HACCP
Combine your plan step-by-step
HARPC

First Edition

Kassy Marsh
COMBINE YOUR HACCP & HARPC PLAN

A PRACTICAL STEP-BY-STEP GUIDE

KASSY MARSH
Combine your HACCP & HARPC Plan
Kassy Marsh

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G5 Cavendish House, Welbeck, Nottingham, S80 3LL, UK

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Kassy started her career in the food manufacturing industry in 1998 and has developed an exceptional ability to implement simple and practical solutions, which can be effectively implemented into the factory environment. With a background of NPD, process control, compliance, auditing and technical management, she has a wealth of experience in effectively meeting the required standards. She is well known for her best practice risk assessments and specializes in food safety principles.

In 2015 she co-authored the book ‘Assessing Threat Vulnerability for Food Defence. This pioneering methodology is now one of the leading risk assessment tools in use for the assessment of food threats.

To meet the increasing demand for a methodology to assess food integrity, in early 2016 Kassy developed and co-authored her second publication ‘Assessing Error Vulnerability for Food Integrity’. This system is now used by a leading UK retailer as a training tool for their supply base.

Since starting her own consultancy business in 2012, she has become well regarded in the field of food safety risk assessment for her ability to provide simple, practical and easily understood step-by-step solutions.
Preface

HARPC (Hazard Analysis & Risk-Based Preventive Controls) is a relatively new term; an acronym developed to suit the new Food & Drug Administration’s (FDA) Hazard Analysis and Risk-Based Preventive Controls Rule for Human Food, which is part of the new Food Safety Modernization Act (FSMA).

The term HARPC (Hazard analysis and risk-based preventive controls) has been developed as an abbreviation to meet the FSMA rule – Preventive Controls Rule for Human Food.

When I first heard of the term HARPC (pronounced harp-see), as a specialist in risk assessment and HACCP, I was intrigued. Keeping up to date with the latest risk assessment systems and food safety laws is an important part of my role as a food safety consultant, in order for me to be able to provide the food industry with the best possible advice.

So, I spent some time researching HARPC and the FSMA preventive controls rule, to try to firstly understand, how this new methodology worked, and secondly, how it should be incorporated with our current HACCP principles. Unfortunately, I couldn’t find the answers I was looking for. The FDA have provided a lot of guidance information with regard to the requirements of a HARPC plan, but there was little detailed advice as to how you should actually go about carrying out a HARPC assessment. There was even less guidance available for facility’s who already had a HACCP plan, on how they could adapt their current food safety systems to meet the new HARPC requirements.

The aim of this book is to provide you with step-by-step guidance as to how you can develop your own combined HACCP and HARPC assessment. It is based on the NACMCF and Codex Alimentarius principles of HACCP and incorporates the new requirements of the FDA’s preventive control rule. Some aspects of the requirements of HACCP and HARPC contradict one another, so where this is the case I have adapted the typical NACMCF and Codex requirements to allow for compliance with both systems. Where the principles have been amended to comply with both systems, the contradictions and solutions are explained, giving you the necessary understanding to be able to explain this if challenged during an inspection.

The book is laid out in a methodical manner, so you can work through it step-by-step. To help you to use the book as a practical tool, I’ve also provided exercises for you to try for yourself. The system provided also meets the requirements of the BRC standard, so that facilities who have this certification can ensure that they meet the clauses of the HACCP section.

During my extensive research for this book, it became very clear to me that HARPC requires a totally different mindset to that of a typical HACCP system. Many of our usual and well-established techniques for assessing risks are turned on their head. As you work through the book try to remember this and maintain an open mind. Although it is a very different approach to assessing food safety, I truly believe there are many benefits to a HARPC system. It encourages food safety to be assessed as a whole, rather than having many risk assessments on a range of topics assessed individually. HACCP, although it has been around for many years now and is well established, in my opinion, is becoming too rigid an approach for today’s food manufacturing environment. As HARPC principles develop, as all systems do over time, perhaps the preventive control approach will even become the more recognised way of assessing food safety.

Kassy Marsh
Director, Techni-K Consulting Ltd
Executive Summary

The Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) was signed by Congress on December 21, 2010 and then became law when it was signed by President Obama on January 4, 2011.

The aim of FSMA is to better protect human and animal health by helping to ensure the safety and security of the food and feed supply.

The act is made up of 5 rules to improve food safety, which are:

1. Intentional adulteration
2. Preventive controls for human food and separately for animal food
3. Standards for produce safety
4. Imports: The foreign supplier verification program for importers
5. Imports: A program for the accreditation of third-party auditors (also known as certification bodies)

It is the preventive controls for human food rule, which requires a hazard analysis and risk-based preventive controls (HARPC) approach.

The preventive controls for human food rule, along with the rule for animal food was the first rule to be published in its final format, on September 17, 2015 and becoming effective from November 16, 2015. There is a staggered approach for compliance to the rule, depending on the business size of the food facility. Businesses other than those that are defined as small or very small must comply within 2 years of the publication, which is 17th September 2017. Small businesses have been given another year after to that to comply (2018) and very small businesses, another 2 years (2019).

The preventive control rule applies to all domestic (USA) processors, packers, or storage facilities which are required to register as a food facility under section 415 of the FD&C Act. It also applies to foreign manufacturers, who import into the United States.

There is therefore no doubt, that the publication of the preventive control rule for human food will change the way we assess food safety across the world, and the introduction of HARPC to meet the requirements of the rule will turn HACCP on its head.

Although at first glance the requirements of HARPC and HACCP look very similar, there are a number of fundamental differences which make compliance to both requirements difficult. For example, the hazard analysis carried out to meet the preventive control rule, must be carried out without taking any controls into consideration. This is contradictory to the NACMCF and Codex principles, where the hazard is assessed taking the controls into account. The consequences of this change are huge, as the number of significant hazards that are taken through to the next stage of the assessment will increase substantially. This leaves us with the problem, of how to handle the number of significant hazards, without producing an over bearing, and probably unfocused number of a CCPs.

Therefore, there is a need for a combined HACCP and HARPC approach, with a structured methodology that meets both requirements.
The Need for a Combined Approach

HACCP has been around since the late 1950s and became a recognized food safety approach, when in the 80s and 90s the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) published the seven principles. The Codex Committee then adopted these and further developed the methodology, by adding the CCP decision tree.

The use of the HACCP principles became law for particular food sectors in the US, the European Commission made it law in 2006 and today it is recognized as the leading food safety system all over the world.

The use of HACCP principles is driven by local law, customer requirements and also by standards, such as Global Food Safety Initiative (GFSI) recognised schemes.

The GFSI benchmarking scheme scope includes HACCP or HARPC-based requirements, which must meet NACMCF and Codex-based methodology.

These drivers mean that, even with the introduction of the preventive control rule and therefore HARPC, the need for a HACCP based system still also remains. Food facilities will continue to be requested by law, by their customers and by the certification standards that they adhere to, to comply with HACCP principles.

Therefore, there is a need for a combined HACCP and HARPC approach, one which takes into account the requirements for both standards and provides one cohesive methodology.

The methodology detailed in this book has been designed to comply with both the HACCP and HARPC requirements. In addition to this, it has been developed to meet the BRC Global Standard for Food Safety Issue 7, which is currently one of the most detailed GFSI recognized standards.
How to Use This Book

This book has been designed to provide you with all the information and practical tools that you need to be able to develop your own combined HACCP and HARPC plan.

The first section of the book provides you with a comparison of the different standards and requirements for HACCP, based on NACMCF and Codex Alimentarius, the preventive control rule from FSMA and then also the requirements set out by the BRC Standard as a GFSI recognised scheme.

The BRC Global Standard for Food Safety has been selected as the GFSI recognised scheme for comparison and analysis, as this standard provides a detailed approach to the requirements of HACCP – with the aim of developing a best practice system, which will meet all other GFSI recognised schemes.

The aim of this book is to provide enough detail about the requirements for HACCP and the requirements for HARPC, and explain where the requirements are slightly contradictory, provide a solution for this.

Each section is colour coded, for ease of use and orientation.

Within each section the requirements are explained and the methodology for a combined system is described. Completed examples are provided and there are exercises at the end of each section for you to complete, to aid your understanding.

The exercises at the end of each section are also available for download for you to complete, and so that you can use the templates, if you wish, in your own combined HACCP and HARPC plan. To download the exercise templates go to (on-line location is advised in the actual copy of the book).

To assist you when completing your plan, at the end of each section also has ‘Top Tips’. Here tips are provided, as a summary and reminder, so you can assess your plan against them to ensure that you’ve got everything covered. There is also a notes page at the end of each section, so you can make notes as you go through the methodology.

By following each section of this book and completing the assessment, following the step-by-step instructions and the exercise at the end of each, you should be able to build up your combined HACCP and HARPC folder. The ‘Top Tips’ will include how to set out your folder.

You’ll also find that we’ve included a ‘Notes’ page at the end of each section, so that you can make any notes that you need to while working through the book.