THE IMPACT OF RISK ANALYSIS ON FOOD SAFETY

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Meneer de (wnd) Rector Magnificus, ladies and gentleman,

In my inaugural address, I will discuss a new, global framework that is currently in the process of being established and implemented by governments and governmental organisations as part of their ambition to protect public health, i.e. to protect the health of consumers. This Framework is referred to as Risk Analysis. Part of this framework consists of a structured and formalised assessment of the risk that a microbiological hazard may pose in a certain complex situation. I will focus some of my attention on this part, which is called Microbiological Risk Assessment, because it links in closely with the activities of the *European Chair in Food Safety Microbiology*. However, restricted by time as I am in this address, I will not be able to give much technical detail on the framework. This is probably to the better, as it still very much is a concept in development. As yet not much practical experience has been gained, and ‘best practice’ is what the most active players make of it.

To start off, I will give some historical background on food safety management to hopefully better understand the rationale for developing the new framework. I will then spend some time going through the concepts of how Risk Analysis in general and Microbiological Risk Assessment specifically are thought to operate. Subsequently I will reflect on whether and how elements of RA and MRA could be relevant in an industrial context, pointing out important differences with the use and application of these in a governmental context. I will end with an outlook on whether the introduction of Risk Analysis in my opinion will change the safety of the food supply as we know it today.

A historical perspective on food safety management

In the course of human history, the scope and complexity of food safety management has increased dramatically. In ancient times when food safety was the sole responsibility of the hunter/gatherer, the chain of responsibility was a very short one. Gradually, the scope increased further over small communities, regions and countries to now reach international scales. Concomitantly, the chain of responsibility has become longer and more complex.

Table 1. Factors influencing the safety of the food supply

<u>Life Style</u> Expectations Traditional skill loss Risk averse 'Soft' information credible	<u>Regulatory environment</u> Precautionary principle Power of consumer groups Extension of hygiene regulations
<u>Population/Industrialisation</u> Global warming Water scarcity Education/awareness/wealth Globalisation of markets Travel	<u>Confounding issues</u> Industry to 'blame' Industry not trusted Understanding of zero risk Ability to use expert judgement Real versus Perceived
<u>Population/Industrialisation</u> Global warming Water scarcity Education/awareness/wealth Globalisation of markets Travel	<u>Future Hazards</u> Chronic diseases Emerging acute diseases Return of 'old' diseases Parasites and viruses Auto-immune challenge

Today, with important changes in lifestyles and demographic compositions and with global food markets becoming increasingly more common place, we see the food supply growing ever rapidly in size and diversity. As shown in Table 1, there is a wide range of conditions and factors that have, in one way or the other, an impact on the safety of the food supply in a given population over time.

At the basis of food safety management, of course, has been our knowledge about the presence and dynamics of microorganisms in the food ingredients and in the food production and consumption environments.

Ever since Antonie van Leeuwenhoek could visually prove the existence of “micro”-organisms, methods of detection and study of ecology and physiology of the many microorganisms around, has taken us deep into the mechanics of what makes these organisms “tick”. Our recognition of the harmful microorganisms has greatly developed over time as well, and necessarily so. Now it is possible to consider the genetic make up and other intercellular traits of a microbe and judge or predict their pathogenic behaviour. Despite the fact that indeed we have in depth knowledge of most of the pathogens, they still can, on occasion, be present in our food.

Controlling the presence, survival or growth of harmful microorganisms has therefore been at the forefront of the development of preservation systems, next to the necessary stabilisation of foods in terms of quality attributes. The oldest known preservation systems, such as here drying or salting, were developed long before the existence of microorganisms was appreciated and are still in use today. Next to those, an array of new

preservation methods has come into practice to serve the need for preservation at particularly larger scales or to allow for product innovation.

To keep pace with all the scaling up in the food supply chain and the diversification of food on the market, it has been necessary to adapt and improve the food safety management systems on a continuous basis as well. In recent years the control over the quality of food produced has become tighter and tighter. Food safety management systems such as Hazard Analysis Critical Control Points (HACCP) and the pre-requisite systems Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP) has provided the professional players in the food supply chain with excellent tools. Excellent, provided they are used for design and implementation of a food manufacturing process in a proper and diligent way. Globally, both with governments and food professionals there is a good buy-in for HACCP and food safety management systems that are based on comparable principles. However, both in terms of the underlying principles and the operational use of such systems, there is a need for better and more consistent education.

Thanks to the increasingly more powerful mathematical and Information Technology (IT) systems, we have seen a strong push in our capability to efficiently and skilfully design and implement food processing techniques. Both is terms of capacity and sophistication, computer systems and mathematical modelling tools, some with predictive ability, have increased radically in applicability. Modern technology allows us to tackle the complexity of our food supply. For instance, by carrying out Risk Assessments on microbiological hazards that are essentially quantitative and follow novel approaches.

Table 2. Stakeholders in and along the food supply chain

– Primary producers	– Governmental bodies
– Transporters	– Scientists
– Manufacturers	– Advisory commissions
– Processers	– Medical community
– Packaging industry	– Industry, trade organisations
– Retail	– International organisations
– Food service	– Consumer representatives
– Consumers	– etc.

As shown in Table 2, many different stakeholders are involved in and along the chain of food production, from primary production, over transport, processing and manufacture, over retail, food service and preparation in the home by consumers. You will appreciate that these various stakeholders are very different in terms of their role in and understanding of food safety management. There is therefore a clear need to co-ordinate how each stakeholder can discharge his responsibility in the chain.

To this end, stakeholders in food safety management, for instance governments, have issued a multitude of guidelines, regulations and advise, for instance in the form of food safety standards and criteria. Sector organisations for primary production and food manufacturing inform and educate their constituencies on a continuous basis with best practice advise. Food manufacturing companies collectively have taken responsibility for technology transfer and education at the operational level via non-governmental organisations. Recognition of the importance of academic education by such a group of companies has resulted in the

establishment of the *European Chair in Food Safety Microbiology*. In all, food safety management is the responsibility of many players in and along the food chain. Education of the various stakeholders, both domestic and professional, is of utmost importance.

It bears little surprise that those that prepare food for domestic consumption are quite confident that they much more reliably provide safe food. There is a large gap in thrust with professionally prepared foods. However, considering the enormous volume of food that is globally produced and processed safely by food professionals, in my mind, this apparent distrust is not warranted.

Analyses of public health problems and their association to the food supply, have brought about the opinion in many a government that our current food supply is probably safer than ever before. This, however, is not at all appreciated by most consumers which is not surprising reading some of the statistics.

Even in industrialised countries, it is estimated that out of every three people, one has a food-borne, microbial illness event every year. While in many cases the disease has a minor impact or may even go unnoticed, up to 20 people per million may die from such diseases. We have to recognise that food safety is not an absolute. It is a continuum of more or less safety. Assuring as much safety in the food as reasonably possible, is the responsibility of governments and every partner/player in the food chain.

As one example, the European Commission now has taken the initiative to modernise legislation and to redesign their role in food safety

management. Risk Analysis will be one of the tools more systematically used in order to build in “transparency” and “sound science” into the latter. One of the strategic priorities of the European Commission was the establishment of the European Food Safety Agency by the year 2002. The primary responsibility of the Authority will be to provide independent scientific advice on all matters with a direct or indirect impact on food safety. I am honoured to have one of EFSA’s recently appointed management board members, Dr. Bart Sangster, in the audience.

Risk Analysis

In 1991, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) communicated that transparent, science-based and internationally recognised standard approaches to risk assessment are needed and that they should be consistently applied across the board of committees establishing such assessments in different discipline domains. This moment, probably, marked the start of the development of a global Risk Analysis framework.

FAO and WHO also called upon countries to apply modern international food safety and quality standards to protect consumer health. One key element of an effective modern national food safety program should be “evidence-based legislation”, which for me follows from combining “transparent and science-based”. Appreciating the complexity of the current food safety supply within and across countries, it has been advocated strongly to start using Risk Analysis as the single framework for building food safety programs.

Risk Analysis is a framework proposed for governmental bodies to define an appropriate level of public health protection and establish guidelines to ensure the supply of safe foods. Public health protection is paramount, but within that ambition fair trade should be possible as well, and that is a second important area of application of Risk Analysis.

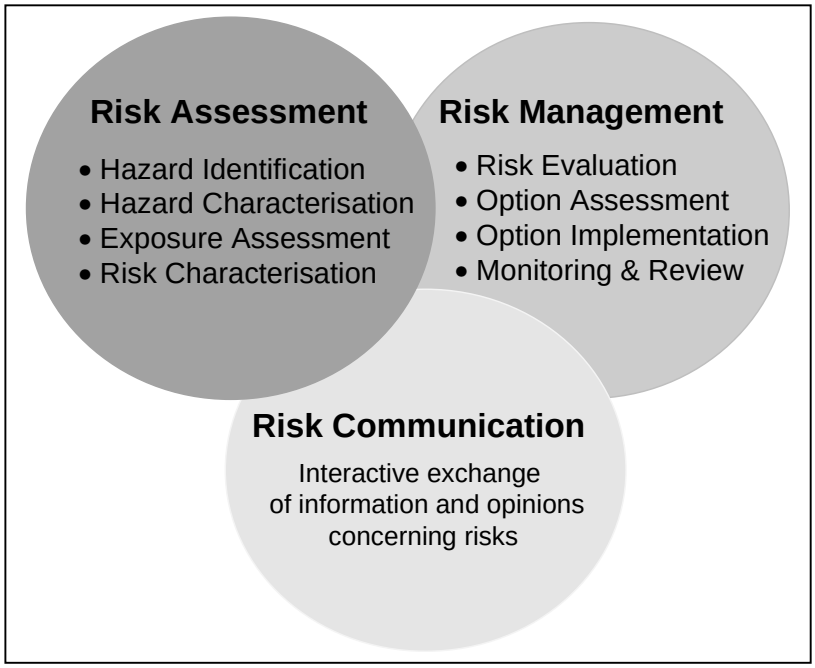

Fig.1. The Risk Analysis Framework according to *Codex Alimentarius*

Risk Analysis is composed of the three elements Microbiological Risk Assessment, Risk Management and Risk Communication (Fig. 1). The framework encompasses managerial evaluation of a problem, scientific assessment of the issue and underlying issues and possible options for intervention or correction, as well as the managerial decision on an appropriate course of action. However, importantly, it also encompasses operational implementation and review of the successfulness of the actions decided on.

A Risk Analysis may be started by a risk manager because epidemiological and surveillance data demonstrate that a specific food is a possible hazard to consumer health due to the presence of hazardous micro-organisms or toxic compounds of microbial origin. Governmental risk managers drive this process with the goal to decide on appropriate actions to manage this particular risk. Also when a risk is not as evident, a Risk Analysis may be started to pro-actively assess the prevailing situation and to decide whether any action needs to be taken.

A risk Analysis may be appropriate, for instance:

- when the food chain is long and complicated, e.g. farm-to-fork
- when many factors influence risk and interventions
- in data poor conditions, to analyse gaps
- when variability and/or uncertainty prevail
- when the impact of a decision possibly is high
- when there is a conflict between values
- to establish a baseline estimate
- to start a cycle of continuous improvement
- for very unfamiliar situations (e.g. new products or practices)

Other pro-active applications hold for problems that have not yet occurred, but are recognised to be emerging issues, or when an assessment is used to forecast an expected risk associated with a new product or manufacturing technology in order for it to be designed out. The advantage with pro-active approaches is that the problems do not call for immediate decisions and actions and that there is time to conduct an analysis thoroughly and diligently, even considering generation of new data when appropriate.

Before going into some more detail of the principles and benefits of Risk Analysis, it is appropriate to consider under which conditions it is not necessarily evident or valuable to employ this framework as it may require a substantial investment in, for instance, time and human resources to carry out a study.

A Risk Analysis may not be relevant, for instance:

- in very urgent situations needing immediate action (e.g. food recalls)
- for routine decisions of little complexity and consequence
- when a risk and possible control options are already well described
- when an issue is not of regulatory or stakeholder concern
- when no relevant data exists at all
- when expertise is not available

Part of the consideration whether or not to start a formal Risk Analysis will depend on the scope of the analysis as well as on the available expertise and resource. The depth and format of a Risk Analysis study, and particularly of the Risk Assessment part, can vary considerable depending on the problem and the objective of the analysis.

In certain cases, a concise *profile* of the risk developed by the risk manager and possibly confirmed by the risk assessor may provide a sufficient basis to make a decision. Qualitative assessments may be sufficient for routine problems or when data are scarce. Quantitative assessments will be required for more complex problems or when data are available.

The expected outcome of the study can differ as well. In some cases a relative estimate of the risk, e.g. comparing the risk with products already

on the market of which the safety record is known, is aimed for. An example of this is the recent exercise in the U.S. to determine the risk associated with the possible presence of *Listeria* in ready-to-eat foods. This study developed a ranking of products from low to high risk. Pate and meat spreads were recognised as high risk and icecream, for instance, as low risk. This was used then by the government to make people, should they not yet be, aware of the high risk foods and to prioritise the allocation of resources on the development of possible intervention strategies.

Risk Communication

In the decision to start a Microbiological Risk Assessment, the execution of that specific work and the decision-making process that follows, Risk Communication is a key process. Risk Communication is concerned with the continuous dialogue between risk managers and risk assessors and many other stakeholders and interested parties. It deals also with communicating the outcome of the decision making process to the stakeholders affected by the actions decided on.

Microbiological Risk Assessment: the process

Microbiological Risk Assessment specifies risks for consumers related to food consumption as a result of the occurrence of pathogenic micro-organisms in the “farm-to-fork” food chain. Within this concept a microbiological "risk" is defined as ‘a health effect caused by a hazard in a food and the likelihood of its occurrence’.

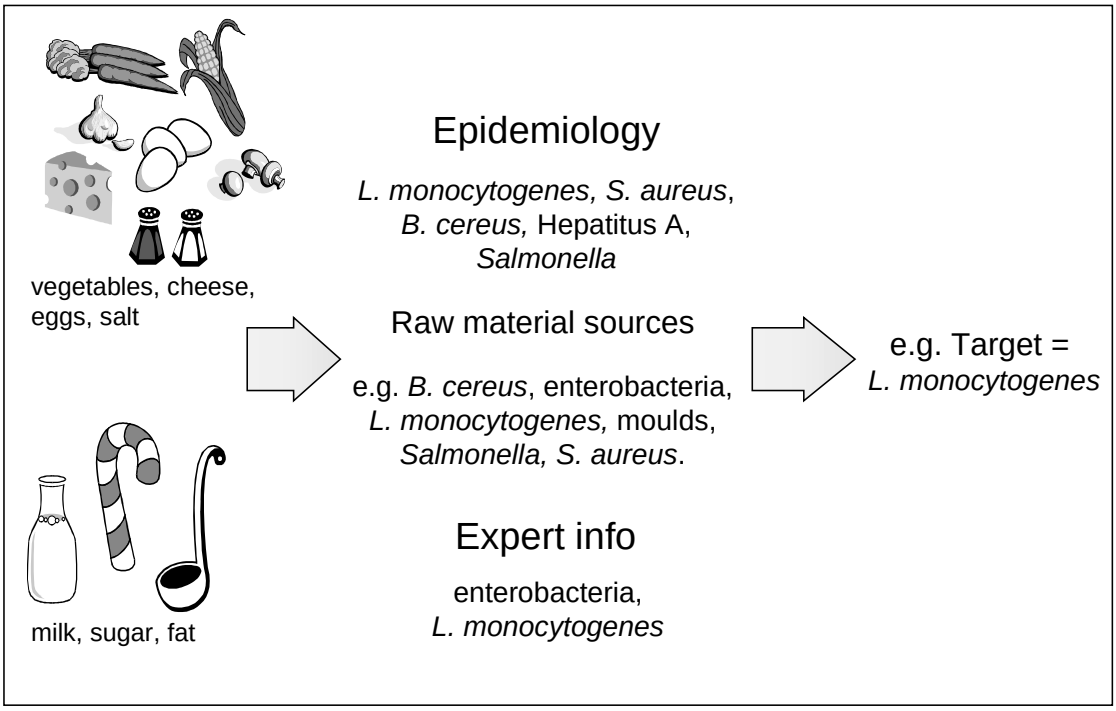

Fig. 2. Hazard Identification

The novelty in the concept is that risks are assessed throughout the food chain on the basis of sound science, combining qualitative and quantitative data in the areas of epidemiology and pathogenicity of micro-organisms with food production and handling.

Microbiological Risk Assessment (MRA) consists of 4 phases or steps.

A. Hazard Identification (Fig. 2) The purpose of Hazard Identification is to identify those micro-organisms or microbial toxins that are a potential hazard in a certain food or product group and to collect evidence in support. Data and expert knowledge are both used in this exercise. The quantities, frequencies of occurrence, and sources of the potential hazards are determined. Knowledge about hazards and their relevance in foods is part of basic training of microbiological professionals, as provided by the European Chair through the efforts of Mike van Schothorst, Martine Reij and Marc Boncz.

B. Hazard Characterisation (Fig. 3.) This step pulls together knowledge about the nature and severity of the adverse effects and of the dynamics of the microbial hazard. Factors important to consider relate to the pathogens, e.g. the mechanisms and dynamics of infection, as well as to the sensitivity of the consumers. Quantitative evaluation is preferred here, for instance dose-response assessments, but qualitative knowledge has some use as well. Within the *European Chair*, Chantal Kandhai currently investigates the dynamics of *Enterobacter sakazakii*, a bacterium that can survive surprisingly well in dry environments and may cause illness under very particular conditions.

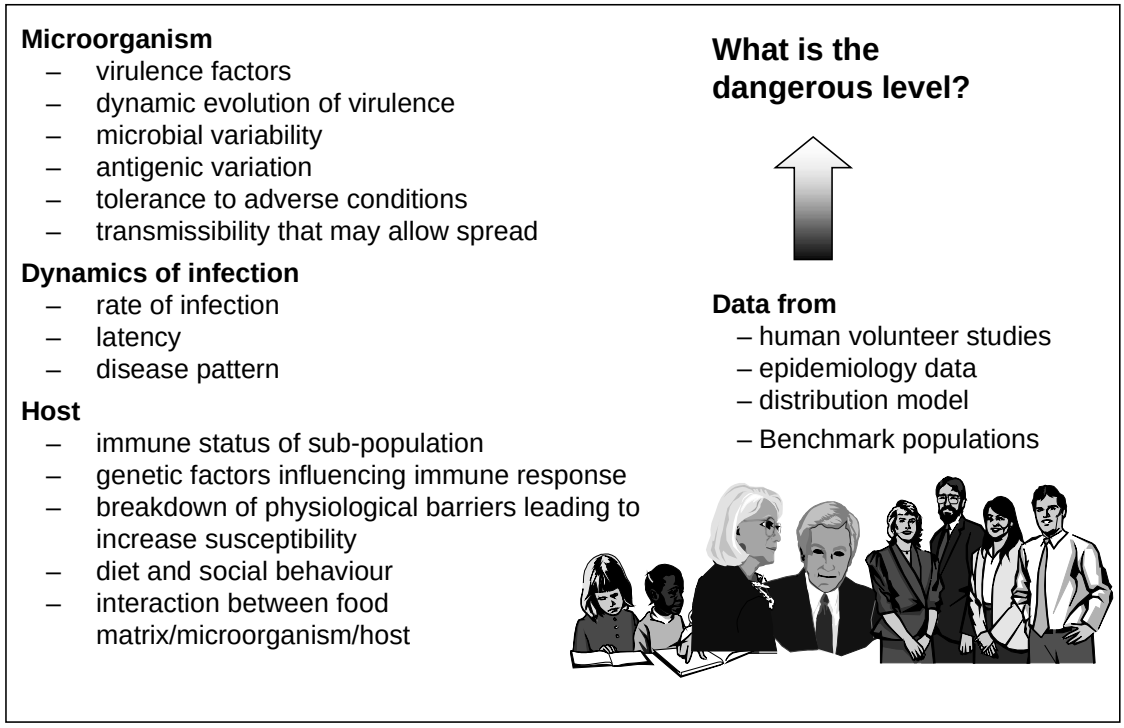

Fig. 3. Hazard Characterisation

C. Exposure Assessment (Fig.4.) In this step, the number of pathogens or the amount of toxins that consumers potentially could be exposed to through the consumption of a certain product is determined.

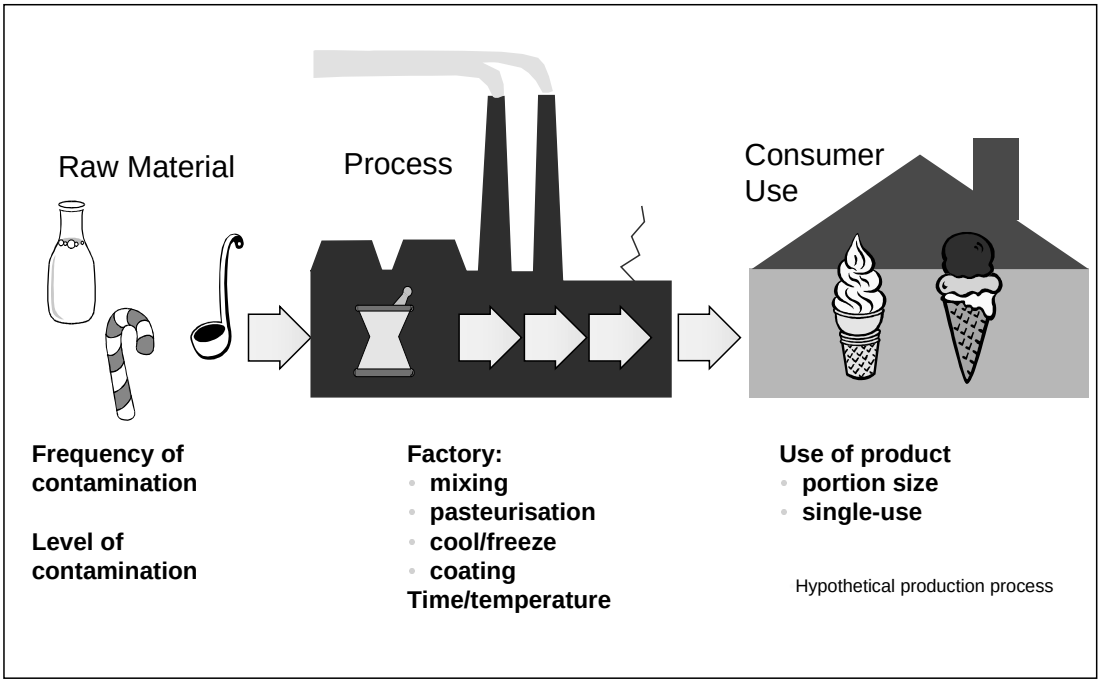

Fig. 4. Exposure Assessment

Exposure Assessment is the part of MRA where food companies can and should contribute in providing data, at least when they collect suitable data. A specific issue is post-processing contamination. This is the phenomenon that micro-organisms are for instance introduced in the product after it has received it's final lethal processing step. This will occur either in the processing line before packaging or during the distribution or preparation by the final user (e.g. retail, vending, kitchens, etc.).

Knowledge of potential sources and of routes of contamination is relatively scarce and hard recontamination data difficult to come by. As was evident during yesterday's academic promotion of Esther den Aantrekker, Wageningen University is leading the development of suitable of recontamination models for use in Risk Assessment studies.

D. Risk Characterisation (Fig. 5). The final step in Microbiological Risk Assessment is Risk Characterisation, which is the calculation of the probability of occurrence and severity of the health effect in a given population. It may consist of different estimates as it can involve different scenarios or assumptions. Importantly, it clearly articulates the attendant uncertainties in the estimates, which may help the risk managers to evaluate the effectiveness of various control options.

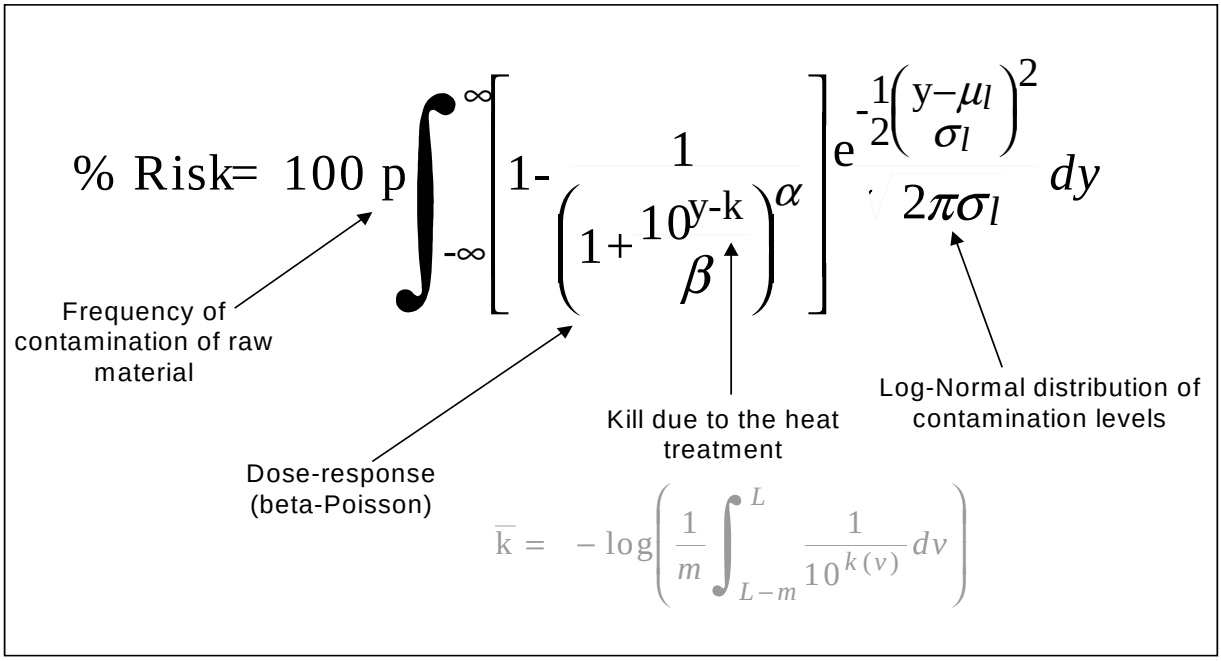

Fig. 5. Risk Characterisation.

There are at least 4 different types of assessment:

- Risk Ranking MRA: one pathogen / multiple foods; assessing one pathogen in different categories or a range of foods, e.g. *Listeria* in ready-to-eat retail foods
- Product/Pathogen Pathway MRA: one pathogen / one food; determining the risk of a specific pathogen in a specific food product, e.g. *Vibrio parahaemoliticus* in raw oysters

- Geographical MRA: assessing the risk for a hazard to be introduced in a new region, as has been studied recently for BSE/TSE
- Risk/Risk Trade-off MRA: comparing safety risks in one domain (e.g. microbiology) with risks is other domains (e.g. toxicology; occupational) or risks (e.g. economical) caused by interventions.

Up to now, not too many countries and organisations have conducted full MRA studies. For most of these studies, the outcome aimed for was an "absolute" measure of risk, a numerical estimate in it's own right. In some, it was a "relative" risk estimate, expressing the risk level between products or compared to other products. I expect that a relative risk estimate or risk ranking will proof to be much more feasible to achieve in practice and that these will be carried out much more often in future.

Risk Management

The risk managers will evaluate the outcome of the MRA, with attendant uncertainties, the intervention options possible included with their expected impact or effect and recommendations or conclusions drawn from the work. Risk managers are ultimately responsible for selecting and implementing appropriate control options. This may well necessitate careful consideration and weighing of policy alternatives. They often have to weigh different types of risk (biological, chemical, physical) and have to balance that against costs and benefits of interventions.
Part of the equation can also be a number of other values and considerations among the various stakeholders that are more societal and less science-based (Table 2).

Table 2. Values to consider by Risk Managers

VALUE	**COMMENTS**
Costs	Costs to public health, costs of implementation, etc.
Feasibility	Technological effectiveness
Ethical	Are all sub-populations covered?
Cultural	Does it comply with consumer choices?
Legal	Consistency with current law, trade agreements?
Public	Perception of risk (‘outrage’) versus ”real” risk?
Risk-risk trade-off	Intervention affecting different risk domains
Time	How urgent is the issue?
Recognition	Is the problem faced? Are stakeholders involved?

A risk can only be characterise truly in it’s particular context. The context helps to get a perspective of the relative degree of the risk, the stakeholders involved and the relevant public health policy goals. As a matter of principle, policy should be in place that helps the risk manager to decide on what Codex Alimentarius has called an “*Appropriate Level Of Protection* (ALOP)” or “*Tolerable Level of Risk*”, and to derive from that a *Food Safety Objective*” .

ALOP (*WTO-SPS definition*):
“Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within a territory”.

Without going into the detail here, there should be an effort to decide on what level of risk, maybe expressed in a numbers of illnesses in the

population per annum, a society is prepared to tolerate or is considering to be achievable. Agreeing on such levels and possibly striving for continuous improvement in the levels over time, is a key element in the Risk Analysis process of which neither Codex nor national authorities have much experience to date.

Likewise, how an appropriate level of protection is used to establish a measure that is meaningful for the supply chain stakeholders, is not yet brought into practice and it is still mainly discussed on a conceptual level. In the current framework, it is proposed to formulate a so called “Food Safety Objectives” that specifies a tolerable exposure level or exposure frequency.

FSO (*definition proposed by ICMSF*):
“The level or frequency of a microbiological hazard that is tolerable in a food at the moment of consumption to provide the appropriate level of public health protection”.

The International Commission for the Microbiological Specification of Food (ICMSF) has proposed that the FSO should be set at the moment of consumption, the ultimate moment when it really matters whether and how much active hazard is present in the food.
As there are often many links in a food supply chain it may be necessary to establish or define several operational targets that help ensure that the chain as a whole operates to meet the Food Safety Objective at point of consumption. This can be a matter of reverse engineering into the food chain from the FSO, but could also mean forward engineering from what is current practice.

In any case, it is evident that close collaboration along the supply chain is needed to achieve the common goal. In my mind, however, the established food safety management systems (i.e. HACCP, GHP, GMP) and supply chain targets (e.g. microbiological specifications or performance criteria) will continue to be used in order to meet the FSO. They will not become obsolete but remain part of the food safety management system.

What then are the benefits of Risk Analysis?

While Risk Analysis does consider a risk in it's wider context, it carefully separates the whole of a risk into it's component parts and gives structure to the risk components. It assesses the most important factors influencing or contributing to the risk and establishes insight into uncertainty and variability associated with such factors.

This approach serves the purpose of an open and honest discussion on the risk between stakeholders, an important aspect of which is effective communication.

Risk Analysis is still rather immature, mainly developed on the conceptual level and relatively little practical experience has been gained to date. Its structured and formal approach to decision-making on issues of food safety or health protection represents quite a paradigm shift.

Risk Analysis provides a framework for considering scientific data as well as policy and societal values pertinent to a risk management question:

– *Structured*: to clearly tell what we know about the problem and possible solutions
– *Descriptive*: to characterise how confident we are
– *Transparent*: to reveal any bias and giving a clear audit train to the decision

As it is such a new tool, among those that are responsible for food safety and health in public or private sectors, there is a virtually global need to increase the understanding of the risk analysis principles, experiment with different approaches and to distil out what “best practice” application of Risk Analysis could look like. Despite that “best practice” on the longer run is important to know, certainly to date, different approaches and new ideas should be encouraged to discover and develop valuable applications and tools within Risk Analysis.

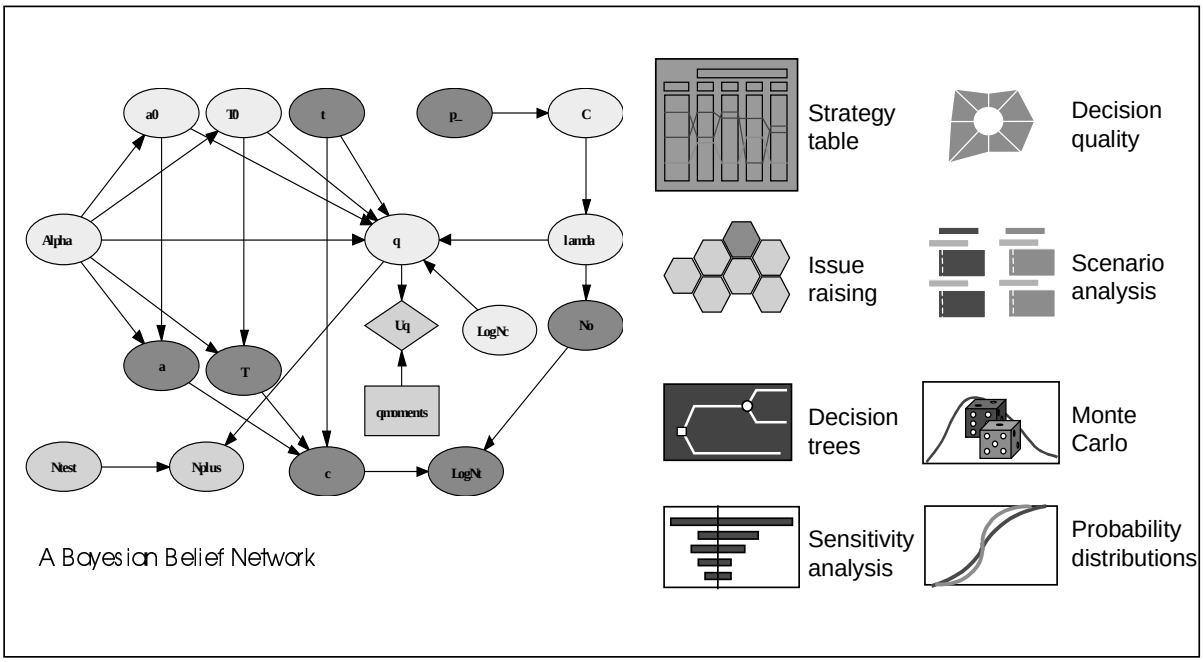

Fig. 6. Bayesian and Decision Analysis tools

I believe that Risk Analysis is and should be “a science-based approach to problem solving”. What does this mean? Risk Analysis helps to define a concrete and pertinent description of the problem. It allows then to systematically work through the solution of the problem and clearly leaves an audit trail in the development of the solution. When appropriate, different scenario’s for possible solutions can be developed.

Interestingly, Risk Analysis is a decision support tool that can be used across the discipline domains relevant to food safety: chemical risks (ingredients/contaminants), biological risks (microorganisms) and physical risks. It might even find application outside food safety domains. Not only the best or most appropriate scientific evidence available for the issue at hand can be considered, but also for instance expert judgement and important societal or legal considerations can be relevant to include in the analysis.

Many tools have now come into the toolbox of the Risk Analysis professional that can help here; Decision Analysis tools and Bayesian Belief Networks (Fig. 6) are at the leading edge of developments that help frame, structure and analyse an issue.

With so many beneficial options and features of the framework, it is important that complexity is managed well. It should be used with as “simple” a format and content as is necessary to solve the problem defined in a professional way. Modular approaches are of interest here as they can cut down complexity in for instance food processing or supply chain studies. The Modular approach that was recently developed by Maarten Nauta and co-workers at RIVM is a good example of how

complexity in a supply chain or production process can be reduced within a risk assessment study.

Evidently, this framework can only be used in a meaningful way when it is accompanied by programs of production and inspection, for instance based on HACCP or systems based on comparable principles, targeted monitoring of contaminants and emerging pathogens as well as active food-borne disease surveillance.

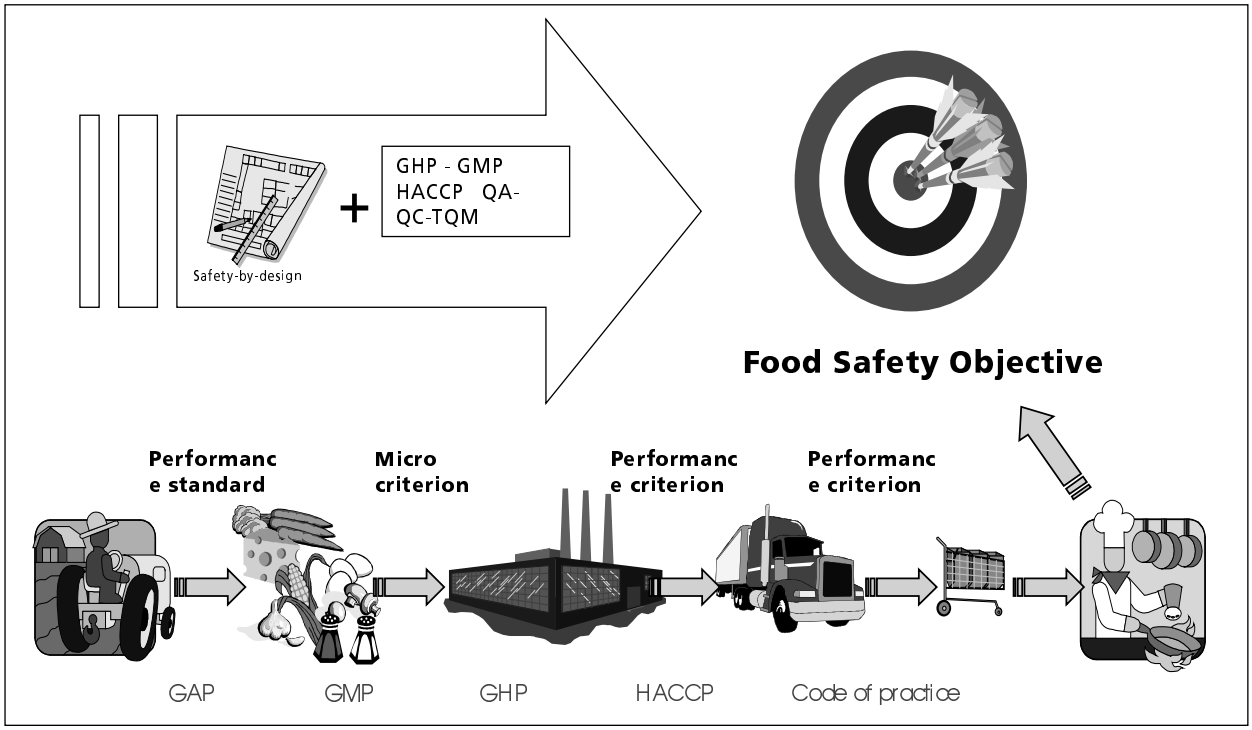

Fig. 7. Food safety management in industry

Relevance of Risk Analysis and MRA to food industry

Industrial Food Safety Management includes various general quality assurance systems, particularly HACCP and its prerequisite systems (GMP, GHP), and optimisation of hazard control throughout the food supply chain (Fig. 7). At the basis of safe food production practises is

the design and manufacture of products with a good safety record. When new products are developed, informed and qualified judgement is used which considers potential microbiological hazards and the necessary control measures.

Food industry conducts an assessment of safety when designing new products, utilising new production processes or changing manufacturing specifications. Use is made of scientific knowledge as well as of practical experience, for instance with suppliers, hygiene of the factory and equipment, and the safety record of products already on the market. There are pertinent differences between the application of Risk Analysis and MRA in a governmental or industrial context, as indicated in Table 3.

In terms of responsibility, the remit of operation for food industry is equivalent to the exposure assessment phase of a formal Microbiological Risk Assessment. On the contrary, Hazard Characterisation is not within the remit of food industry, and the many successful developments in that field have been to the courtesy of governmental bodies and academia.

Table 3. Values to consider by Risk Managers

Governmental context	Industrial context
– Full Risk Assessment	– Exposure Assessment
– Risk estimate / ranking	– Benchmarking
– Products on the market	– Pre-market design
– All products/producers	– Single product/producer
– Farm-to-fork	– Factory-to-fork
– Sensitive sub-population	– General public
– “Risk Manager” role	– “Operational/stakeholder” role

As food industry is not involved nor qualified in all phases of risk assessment, it is evident that the industry should not adopt the full risk assessment approach as the method by which the safety of food products is assessed.

However, there are certain elements of Microbiological Risk Assessment as used by governments that the food industry could benefit from, particularly in the pre-market phase where the safety of the design of a new product and/or manufacturing process needs to be assured.

Examples of elements of Risk Analysis and MRA that may be beneficial to apply in an Industrial context:

- Language and terminology
- Understanding governmental risk management interventions
- Transparency, auditability
- Recording knowledge/data and rationale for use/disregard
- Analysis of risk management options
- Analysing equivalence between food products/categories
- Sharing of risk assessment tools and data

Some benefits are explained here:

- Understanding and use of the language and terminology of MRA by food manufacturing industries may facilitate discussions in the context of product safety approvals, risk-reduction interventions proposed by governments or trade issues. To be a stakeholder in the discussion, one must speak the language and understand the framework.
- The structured and systematic approach of risk assessment and the custom in MRA to make facts and assumptions explicit makes an assessment more transparent and auditable. Especially in complex

situations, with considerable variability and uncertainty or gaps in data and knowledge, MRA may prove to be of particular value.

- The careful recording of the available knowledge and data and the rationale for use or disregard thereof, as practised in MRA, makes the exercise open and of greater value for future reference, either in re-evaluating an assessment or for knowledge/data retrieval.

- The practice in risk assessment to develop structured and explicit risk management options is another potential benefit.

- In all, use of MRA approaches and tools may help industry to become increasingly more pro-active in product design, to make better use of knowledge/data generated world-wide and to develop novel risk assessment approaches.

It should be noted that with such potential benefits as listed above, there is a strong dependence to an industry's or producer's capabilities and capacities in determining which benefits really may apply. SME's in many cases will not be able to benefit from the full gamma, unless supporting organisations help and facilitate.

Back now to the title of my address:
"The Impact of Risk Analysis on Food Safety"

I trust that my address has conveyed the understanding that assuring a safe food supply is by far a straightforward undertaking, when it is to be done on national or international scales.

Given such complexity that there is under such circumstances, the introduction of Risk Analysis holds in it the promise that complexities can be overcome and that therefore decision making can be improved. By consequence, one would expect as well improvements of current food safety situation or the public health situation.

Although there is no basis for delivering to you any quantitative estimate or prediction of the improvements that we should expect in terms of reduction of illnesses, there is sufficient proof that there is at least a true ambition to start applying the framework of Risk Analysis, and the risk assessment tools in it, to improve on consistency and equivalence of decision making in the context of food safety management and ultimately on the public health goals they deliver on.

We must not forget that Risk Analysis is merely a tool. It will help get estimates closer to reality, but as any other tool, it needs to be employed and interpreted by someone who is skilled and experienced in using the tool. Obviously, Risk Analysis is not an easy tool that can be used with little experience of expertise. Its use is currently restricted to a number of what is often referred to as “experienced” countries or organisations. It should be appreciated that these are striving to share their experience and data with the inexperienced, but it remains to be seen how quickly the tool can be taken up and applied adequately on a global scale.

Some countries have made the decision to deploy Risk Analysis is all areas for assessing risk, whether safety, economical or other. The U.S. is an example of this. Also the European Commission, through the establishment of the European Food Safety Authority clearly expresses

to buy-in to transparent and formal assessments of risk, using Risk Analysis as an important instrument.

A cynic may say that until now, Risk Analysis and Microbiological Risk Assessment have not proven to be “value for money”. A lot of resource has been spent on the studies carried out to date by WHO, FAO or the USA regulatory bodies (FDA, USDA, FSIS). The result of those exercises may yet not be very impressive to many an expert, as none has come up yet with a really new insight. I do believe, however, that they are a valuable part of the steep learning curve that those that actively advocate and experiment are going through in becoming “experienced”. Their effort will provide a wealth of practical information on the operation of the framework, such that the inexperienced countries do not need to make the same mistakes.

And indeed, nevertheless, on the basis of the results achieved, some small and rather local successes in improvements of food safety assurance systems and practices have been seen.

A bigger positive impact on food safety can realistically only be expected when the following three conditions are met:

- full commitment of national/regional bodies responsible for food safety to base their work, where relevant, on Risk Analysis principles, understanding their responsibility in driving the process.....

- monitoring and review of the successful use of Risk Analysis and amendment when actions do not deliver the expected result or improvements: only when the outcome of the actions agreed on is

measured and evaluated, is the system taken seriously. When improvements are then achieved, there be trust among the stakeholders in the system and possibly dedication to its use for continuous improvement of the food safety situation and it's impact on public health.....

- proper information and education for the various stakeholders in the farm-to-fork food chain, including food professionals and consumers or their representatives; their capacity to be involved stakeholders and responsible players in the food chain needs to be build up, in order to ascertain that decisions are taken well and actions are implemented as agreed....

The *European Chair* and Wageningen University more generally should be able to contribute significantly to this last condition.

Closing and credits

Meneer de Rector Magnificus, ladies and gentlemen,

Microbiology has seen many developments over the few centuries since some of the early pioneers started to accumulate knowledge and experimental data and to share their new insight with professionals via education. The *European Chair in Food Safety Microbiology* has those ambitions as well and realised many of them already in the first 5 years. Please allow me to express my warm appreciation for the individuals and organisations that have and will be supporting the *European Chair*.

Thank you to the sponsors and Wageningen University. For the last 5 years the *European Chair in Food Safety Microbiology* has been located at the Laboratory of Food Microbiology of Wageningen University and Research. It has been sponsored by four international food companies, Nestlé, Unilever, Kraft International, and Danone, and the Dutch Ministry of Agriculture, Nature Management and Fisheries. Both the outgoing and the incoming Chairs are very grateful to the sponsors for their important support and thank the various distinguished representatives, some of which are present here, for their active involvement. I gratefully acknowledge that the companies have decided to continue their support and that DSM will join in as well. I hope that we will see even more commitment and more companies joining to support our work.

Thank you *College van Bestuur* and *Benoemings Advies Commissie* for continuation of your support to the European Chair and for nominating myself as the candidate.

Thank you to the collaborators at Wageningen University. The *European Chair* could not have been as effective as it has shown to be, without the willingness and enthusiasm of the many departments and individuals that have shared initiatives and ideas for collaboration: The Department of Food Science (Food Hygiene and Food Microbiology, Food Process Engineering, Integrated Food Technology, Food Toxicology and many others), the section Applied Informatics, Graduate Research School “VLAG", and many more again.

A special thank you to Prof. Frans Rombouts, the former chair of the Food Microbiology laboratory, and his many colleagues. Together, the chairs

offer a wide range of skills and expertise relevant to the management of safe food

As the first chair holder, Prof. dr. Mike van Schothorst and his team of very active co-workers have set-up a range of programs on education, research and external activities to further skills, knowledge and understanding of modern food safety management systems. Much of this has been the result of fruitful collaboration with other groups and departments of Wageningen University, but through the wealth of his contacts, Mike has been able to involve many experts from around the globe as well. He has contributed much in terms of vision, conceptual knowledge and insight in the operational needs of the various stakeholders in food safety. Without doubt, Mike has put the European Chair clearly on the world map as a catalyst of modern food safety management education and research. Mike, I hope that there now has come a time for you to be reflect on all your achievements and be proud of them. It certainly is a great honour for me to take over from you at this point, but hope that I can persuade you on occasion to give more valuable input into the work of the European Chair.

Thank you to Martine Reij, who has put tremendous energy, drive and ideas into the activities of *European Chair* and the section. She has contributed to both education and research in a very professional manner. I hope that she will be recognised for this by the University and trust that we will work together for many years more.

Thank you also to Marc Boncz who, together with Martine, Esther and Rob Hartog, has worked hard to design and give content to the e-learning MSc

course in Food Safety Management. It looks to be a brilliant product that will draw a lot of interest.

Thank you to Esther den Aantrekker, the “young doctor” supported by Unilever who studied recontamination routes and captured them in mathematical models in order for them to be linked better to future risk assessment and exposure studies.

And thank you Chantal Kandhai, who started a year ago with support from Nestle, to study the dynamics of microorganisms in particular factory environments. Her results with *Enterobacter sakazakii* are timely and of international importance.

Lieve familie, Saskia, Ellen en Niek, beste vrienden. Jullie bedank ik het laatst en in het Nederlands omdat jullie zo speciaal zijn. Jullie voortdurende steun en begrip maakt het mij mogelijk prive en werk op een wel erg ongewone manier te combineren Ik hoop dat ik jullie steeds voldoende liefde en vriendschap daarvoor teruggeef.

Meneer de (wnd) Rector Magnificus, ladies and gentlemen,

I thank you for your attention and interest.

Ik heb gezegd.