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Hazard identification: from a quantitative to a qualitative approach

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Abstract

Hazard identification is a common step in the hazard analysis and risk-assessment processes. The fact that this step is shared between the two processes is creating some confusion about how they can be used in our food safety programs. Hazard analysis and risk assessment are fundamentally different and independent processes.

Hazard analysis is a qualitative, local process conducted by a food plant's HACCP team. This process usually requires several weeks or months to complete. In contrast, risk assessment is a quantitative, global process in which a numerical degree of risk can be calculated for a particular hazard. It is usually conducted by a large consortium that includes regulatory, public health, academic, and industry participation. It is a longer process, typically requiring several months or years for completion.

In hazard analysis, one major method for the identification of hazards consists of a review of the sensitive ingredients used in food production. Many food companies maintain sensitive ingredient lists for hazards such as *Salmonella*, *Staphylococcus aureus*, *Bacillus cereus*, *Listeria monocytogenes*, aflatoxin, allergens, etc. Another major method for the identification of hazards consists of an open-ended brainstorming process by the HACCP team, which in 1992 replaced the brief, formal hazard analysis process that was first used about 30 years ago. The limited number of questions considered in the formal process proved to be insufficient to address the needs of the food industry, which is continually dealing with new hazards, new products, new processes, new markets, and new regulations.

HACCP systems are designed to control identifiable hazards. Additional hazards that may need to be included in HACCP plans include previously unknown hazards that are identified by epidemiological efforts, and "regulatory hazards" that are mandated in new food regulations.

Keywords: HACCP; Hazards; Hazard analysis; Risk assessment

The principal topic of discussion for this morning's session on hazard identification is the question, "How are significant hazards identified?" I want to address this question from the perspective of the HACCP team, since my many years of experience with HACCP implementation have largely been focused on designing safety into food products, and developing HACCP plans for our food manufacturing facilities. The HACCP team is the group of people at each plant that is responsible for organizing the plant's HACCP plan. From this perspective, the answer to this question is short and simple – significant hazards are identified mostly from past experience. I think that bears repeating: significant hazards are identified mostly from past experience.

In identifying the hazards that may be important for your HACCP plan, most, if not all, of the hazards that you will need to consider are already known. And the relevance, or significance, of those hazards to your process is also known. It is simply a matter of an experienced HACCP team being prepared to conduct its hazard analysis. In the areas of food safety and public health, when we speak of hazard identification, we are usually speaking about hazard analysis or risk assessment, so let us begin with a comparison of these two processes.

1. Hazard analysis

The Code Alimentarius Commission (1997) defines hazard as, "A biological, chemical, or physical agent in, or condition of, food with the potential to cause an adverse health effect." The US NACMCF (1998) has a slightly different definition: A hazard is: "A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control."

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Codex defines the hazard analysis process as, "The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant to food safety and therefore should be addressed in the HACCP plan." The NACMCF's description of hazard analysis is, "The purpose of hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled."

Hazard analysis consists of two steps: hazard identification, which is an open-ended brainstorming process to determine potential hazards, and hazard evaluation, to determine which identified hazards are of such significance that a Critical Control Point (CCP) is required to control the hazard (NACMCF, 1998). Today we are concerned only with the hazard identification portion of hazard analysis.

2. Risk assessment

The topic of risk assessment is receiving a great deal of attention and I believe that several of the speakers who follow me will address it in great detail. I want to spend just a little time on this topic because in the US the process of risk assessment has sometimes been confused with the process of hazard analysis. Carried to its extreme, this confusion could result in inaccurate hazard analyses; with serious implications for the public health and for the financial fortunes of the plant(s) and companies that were victimized by the inaccurate or incomplete hazard analyses.

One major example of how this confusion can develop began in South America in 1991 when a pandemic of cholera was triggered largely by the decision of a major city to stop the chlorination of its water supply. The public health officials in this city had been informed about the publication of a risk assessment that concluded that chlorination of drinking water could lead to the formation of trihalomethanes, which, in turn, might lead to liver cancer. Not wanting to expose their population to this calculated risk of liver cancer, the officials gave the order to stop chlorination of the municipal water supply. They overlooked the obvious fact that untreated, unchlorinated water would likely harbor enteric pathogens. Their decision triggered the first pandemic of cholera that originated in the Western hemisphere. As a result, at least 1,000,000 people are known to have contracted cholera, and about 1% of them died as a result. This was truly a most regrettable situation that could have been prevented by an accurate or complete hazard analysis.

A few definitions are in order: Risk is defined as, "An estimate of the likely occurrence of a hazard." Risk assessment is one of three parts of the greater process of risk analysis, which also includes risk management and risk communication. Risk assessment consists of four steps – hazard identification, dose response, exposure assessment, and risk characterization (Council for Agricultural Science and Technology, 1994).

The fact that hazard analysis and risk assessment each contain a hazard identification step probably contributes to the confusion between the two processes (Fig. 1). For our discussion today, I believe that there are four principal features that distinguish the two processes (Fig. 2).

Hazard analysis is a qualitative process. An identified hazard is either significant enough to warrant inclusion in the HACCP plan, or it is not. This is a simple, qualitative decision made by the plant's HACCP team. Therefore, hazard analysis is a local process. It is performed by individual HACCP teams at each food plant in the world. It is also a relatively brief process, occupying several weeks or months.

In contrast, risk assessment is a quantitative process in which a numerical degree of risk can be calculated for

Hazard Analysis	**Risk Assessment**
• Hazard Identification	• Hazard Identification
• Hazard Evaluation	• Dose Response
	• Exposure Assessment
	• Risk Characterization

Fig. 1. Hazard analysis and risk assessment each contain a hazard identification step.

	Hazard Analysis	**Risk Assessment**
Process:	Qualitative	Quantitative
Done By:	HACCP Team	Major Consortium
Time Frame:	Weeks – Months	Months – years
Scope:	Local	Global

Fig. 2. Differences between hazard analysis and risk assessment.

each hazard – increased risk of cancer per million population, increased number of foodborne illnesses per million population, etc. Risk assessments require major human and monetary resources and result in analyses that may be several hundred pages long. They are usually conducted by a major consortium that includes regulatory, public health, academic and industry participation. Risk assessment is a relatively long process, typically occupying several months or years. This is a global process since the conclusions of a single risk assessment can be applied at any food plant in the world. My point is, do not let anyone tell you that risk assessments are conducted by a HACCP team! This suggestion has, in fact, been made in the US, but you can see that it is quite an impractical suggestion, because the HACCP team is not going to spend months or years conducting a risk assessment for each potential hazard.

One example should reinforce the point that risk assessment is a global process that is not performed by HACCP teams. In the 1990s it was discovered in the US that *Escherichia coli* O157:H7 in dried sausages could be the cause of foodborne illness. Very quickly the US Department of Agriculture organized a consortium of regulatory, academic, and industry representatives to study this problem. Within about one year, a risk assessment was published along with measures that could be used to control this hazard. There are several hundred plants in the US that produce this type of sausage. Before the illness outbreaks and the ensuing risk assessment, very few of them would have identified *E. coli* O157:H7 as a significant hazard in their process. Now, because the risk assessment has been performed, they will all correctly identify this hazard and implement effective control measures. Hundreds of plants conducted their individual hazard analyses; none of them conducted a risk assessment. All of them benefited from the global risk assessment that had been conducted for the benefit of the entire industry.

3. Hazard identification

HACCP plans are only capable of controlling identified hazards. The major input for hazard identification comes from the knowledge of existing hazards, either from sensitive ingredient lists; or from brainstorming by the HACCP team. Lesser inputs originate from regulatory actions and previously unidentified hazards. The regulatory hazards can emerge during the regulated implementation of HACCP. A regulation may declare that "hair" or "brown specks" on animal carcasses are a hazard and must be controlled by a CCP. The HACCP team must include these in the HACCP plan, even when there is no scientific basis for these requirements. In other instances, for example, in the production of pasteurized dairy products or low-acid canned foods in the US, the regulatory requirements are scientifically established. In these instances, the HACCP team should arrive at the same CCPs and critical limits that were established in the regulation. Sometimes a previously unidentified hazard is detected. For example, before 1982 we did not realize that *E. coli* O157:H7 could be a foodborne hazard. It is the role of epidemiologists to detect these emerging hazards and communicate this risk so that HACCP teams may address them properly.

3.1. Sensitive ingredients

The major method for the identification of known hazards is the review of sensitive ingredient lists. A sensitive ingredient is defined as, "A material that has been historically associated with a known hazard (NACMCF, 1992)." In my experience, most food companies have developed their own sensitive ingredient lists. This information is not comprehensively available from regulatory or public health sources.

The lists I will briefly present here are illustrative only. They do not contain all of the materials that could be identified as a sensitive ingredient. One fact of life is that it is relatively easy for an ingredient category to get placed onto a sensitive ingredient list; however, it is very difficult to have an ingredient taken off the list. For example, some of the materials on the *Salmonella*-sensitive list were responsible for several outbreaks of salmonellosis more than 30 years ago (Fig. 3). Despite a relatively unblemished record for some of these materials during the past 30 years, the food industry still manages them as sensitive ingredients. From my experience I can claim that you will have a very difficult time finding *Salmonella* in cocoa powder. It's not there anymore.

The *Staphylococcus aureus*-sensitive ingredients are usually fermented foods, where failure of the starter culture could lead to growth and toxin production by *S. aureus*, or they are foods that are handled after cooking and may be contaminated by the food worker (Fig. 4).

The *Listeria monocytogenes*-sensitive ingredient list is very short (Fig. 5). It can be used to emphasize the point that hazard analysis should be a practical process. Only two *bonafide* outbreaks of foodborne listeriosis have been documented in the US. These were caused by a soft, fresh cheese in 1985 and by several refrigerated meat products in 1999. A similar profile has been observed in Europe with listeriosis outbreaks being attributed to soft ripened cheeses and several refrigerated meat products. The foods that can be implicated in listeriosis are not a mystery. The knowledgeable HACCP team or food safety expert must know about the hazard of foodborne listeriosis in all foods that are refrigerated, have an extended shelf life, can support the growth of *L. monocytogenes*, and can be consumed without heating or another process to eliminate this hazard. We do not need an elaborate quantitative risk assessment to be

Salmonella
Sensitive Ingredients

- Cooked meat and poultry products*
- Dried milk products**
- Dried egg products**
- Cocoa, chocolate, milk chocolate
- Dried yeast
- Enzymes and glandular products of animal origin
- Dried coconut
- Soy flour and protein products
- Peanuts and peanut butter

* Raw meat and poultry are assumed to contain *Salmonella* and are handled accordingly
** Liquid eggs, liquid milk, cheese, butter are not considered to be *Salmonella* sensitive.

Fig. 3. *Salmonella*-sensitive ingredients.

Staphylococcus aureus
Sensitive Ingredients

- Cured meats
- Fermented sausages
- Hard and semi-soft cheeses
- Dried pasta products
- Hand-deboned cooked meat and poultry
- Processed shellfish

Fig. 4. *S. aureus*-sensitive ingredients.

Listeria monocytogenes
Sensitive Ingredients

- Soft, ripened cheeses
- Refrigerated, RTE cooked meat, poultry and seafood products

Fig. 5. *L. monocytogenes*-sensitive ingredients.

aware of the potential hazard of foodborne listeriosis, or to know how this potential hazard can be controlled. We are, however, in fact, proceeding down this path in the US. While I agree that the US *L. monocytogenes* risk assessment may ultimately be useful, it should not be used as an excuse to delay the immediate implementation of more effective control measures where they are needed. Unfortunately, some in the US industry have suggested that no actions be taken until the risk assessment is completed. I do not agree. We know some types of foods that are potential listeriosis hazards. Let us control these now.

The *Bacillus cereus*-sensitive ingredients are primarily farinaceous foods such as cooked rice or potatoes (Fig. 6).

The HACCP team must consider not only potential biological hazards, but also the potential chemical and physical hazards. Here are brief lists of representative chemical hazards (Fig. 7), aflatoxin-sensitive ingredients (Fig. 8), and significant food allergens (Fig. 9). Typical potential physical hazards include glass, bone, metal, wire, sand, dirt and stones, pits or shells, and pest or

Bacillus cereus
Sensitive Ingredients

- Cooked rice
- Cooked or dried potatoes

Fig. 6. *B. cereus*-sensitive ingredients.

Representative Chemical Hazards

- Pesticides
- Mycotoxins
- Lubricants
- Cleaning/Sanitizing Chemicals
- Solvents
- Dioxin
- Allergens

Fig. 7. Representative chemical hazards.

Aflatoxin Sensitive Ingredients

- Peanuts and peanut products
- Corn and corn products
- Tree nuts
- Dried coconut
- Tapioca flour
- Cottonseed meal
- Figs

Fig. 8. Aflatoxin-sensitive ingredients.

Common Food Allergens

- Peanuts
- Eggs
- Tree nuts
- Bovine milk
- Fish
- Shellfish
- Soybeans
- Wheat gluten
- Sulfites
- Some artificial colors

Fig. 9. Common food allergens.

parts of pests. What is worse than finding an insect in your candy bar? Finding one-half of an insect in your candy bar!

3.2. Brainstorming by HACCP team

The previous slides have indicated many dozens, if not hundreds, of potential hazards to be evaluated by the HACCP team. I indicated earlier that brainstorming was another process that the HACCP team can use for hazard identification. When HACCP was first implemented in the food industry 27 years ago, it included a brief formal hazard analysis procedure in which three questions were asked about the hazard characteristics of the food being produced:

1. Does it contain a sensitive ingredient?
2. Is there a process step to control the hazard?
3. Is there a potential for product abuse that could increase the potential hazard?

Hazard categories (not presented here) were based on the answers to these questions (National Research Council, 1969).

As we worked with this hazard analysis procedure for a number of years, we recognized that a thorough hazard analysis could not be accomplished by considering only three questions. Therefore, in 1992, the NACMCF recommended that an open-ended hazard analysis, or brain-storming, procedure be used. A list of 48 representative questions were organized in the 12 areas shown in Fig. 10. The HACCP teams are encouraged to consider even more questions based on their knowledge of the products they are manufacturing. It is almost certain that you will need to conduct laboratory research and plant trials to answer these questions. At Cargill we have one training seminar devoted exclusively to this topic.

The original exercise involving hazard characteristics and hazard categories was an attempt to provide a semi-quantitative aspect to hazard analysis, in which the foods produced for "at-risk" populations were subjected to more intensive microbiological testing before distribution. This exercise has fallen into disuse for two reasons in addition to the limitation discussed above. First, it is now realized that a large percentage of the population is immunocompromised (estimates range from about 20% to 40%) (Council for Agricultural Science and Technology, 1994). Food companies must produce foods that are safe for all consumers, so there is limited need to differentiate foods based on the likely consumer. Second, microbiological testing of finished products is not an effective way to assure food safety. That is how HACCP originated in the first place. Food companies now prefer to use a limited amount of microbiological testing to verify the effectiveness of their HACCP and hygiene programs.

In summation, I want to reemphasize my major point: hazard identification is a qualitative process in which the significant hazards are already known. Additional "hazards" may be decreed by regulations. Emerging hazards may be identified by epidemiological studies or risk assessments. Hazard analysis consists largely of an evaluation of sensitive ingredients and brainstorming sessions by the HACCP team in which all relevant questions are considered. For the purposes of HACCP training and implementation, it is important that the processes of hazard analysis and risk assessment not be confused. They are different and independent processes.

Open-Ended Hazard Analysis Since 1992

Questions considered in these suggested areas:

• Ingredients	• Sanitation
• Intrinsic factors	• Employee health, hygiene and education
• Procedures used for processing	• Conditions of storage between packaging and end user
• Microbial content of food	• Intended use
• Facility design	• Intended consumer
• Equipment design and use	
• Packaging	

Fig. 10. Open-ended hazard analysis since 1992.

I do not want to leave the impression that I am anti-risk assessment. While I have spoken very forcefully for the proper place of hazard analysis, there is, of course, also a proper place for risk assessment. In reviewing the affiliations of those attending this conference, it seems that about 10% of you are affiliated with regulatory bodies, while more that 50% are affiliated with food companies. When we all go back to work next week, many of the industry people will be working on hazard analyses and some of the regulatory people will be working on risk assessments. About 30% of the registrants are educators. One of your responsibilities is to educate students in food safety principles so that they can understand and accurately use important tools such as hazard analysis and risk assessment.

References

Code Alimentarius Commission (1997). Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application. Annex to CAC/RCP 1-1969, Rev. 3 (1997). In *Food hygiene basic texts*. Rome: Food and Agriculture Organization of the United Nations, World Health Organization.

Council for Agricultural Science and Technology (1994). *Foodborne pathogens: risks and consequences*. Task force report No. 122. Ames, Iowa, USA.

National Advisory Committee on Microbiological Criteria for Foods, NACMCF (1992). Hazard analysis and critical control point system. *International Journal of Food Microbiology, 16*, 1–23.

National Advisory Committee on Microbiological Criteria for Foods, NACMCF (1998). Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection, 61*, 762–775.

National Research Council (1969). *An evaluation of the Salmonella problem*. National Academy of Sciences, Washington DC: USA.