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limits?

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SAFE FOOD WITHOUT LIMITS ?

Introduction

Mijnheer de Rector Magnificus, ladies and gentlemen,

Earlier this year, when announcing President Clinton's food safety initiative, United States vice-president Gore said "Our food supply is the safest in the world, but the nation has much more to do." It is difficult to verify the first part of Mr. Gore's statement because data are not available about the comparative safety of the food supplies. Any grocery shopper knows that foods from all over the world are available everywhere. Thus, one might ask what makes the United States so special. It would also be very interesting to know which countries Mr. Gore had in mind when he assumed that other countries had a less safe supply, and which measuring tools he used to classify food supplies as "unsafe", "safe", "safer" and "safest". The data on the incidence of foodborne illness reveals that the US population is certainly not better off than that of many other industrialised countries. The food supply may be safe but the practices related to the handling, preparation and use are not safe enough.

This leads me to address three crucial questions in the area of food safety:

- what is safe food
- how can such safe food be obtained
- how can such food be traded in a global market

What is safe food

The Codex Alimentarius, FAO and WHO's Food Standards Programme, provides an official definition of

food safety, but I would like to begin by discussing what safe food means to the consumer. Webster's dictionary defines safe as "freedom from the risk of damage, danger or injury". This definition corresponds with the normal perception of safe food: it can be eaten without any risk of getting ill. However, Mr. Gore's statement could imply that there is safer and safest food, that only the safest is good enough and thus that there may be a risk associated with a "safe" food.

This is why I have decided to address the question "are there limits to the safety of food". To describe what I mean by "limits", I refer again to Webster's dictionary: it is "the boundary beyond which something ceases to be possible". What are the boundaries of safety and are there criteria determining what is unsafe and what is safe, safer or safest? Are there clear lines separating these classes of safety or is it difficult to see when safe becomes unsafe, as it is difficult to see when a fish becomes a bird in the famous picture of Escherl? Limit also means "the greatest number or amount allowed". How are such limits established and how is compliance internationally achieved? These are a few of the questions I would like to discuss.

Safety levels

When we buy a car, we take for granted that the basic safety requirements have been met. All cars have to comply with certain specifications. There are also cars on the market with added safety: with airbags, more powerful brakes and ABS, side protection, shock absorbing zones etc. These additional safety devices

normally increase the price. Some drivers may have special requirements; for example, they may want to drive fast, and the design of the car should allow them to do this safely. Sports cars hold the road well, have excellent brakes, but may be less comfortable. Formula 1 automobiles are the safest, used only by a happy few, and not on the road. In all these cases, safety is linked to the intended use of a car. Still, even with the safest car, a lot depends on the driver and driving conditions.

The situation with food is similar. Normally, food is safe when properly handled. Foodborne illness is often caused by mishandling somewhere in the food chain, or by misuse. Some foods are designed for a specific use, such as foods for infants, enteral feeds used for intensive care patients, and food used by astronauts. Such foods receive extra care during processing and preparation. In addition, the population of consumers is not uniform, some people are more vulnerable than others, and all foods are not fit for all purposes or uses. These are some facts to consider in managing the safety, and particularly the microbiological safety, of food. It will not come as a surprise to you that I will focus on the microbiological aspects, even though much will have also relevance to the chemical aspects of food safety.

Human response to microorganisms in food

Every day, we ingest many millions of microorganisms without any effect. Negative reactions to microorganisms or their toxins are the exception rather than the rule, and there are several factors affecting the likelihood of their occurrence.

It might seem that the easiest way to study exposure-response relationships would be to perform feeding studies with animals, as is done with chemicals. However, this method cannot be applied to the study of reactions to microbes. Experimental animals may react differently, or not react at all, to microbes which are known to cause illness in human beings. Feeding these microbes to volunteers is also not an effective method. Healthy volunteers often can swallow millions of bacteria such as *Salmonella* and *Campylobacter* without showing any sign of illness.

Much of what we have learned about the effects of foodborne microorganisms has come from studying people who became ill after having a nice dinner, barbecue or snack. The causative agent was then diagnosed by laboratory analysis of the stools of patients and the food. This is how *Salmonella typhi*, *Vibrio cholera*, *Clostridium botulinum* etc. were established as foodborne or waterborne pathogens in the early days of Microbiology. As isolation and identification techniques have improved, other microorganisms were identified. These investigations of negative human responses to microbes in food have also identified three classes of factors which influence the reaction: the type of microorganisms, the type of food in which it is found, and the characteristics of the host.

To start with the last class of factors, infants, elderly, pregnant or diseased individuals, and people receiving certain drugs, such as antibiotics, cortisones, immunosuppressants, may be particularly susceptible to foodborne illness. Using antacids may also have a

predisposing effect by neutralising the acidity of the stomach fluid. Many of these vulnerable consumers do not know that they are more sensitive to the attack of foodborne pathogens. Thus, consumer information is an important aspect of the prevention of foodborne diseases.

Factors associated with the food include: the fat content, whether the food is solid or fluid, whether it is a snack eaten on an empty stomach or is part of a six course dinner. Fat may protect the bacteria against the attack by the gastric juices. The fluidity of a food determines whether it can pass the stomach quickly and whether the gastric juices mix easily with the food. The time of consumption and the amount of food affect the passage through the stomach, and thus the chance that microorganisms will survive.

Finally, the virulence or pathogenicity of the microbes is important. Large numbers of *Bacillus cereus* need to be ingested to cause illness. A few *Listeria monocytogenes* will not trigger a reaction. Some microbes, however, are particularly nasty, and ingesting only a few will cause a serious disease. Among these are the recently emerged *E.coli* strains with names such as: O157.H7, VTEC, and EHEC. These microorganisms are reported to have a higher acid tolerance; this means they can survive the passage through the stomach. They also have adherence factors, which allow them to attach themselves to the intestinal lining and colonise. They may even cause lesions to the intestinal cells, and thus penetrate more easily the rest of the body. These bacteria produce several toxins, some of them may cause a very severe disease called HUS, or Haemolytic Uremic Syndrome.

The logical conclusion is that a non-fat food containing a few *Listeria* is a much safer food, even for infants and old people, than a fatty food containing a larger number of the EHEC bacteria, even for people without increased susceptibility. Safety limits will thus vary depending on the organism, the food and the targeted group of individuals in a given population.

Food Safety Objectives

This brings us to the question: can we establish safe levels for a given microorganism in a particular food, taking into account the way it will be used? It is very difficult, because of all the factors that have to be taken into account, moreover, not all factors are known and quantitative data are often not available. Certainly when a food does not contain one single potential pathogenic microorganism or a single molecule of a microbial toxin, such food is 100% safe from a microbiological point of view. Thus, in theory at least, one way to assure that a food is safe is to establish a zero tolerance, meaning total absence of pathogens or toxins in foods. In practice, this would mean that all food had to be sterilised, and that all growth of microbes which can produce heat stable toxins should be prevented at all stages of the food chain. This is clearly not a realistic solution to the problem.

The concept of Food Safety Objectives may help us out. To understand this concept, one has to start with defining food safety. As I mentioned before, safe food is food you can eat without getting ill. To become meaningful for the trade in foods, some words have to be added to this description. The Codex Alimentarius, has defined

safe food as follows: "food that will not cause harm to the consumer *when it is prepared and/or eaten according to its intended use*". The reason for this addition to the description mentioned earlier is that in practice, the occurrence of a few pathogens or the presence of low amounts of a toxin in some unprocessed foods, is inevitable. These levels are so low that when handled and used as intended, the food does not cause illness. It is well known that fresh and frozen poultry may contain potentially harmful bacteria such as *Salmonella* and *Campylobacter*. This is not a problem because normally, poultry is thoroughly heated before consumption. Undercooking may cause salmonellosis or campylobacteriosis, but undercooking is not the proper way to prepare chicken.

This does not mean that we should not try to reduce or, if possible, eliminate these bacteria in poultry. First, as the number of these bacteria on carcasses increases, so does the possibility that a few survive. Second, raw poultry may contaminate hands, knives, cutting boards and other items. If prepared foods come in contact with these items, they can pick up these bacteria and cause illness. We certainly must try to reduce the occurrence of pathogens in our food supply for these and other reasons, but this should not lead to the establishment of unrealistic zero tolerance policies. There is a limit to safety. It should be realised that, and here I quote Dr. Betzler, an economist with the US government, "in the end, all costs of food safety regulations are born by households".

Instead we should try to establish Food Safety Objectives

which are realistic and achievable, offering acceptable consumer protection. Food Safety Objectives are simply "the maximum level of a potentially harmful microorganism or its toxin(s) in a food considered to be acceptable". They may be expressed as the number per gram or serving, or absence in a certain quantity of food. They are specific to a product, microorganism and intended use. They should be established on the basis of sound scientific data, but often socio-economic factors also have to be taken into account. This is part of what is called Risk Management.

Risk Management

Fresh food and raw materials can contain potentially pathogenic microorganisms; thus, there is a risk, and something has to be done to control it. To control refers to "having the situation under control", not to "testing of foods". It means selecting control options and setting priorities. Mr. Gore said that much more has to be done, but with the 43 million dollars he wants to make available, there is a limit to what can be done. Choosing control options is an important aspect of Risk Management.

It starts with problem evaluation; for instance, what are the possible consequences for public health of *Salmonella* in poultry? Then, a risk estimate is made. Techniques originally developed for chemicals are beginning to be applied to microbiological risk assessment. One problem with this technique is the current lack of dose-response relationships for the various types of microbes, foods and consumers. I am

convinced that these data will become available, but for now, we apply a "worst case scenario" technique. This allows us to estimate risks; i.e. what is the maximum number of people who will get ill (and how serious will this be?) as a result of having a certain food on the market. If this risk is unacceptable, control options have to be considered.

Let me take the example of *Salmonella enteritidis* in eggs. We know that eggs may contain a few of these bacteria. Due to unchilled storage the level may increase and eating an undercooked egg containing high numbers of salmonellae may result in salmonellosis. The number necessary to provoke illness may vary according to the factors described earlier. A management option is refrigeration of eggs from farm to cooking, thus assuring that the numbers were kept low. Another option is to eradicate *Salmonella enteritidis* in poultry; this would result in a lower contamination frequency. A third option is to pasteurise all eggs.

During pasteurisation the number of target micro-organisms is gradually reduced. Some microbes are killed more quickly than others, but the higher the temperature and the longer the time the more microbes will be killed. Unfortunately, egg products cannot be heated to very high temperatures, but the level of salmonellae in raw eggs is very low; thus, with a temperature of 62°C for 2.5 minutes, a level of less than one *Salmonella* per ton of pasteurised egg can be achieved. Epidemiological evidence has demonstrated that this is safe enough. This level could therefore be accepted as the Food Safety Objective, it is realistic and

achievable. It is a good example of making food safe, but there is more to it, as I will explain.

Producing safe food

Plants, fruits, cereals, nuts and animals are all used as raw materials in the industrial production of foods. Many of these reach the consumers without any processing. In industrialised countries, unprocessed foods are estimated to represent about one quarter of the food supply. In developing countries it may be around 50%, depending on the degree of urbanisation and distances between production site and market. These primary agricultural products are growing in an environment heavily influenced by man. To secure high yields, fertilisers, pesticides, and growth promoting agents are used.

Use of these agents is regulated; thus they do not normally cause any harm to the consumer. This does not mean that further efforts to reduce the use of chemical fertilisers, pesticides etc. may not have potential benefits, but new problems may also be created. The use of manure for fertilising crops or even pastures, for instance, can create cycles of infection of potential human pathogens.

Waste, be it of animal or human origin, may be a source of contamination, because it may be spread by birds, insects, and rodents. This is how food producing animals become carriers of pathogens such as *Salmonella*, *Campylobacter*, specific types of *E.coli* etc. Other pathogens, such as *Listeria monocytogenes*,

C. botulinum and *B. cereus* are normal inhabitants of soil and may be picked up by animals and plants. Parasites such as *Cryptosporidium* may be found in surface water. *Toxoplasma* may be spread around by pet animals such as cats, and finally, *Anisakis*, the so-called herring worm, has its natural host in seals.

The point I am making is that products grown on farmland, fish swimming in rivers or even in the sea, animals grazing on pastures or fed with animal feed derived from all sorts of raw materials, may "naturally" be in contact with microbes which can be harmful to people. Although some of these microorganisms can cause infections to the host animal, or certain mycotoxin-producing fungi may be infectious to plants, the visitors often do not bother the hosts. Consequently, meat and poultry inspection programs cannot detect such microorganisms. Slaughtering procedures may limit the spread of *Salmonella* and *Campylobacter*, but it is quite difficult to prevent all cross contamination.

Thus, something needs to be done during food processing or preparation. Milk may contain pathogens and should be treated either at the dairy plant or at home. Drinking raw milk has been, and continues to be, a source of *Salmonella* and *Campylobacter* infections. This brings me to the concept of Hazard Analysis and Critical Control Point (HACCP).

The Hazard Analysis and Critical Control Point concept

When the US began developing the space program, they

were also developing systems to assure the health of the astronauts. In the early sixties, the normal government system to “control” food safety was to analyse samples for known hazards. The industry relied upon adherence to Good Manufacturing Practices and argued that testing could not confirm that foods were safe. Since the authorities responsible for the safety of the food eaten in space wanted to be sure that the food would not lead to uncomfortable situations in cramped conditions, the HACCP system was developed. The essence of the system is that potential microbiological, chemical or physical hazards are anticipated and prevented from occurring, or made and kept harmless, by product and process design.

HACCP has continued to develop since the early seventies, and is now the world-wide standard for making and keeping food safe. However, the effectiveness of HACCP depends on knowledge and expert judgement. For example, microbiological Hazard Analysis involves examining the whole food chain for conditions which may lead to unacceptable survival, growth, and spread of selected microorganisms, and defining where and how they can be controlled.

HACCP must be applied along the whole food chain, from farm to fork, to make it work. I will demonstrate this with two examples. If meat contains *Salmonella*, and if processing consists of mincing the meat, adding some salt and spices, formatting, packing and freezing, the final product may still contain *Salmonella*. Contamination of the animal at the farm with *Salmonella* cannot be prevented, and thus control has to take place

further down the food chain. The Critical Point for controlling this potential hazard is in the kitchen, where the food is heated before consumption.

Many chemical potential hazards have to be controlled at the primary agricultural level. Most mycotoxins, pesticides, veterinary drugs etc. are relatively heat stable, neither processing nor cooking will reduce unacceptable levels to acceptable ones. The Critical Control Point (CCP) is clearly at the farm. However, microorganisms can be influenced in many ways during processing. Microorganisms are also responsible for most acute foodborne diseases. For this reason the assurance of the microbiological safety of foods is of utmost importance to food production or preparation establishments.

When Food Safety Objectives have been established, assuring microbiological safety means achieving this acceptable level (such as less than one *Salmonella* per ton of egg-product). At the present time, not many Food Safety Objectives have been established. as Mr. Gore said: much needs still to be done. Thus, it is up to the food industry to use best judgement during Hazard Analysis and use the experience obtained during the many years of production of safe food.

To make this best judgement, the industrial microbiologist should know, which potential hazards may be present in raw materials, at what levels, and the effect of the processes applied. He should be aware of potential hazards in the environment, the likelihood that the product will become contaminated, and how this can

be prevented. He has to estimate the fate of potentially remaining hazards during distribution, sales, preparation and use. He needs to know how factories should be designed, how lines should be laid out, what cleaning systems should be used for the various operations, which equipment is best designed from the hygienic point of view and how operators should be trained in hygienic behaviour. This and much more will be presented during courses in Food Safety Microbiology conducted at this University.

Food in International trade

Safe food results from applying Good Hygienic Practices and HACCP from farm to fork. Nowadays, because of urbanisation and globalisation of the food supply, the farms and the forks are not always in the same country. Processed foods are shipped all over the world and, due to differences in eating habits, they may not be used as intended. Global rules and regulations are therefore necessary to prevent foodborne diseases. The Codex Alimentarius was created for this reason and to assure fairness in trade. The GATT was established to achieve an open market system where food could be moved freely across borders. The last barriers were removed with the acceptance of the agreements developed during the Uruguay round of negotiations. The World Trade Organisation (WTO) was created to assure that the agreements are respected.

Governments have the sovereign right to protect the health of the inhabitants of their country, and they may block food imports for safety reasons. This makes it very important to define what safe foods are and how

they are produced. Governments may be tempted to support the local production of food by allowing only the safest supply to enter their country.

The agreement on Sanitary and Phytosanitary (SPS) measures deals with these aspects of the trade. Safety criteria should be scientifically based, risk assessment techniques should be used and, whenever possible, the recommendations, guidelines, Codes and Standards of the Codex Alimentarius should be applied. Important texts for the microbiological safety of foods are the documents describing General Principles of Food Hygiene, HACCP and the Establishment of Microbiological Criteria. The document on the Principles of Food Hygiene pertains to all foods, more specific documents will be worked out. The HACCP document gives clear guidance concerning the system but not concerning how equivalence in application should be determined. For example, Critical Control Points are defined as "locations, procedures and practices where identified hazards can be eliminated or reduced to acceptable levels". A Critical Limit is defined as: "a criterion which separates acceptability from unacceptability". How to determine these limits or acceptable levels is not worked out yet, much more needs to be done.

Import control

If governments want to assure the safety of the food supply, they have to control the safety of imported food. The best way to do this is to assure that the other country applies the same principles for the production of safe

food, and that their Food Control system is equivalent. However, systems, their interpretation and implementation differ widely all over the world and there is still reliance on testing of incoming goods or foods to be exported. The microbiological criteria for accepting or rejecting a lot ideally should be established according to the Codex document dealing with this matter and mentioned earlier. This is often not the case, and the document provides only limited guidance. It prescribes a sampling plan; this means how many samples have to be analysed, and which microbiological limits have to be applied. However, it does not describe how such sampling plans have to be established.

These criteria should not be confused with Food Safety Objectives. The objectives are targets – for example, one Salmonella per ton of egg product -- and compliance often cannot be determined by microbiological testing. Microbiological criteria are designed to examine foods by testing, they can sometimes detect unacceptable lots, they are not designed to assure safety. Food Safety Objectives are met by designing safety into the production, processing and preparation of food, they can be achieved in many different ways.

Conclusion

At this point, I would like to make a few concluding statements. We all need food and we need safe food, because unsafe food may lead to disease and contribute to malnutrition. Food should support life and contribute to the quality of life, eating should be a pleasure.

We have seen that many factors may influence the safety of food. We have also seen that what is considered to be safe for one person may not be safe for another. Tourists know that they should be careful in their choice of food in certain countries. Likewise, susceptible individuals should be aware of their vulnerability and take precautions. Foods produced or prepared for them should have an increased level of safety. This concept is very important in countries with an increased number of elderly and other people with diminished immunocompetence. Targeting the highest level of safety for everyone around the globe (safety without limits) is unnecessary, unrealistic, and costly.

In a free market system, foods are moved freely across borders. Preservation techniques may render ready-to-eat foods safe, but many other foods need still some preparation before consumption. The safety of these foods largely depends on their preparation and use at the end of the food chain. However, even if food is perfectly safe at the moment of delivery to the consumer, mishandling may still cause foodborne disease.

Governments may ban the importation of unsafe foods to protect the health of the inhabitants of their country. To prevent misuse of this sovereign right, they have to apply the rules of the world trade Organisation. Details of these rules have still to be worked out.

One of remaining problems is to define the limits of microbiological safety; the point at which safe food becomes unsafe. This is a multidisciplinary task to be accomplished by governments, users, and producers.

Since these stakeholders have different priorities, it is important that these negotiations are supported, or carried out, by international organisations. This is nicely summarised by the WHO "Food Safety Temple²."

Clearly, the negotiators must be knowledgeable and well informed. It is the role of scientists to find and provide the necessary information. In my opinion, this University can and should be a major player in this process of gathering and transferring knowledge. I consider it a great privilege to become a part of this process through this European Chair in Food Safety Microbiology.

Let me conclude with a paraphrase of Mr. Gore's statement: "we can assure the supply of safe food in this world, but much more needs to be done, to consistently achieve this".

Mijnheer de Rector Magnificus, ladies and gentlemen,

I would like to take this opportunity to thank a few people and organisations that have been behind me, and behind the creation of this Chair.

Dear members of my family and friends,

I will address you in my mother tongue. Mijn moeder heeft mij niet alleen bijgebracht hoe ik deze taal moet gebruiken, maar zij heeft mij ook laten ervaren wat het woord liefde betekent. Hiervoor ben ik haar bijzonder dankbaar en ook dat ze er vandaag bij heeft kunnen zijn. Gelukkig zijn er ook nog vele andere familieleden en

vrienden. Dat jullie er allemaal zijn is eens te meer een bewijs dat voor ons "samen delen" en "samen beleven" essentieel is.

Hooggeleerde Kampelmacher, beste Dan,

Veel van wat ik vandaag heb besproken heeft zijn oorsprong in de stimulerende discussies die wij op het RIVM, maar ook later, gevoerd hebben. Er is echter meer. Zoals een Menuhin zijn leerlingen niet alleen het vioolspel heeft bijgebracht, maar zich ook als pedagoog heeft opgesteld, zo heb jij niet alleen je vakkennis maar ook je levenswijsheid met mij gedeeld. Dank hiervoor en voor "all the games we played".

Hooggeleerde Rombouts, beste Frans,

Dat deze leerstoel gestalte heeft kunnen krijgen is voor een groot deel te danken aan jouw inspanningen. Ik zie er naar uit met jou, Dr. Rijkelt Beumer, Dr. Meike te Giffel en andere leden van het departement, met name Dr. Marcel Zwietering en Prof. Wim Jongen het onderwijs en het onderzoek in Food Safety Microbiology verder uit te bouwen. Het is plezierig om aan een vlot rijdende trein aan te kunnen haken, ik hoop dat ook mijn wagon goede diensten zal bewijzen.

Geachte leden van de Benoemings Advies Commissie en het College van Bestuur,

Toen ik vernam dat er een initiatief genomen was om deze leerstoel te creëren, en dat ik als potentiële kandidaat genoemd zou worden was ik blij verrast en

enthousiast. Het is een voorrecht dat ik u op deze plek kan danken voor het aanvaarden van het initiatief en het benoemen van de kandidaat.

Distinguished representatives of Unilever, Danone, Kraft, Jacobs-Suchard and Nestlé,

Concern for the safety of your products is the reason for establishing this European Chair in Food Safety Microbiology. As I have explained in my presentation, food safety is a complex affair; we still have much to learn and much to do. I feel honoured that you have given me the opportunity and the challenge to develop your initiative further; I will need, however, your continued support. I would also like to take this opportunity to thank the Dutch Ministry of Agriculture for sponsoring a scientific collaborator.

To the students,

In the future, we will need more food because there will be more people. We will have to be even more concerned about food safety than we are today, because factors such as increased life expectancy will lead to a growth in the percentage of the population with heightened sensitivity to foodborne illness. It will be your task to ensure that these needs are met. I hope that I will be able to give you a start, but it will be up to you to continue, because in a few years I, too, will belong to the more vulnerable part of the population, and I trust that I will be in safe hands. This University offers you optimal possibilities for success.

Mijnheer de Rector Magnificus, ladies and gentlemen,

I thank you for your attention and interest.

Ik heb gezegd.

Lucht en water, M. C. Escher

**"Food Safety Temple",
adapted from WHO design**