding potential hazards

7.2 Scheduled HACCP System Review

At least annually, the HACCP Team must meet to discuss the HACCP System from start to finish in a scheduled HACCP Review. Minutes must be kept of Scheduled Reviews for future reference. Among the issues to be considered are:

The records of any breaches of critical limits, corrective actions that were implemented at the time and the lessons to be drawn from this. The aim should be to ensure that critical limits are never breached.

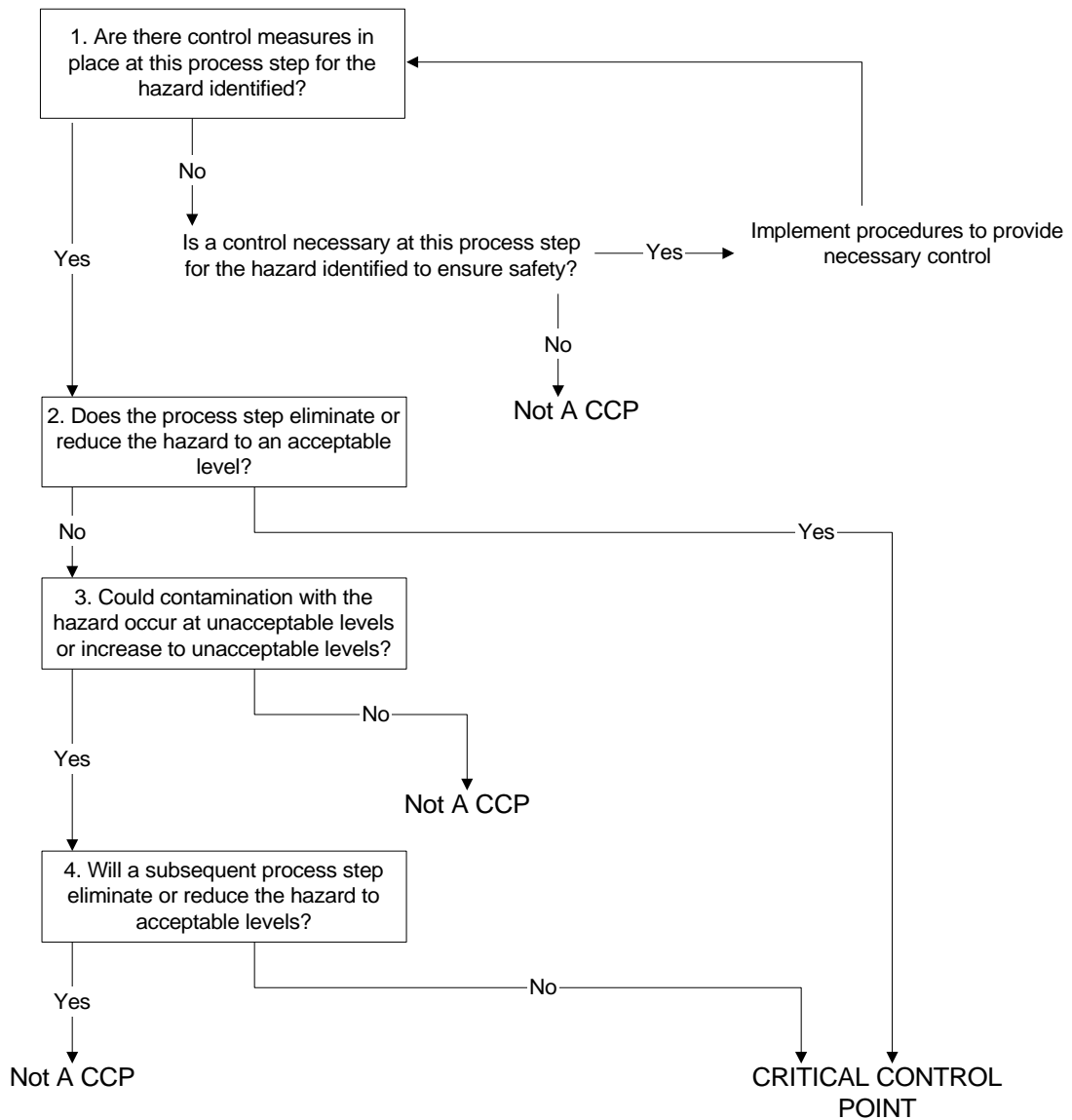
Records of any deviations from targets and the lessons to be drawn from this. Excessive deviation from targets may indicate controls are too loose and need to be tightened. Very few deviations from target may suggest controls are too tight and excessive costs could be incurred as a consequence. The results of any internal or external audits and any lessons to be drawn from these. (It is however essential not to use an impending review as an excuse to leave corrective actions unresolved).

The continued validity of the principles upon which the HACCP system has been built. Do changes in regulations, industry and company practices, equipment or personnel require changes to be made in the HACCP system? (This is to ensure that no changes have escaped Immediate Review.)

In any effective HACCP system fully integrated within a business, the above areas should be addressed on a routine basis as necessary and not left for the scheduled HACCP system review.

Appendix 1 HACCP Critical Control Point Decision Tree

Questions should be followed in sequence for each hazard identified at each process step



Appendix 2 Risk Score Table

Risk Score =severity of hazard X probability of occurrence

Risk Assessment		Probability of Occurrence (if not controlled)		
		High (3)	Medium (2)	Low (1)
Severity Of Occurrence	High (3)	9	6	3
	Medium (2)	6	4	2
	Low (1)	3	2	1