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# HACCP: Past, Present and Future Challenges*

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## The past

The principles behind the HACCP concept have already a very long history. The safety of food has been managed for many years by knowing potential problems and by controlling them. Pasteurisation to control *Mycobacterium bovis* and sterilisation to control *C. botulinum* are good examples. In the late sixties the concept was described in a more structured manner in order to provide auditors from NASA with the evidence that food intended to be used by the astronauts were safe. In 1972 the first HACCP workshop was organised by the industry to demonstrate how the concept worked in practice and to show governmental inspectors and customers that the system could provide evidence that safety requirements were obtained.

The food industry had a good record of providing safe foods when Good Manufacturing Practices were adhered to and a well controlled killing step applied. Canned low acid meat products which received a sterilising treatment called a "Botcook" (a 12D reduction of spores of *C. botulinum*) had indeed a very good safety record. Many other foods could be mentioned here as well, but unfortunately sometimes they were implemented in foodborne diseases. When such cases were analysed, it was found that deviations from GMP/GHP had occurred, or that incidents were not detected in time. Conditions contributing to foodborne illnesses could be summarised as: unacceptable contamination, survival, growth and spread of pathogens. Eliminating pathogens, preventing the just mentioned conditions or reducing pathogens to acceptable levels became the basis of HACCP.

In short the HACCP concept comprises of:

- anticipating and identifying potential food safety problems;
- determining how and where and to which extend these can be controlled or prevented;
- describing what to do and training the personnel;
- implementing and recording.

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The recording is essential in the application of HACCP, recording plays a less important role in Good Hygienic Practices.

The WHO requested the ICMSF in 1980 to elaborate the HACCP concept further (1). The ICMSF described hazards as the agents that may cause public health problems, but also the conditions leading to them. Moreover the ICMSF made a distinction between CCP 1's and CCP 2's. At a CCP 1 control is assured (for example by a Bot-cook), at a CCP 2 a hazard will be reduced but control is not assured (for instance by applying certain good hygienic practices). The ICMSF also described in its book on HACCP a farm to fork approach (2). In this book no distinction was made between points where major hygiene problems were controlled to prevent spoilage, and points which were intended to have a specific effect on pathogens. This was based on the opinion that many hygiene measures have also an effect on pathogens.

In 1990 ILSI Europe published a concise monograph in which decision trees to determine CCP's were described. These decision trees were meant to determine whether conditions which could lead to unacceptable contamination, spread, growth or survival of pathogens could occur. In principle they were designed to facilitate the hazard analysis, but since hazards need to be controlled at CCP's, these points were described rather than the hazards.

In 1993 Codex published the first HACCP document in which they incorporated CCP decision trees based on, but modified from, the ILSI ones. The definition of hazard was in that document "The potential to cause harm". In the revision of the Codex document in 1997 this definition was changed into the one which is still in use: "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect" (4). The original concept to deal with microbes was thus enlarged to deal with chemicals and foreign bodies as well. The Codex HACCP document has two parts, the Principles which set the basis for the minimum requirements for the application of HACCP, and the Guidelines which provide general guidance on how to apply the concept. The seven principles are considered to be mandatory while the guidelines do not necessarily need to be followed. It is worth mentioning that in recent years FAO/WHO experts recognised that HACCP is not a stand alone system, it should be based on what is currently described as "prerequisites" (5). These prerequisites are defined as: "practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in the Codex General Principles of Food Hygiene and other Codes of Practice". In short GMP as basis of HACCP is again reinforced and the concept of CCP2's is still valuable. The original idea of HACCP was indeed to highlight those good hygienic practices that were essential in assuring the safety of the food.

A milestone in the history of HACCP is the signing of the WHO/SPS agreement in 1994 (6). This agreement sets the rules for trading safe foods between member countries. Safe foods may be traded without restrictions. Safety is defined by the

SPS agreement as those requirements mentioned in international standards and particularly Codex. Application of HACCP thus became more or less mandatory for foods in international trade. A key element of the SPS agreement is that imported products should not endanger a country's appropriate level of health protection (ALOP). An ALOP should be based on scientific principles, in particular Risk Assessment. It further mentioned that sanitary measures and control systems should be transparent, consistent and equivalent.

**The present**

The ALOP concept may change the way in which HACCP plans will be elaborated in the future. Another term for ALOP is acceptable level of risk (ALR). How an ALOP is established and how it is expressed is not yet very well established, however, it may be expressed for example as: "The number of cases of (a certain) illness/year/100000 persons in a given population caused by a certain microorganism in a food considered to be appropriate/acceptable/tolerable" (7). This concept, dealing with the number of illnesses, is difficult to work with. The statistics concerning the number of illnesses due to a certain pathogen in a certain food are not very reliable, moreover, it is psychologically difficult for consumers to accept a certain number of illnesses. In their perception food should be safe. In order to avoid this problem the Food Safety Objective (FSO) concept was developed (8). While the ALOP deals with a level of risk, the FSO deals with the level of a hazard in a food. The current working definition is: "the maximum frequency and/or concentration of a microbiological hazard in a food at the moment of consumption that provides the appropriate level of health protection (ALOP)" (7). There is a relationship between the level of the hazard in a food and the probability that this level causes a number of illnesses. This relationship is called a hazard characterisation curve in Risk Assessment. Clearly a hazard level, for example <100 *Listeria monocytogenes*/gram of food at the moment of consumption (9), is easier to establish than an acceptable number of illnesses.

When food products are put on the market, several events may happen. If the food and the conditions during commercialisation, preparation and use allow multiplication of a pathogen, its level before commercialisation should be lower than the FSO. If no growth is supported this level, called a performance criterion (PC) (7), may be the same or somewhat lower than the FSO. The PC can be higher than the FSO if the food is heated before consumption. An example of an FSO may be "absence of Salmonella in a serving of poultry meat", while the PC could be "not more than 15 % of frozen poultry carcasses are allowed to be contaminated with Salmonella". This performance criterion will serve an important role in elaborating HACCP plans. The definition of control measures is: "Actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to *an acceptable level*" (4). This acceptable level is clearly related to a PC or an FSO. Control measures such as heating steps should assure that the pathogen should at that point in the

food chain be below a specified level. The amount of heating necessary to arrive at this PC is depending on the food and the pathogen, but also on the initial number of the pathogens before heating. The time and the temperature chosen to achieve the required reduction are in the HACCP concept called the critical limits. The initial number will depend on the good agricultural or good manufacturing practices applied by the supplier of the raw material. The initial count, abbreviated as $H_0$ is the PC of the supplier (see fig. 1). Clearly using an outcome oriented HACCP plan makes the food chain very transparent, one of the requirements of the SPS agreement. Specifying control performance criteria as for instance D-values at heating steps makes also the validation of these control measures much easier.

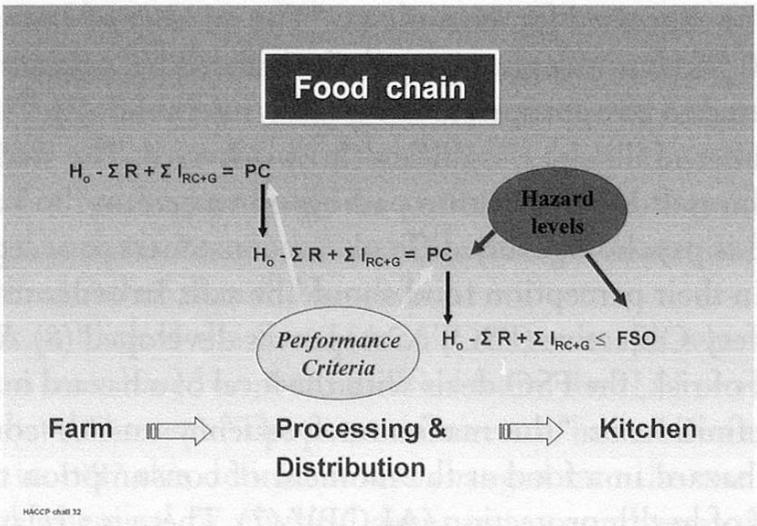


Figure 1 **Product pathogen pathway from farm to fork.** $H_0$ is the initial number of a pathogen before production, processing or preparation of a food. R is the reduction of the number by heating or other processes. I is an expression of the increase in number due to, for example, (re)contamination ($I_{RC}$) or growth ($I_G$). The sigma symbol indicates that various reductions or increases can occur and can be summed up. PC means performance criterion expressed as the level of a hazard at a point in the food chain. FSO (Food Safety Objective) is the level of a hazard at the moment of consumption

## The future

Validation of HACCP elements is getting more attention, also in the light of the SPS agreement (10, 11). Unfortunately there is still some confusion between validation and verification, because their definitions in the Codex document on HACCP (4) are not very clear. Both activities will play most probably an important role in providing evidence by a governmental inspection service or third party auditor that equivalence as mentioned in the SPS agreement is obtained. Equivalence is defined as: "the capability of different inspection and certification systems to meet the same

objectives" (12). An importing country should rely on the exporting country's inspection systems for the assurance that only safe food will be exported to their country. During a FAO/WHO consultation in 1998 the expression "regulatory assessment" was introduced to describe what the basis of such an acceptance of another country's exported products would be (5). Regulatory assessment refers to governmental activities carried out with the objective of obtaining evidence that the 7 principles have been effectively applied and that the HACCP plan and prerequisites to HACCP are correctly implemented and that the system has been maintained.

Future challenges are clearly related to the demonstration of equivalence in the application of HACCP, regardless location, size or sophistication of the food business operation. Another challenge is to obtain international agreement on which validation and verification data need to be provided and evaluated in regulatory assessment.

Hazard analysis is not well developed and standardised at the moment. It is often misinterpreted as risk assessment and wrongly described as qualitative while risk assessment would be quantitative. Hazard analysis must be quantitative if it is to be meaningful as was already expressed by the ICMSF in its book on HACCP in 1988 (2). To give an example, in hazard analysis questions have to be answered such as: "is presence of *Salmonella* in raw material X possible?" If the answer is yes, than it is a potential hazard. The next question would then be: "is the presence probable?". If the answer is yes, then *Salmonella* becomes a significant hazard which needs to be addresses in the HACCP plan. Another question to answer is: "is presence of *Salmonella* in line environment X probable?" If the answer is yes, *Salmonella* becomes a potential hazard. Now we need to consider whether product contamination is possible. If the answer is yes, we have to deal again with a significant hazard. It will certainly become challenge to obtain international consensus regarding how hazard analysis should be performed and how "possibility", "probability" and "likelihood of occurrence" should be estimated and expressed.

Although the concept of FSO is easy to understand, it will again be a challenge to arrive at acceptable FSO's or performance criteria for foods in international trade, because they may differ according to region, culture, eating habits etc.

Finally, HACCP is only successful when it is applied from farm to fork. This means that HACCP should also be applied by consumers. Thus consumers should have the necessary knowledge or should know where such knowledge is available and how it can be obtained. They should understand the risks of certain eating habits and be willing to accept them, or change their habits. Finally they should accept the concept of shared responsibility in food safety of producers, processors, retailers, caterers etc. and consumers. It should be remembered that the definition of food safety by Codex is: "assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use" (13). Hopefully national and international food safety authorities, health educators, schools and universities as well as national and international risk communication bodies will take this challenge up in order to assure the safety of our foods.

**Summary**

ICMSF's book 4: "Application of the HACCP system to assure microbiological safety and quality", was the first major publication on HACCP from farm to fork. Since many hygiene measures have an effect on a product's safety no difference was made between CCP's for safety and for hygienic quality. Since the Codex Alimentarius adopted the HACCP system its concept was limited to agents in the food that could harm the consumer of biological, chemical and physical nature. The levels of microbiological agents that are considered to be acceptable will in future be linked to the concept of Food Safety Objectives (FSOs). FSOs, as expressions of Appropriate Levels of Protection (ALOPs), will facilitate international trade of food as governed by the WTO/SPS agreement. However, many aspects of mutual recognition of food inspection systems, ALOPs, FSO's, and HACCP need to be worked out further before they become effective in international food safety management.

**Zusammenfassung**

ICMSF's 4. Auflage: «Anwendung des HACCP-Systems zur Sicherung der mikrobiologischen Sicherheit und Qualität» (1998) war die erste grössere Publikation über den Einsatz des HACCP-Systems von der «Farm bis zur Gabel». Da viele hygienische Massnahmen der Sicherheit des Lebensmittels dienen, wurde nicht extra ein Unterschied gemacht zwischen den kritischen Kontrollpunkten (CCPs) zur Sicherheit und zur hygienischen Qualität des Lebensmittels. Als der Codex Alimentarius das HACCP-System übernommen hat, war sein Konzept limitiert auf die Bestandteile im Lebensmittel, welche dem Konsumenten schaden könnten, biologischer, chemischer und physikalischer Art. Die als «akzeptabel» bezeichnete Ebene von Bestandteilen wird in Zukunft, verbunden mit dem Konzept der Lebensmittelsicherheits-Vorschriften (FSOs), eines der Risiko-Management-Werkzeuge, die von den Regierungen angewandt werden. FSOs und ihre Übertragung aus «akzeptierbaren Ebenen» der Gefahren werden den internationalen Handel auf dem Lebensmittelmarkt erleichtern, nach den WTO/SPS Vereinbarungen. Jedoch müssen weitere gemeinsam anerkannte Reglementierungen der Lebensmittel-Überwachungssysteme, FSO's, ALOP's und HACCP weiter ausgearbeitet werden, bevor sie im internationalen Lebensmittelsicherheits-Management angewandt werden können.

**Résumé**

ICMSF's livre 4: «Application du système HACCP pour assurer la sécurité et la qualité microbiologique» était la première publication sur HACCP de «Ferme à fourchette». Puisque beaucoup de mesures hygiéniques ont un effet sur la sécurité du produit, aucune différence n'a été faite entre des CCPs concernant la sécurité, et ceux concernant la qualité hygiénique. Depuis que le Codex Alimentarius a adopté le système HACCP, ce concept a été limité aux agents dans des produits, ayant la possibilité de nuire aux consommateurs, de nature biologique, chimique et physique.

Le niveau des agents microbiologique considéré comme acceptable, sera en future lié au concept des objectifs de sécurité alimentaire (Food Safety Objectives, FSOs). FSOs, comme expression des niveaux de protection appropriés (Appropriate Levels of Protection, ALOPs), peuvent faciliter le commerce international des aliments, gouverné par l'agrément du WTO/SPS. Pourtant, beaucoup d'aspects de la reconnaissance mutuelle des systèmes de l'inspection alimentaire, ALOPs, FSOs et HACCP, devront être élaborés d'avantage, afin de devenir efficace en sécurité alimentaire internationale.

**Key words**
ALOP, FSO, HACCP

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