Microbiological Risk Assessment (MRA) in Food Processing

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QUICK SUMMARY

Microbiological risk assessment (MRA) is one of the most important tools in food safety management. It provides a structured way of identifying and assessing microbiological risks in food but can be a challenge for those responsible for food safety in a processing environment.

This whitepaper provides an overview of the main steps in MRA and practical tools for conducting each step. These can be used by practitioners to improve the quality of local HACCP plans and improve overall food safety.
1 INTRODUCTION

Throughout food safety management standards Risk Assessment (RA) has become the core tool required to determine the scope and nature of specific food safety controls and programs. From HACCP to pest control, companies are now required to conduct an assessment of risk to support and justify their food safety management system. Yet it is widely believed that the skills and knowledge necessary to conduct such risk assessments may not exist in the majority of food businesses.

In the GFSI series of standards, recent revisions have seen the requirement for conducting risk assessment increase dramatically. How these risk assessments should be conducted and to what extent has not been highlighted, leaving a wide gap for local interpretation. The value of risk assessment is generally accepted. It is a scientific and analytical process or tool that requires various factors to be assessed before deciding on the significance of a particular hazard. This has the benefit of ensuring that the resources in a food processing operation can be focused on the areas of greatest importance for food safety. However, its effective use requires knowledge of the principles and practices of RA and good quality data to drive valid decisions. In the world of food safety, microbiological hazards represent the greatest risk in terms of poor consumer outcomes when an outbreak occurs. On the serious end of the scale these incidents often result in widespread illness, hospitalizations, chronic medical conditions and deaths.

In this whitepaper, we will cover the specific area of Microbiological Risk Assessment (MRA) and provide workable tools to assist you in better determining the risks associated with microbiological hazards. This should drive better and more robust HACCP planning within your plant. It is not intended to address all the areas of MRA (which is a vast subject) but rather to cover the general principles and provide some workable tools for their application.

2 MICROBIOLOGICAL RISK ASSESSMENT OVERVIEW

Those responsible for the implementation and maintenance of food safety plans in processing plants are frequently preoccupied with questions such as how best to identify hazards, how to determine whether hazards are important or significant and where to find information on hazards? In particular, microbiological hazards present the most difficulty since many food safety managers with the responsibility of hazard analysis and HACCP planning are not microbiologists and when they find information on the subject, may not always be in the position to interpret it correctly.

The evolution of risk based food safety systems such as HACCP have played a major role in protecting public health and underpinning our efforts in a structured and scientific way. However, the practical impact on those in our industry who are required to develop these systems is significant and often characterised by what we don’t know rather than what we do. There is a documented case where a food business producing salami products decided to develop a snack version which was smaller and had a higher mass to surface area ratio. The product dried out faster, water activity fell faster and acidification was incomplete. This gave rise to favourable conditions for Salmonella growth and resulted in a market recall.
The case highlights the difficulty with microbiological risk assessment as part of HACCP. The simple act of producing a smaller version of the same product led to a microbiological hazard that previously did not exist. It also indicates the knowledge required to conduct proper hazard identification.

Much has been written on the subject by experts trying to understand why HACCP plans fail and lead to recalls. Research reviewed by Kane, Mayes & Mortimore identified poor hazard identification and hazard analysis as a significant reason. So how do we conduct microbiological risk assessment in food processing plants? How do we ensure that our risk assessments are robust enough to support our HACCP plans and reduce the chances of product failures?

In this whitepaper you will find practical support and resources for conducting MRA. It is not an easy topic to address, yet it is an essential part of what we do as people responsible for food safety. There are four main steps in conducting a Microbiological Risk Assessment:

- Hazard Identification
- Hazard Characterisation
- Exposure Assessment
- Risk Characterisation

These steps have been defined by bodies such as the WHO/FAO and bearing in mind that no food processing plant has the massive resources of these bodies, we can use simple tools to conduct a good quality MRA depending upon the complexity of your products and processes.

3 HAZARD IDENTIFICATION [STEP 1]

This is the first step in conducting microbiological risk assessment and perhaps the most important since if you don’t identify the hazards correctly no amount of subsequent HACCP planning will make your product safe. The purpose of hazard identification is to identify the micro-organism(s) of concern that may be present in the food you manufacture.

While on the face of it this may appear to be straightforward it can often prove to be difficult without expertise. Assuming you do not have a large budget to employ the services of a microbiologist you will need to undertake this process yourself. Nor should you depend solely on the senior microbiologist in your external testing laboratory that may not be fully knowledgeable with all aspects of your product and processes.

The hazards of concern may come from a variety of sources including:

- Raw materials
- Methods of production
- Use of the food

In short, you are looking to generate a list of potential microorganism that may have adverse impacts on human health should they be present in the food. And to do this you need Information. Remember this takes time but the effort will ensure your HACCP plan is robust and valuable from the outset. There is a wealth of information available on food hazards and much of it is freely available from quality sources on the internet. Table 1 contains a list of some of these sources but there are many more.
For example, the Big Bug Book provides excellent information on specific pathogens including details on associated food products and outbreaks. Foodrisk.org contains a good database of food hazards organised according to commodities. The database can be easily searched.

<table>
<thead>
<tr>
<th>Source</th>
<th>Notes</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU Commission Food &amp; Feed Safety website</td>
<td>Useful all-round web site for food safety management. The Biological and Chemical safety links at the top contain reliable reference on hazards. You’ll find links to many decisions, opinions and scientific reports from the Commission.</td>
<td><a href="http://ec.europa.eu/food/food/index_en.htm">http://ec.europa.eu/food/food/index_en.htm</a></td>
</tr>
<tr>
<td>Food Risk.Org</td>
<td>Formally known as the Food Safety Risk Clearing House. Run by the FDA, University of Maryland and JIFSAN. Excellent source of hazard and risk data on food with an excellent search facility [Hazard and Product]. Also has tools for conducting RA including micro modelling.</td>
<td><a href="http://www.foodrisk.org/">http://www.foodrisk.org/</a></td>
</tr>
<tr>
<td>United States Department of Agriculture (USDA)</td>
<td>HACCP AND PATHOGEN REDUCTION PROGRAMMES: This is useful to gain an understanding of the practical outputs of risk assessments, food safety objective (FSO’s) and relationship with local HACCP plans.</td>
<td><a href="http://www.fsis.usda.gov/Science/hazard_analysis_&amp;_pathogen_reductio">http://www.fsis.usda.gov/Science/hazard_analysis_&amp;_pathogen_reductio</a></td>
</tr>
<tr>
<td>WHO/FAO</td>
<td>Website with extensive risk assessments and other food safety resources.</td>
<td><a href="http://www.who.int/foodsafety/en/">http://www.who.int/foodsafety/en/</a></td>
</tr>
<tr>
<td>CODEX Alimentarius</td>
<td>CODEX Standards, guides, RA etc</td>
<td><a href="http://www.codexalimentarius.net/web/index_en.jsp">http://www.codexalimentarius.net/web/index_en.jsp</a></td>
</tr>
</tbody>
</table>
Table 1: Hazard Data Sources

Once you have compiled your list of potential microorganisms you will need to decide whether they are significant and require more detailed analysis in Step 2: Hazard Characterisation.

To do this you will need to apply a series of logical questions which can come in the form of a decision tree not unlike that found in HACCP. However, these questions are very specific for microorganisms and more focused than the generic ones found in the four-question HACCP decision tree. Table 2 contains a template of this decision tree which has been adapted from P. Vosey et al.

<table>
<thead>
<tr>
<th>State pathogen:</th>
<th>Question</th>
<th>Answer (YES / NO)</th>
<th>Outcome</th>
<th>Reference / Notes / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the pathogenic micro-organism present in raw materials?</td>
<td>If YES proceed to Question 2</td>
<td>If NO Eliminate Organism from List</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Will the production process eliminate micro-organism completely?</td>
<td>If YES Eliminate Organism from List and proceed to Question 3</td>
<td>If NO proceed to Question 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Can this pathogenic micro-organism contaminate the product after processing/production?</td>
<td>If YES proceed to Question 4</td>
<td>If NO Eliminate Organism from List and proceed to Question 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Has this micro-organism caused problems in the past with identical or related products? (Literature Review)</td>
<td>If YES proceed to Question 5</td>
<td>If NO Eliminate Organism from List</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Is the pathogen an INFECTIOUS or TOXINOGENIC organism?</td>
<td>If TOXINOGENIC proceed to Question 6</td>
<td>If INFECTIOUS it is a Potentially Hazardous Micro-organism</td>
<td>ADD TO FINAL LIST FOR RISK PROFILING</td>
<td></td>
</tr>
<tr>
<td>5. Will there be growth of the organism in the product?</td>
<td>If YES it is a Potentially Hazardous Micro-organism</td>
<td>If NO Eliminate Organism from List</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ADD TO FINAL LIST FOR RISK PROFILING</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
You should work your way through the questions until you have developed your final list of pathogens. Don’t forget to keep a copy of all your work and reference sources for the auditor when he/she arrives. The key to Hazard Identification is to review as much information and data as possible. You can do this over time and build up your own data bank of information. The more you know the better your risk assessment and resulting HACCP system will be. None of this time will be wasted.

4 HAZARD CHARACTERISATION [STEP 2]

Once you have identified the specific pathogens of concern the next step is hazard characterisation. This should be conducted for each pathogen identified. In its simplest terms, hazard characterisation is an assessment of the pathogen and the nature of the problems it can cause. We are trying to answer a number of questions in order to develop a true understanding of the character of the hazard. These questions include:

- What is the disease caused by the pathogen?
- What are the symptoms and how long before their onset?
- What are the range and likelihood of adverse outcomes, e.g. death?
- What is the minimum dose required to produce symptoms?
- Who are the main 'at risk' groups in the population?

To answer these questions you will need good sources of information. Remember, this data may not always be available so there will likely be a degree of uncertainty in your answers. This is unavoidable; however, what is important is that you identify this uncertainty. The New Zealand Food Safety Authority has produced some excellent datasheets on the main food pathogens where you will find much of the information required for hazard characterisation. The image below is part of the datasheet for E. coli O157 (refer to Table 1 for link to this source).
An important concept of hazard characterisation is ‘Dose-response’. This is the minimum level of the pathogen required to be ingested to cause an adverse response, e.g. 10 cells. Again, this information can be found in the above mentioned data sheets.

**MRA Risk Assessment Model**

Once the hazard(s) have been identified, the data and decisions of your risk assessment need to be combined for steps 2, 3 and 4 including Hazard Characterisation. You will find a model developed in Excel which allows you do this. It is based on a variety of sources and tools that have been referenced. It can be used to capture and score the required questions. The model contains all the steps required for good quality risk assessment with the final total score providing a measure of the risk. The model is easy to work and can be updated as more information comes to light.

To access and download a copy of the model go to: [http://www.safefood360.com/resources/](http://www.safefood360.com/resources/)

**Picture 1: MRA Excel Model**

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**5 EXPOSURE ASSESSMENT (STEP 3)**

In the previous two steps we a) identified the likely hazards of concern and b) characterised these hazards in terms of the dose and response. When conducting a microbiological risk assessment the next step is exposure assessment. The aim of exposure assessment is to determine the level of the microorganism (or toxin) likely to be present in the food at the time of consumption. Here we must take into account a number of potential paths or routes of contamination and the impact of various processing steps on microbiological levels.
The following are important:

- The microbiology of the raw material, e.g. raw meat will have certain pathogens associated with it
- Initial contamination levels of raw materials
- The effects of production, processing, handling, etc. on the levels of pathogens in the final product
- Sanitation standards in your processing plant
- Potential for re-contamination after a specific control point, e.g. cooking
- Characteristics of the food being produced
- Product usage and instructions

Data required to conduct Exposure Assessment may be found from the following:

- Pathogen data sheets (see previous posts for references)
- In-house micro testing reports and history
- Outbreak data
- Complaints data
- Guides, standards and codes of practices
- Micro modelling, challenge testing, etc.

The Risk Assessment Model gives you a structured approach to the above and ensures you cover all the exposure paths. You use a scoring system to reflect your assessment and the sum of your score provides you with an assessment of risk.

While a score is applied to your answer this does not mean your MRA is quantitative. It is in reality a qualitative risk assessment since only large agencies and research centres have the resources to conduct full quantitative MRA's. Also, be aware that uncertainty in risk assessments is as important as what you know. Don't be scared to document any uncertainty and be open about it, i.e. 'there is not enough available data to conduct an accurate assessment...' Understanding the uncertainty allows you to be more cautious on certain aspects of the process.

6  RISK CHARACTERISATION [STEP 4]

This is the final step and is basically the total score produced at the bottom of the Excel model. It is the measure or character of the risk as assessed by you.

7  REFERENCES

Microbiological risk assessment in food processing: ed. by Martyn Brown, Martyn Brown Michael Stringer

Microbial Risk Analysis Of Foods: Donald W. Schaffner

**Product Benefits**

- Easily record and manage all elements of your food safety system including HACCP and CCP monitoring, PRP’s, management systems and documents
- Eliminate paper using the 30 integrated modules that come as standard
- Access and work with your system from any location at anytime
- Stay up to date and fully compliant with software that updates automatically in line with changes to global food standards
- Improve compliance and audit outcomes through the action driven features of the software
- Accelerate compliance with all of the international food safety standards including the BRC, SQF, IFS & FSSC 22000.
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- Roles & security
- Actions management
- Safe and secure web based solution
- No internal IT support or data back-up required
- Unlimited Users
- 24/7 world class customer support
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