Significant Hazards in relation to Prerequisite Programmes - Problems in the application and implementation of HACCP Plans

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(from unpublished work in preparation by Tony Mayes and Sara Mortimore)

Abstract

After nearly 40 years of being used as the primary food safety management tool there are still different interpretations and misunderstanding of HACCP that continue to cause problems. For what appears to be such a straightforward and logical approach it is surprising, in the least, that academics and senior industry practitioners continue to debate the topic at such a high level. Perhaps, given the difficulties that there appear to be in application, the approach is not as helpful as was once thought? Or perhaps a clearer understanding of what HACCP is and what it is not will open up a way forward. There is a sense that this is the case and a number of developments point to this:-

- Clearer understanding of the role of prerequisite programmes based on the Codex Hygiene Principles(Codex, 1997a)
- The publication of draft guidelines on risk analysis (Codex, 1998)
- The recognition that for smaller and less well developed businesses additional guidelines were needed (WHO, 1999)

Generally there is an open acknowledgement that businesses have had problems with the application of the HACCP Principles and a frank and open discussion is, perhaps, a positive step towards finding some solutions. A review of the experiences given by a number of practitioners drawn from industry, retailing and regulatory bodies has given a clear view of the primary issues that face food businesses when they implement their HACCP Plans (Mayes & Mortimore, 2001, in-press). These issues have been grouped and summarised with an attempt to gain from the learning embedded in these experiences. They are presented here as a guide to others who will follow the same path and as an aid to understanding so that, in future, trainers, educators and those responsible for implementation are better able to face the tasks that confront them.

At the Preparation Stage

Problem	**Possible Solutions**
1. The wrong perception HACCP is seen as an unnecessary activity, burdensome and bureaucratic. If a business is grudgingly forced to implement it, then it will inevitably become a burden.	Perception needs to be changed through education in a variety of ways:- • Education about foodborne illness and trends. • Education that HACCP really is a *minimal* system to ensure *maximum* control. Education to get across the main benefits (that the focus on food safety can truly help to reduce sanitation costs and down time, lengthen shelf life, improve efficiencies, reduce waste etc. - all as a result of understanding the *product* and the *process*).
2. Lack of expertise The lack of understanding of the HACCP concept or methods, and separately the lack of microbiological and toxicological knowledge. This leads to over-reliance on advice from anyone and everyone that results in over-complex HACCP systems. This is further confounded by reliance on "off-the-shelf" HACCP packages, generic plans and consultant plans that do not fit. This is particularly a problem for SMEs, but also for many larger companies and the resultant lack of understanding of hazard significance is a major concern.	To an extent this can be overcome by good training of the HACCP Team Leader and the business manager. The HACCP team should be recruited to have sound scientific backgrounds and/or the appropriate experience and education to undertake the role. They must be honest about their ability to make informed decisions. Where external specialist support is needed, there should be some means of selecting or vetting external experts against a standard.
3. Getting the scope wrong If the scope is too wide then the HACCP Study and its implementation will be unmanageable. An example of this would be to confuse food safety and product quality (spoilage) and not separating non-significant hazards and quality issues into prerequisite programmes (PRPs) before going on to undertake HACCP.	It is important that practitioners understand the relationship between HACCP and prerequisite programmes such as hygiene. The PRPs should be in good order before undertaking HACCP.
4. Weaknesses in process analysis Incorrect or incomplete process flow diagrams can mean that steps and processes are missed when it comes to hazard analysis.	It is important to involve the right people - and often it is the line workers and supervisors who understand this aspect best of all. Also, the process flow diagram must be verified before doing the hazard analysis.

At HACCP Principles 1 and 2

Problem	**Possible Solutions**
5. Identifying too many "Hazards" and "CCPs" This results in a complex HACCP System and is one of the more frequent reasons why HACP fails. It can be related to a number of issues:- • Getting the scope wrong and confusing safety with quality. • The inability to identify significant hazards. • Misunderstanding the role of PRPs. • Additional unwarranted "CCPs" are added on the misguided insistence of customers and regulators.	The key influencers upon a business (trainers, customers, regulators, third-party auditors) need to have, themselves, a consistent understanding of the PRP - HACCP relationship. Better quality training is required for HACCP Teams and Team Leaders that must be combined with education in microbiology and toxicology. HACCP teams at a business level will be making a qualitative risk evaluation during Hazard Analysis. They have to decide what hazards are likely to occur, and only when they have done that will they be able to decide whether they are managed by:- • CCP - where a hazard is significant and must be controlled in order for the food to be safe. • CP - where a preventative control measure is used (e.g. magnets for removal of metal where a later metal detector is in place as a CCP. • PRPs - where the hazard is not significant or is ubiquitous (e.g. Listeria control through a sanitation programme).

In this area the three key definitions of Risk. Hazard Analysis and Critical Control Point should be equally understood and embedded in the approach of all participants in the process.

Risk (Codex, 1998)	"A function of the probability of an adverse health effect and the severity of that effect consequential to hazard(s) in food."
Hazard Analysis (Codex, 1997b)	"The process of collecting and evaluating information on hazards and information leading to their presence, to decide which are significant for food safety and therefore should be addressed in the HACCP Plan."
Critical Control Point (Codex, 1997b)	"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" (CCPs relate to control of significant food safety hazards only.)

At HACCP Principles 4 and 5

Problem	Possible Solutions
6. Ineffective Monitoring and Corrective Action This can be seen in situations where monitoring forms are not filled out or are illegible, and corrective action procedures are not followed. Monitors do not understand their duties and this can often be found where too many "CCPs" exist and thus people fail to see the point of doing anything as the controls are not *critical*. Again, if only significant hazards are addressed in the HACCP Plan then the process of monitoring becomes less onerous.	There are a number of activities that will serve to alleviate this problem:- • Ensure the monitoring frequency is appropriate. • Keep the documentation simple and easy to use. • Involve the CCP monitors themselves in designing the forms. • Train the monitors thoroughly and be clear about what is expected of them. • Use verification (review of records and audits) to properly follow-up when expectations are not being met. • Be clear on the requirements for corrective action - what to do with the product and what to do to bring the process back under control.

At HACCP Principle 6

Problem	Possible Solutions
7. Documentation This is a problem area particularly for SMEs or where no previous quality management system was in existence and thus record keeping is not part of the culture. In this case a business and its operatives can be swamped by the demands of setting up new procedure (monitoring and corrective action) and keeping records. With too many "CCPs" this can become a burden in that more documentation is produced than is needed. It is important to record some aspects of PRPs but there must be some value to the business, e.g. evidence of temperature profile in cold stores.	In such cases it is important to keep the documentation simple, as described above. It should be used only where necessary and where it actually adds value to the business. Ways of organising the records can be considered such as indexed file, manuals and a computer database. The latter, particularly, can be used later for trend analysis and optimisation of the monitoring frequency.

At HACCP Principle 7

Problem	**Possible Solutions**
8. Validation and Verification This results from misunderstanding the requirements of validation (of the HACCP Plan to ensure that it is capable of controlling the identified hazards) and verification (during and after implementation to ensure that the Plan has been deployed and is effective).	Simply training and education (again!).

Post Implementation

Problem	**Possible Solutions**
9. Continuing motivation and momentum once the HACCP Plan is completed A number of factors such as staff turnover, illness, absenteeism and competition for resources from other projects and initiatives all may contribute to the potential for the HACCP System to fail once it has been implemented. This can be as much a problem in large businesses as it can be in small ones.	Key workers must be identified and they must all have a nominated and fully trained back-up person. There are ways in which the interest can be maintained such as Food Safety Clubs, competitions, newsletters etc. - but such activities must be well presented and meaningful and not just tokenism.

In the reported problems of implementation there were hardly any mentions of Principle 3 (Establish Critical Limits) and therefore there are no possible solutions offered. However, we could make the assumption that this could be a problem area especially for SMEs and less well developed businesses.

Conclusion

The reported causes of failure to implement HACCP effectively are remarkably consistent across a range of business experiences. These mostly relate to both poor training and lack of education on the topic. The distinction between the two should be noted, as it is important. This has mainly resulted in misunderstanding of prerequisite programmes, the inability to determine hazard significance and thus has delivered over-complex HACCP Plans with too many "CCPs".

It is essential that this relationship (CCPs versus CPs) is clearly understood by all the HACCP team members in order to ensure that only safety points are determined as CCPs. Not doing so can undermine the system, losing credibility and can make implementation more difficult to manage because resource is spread too thinly. On the other hand too few CCPs may result in the production of unsafe food.

Identification of CCPs can be carried out by using tools such as Decision Trees of which the most widely used Decision Trees are those published by Codex (1997b) and NACMCF (1997) though variations exist (ILSI 1997, Mortimore & Wallace 1998). The essential skills needed for CCP identification are thorough knowledge of the product, the process, the identified hazards and the measures for their control. The information collated during the product description and hazard analysis stages is used by the team to determine the CCPs whilst Decision Trees are helpful in providing a structured approach.

Expert judgement must always be used and specialist advisers can be usefully drafted into the team at this stage if necessary. It is at this point that consideration must be given to the background and experience of these expert advisors. The experiences described give clear pointers not only to localised solutions within businesses, but also to the generalised approach that must be taken in the setting of standards for training, education and prior experience of all those involved in guiding the process. This is particularly true for "expert" consultants, trainers, regulatory and third party assessors - and such standards must be set at national and multi-national levels.

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