

How can the principles of validation and verification be applied to hazard analysis?

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Received 17 October 1998; received in revised form 29 January 1999; accepted 3 February 1999

Abstract

The acceptance of Hazard Analysis Critical Control Point (HACCP) as the food safety control system of choice by the food industry, governments and regulatory bodies with responsibility for food safety, has led to the proliferation of HACCP plans on a world wide basis. The adoption of the Codex Alimentarius text (Alinorm 97/13A) as the authoritative text on Principles and Guidelines for HACCP has contributed significantly to a more harmonised approach and agreed terminology, but there is still some lack of clarity over the specific activities of validation and verification. A logical interpretation of the Codex text would lead one to believe that validation is primarily concerned with those activities that evaluate the scientific and technical content of the HACCP plan, whereas verification focuses primarily on procedures required to determine compliance with an operational HACCP system. Using the above criteria this paper looks at the application of validation and verification to the HACCP Principle of Hazard Analysis.

Hazard Analysis is concerned primarily with the identification of hazards that are of such a nature that they must be controlled to ensure safe food and must therefore be included in the HACCP plan. As such Hazard Analysis is probably the key HACCP Principle. The paper proposes mechanisms to validate the identification of hazards for inclusion in the HACCP Plan and concludes that validation in particular has a very important role to play in providing both scientific and technical support for hazard selection as well as providing focus for the subsequent development of the HACCP plan. © 1999 Elsevier Science Ltd. All rights reserved.

1. Introduction

The increasing acceptance of the Hazard Analysis Critical Control Point (HACCP) system by the food industry, governments and regulatory bodies responsible for food safety, and the incorporation of HACCP principles and guidelines in Codex text is leading to the ongoing application of the seven HACCP principles and the preparation of HACCP plans on a world wide basis.

There are a number of excellent texts outlining practical approaches to the application of HACCP that are being used as guidelines, with the most authoritative being that by the Codex Alimentarius (Alinorm 97/13A). However, almost without exception such guideline documents concentrate primarily on the essential activities that go into the preparation of the HACCP plan – the document that results from the activities of the HACCP study team. Very few documents adequately address the key issues surrounding the essential re-

quirements of the actual implementation of the HACCP plan on the factory floor and very few adequately address the important issues of validation and verification. Although both the above terms are defined in key texts there is still much debate concerning the precise roles played by these two activities.

Implementation of the HACCP plan will not be covered in this paper but application of validation and verification is one of the key issues for current debate in HACCP and will be considered further here in the context of a discussion surrounding the application of validation and verification to the Principle of Hazard Analysis.

2. Terminology

Prior to any discussion concerning the application of principles we must clarify the appropriate terminology. Although there are different definitions in various texts, increasingly the use of the Codex Alimentarius Alinorm

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97/13A text is becoming accepted as standard and will be used here.

2.1. Validation

Obtaining evidence that the elements of the HACCP plan are effective (Codex Alimentarius, 1997). The Codex text gives no additional explanation of the use of validation.

2.2. Verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan (Codex Alimentarius, 1997). In the guidelines to the application of HACCP Codex provides additional explanatory text: “Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Examples of verification activities include:

- review of HACCP system and its records,
- review of deviations and product dispositions,
- confirmation that CCPs are kept under control where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan”.

2.3. Hazard analysis

Hazard Analysis is defined as “the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan” (Codex Alimentarius, 1997). In the guidelines to the application of HACCP, Codex provides additional explanatory text: “The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food. In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and
- conditions leading to the above”.

The text then goes on to give consideration to control measures as part of Principle 1.

3. Application of validation and verification to hazard analysis

There is undoubtedly some confusion surrounding the precise relationship between the activities of validation and verification. The Codex text above provides separate definitions for the two terms but includes validation under Principle 6 – Verification, thereby promoting the concept that validation is a sub-set of verification. The confusion is maintained by the fact that Codex provides no clarification of the activities comprising validation whilst actively describing verification activities.

An examination of the activities defined under verification would lead one to believe that verification activities are meant to assess the efficacy of the HACCP system once defined and implemented in practical terms, – in effect verification of an operational system. For example, it is not possible to review the HACCP system and its records until the HACCP plan is operational. Similarly it is not possible to review deviations, product dispositions and confirm CCPs are under control until the HACCP plan is in place.

Validation, on the other hand, is more concerned with obtaining evidence that elements of the HACCP plan are effective and as such is particularly appropriate to the scientific and technical input into the overall HACCP plan rather than determining compliance with the plan.

In the context of HACCP it is not intended to apply validation or verification to the Hazard Analysis Principle alone, nor indeed to any one Principle in isolation because all (Principles) contribute to the overall HACCP plan. None of the Principles is of value in isolation. Nevertheless, for the purposes of discussion only, this paper will focus on the application of validation and verification to the Hazard Analysis Principle.

3.1. Validation of hazard analysis

Although all HACCP Principles are linked in their contribution to the HACCP plan, Hazard Analysis is probably the key Principle in the whole HACCP system and the one people find to be the most difficult to apply.

The above definition of Hazard Analysis identifies that the key requirements are the identification of which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food. (The hazards to be selected from a list previously drawn up containing all hazards that may reasonably be expected to occur in that part of the food chain under study.)

If validation is concerned with obtaining evidence that elements of the HACCP plan are effective, persons should validate the identification of hazards for the HACCP plan using data derived from the following sources.

- Scientific literature reviews and/or other historical data detailing those hazards known to be, or that could reasonably be expected to be, present in the raw materials and/or final products under study that have been proven to be associated with food safety incidents in the consumer population. Level of hazards proven to be associated with safety incidents would be particularly valuable information.
- Scientific literature reviews and/or any “in house” data indicating the likely presence of food safety hazards in the manufacturing environment.
- Reports of foodborne illness associated with the raw materials and/or final products under study.
- Data on the survival or multiplication of microbiological hazards likely to be significant for product safety.
- Data on the possible allergenicity of all raw materials under study, and those raw materials that could inadvertently contaminate product during manufacture.
- In all the above cases the likely occurrence of such hazards, the realistic quantitative presence of such hazards and the severity of their adverse effects should be taken into account.

Validation above should be carried out at the completion of the HACCP Plan prior to implementation, and also whenever new data becomes available, (e.g. from review or verification activities), to indicate that new hazards require consideration in the HACCP Plan. Where the validation exercise highlights the existence of hazards that must be controlled to ensure the manufacture of safe product and those hazards are not identified or represented in the Hazard Analysis study, this would indicate that the Hazard Analysis procedure was not effective and requires amendment. It should be remembered that not all hazards identified in the Hazard Analysis procedure need to be addressed individually in the HACCP plan. Many hazards may be represented by the inclusion of one or more specific examples relevant to the larger group. A number of infectious pathogens identified as hazards in a study may be represented by the inclusion of e.g. pathogenic *Escherichia coli* or *Listeria monocytogenes* as specific hazards in the HACCP plan provided that control measures, critical limits, and monitoring procedures subsequently identified are effective for all infectious pathogens relevant to the raw materials and/or final product under study. It is also important during this validation exercise to examine the hazards identified to ensure that their control is essential for the safety of the food. Quality related hazards should be outside the scope of HACCP.

3.2. Verification of hazard analysis

Verification of Hazard Analysis, (as part of verification of the entire HACCP system), should consist primarily of an examination of the records of the validation exercise to determine if there is evidence that validation has been carried out correctly. Verification roles and responsibilities must be clearly outlined in the HACCP Plan.

4. Conclusion

The confusion that still arises over the precise activities involved in validation and verification make it difficult for many HACCP practitioners to easily identify relevant procedures. This paper proposes that validation covers the scientific and technical quality of the elements making up the HACCP plan and verification encompasses those procedures to determine compliance with the operational HACCP system.

There is no doubt that Hazard Analysis is the Principle that most persons have difficulty in applying and this paper demonstrates how validation and verification can be applied to the Hazard Analysis stage. Validation is particularly important in Hazard Analysis as failure to identify the correct hazards can render the entire HACCP Plan ineffective. The use of a validation procedure as described above would, in my view, be of significant benefit to many HACCP plans, resulting in a plan that would be both scientifically and technically supportable in its breadth of hazard selection and also appropriately focused to enable practical HACCP plan development.

An additional advantage of including validation as a formal procedure in the HACCP plan is that the use of scientific and technical data will help justification of HACCP plans to third parties wishing to assess HACCP systems. This is most important as we move towards a system of equivalence of QA systems within a world trade structure whereby it is the role of food companies to define their own food safety targets and the role of Government to check that all reasonable steps have been taken and that HACCP plans have been implemented and are operational.

Verification of Hazard Analysis should consist primarily of seeking evidence that validation has been carried out correctly.

References

- Codex Alimentarius (1997). Hazard Analysis and Critical Control Point system and guidelines for its application. Alinorm 97/13A, Codex Alimentarius Commission, Rome.