HACCP misconceptions: Part I

What HACCP is and what it is not

1. HACCP should not be seen only as an obligation for authorities.
HACCP is required internally and externally by a number of national and international authorities. Internally, HACCP is a mandatory element of the First Priority level of the Nestlé Quality System. It is a legal requirement in many countries and recognised by the Codex Alimentarius as an essential tool in ensuring food safety.

However, the principal reason for making a HACCP study is not to satisfy authorities, but to effectively manage food safety, i.e. taking the right decision, ensuring that the decisions are actually valid and correctly implemented. In particular, it can help managers to identify those steps in the process where food safety resources should be focussed. When HACCP is applied to comply with authorities, it will only lead to a massive amount of paperwork without much added value.

2. HACCP is not a panacea for all problems. HACCP is a tool for the management of food safety; it reduces risks of food safety incidents but does not eliminate them. Its potential to help depends on how well it is understood, applied and maintained, and also on whether some basic requirements in terms of GMP or basic hygienic principles are already in place. The HACCP system cannot be expected to overcome malpractice related to fraud or human error.

3. HACCP should not be seen as or reduced to simple paperwork. Since documentation is a key part of the HACCP concept, studies do require a certain amount of paperwork. However, the effective application of HACCP implies research, monitoring of CCP parameters, verification of GMP on the factory floor or in the pilot plant audit of suppliers, reviewing verification data (e.g. results of environmental monitoring, review and investigation of consumer complaints), calibration of key equipment, training of people, etc.

4. HACCP is not a one-time exercise. Maintenance of a HACCP plan is as important as its development and implementation. HACCP is also a tool for decision-making. As such it should be flexible and part of everyday work. Verification data (e.g. pathogen or contaminant monitoring, consumer complaints, raw material monitoring, audit reports, source of the raw material) and any other new information, whether scientific, regulatory, or related to a change in practice or process, should be used to evaluate whether the decisions taken for management of food safety remain valid or need to be modified.

5. HACCP is not a stand-alone system. Applying HACCP alone will not resolve food safety issues. HACCP can enhance food safety assurance if other systems or measures such as Good Manufacturing Practice, traceability, pathogen monitoring, training of personnel, audits, etc. are properly implemented.

6. HACCP is not one person's job. One of the biggest added values of HACCP is the promotion of teamwork and help in gathering all kinds of information that can impact on the safety of products from all angles (chemical, microbiological, physical hazards). Therefore, a HACCP study, particularly at the product development stage, requires a multidisciplinary approach, i.e. involving scientists with different backgrounds (chemical, microbiological, technological, etc.) as well as personnel with operational expertise. In HACCP implementation, it is important to involve all personnel (from maintenance, cleaning, storage, etc.) and raise their awareness.; it is important that they have a clear understanding of their direct or indirect role in food safety is important.

7. HACCP does not start at production. In order to be fully effective, HACCP must be initially applied at product development stage. Thus, risks can be anticipated and minimised during product development and the industrialisation process.

8. HACCP does not work without proper understanding of the whole process. To be able to anticipate risks, which is the purpose of a HACCP study, all stages in the process, from the raw material (including packaging) to final consumption should be well understood. This is equally important for the maintenance of a valid HACCP plan.

9. HACCP does not work without proper validation. Much can be decided under the HACCP study and plan. However, if the information and assumptions underlying the decisions are not valid, the HACCP plan will not be effective in enhancing food safety. Validation of elements of the HACCP plan is essential to ensure that the food safety assurance system provides the required safety.

HACCP misconceptions: Part II

Common errors in HACCP

1. Scope of the HACCP study. Very often, HACCP plans do not adequately address chemical hazards (agrochemicals, naturally occurring toxins, environmental contaminants or chemicals formed as a result of processing). Allergens or vitamins with potential toxicity (e.g. vitamin A and D) are not always considered in the HACCP study either.

Understandably, there are many good reasons to focus on microbiological hazards as a starting point. However, the HACCP approach must also be applied to chemical hazards. This will ensure:

I. Improved awareness with respect to possible chemical hazards.

II. A conscious decision is made regarding potential chemical hazards, including proper justification for those which require or do not require monitoring [1]as CCP.

III. Specifically for allergens, potential cross-contamination issues are fully considered.

The study should additionally consider vital food components which, if not included, can present a health risk for the target consumer. For instance, the lack of certain nutrients in infant formula will be detrimental and should be considered as part of the HACCP study.

2. Product description. On several occasions, we note that the product description is so short that important information, e.g. full description of packaging, processing aids or other auxiliary products, is missing. In food safety, any detail may be important. Lack of adequate information may result in certain potential hazards not being considered during the hazard analysis process. According to the NQS, auxiliary products, e.g. promotional material should also be part of the HACCP plan and should be properly described.

3. Consideration of distribution channels, intended use and food preparation practices in the HACCP study. Frequently, this step in the food chain is not very well considered in the HACCP plan. For certain types of products, the target customer/consumer or the potential

[1] Note that in Nestlé, in relation to HACCP, the term monitoring has two different meanings which may sometimes lead to confusion: a) a scheduled measurement or observation of a CCP relative to its critical limits with the objective of detecting loss of control at CCP, e.g. monitoring the pasteurisation parameters; and b) a scheduled measurement or observation of a control measure for verification purposes, i.e. confirmation that the HACCP plan is working effectively, e.g. pathogen monitoring, monitoring raw material for a given chemical hazard.

mishandling of the product during distribution or preparation may be crucial for the design of safety in the product development and ensuring the safe consumption of the product. Better consideration of the target consumer, intended use and the preparation before consumption not only is a due diligence measure, but helps in improving product design or information on the package in order to minimise risks for consumers. Where preparation is considered as crucial for ensuring food safety, the information on the package should also be validated for accuracy as well as clarity in communication. The objective should be the safe consumption of products rather than product safety.

4. Flow diagram. Very often, flow diagrams used for the HACCP study do not reflect the true processing and manufacturing conditions of the product. Lack of accuracy may seriously jeopardise the quality of the HACCP study and the validity of decisions. For a successful HACCP study, the flow diagram must be an updated and verified on-site.

5. Consideration of flow of air, water, material and employees. When conducting the HACCP study, the flow diagram is often limited to the product. It is important to also consider how the flow of water, air, and employees can impact on the safety of the product and for this purpose, the flow diagram of water, air and employee movement should also be considered.

6. Hazard analysis. Very often hazards are described in general terms, e.g. "microbiological hazard". Although such an approach may be justified in certain cases, in relation to microbiolgical hazards this may be very risky and will certainly decrease the value of HACCP. The reason is that microogranisms differ in their behaviour, ecology and control measures. Thus, it is important that, as far as possible, we consider microoganisms in a specific manner. Short of this, we may miss important control measures. Similarly, chemical contaminants should be clearly defined to correctly estimate their upper tolerable limit in products and to choose the method of monitoring. Exceptions can be made when pathogens present similarities in their ecology or epidemiology.

7. CCP versus significant hazard. Often these two terms are used in an erroneous manner (for instance, "*Aflatoxin is a CCP"*). CCP, which stands for Critical Control Point, refers to a **step** in the process **where** the hazard is reduced to an acceptable level or eliminated; whereas a hazard is a biological, chemical or physical agent in food with the potential to cause an adverse effect, when present at an unacceptable level. For instance aflatoxin is a hazard.

8. CCP versus GMP. One of the major difficulties in HACCP is the differentiation or understanding of the relationship between CCP and GMP. For instance, there have been statements of the type "it cannot be a CCP because it is GMP". A first difference is that a CCP refers to a step in the process, whereas a GMP is a "practice". There are times that a GMP is also a process step. To further explain, we need to go to the time before HACCP. Food safety was ensured through a number of actions

which were considered as part of GMP, and were specifically referred to as Good Hygienic Practice. Our processing, e.g. thermal treatment, was also part of our GHP. Thus, all actions that today are implemented at a CCP to render food safe are at their basis a GHP or GMP action. With the introduction of HACCP, we have learned to make differences in the importance of these measures in terms of food safety and put some weight in the different GMPs/GHPs, depending on the role they play for ensuring food safety. Where we consider that a GMP action is of such importance to food safety that if it is not ensured, we run a high risk of compromising the safety of our product, we should consider this GMP action as a critical measure and the step at which the action takes place as CCP. The HACCP study may also help in identifying other GMPs (which could also be considered as critical) which may have originally not been considered but are important for that specific product or process.

9. Monitoring. It has been experienced that some steps have not been considered as CCPs on the grounds that "continuous" monitoring, or a physical method which could measure the control parameters objectively is not available. It is certainly much better to measure control parameters in an objective manner. For instance, measuring pressure difference in filters is certainly more efficient than visual inspection. However, the lack of such methods for monitoring should not be a reason for not considering a step in the process as a CCP, if control at that step is important and visual control can still be effective in minimising the risk. As to the concept of continuity, the frequency of monitoring required depends on the control measure. The frequency should be set in such a way that if a deviation is observed and critical limits are violated, the corrective actions can be implemented in a timely manner.

10. Monitoring of CCPs. When monitoring a CCP, care should be taken that critical limits refer to the relevant variable or set of variables. In several occasions where the CCP was the heat treatment of the product, only the temperature was monitored and the flow rate which would have been a determining factor for the duration of heat treatment was not monitored. Generally speaking, care should be taken to properly identify the factors which will impact the efficiency of the control measure; e.g. for water disinfection, obviously chlorine concentration and time of contact are essential, but also the pH of water and its turbidity impact on the chlorination efficiency, and therefore all four parameters need to be monitored at such a CCP, i.e. the chlorination step.

11. Corrective actions. These are not always well defined. There are times when they are mentioned as *"see the QA manager or Production manager*". While it is a good practice that in times of problems the operator consult his superior, it is nevertheless important to document what kind of corrective actions have to be performed to restore control.

12. Verification. The results of verification activities, e.g. monitoring, audits are often not well exploited for validating the decisions and verifying if the decisions taken under the HACCP plan continue to be

accurate or need modification. For instance, time and again it has been noted that data collected through environmental or pathogen monitoring are not effectively used to verify the proper implementation or efficacy of the cleaning procedure, or that audit reports or raw material monitoring data are not been used to evaluate the supplier and whether tighter control of the raw material would be justified.

13. Frequency of monitoring for verification. Where the monitoring of the raw material is carried out for verification purposes, the sampling plan and frequency of monitoring should be based on the relationship with the supplier and confidence that you have in him/her. When the supplier is changed, greater attention should be paid.

14. Validation[2]. Frequently, the elements of the HACCP plan, in particular decisions regarding hazard analysis and critical limits are not validated or documented. In the absence of validation, there is no assurance that our control measures will be effective in ensuring food safety. The supportive documentation will ensure that validation is adequately carried out, and will help in understanding the basis for decisions and when these may need to be changed.

15. Documentation. Documentation is sometimes seen as bureaucratic work. Sometimes it is. However, documentation can play an important role in food safety. Among others, it is an effective means of communication. Communication with other colleagues on how food safety is planned and implemented and what the bases for decisions are. Documentation can play an important role in maintenance of a HACCP plan, revising decisions, providing evidence that appropriate measures have been taken in times of problems. However, the value of the documentation lies in the quality and quantity of information that it contains. If the information is superficial or not adequate, the documentation becomes more a bureaucratic exercise than a communication tool.

16. Different HACCP plans. Sometimes, due to the complexity of production, it is easier to develop different HACCP plans for different parts of the production line. It is important to ensure that a proper link between the different HACCP plans exists and that errors do not occur as a result of this practice, i.e. at the interface of HACCP plans.

17. Maintenance of HACCP plans. Maintenance of HACCP plans is not a yearly exercise but a continuous exercise: i.e. as mentioned before, every new information (be it change in supplier, process or production, customer or consumer, or a new identified hazard) should be evaluated in terms of its significance for the HACCP study and for food safety. Eventual changes in decisions should be indicated on the HACCP plan or documented in an appropriate manner.

[2] Sometimes validation may be simply providing justification for decisions.

18. HACCP software. The use of the software, though recommended, is not mandatory. If it feels more comfortable to carry out a HACCP study without the software, do so. In our opinion, the software can nevertheless be useful for documenting the HACCP study and also as a database. It may not always reduce the time for carrying out a HACCP study, but it can ensure consistency in the thinking process. The limitations of the software should not discourage the proper carrying out of a HACCP study. For instance, if the software does not give the opportunity to write the technical data about the process on the flow diagram, another type of software or simple tools such as paper and pen may be used.

In fact, it is not possible that a software replace critical thinking and provide at the same time the flexibility which is needed in the decision making process, in order to cover all situations as well as the rigidity which is needed for a systematic approach to food safety.