Bulletin
of the International Dairy Federation
430/
2008

Standards, Hygiene and Food Safety of Dairy Products :

- Risk Management
- Practical Food Safety Management
- Predictive Modelling
- Emerging Issues

VIEW THE UPCOMING IDF EVENTS AT:

http://www.fil-idf.org/EventsCalendar.htm

Bulletin of the International Dairy Federation 430/2008

GENERAL TERMS AND CONDITIONS FOR USING THIS ELECTRONIC PUBLICATION

Introduction
Use of the material provided in this publication is subject to the Terms and Conditions in this document. These Terms and Conditions are designed to make it clear to users of this material what they may and may not do with the content provided to them. Our aim has been to make the Terms and Conditions unambiguous and fair to all parties, but if further explanation is required, please send an e-mail to info@fil-idf.org with your question.

Permitted Use
The User may make unlimited use of the Content, including searching, displaying, viewing on-screen and printing for the purposes of research, teaching or private study but not for commercial use.

Copyright
Site layout, design, images, programs, text and other information (collectively, the "Content") is the property of the International Dairy Federation and is protected by copyright and other intellectual property laws. Users may not copy, display, distribute, modify, publish, reproduce, store, transmit, create derivative works from, or sell or license all or any part of the content obtained from this publication. Copyright notices must not be modified or removed from any Content obtained under the terms of this licence.

Any questions about whether a particular use is authorized and any requests for permission to publish, reproduce, distribute, display or make derivative works from any Content should be directed to info@fil-idf.org

Availability
Although the International Dairy Federation publications are developed in view of maximum user-friendliness, the International Dairy Federation cannot guarantee any of these products to work on or with any particular computer system.

Liability
Although the International Dairy Federation has taken reasonable care to ensure that the information, data and other material made available in its publication is error-free and up-to-date, it accepts no responsibility for corruption to the information, data and other material thereafter, including but not limited to any defects caused by the transmission or processing of the information, data and other material. The information made available in this publication, has been obtained from or is based upon sources believed by the International Dairy Federation to be reliable but is not guaranteed as to accuracy or completeness. The information is supplied without obligation and on the understanding that any person who acts upon it or otherwise changes his/her position in reliance thereon does so entirely at his/her own risk.

Send any comments or inquiries to:
International Dairy Federation (I.N.P.A.)
Diamant Building
Boulevard Auguste Reyers 80
1030 Brussels
Belgium
Phone: + 32 2 733 98 88
Fax: + 32 2 733 04 13
E-mail: info@fil-idf.org
Web: www.fil-idf.org

ISSN 0250-5118

Bulletin of the International Dairy Federation

PRICE : 89 Euro

430/2008

CONTENTS

Proceedings of the Conference on Hygiene and Food Safety of Dairy Products and Food Standards for International Trade, IDF World Dairy Congress, Shanghai (CN), October 2006

Subscription Price for the electronic version of the 2008 Bulletin : 327 Euro for all issues.
Adress orders to :
INTERNATIONAL DAIRY FEDERATION / FEDERATION INTERNATIONALE DE LAITERIE
Diamant Building, Boulevard Auguste Reyers, 80 - 1030 Brussels (Belgium)
Telephone : +32 2 733 98 88 - Telefax : +32 2 733 04 13 - E-mail : info@fil-idf.org - http://www.fil-idf.org

Proceedings of the Conference on Hygiene and Food Safety of Dairy Products and Food Standards for International Trade, IDF World Dairy Congress, Shanghai (CN), October 2006

Foreword

IDF's World Dairy Summit and 27th IDF World Dairy Congress in Shanghai, China, in October 2006 was no doubt a very interesting experience for all those who participated, including the Chinese hosts. As the programme comprised a great variety of conferences, workshops and seminars, diverse both in approach and topics, the proceedings of the event are published according to the nature of each conference, seminar or workshop in peer-reviewed journals or in the Bulletin of the IDF.

This issue of the Bulletin of IDF contains the proceedings of the conference on Hygiene and Food Safety of Dairy products and Food Standards for International Trade.

The Conference was organized with the support of the Food and Agriculture Organization (FAO) and was the second of three planned consecutive food safety events organized by the IDF (the first being the UBISI Symposium on Dairy Safety and Hygiene (Cape Town (ZA) 2004) and the third the symposium "A Revolution in Food Safety Management" (Bali (ID) 2008)).

The objective of the conference was to provide a "snapshot" of current issues on the international food safety agenda of key interest to the dairy sector, organized in four sessions:

1) Recent Developments in Risk Management, introducing the new approach to quantitative risk management
2) Practical Food Safety Management, providing examples of developments in food safety management in various geographical regions
3) Predictive Modelling in Decision Making, providing an update on new tools and models
4) Emerging Food Safety Issues, addressing specific food safety issues under debate on the international scene.

A series of 15 presentations provided by key persons involved in the various fields contributed to the success of the conference.

IDF wishes to acknowledge the IDF National Committee of China for organizing the conference and the members of the programme committee for their assistance in developing the technical programme: Claus Heggum (Denmark) (chair), Anthony Bennett (FAO), Oliver Cerf (France), Robin Condron (Australia), Koenraad Duhem (France), Guicheng Huo (China), Maosheng Li (China), Fazheng Ren (China), Andrew Speedy (FAO), Merdhad Tajkarimi (Iran), Xinxiang Wang (China), Di Xuefeng (China), and Zhiqiang Zhang (China). A special extra thank you also is owed to Claus Heggum for collating and desk-editing the papers.

Christian Robert
Director General

April 2008

1. New Tools for the Management of the Microbiological Risks

O. Cerf[1], C. Heggum[2]

1.1. Introduction

The aim of **"microbiological risk management"** is to retain or reduce the frequency of infectious food-borne diseases arising in the population to a level deemed acceptable by the society. Based on work of the International Commission on Microbiological Specifications for Foods (ICMSF), an important effort of rationalization has been done by the Codex Alimentarius Commission (CAC) for the last ten years. A corpus of new concepts and their definitions is now available. As a result the prevention of foodborne infectious diseases is centred onto the central paradigm of risk. Two partners are deeply involved: the **competent authority** of each country, that is the governmental organization in charge of public health, and the **industry**, that *"includes all relevant sectors associated with the production, storage and han-dling of food, from primary production through retail and food service level"*[1].

1.2. The old and present risk management: the control measure based approach

Food may contain **hazards**, defined as *"biological, chemical or physical agents in, or conditions of, food with the potential to cause an adverse health effect"*[2]. Hazards are traditionally treated by **control measures**, defined as *"any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level"*[3]. As regards micro-organisms, generic control measures effective against any kind of micro-organisms, pathogenic or not, are described in the Rec-ommended International Code of Practice - General Principles of Food Hygiene of the Codex Alimen-tarius Commission[3]. Cleaning, disinfection, pest control are examples of generic control measures. Control measures targeted at specified pathogenic micro-organisms can be organized whenever possible according to the Hazard Analysis - Critical Control Point system[4] described in an Annex to the above Code.

Besides, industry is under pressure to comply with standards of quality management, such as ISO 9001-2000. To help industry to apply the Codex standard including its Annex as well as the ISO one, and avoid being audited twice, a quite recent standard marries both approaches: this is ISO 22000[5].

The "condition" part in the definition of hazards has lead to some food businesses using HACCP as a type of Quality Assurance system that focuses on "everything that goes wrong", including e.g. control measure malfunction and other similar events – an approach that does not fit with the new Risk Assess-ment methodology and also results in loss of focus. It is also worth noting that a hazard is not automati-cally hazardous, as this depends on the level and the context in which the consumer is exposed to the hazard; this new understanding also assists in moving away from zero-tolerance strategies and into the future.

What characterizes the old and present risk management is its focus on the hazards: everything is done to reduce their level independent on the starting point, in order to minimize potential adverse health effects to individual consumers. Yet no reference is made to the frequency of the effects in the popula-tion: the approach is focused on public health in an indirect way. It is also worth noting that the new risk assessment approach results in more and more emphasis being put on hazards as "agents" rather than as "a condition of the food".

1.3. The new and future risk management: the risk based approach

It results from the word "probability" in the definition of **risk**: *"A function of the probability of an ad-verse health effect and the severity of that effect, consequential to a hazard(s) in food"*

[1] Prof. emer., Alfort Veterinary School, Maisons-Alfort (France)
[2] Chief Consultant, Quality & Food Safety, Danish Dairy Board, Aarhus (Denmark)

that the focus of the new and future approach of food safety is directly public health[2].

It is clear also that, while hazards are dealt with by the industry (of course with strong incentive from the public administration) risk management is under the responsibility of the competent authority. The following two definitions will bring an unambiguous demonstration:

- "**Risk Management**: *the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options"*[2];
- "**Risk Manager**: *a national or international governmental organization with responsibility for microbiological risk management*"[1].

The weighing of policy alternatives obviously belongs to the political sphere. The risk manager should work under the supervision and with objectives given by those governing the Country. This is stated in this quotation too: *"The focus of the definition on risk manager is restricted to governmental organiza-tions with authority to decide on the acceptability of risk levels associated to foodborne hazards"*[1].

Furthermore an individual food business does not manage risks – nor does it monitor risks. This is the task of authorities. Food businesses concentrate their efforts in controlling those hazards that occur in their processing and products and which have the potential to cause adverse health effects ("potential" means that it has the ability to cause negative health effects, not that it actually does it).

Regarding food safety as well, countries live under international rules. The one that matters in the present context is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agree-ment)[6]. This international treatise stipulates that each country may choose its own **Appropriate Level of Sanitary or Phytosanitary Protection (ALOP)** that is *"The level of protection deemed appro-priate by the Member [State] establishing a sanitary or phytosanitary measure to protect human, ani-mal or plant life or health within its territory"*. An ALOP can be expressed in terms of a desired reduction in the current level of risk within a given period of time. It can also be expressed as the maximum tolerable incidence of infectious foodborne disease[7] or as acceptance of the current level of protection (e.g. *Salmonella* in Sweden when they joined the European Union).

According to the SPS Agreement ALOPs may differ from one country to another. The same is true for the derived instruments that will be described below.

1.4. Implementation of the risk based approach

1.4.1. Translation of the ALOP into a practical instrument: the Food Safety Objective

An individual food business operator cannot be requested to compute the risk in the population arising from his products. Therefore industry cannot base control measures on an ALOP. ALOPs are expressed in terms of illness (risk) whereas industry needs practical targets that are expressed in terms of hazards. So the challenge is to translate risk into hazards. The tool to do that has been identified as the **Food Safety Objective (FSO)**: *"the maximum frequency and/or concentration of a hazard* in a food at the time of consumption* that provides or contributes to the appropriate level of protection (ALOP)"*[2]. (Note: a hazard being "a condition of the food" does not fit in here).

Yet what is the correspondence between the incidence of an illness and the concentration** of a micro-biological hazard in a food? Be a specific health effect, such as transient troubles, chronic disease, death, etc. The dose is defined as the amount of ingested pathogenic cells in a serving (mass of the serving times the concentration of the hazard). The response is defined

---

* Underlined by the authors of the present communication

** the usual unit for concentration, cell/g, is not convenient when concentration is low, e.g. 1 microbial cell per kg food. In such a case, concentration can be replaced by frequency, e.g. 1 microbial cell per kg food is equivalent to 1 positive 10 g serving out of 100 servings.

as the probability of the studied effect in the population resulting from a given dose. The dose-response curve illustrates the relation-ship between the probability of the studied effect and the dose (Figure 1).

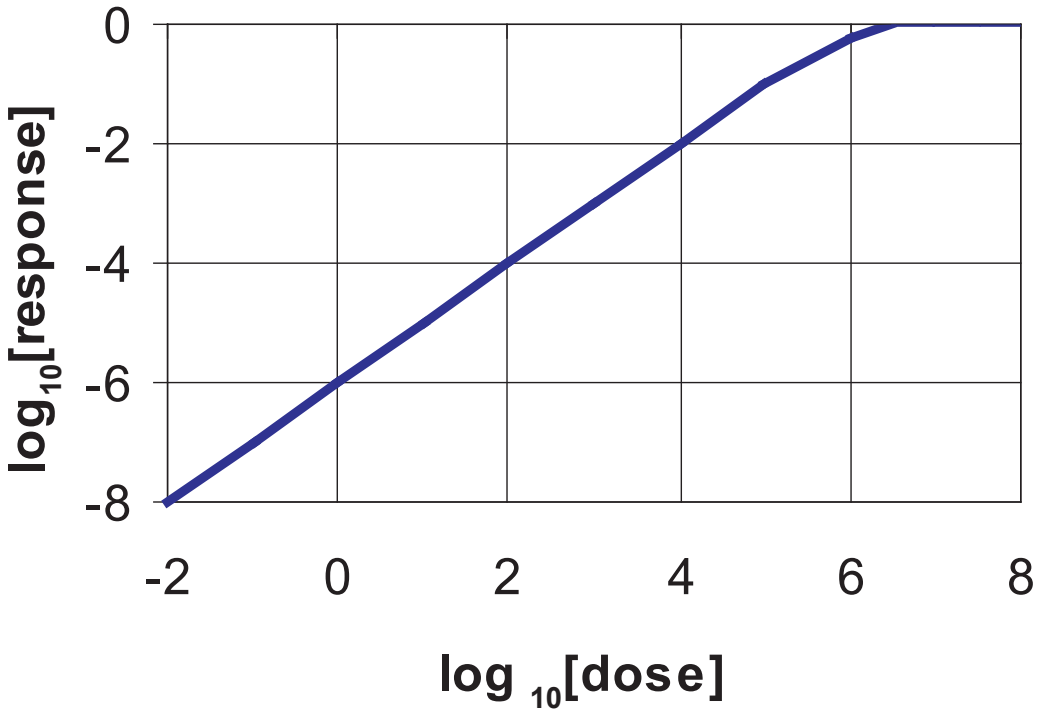

Figure 1. Hypothetical dose response-curve showing the probability of a studied illness as a function of the amount of ingested pathogenic microbial cells (log_{10} scales)

Be an ALOP per serving defined by the competent authority. The dose-response curve can be used to infer the maximum dose that is permissible for the ALOP not to be exceeded. According to the example of Figure 1, if the ALOP/serving is "no more than one case per 10^8 servings" (corresponding to a re-sponse or probability of illness of 10^{-8}), then the FSO should be "no more than 1 cell per 100 servings" (corresponding to a log_{10}(dose)=-2). The dose is then converted into a concentration, based on e.g. a typical serving size or the 99% percentile of the serving size distribution, and communicated to the in-dustry as "the FSO".

1.4.2. Derived instruments

By its very definition the FSO is established for the time of consumption. However, as shown on Figure 2, many things can happen between the time of consumption and the placing onto the market by the food producer, when the food is no longer under his responsibility. In addition it is difficult if not im-possible to take samples of a food "from consumer's mouth". Therefore the producer (or the compe-tent authority) has to account for expected shelf life and "reasonably foreseeable storage conditions"[8] and establish other objectives for the food prior to actual consumption. Such further objectives should be established by the producer at earlier points in the food chain as illustrated in Figure 2. These objectives are named **Performance objectives (PO)**: *"The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption* that provides or contributes to an FSO or ALOP, as applicable"*[2].

* Underlined by the authors of the present communication

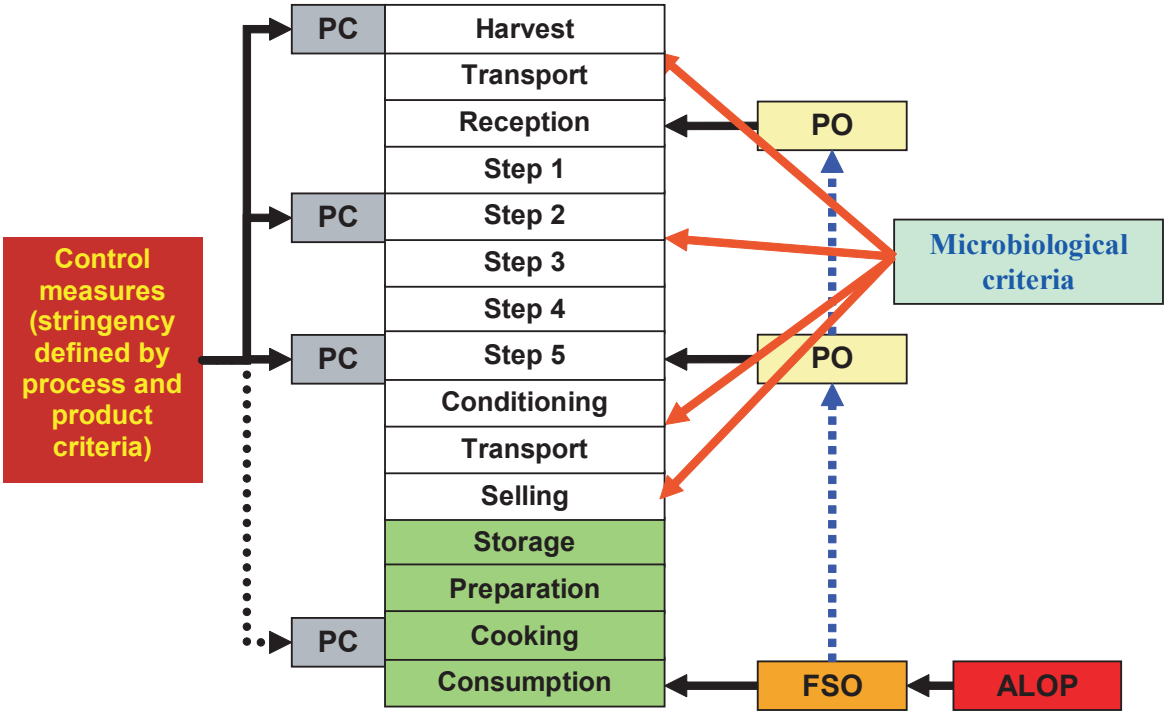

Figure 2. Flow diagram of a hypothetical food process from crop harvest to consumption with examples of steps where FSO, POs, PCs and MCs apply. For abbreviations, see text. Steps colored green are beyond the control of the food producer

To achieve the POs, technological operations aimed at inhibiting or slowing down the microbial growth, or at reducing the microbial population are often needed. They result in a measurable effect on (a de-sired change in) the number of micro-organisms. When the safety of the food is relying on the effec-tiveness of a growth inhibition measure and/or a reduction step, its effect against the hazard is described as a **Performance Criterion (PC)**: *"The effect in frequency and/or concentration of a hazard in a food that must be reached by the application of one or more control measures to provide or con-tribute to a PO or an FSO"*[2]. PCs are typically expressed by the number of divisions or multiplications per 10 of the microbial population (or log reductions/log increases). Examples of PCs are minimum 12 decimal reductions in the *Clostridium botulinum* spore population that is recommended for canning process and maximum 3.4 decimal multiplications of *Listeria monocytogenes* in some RTE food during its shelf life that is enforced in the EU.

The *"Parameters of a control measure that if properly applied have been established as meeting, ei-ther alone or in combination with other control measures, a performance criterion"* are called **Process Criteria**. The process criterion expresses the stringency of a control measure. Two examples of differ-ent process criteria for the same control measure, heat treatment, are (i) the recommended 2.4 min at 121.1°C aimed at obtaining the PC of minimum 12 decimal reductions of *C. botulinum*, and (ii) the time-temperature combination recommended for milk pasteurization: 15 s at 72°C.

"A physical or chemical attribute of a product that if properly applied as a control measure has been established as meeting, either alone or in combination with other control measures, a performance criterion" is called a **Product Criterion**[1]. The product criterion expresses the stringency of the con-trol measure. Well-known examples of product criteria are acidity, water activity, and preservative concentration. The hurdle technology entirely rests upon combinations of product criteria.

1.4.3. Microbiological criteria and performance objective

Microbial criteria (MC) are used for a long time and are familiar to everybody. There are defined as: *"A physical or chemical attribute of a product that if properly applied as a control measure has been es-tablished as meeting, either alone or in combination with other control measures, a performance cri-terion"*[9].

The verification of food compliance to a MC is done through a measurement. Therefore it is fraught by a measurement error, or uncertainty. The later must be accounted for when comparing the actual measurement with a PO. Therefore a MC will never be equal to a PO or a FSO. It should be emphasized that the purpose of a MC is different from the purposes of POs and FSOs. A MC is only established when verification is to be done by analytical testing. If verification of compliance can be done using other means or where the levels expressed by a PO or a FSO is lower than what can be analytically detected (e.g. 1 cell per kg), a MC is not required or useful. One of the psychological obstacles in implementing the FSO/PO approach is that MC has been traditionally used to express risk management targets – a role that in the future will be taken over by FSOs and POs. In many cases FSO, PO and the limits within a MC are expressed with the same unit (a concentration), but they must not be confused.

1.5. Conclusion

A new era is opening to the risk managers and the industry. Although practical means for ensuring food safety are well established this new approach provides a unique opportunity to improve the design of food safety systems, to establish documentation, and to evaluate new treatments. A number of dose-response curves are already published for the most dreadful pathogens and research work is continu-ously improving them as well as producing more of them. Hence a rational approach can now be taken by the risk manager to optimize his decisions as regards public health. Of course the first gap to be overcome, the establishment and publication of an ALOP and/or a FSO, depends on a political decision. This is a restraint that will have to be relieved. Meanwhile, the old and present management system will continue to demonstrate its effectiveness.

References

1. Report of the 37th session of the Codex Committee on Food Hygiene, Buenos Aires, Argentina, Codex Alimentarius Commission, Rome (Italy) (2005).
2. Procedural Manual, Codex Alimentarius Commission, Rome (Italy) (2004)
3. Recommended International Code of Practice-General Principles of Food Hygiene, Codex Alimentarius Commission, Rome (Italy) (2003).
4. Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Applica-tion, Codex Alimentarius Commission, Rome (Italy) (2003)
5. EN ISO 22000:2005 Food safety management systems - Requirements for any organization in the food chain, ISO, Geneva (Switzerland) (2005).
6. Agreement on the Application of Sanitary and Phytosanitary Measures, World Trade Organization, Geneva (Switzerland) (1994).
7. Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts, Kiel (Germany) 18 – 22 March 2002, Joint FAO/WHO Consultation, Rome (Italy) (2002).
8. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for food-stuffs. *Official Journal of the European Union* L 338 (22.12.2005):1-26 (2005).
9. Principles for the Establishment and Application of Microbiological Criteria for Foods, Codex Alimen-tarius Commission, Rome (Italy) (1997).

2. Practical Risk Management and Public Health Goals

J.T. Jansen[1]

2.1. Introduction

Diseases caused by foodborne microbial hazards constitute a world-wide public health concern. In addition to well-recognized food safety concerns, new disease agents have emerged and new challenges have arisen as a result of changes in food production and supply chains and, changes in the exposure and susceptibility of populations to foodborne pathogens. At the same time, the necessity of basing food safety measures on a sound understanding of science has assumed increasing importance, not least as the result of globalization of food markets.

During the course of the past ten years, FAO, WHO, the Codex Alimentarius Commission and individual countries have made significant progress in the development of a generic Risk Management Framework (RMF). This framework identifies the different activities that need to be conducted in a structured, on going and iterative manner to manage food safety risks. It is a systematic process that uses the results of risk assessment and other scientific evaluations to develop effective risk management options for implementation at appropriate steps along the food chain. Food safety risk management can be described in general terms as:

> *The process of weighing control alternatives by government (and international standard-setting bodies) in consultation with interested stakeholders, taking into account scientific information on risks to consumers as well as other relevant inputs (e.g. economics, technical feasibility, societal preferences), and choosing and implementing food safety measures as appropriate.*

The risk analysis framework, laid down by Codex Alimentarius during the past ten years, creates a new opportunity; it enables linking food safety activities to public health via risk assessment. All this applies to all aspects of food safety, including chemical, microbiological and other hazards. This presentation specifically deals with microbiological food safety risk management.

2.1.1. Microbiological food safety risk management

As a key component of Microbiological Risk Management (MRM), Microbiological Risk Assessment (MRA) seeks primarily to guide specific decisions on microbiological food safety and to facilitate the development of targeted and effective food safety risk management strategies.

MRA has evolved as an increasingly important tool to manage food safety. Its purpose is to provide a transparent, scientific and informative basis for risk management decisions in this area. The Codex Alimentarius Commission adopted "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" in 1999. Since then, many microbiological risk assessments have been undertaken at both national and international level and the methodology and tools for this type of assessment continue to evolve.

However, the establishment of a clear understanding of how, and a process to optimally utilize this MRA tool in the risk management decision-making process has been more difficult. Countries struggle to develop guidance on the application of the use of a tool they are only starting to become familiar with. There is a general recognition that MRA as a tool has great potential. However, we strive to understand how we can effectively use MRA to set appropriate food safety targets and subsequently meet them.

2.1.2. Key problem: How to use MRA to manage microbiological food safety risks?

Adequate utilisation of MRA in the development of MRM requires a clear, instructive and practical protocol to effectively manage foodborne hazards.

---

[1] Department of Food Safety, Zoonoses and Foodborne Diseases, World Health Organization, Geneva, Switzerland

Previous FAO/WHO meetings in Kiel focussed upon the interaction between assessors and managers of microbiological hazards (in 2000) and incorporation of microbiological risk assessment in the development of food safety standards (in 2002). The latter provided useful advice, particularly in the area of commissioning a risk assessment, setting risk assessment policy and implementing a risk assessment. However, specific guidance on using the outputs of the risk assessment in microbiological risk management (MRM) was less concrete owing, at least in part, to the relative paucity of microbiological risk assessments completed at the time of the meeting. Thus, in spite of the efforts of international organizations and several countries, the use of the outputs of these risk assessments in developing food safety risk management strategies has proved to be difficult, at both national and international level.

In response to specific requests from the Codex Committee on Food Hygiene (CCFH), FAO and WHO have the last years jointly developed a range of microbiological risk assessments for a number of pathogen-commodity combinations (see at: www.who.int/foodsafety).

These MRA's have integrated a wealth of scientific information and data on food microbiology with applied statistics and modeling. While attempting to provide specific answers to risk management questions posed by CCFH, they constitute comprehensive resource documents on the food safety problems of concern, as well as on risk assessment methodology itself. Nationally, various countries have also developed, or plan to develop, risk assessments suited to various pathogens, products, and processing systems.

2.1.3. Practical Microbiological Risk Management and Public Health Goals

MRM is the process of weighing control alternatives, taking into account scientific information on risks to consumers as well as other relevant inputs, and choosing food safety measures as appropriate. So it identifies the different activities that need to be implemented at appropriate steps along the food chain to properly protect consumers.

Codex Alimentarius has recently adopted definitions of food safety targets that could be established by means of MRA i.e. food safety objective (**FSO**), performance objective (**PO**) and performance *criterion* (**PC**), the definitions are presented chapter 3, in "Using MRA to select/ evaluate Intermediate Targets". Codex so far did not provide guidance as to how these targets could be established and achieved.

At the same time FAO, WHO and Codex observed the difficulties within the Codex system of utilising the outputs of the MRA's developed by FAO and WHO at the request of Codex, to develop adequate food safety risk management.

In 2005 FAO and WHO agreed that more work was needed, so they reported to the 37th Session of CCFH) their plans to undertake work on "Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs". In order to ensure that such work provided information that would be of use to Codex, FAO/WHO asked CCFH to identify specific areas of interest.

In response CCFH forwarded a Discussion Paper on "the Needs of CCFH for the Provision of Scientific Advice by FAO/WHO on the Application of Risk Assessment to Risk Management". This highlighted the needs on this issue by the Codex Committee. The response of CCFH provided FAO and WHO with a definition of its specific needs of how to use MRA to establish food safety objectives and related metrics. Thus further activities of FAO and WHO on these issues were endorsed. In CCFH's response particular reference was made to the development of specific quantitative microbiological targets such as FSOs, POs, and PCs, that intended to relate public health goals with the degree of stringency required in terms of food safety measures and systems to achieve these targets. These specific risk-based quantitative microbiological targets can play an important role in food safety risk management by linking public health status and information from the risk assessment process with measures to control the identified risk. They can also serve as a basis to more scientifically establish traditional "operational" control measures, including microbiological criteria, product criteria or process criteria that are employed to establish the level of control required and verifying that that level of control is achieved.

2.2. Preparation of Expert Meeting: Case Studies

In 2005 FAO/WHO prepared an expert meeting to undertake work on "Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs".

Discussions on this issue for a number of years had indicated the need for extensive consideration and discussion in order to develop practical guidance as required by Codex and member countries.

Rather than to focus all discussions in one 5 day expert meeting only, a preparation process was designed, involving a number of working groups to develop relevant background papers in advance, in order to support a subsequently held expert meeting. Such preparation was also proposed when discussing the issue during the 27th CCFH session in March 2005, Buenos Aires. CCFH also requested that FAO/WHO more explicitly focus future work at the development of practical guidance on how to establish FSOs and microbiological criteria derived thereof, on the basis of Risk Assessment outputs.

The struggle at both the national and international levels to effectively and efficiently use microbiological risk assessment as a tool to support risk management had highlighted the need to revisit this area in more detail and to look at the experiences in the countries that are using MRA with the objective of developing practical guidance that would facilitate the work of national and international risk managers.

Taking all the above into account, the objective of the FAO/WHO work was defined as:

> *The elaboration of guidelines for the use of the outputs of qualitative and quantitative microbiological risk assessments in developing or determining practical strategies and risk management standards for microbiological hazards in foods.*

In order to achieve this, issues for consideration were identified (abbreviated):

- Identification and consideration of the difficulties or stumbling blocks that have been encountered so far in developing practical MRM guidance based on the outputs of MRA
- The kind of risk management actions that can be developed using MRA in combination with other scientific and technological information.
- How MRA can be used together with other MRM support tools, to develop practical risk management strategies, such as Codes of Hygienic Practice and HACCP systems, with interventions for risk reduction both at primary production and processing level.
- MRA's are developed both nationally and internationally. The meeting will examine how a risk assessment can be used both at the international level by Codex and at country level as the basis for risk management. Due to regional, cultural and geographical differences across the world, risk management guidance produced, will need to be adapted. How can MRA and other information be used to facilitate its adaptation at the national level?
- It is necessary to consider how the type of MRA chosen, will impact the way it can be used in microbiological risk management.
- Technical and economic feasibility are also issues that have to be considered in the risk management process, but to address this in more detail, a separate meeting is advised.

2.2.1. Working Groups to provide Background Papers to be used at Expert Meeting

It became clear that a stepwise approach was warranted. At first working groups were established to undertake case studies to address some of the issues identified above. In addition, a framework document was prepared with the objective of addressing some of the overarching issues and to set the context in which the guidelines are being developed and will apply, so the paper would set the framework for the requested practical guidance.

FAO and WHO selected six pathogen-commodity combinations as suitable subjects for the case studies, considering the need to address different types of risk management interventions at different steps along the food chain. The case studies were undertaken by different working

groups, each consisting of three to five experts, undertaking their task primarily by electronic means. The case studies addressed the following food safety issues:

- *Staphylococcus aureus* in cheese
- *Escherichia coli* O157:H7 in meat
- *Vibrio vulnificus* in oysters
- *Listeria monocytogenes* in smoked fish
- *Salmonella enteritidis* in eggs
- *Campylobacter* spp. in broiler chickens

2.2.2. Tasks of the Case Study Working Groups

Specific tasks of the case study working groups (abbreviated):

- Develop an approach for establishing FSOs and related relevant standards based upon the results of the MRA.
- Consider how to use MRA (and other available scientific information) to evaluate specific MRM measures.
- In a specific MRM system, what metrics associated to a specific MRM measure could be used to monitor the overall performance or specific measures; what metrics are necessary for the review its efficacy.
- How can the system of FSO and related standards support and improve existing food safety management tools such as HACCP and GHP's?

Finally, background papers reporting the results of the work became available to be used for the discussions of the expert meeting, in order to provide an overview of the status quo in terms of the application of MRA to MRM and subsequently, and inform how practical guidelines should be developed.

2.2.3. Key findings of the Case Study Working Groups[1]

The case studies addressed most of the tasks through the use of different approaches.

The complexity of the issues was highlighted by the different ideas and contrasting conclusions presented in the various case studies. The findings are concisely summarised as follows (abbreviated, for more detail see the FAO and WHO food safety websites):

1. When the hazard of concern needs to be addressed from the primary production stage, the establishment of an FSO was found to be difficult and may not be appropriate. It was found to be more feasible to establish POs. Quantitative MRA can be used to directly link targets in the food chain to public health goals.
2. As FSO and PO are currently defined by Codex, it is not easy to understand how uncertainty and variability can be taken into account; in some cases this was avoided by using a deterministic risk assessment.
3. Backward calculation from an ALOP to a PO, PC or MC is technically very difficult if variability and/or uncertainty are taken into account. Forward calculation is technically possible and the preferred option.
4. The issue is how to take uncertainty and variability into account when establishing FSOs, POs or other relevant metrics. There is a need for more precise definitions of Codex new food safety concepts such as FSO and more guidance on their practical implementation.
5. Providing a range of potential POs, FSOs, and ALOPs was found to be a useful, providing the risk managers with a series of options.
6. Often multiple combinations of control measures can achieve an FSO and would give an equivalent degree of risk reduction. This is consistent with establishing stringency without hampering innovation.

[1] The complete case study texts are available at the FAO and WHO Food Safety websites.

7. When cross-contamination during consumer preparation is assumed to be the major route of contamination, FSOs were not seen as an appropriate risk management option.
8. The techniques for relating microbiological criteria to POs are still in their infancy; FAO/WHO should encourage the development of "user-friendly" tools to enable a broader range of risk managers to perform these calculations.
9. The capability of MRA to carry out scenario analysis such as addressing "What if?" questions is important and useful
10. When a pathogen is linked to a specific product from a specific region, it is a comparatively straightforward task to apply the risk assessment in risk management.
11. For pathogens with multiple sources/reservoirs, the question of food attribution arises: how many cases can be attributed to the source in question
12. Quantitative risk assessment models are valuable for describing the complex dynamics of pathogens during food processing and also for evaluating the relative public health effect of different interventions strategies. Burden of illness estimates will probably be more accurately assessed using "traditional" epidemiological methods.
13. Risk assessment models can be used to directly bridge any parameter in the food chain and the consumer risk and demonstrate that interventions can result in risk reduction.
14. There is a great deal of variability in the way that products are manufactured, distributed, and marketed. Without simplification, one could easily get lost in the details. This could be avoided by using a more sophisticated probabilistic approach, which is more difficult.
15. A good level of interaction between the risk assessors and risk managers facilitates the utility of the risk assessment to the managers.
16. Where risk assessments are going to be used in combination with other tools e.g. economic analysis it is useful anticipate this from the beginning.

2.3. Meeting Aims: Improve Risk Management, Relate to Public Health Goals

The expert meeting was held in Kiel, Germany from 3-7 April 2006, hosted by the Federal Research Centre for Nutrition and Food in collaboration with the German Ministry of Food, Agriculture and Consumer Protection[2].

Risk managers considering the application of MRA have to take several decisions in the course of the management process. In the preliminary stage, when a risk profile has become available, they need to decide whether or not to commission an MRA. If a decision is made to undertake a risk assessment, they then have to decide on the scope of the assessment, defining the precise pathogen-commodity combination, type of production and distribution processes to be covered, etcetera. They also have to decide, probably in consultation with risk assessment experts, what type of risk assessment is most suitable for the purpose, considering also available budget and expertise.

The microbiological risk management process is described by Codex *Principles and Guidelines for the Conduct of Microbiological Risk Management* and will not be described here in detail. Figure 1 provides a diagrammatic overview of the process and in Annex 1: "Food safety management in practice" some practical general guidance is provided.

It is worth noting that the ultimate aim of any microbiological risk management process in the availability of safe food and improved levels of consumer protection. Risk managers are responsible for choosing and implementing food safety controls and may act in different roles:

- Setting public health goals and articulating appropriate levels of protection, in consultation with stakeholders, including scientists, industry, consumers and other regulatory authorities;

[2] The report of the Expert Meeting "The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies" can be downloaded from this web-site: http://www.who.int/foodsafety/micro/jemra/meetings/2005/en/index.html.

- As the competent authority involved with compliance with trade and legal requirements and meeting the country's obligations under the SPS Agreement;
- Enforcing control measures to be implemented by appropriate stakeholders;
- Evaluating to verify the performance of the implemented system and its impact on public health outcome.

Risk-based management actions are aimed at establishing and achieving a level of health protection, which can be explained and validated in terms of "risk" to human health. Thus the objective of risk management may be expressed in terms of a public health goal.

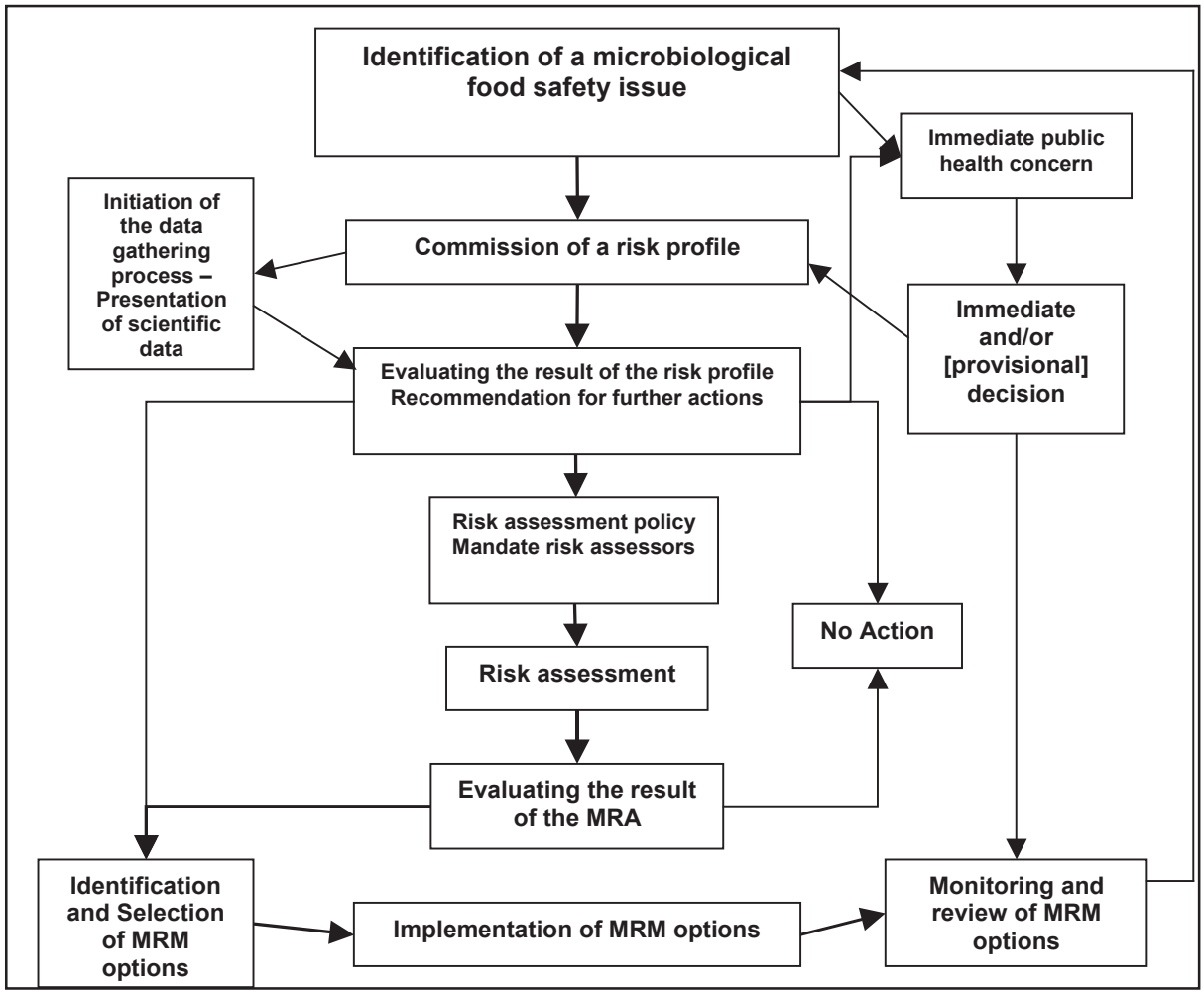

Figure 1. Diagrammatic overview of the microbiological risk management framework

2.3.1. Main Tasks of the Expert Meeting

FAO and WHO had implemented an first expert meeting in Kiel in 2002 to address principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. The Kiel meeting in 2006 sought to build on that report, whereby the draft Codex principles and guidelines for the conduct of microbiological risk management were also taken into consideration.

The participants identified a series of questions and issues to be addressed; three main thematic areas were developed for working groups to address during the meeting:

- The role of MRA in articulating Appropriate Levels of Protection (ALOP) or public health goals;
- The role of MRA in setting food safety objectives (FSO) and/or performance objectives (PO), and performance criteria (PC), such as microbiological criteria, product criteria and process criteria;
- The role of MRA in establishing and evaluating control measures.

2.3.1.1. Public Health Goals and ALOP

Public health goals are set to inspire action to improve the public health status and reduce disease burden, and will usually be set by government. The goals imply some consideration of the current health status and disease burden (in the population as a whole or in vulnerable sub-populations). For risk managers it is critical to understand whether a risk management program delivers an expected public health outcome. This is particularly relevant when attempting to weigh economic consequences or the equivalence of approaches.

In the risk management of food safety hazards, acceptable levels of risk can be expressed as a public health goal, which could be expressed as a reduction in the level of a particular food-borne illness. The MRA can be used to assess the risk resulting from the control measures currently in place and compare this to the public health goal. When it is exceeded, the MRA can be used to calculate what changes in the control measures or which new control measures could result in a reduced consumer risk. Typically, different scenarios of choices of control measures are run through an MRA and a menu of associated risk outcomes is calculated.

The public health status is a measure of the current health situation in the population, and it may be used as a basis for future public health goals or as a measure of the effectiveness of risk management actions. A particular expression of the current public health status is the Appropriate Level of Protection (ALOP). This concept originated from the SPS Agreement, where it is defined as follows:

> *"The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."* [3]

An ALOP is an expression of the level of protection achieved in relation to food safety at the current time, not the formulation of some future objective. However, because the currently achieved public health status may change (for example, new technologies may change the level of a contaminant in a food), an ALOP may be revised over time. Further guidance in this area in the context of the SPS agreement has been provided by WHO[4].

2.3.1.2. Facilitating International Trade

The application of proper risk management when producing food to be internationally traded, contributes to the confidence of importers of this food, as well as facilitating a country's compliance with the WTO SPS and TBT agreements. As it is important for countries to be able to demonstrate how they are addressing their food safety problems and meeting their established targets, the role of risk based management approaches becomes ever more important.

As the same types of control measures are neither necessary nor even appropriate to address a specific hazard in all countries, a risk management process based on sound application of risk assessment will allow the determination of equivalence of different approaches. Risk management that focuses on the achievement of targets can promote the harmonization of overarching food safety standards.

As the application of MRM becomes more widespread, the adoption of MRM systems by countries becomes more critical for trade. While WTO promotes the harmonization of international standards and Codex develops the relevant food safety standards, a country may in some cases

---

[3] The Agreement on the Application of Sanitary and Phytosanitary Measures - WTO 1994.

[4] Guidelines to further the practical implementation of article 5.5.WTO Committee on Sanitary and Phytosanitary Measures G/SPS/15, 18 July 2000.

need to exceed the international standard. In order to do so a justification is required which can be validly provided through the implementation of risk management actions based on risk assessment.

2.3.2. Outputs of the Expert Meeting

The aim of the meeting was to elaborate guidelines for using the outputs of different types of microbiological risk assessments to develop practical risk management of microbiological hazards in foods. It was intended to focus at guidance for establishing FSOs and criteria derived thereof, on the basis of risk assessment outputs, more specifically, scientific advice was needed on concepts, methods, and practical examples of how POs and PCs can be related to public health goals and/or FSOs. And also how POs and PCs can, in turn, be translated into more traditional measures of food safety system stringency, such as process criteria, product criteria, and microbiological criteria.

All these issues were extensively discussed and elaborated, including a number of related issues, mainly the following:

- The selection of type of microbiological risk assessment (MRA),
- The use of MRA to select FSOs and derived criteria, and
- Turning these into operational standards.

Direct use of MRA in the selection/evaluation of control measures was examined. Additional, related issues were considered, such as epidemiology-based tools, the use of MRA to verify compliance and economic analysis.

The expert meeting outputs on the above issues are summarized below.

2.3.2.1. Microbiological Risk Assessment (MRA)

Effective management of risk arising from microbiological hazards is technically complex and the implementation of sound and scientifically justifiable measures requires the use of different tools, data and information. Basing food safety management approaches on science means that decisions, actions, regulations and standards are based on objective, reliable and verifiable scientific and technical information, combined with robust data and sound scientific expert judgement and /or advice.

The outputs of an MRA significantly contribute to the information that the risk manager will need to determine which interventions (if any) are necessary to achieve the public health goal. A well-written MRA will present outputs in a manner that the risk manager can readily discern the conclusions, without need for additional technical explanation. MRA starts from the dynamics of the hazard in the food chain and uses predictive models to estimate the outcomes in terms of public health ("bottom-up approach"). In general, MRA provides a high level of detail on microbial events that occur along the food chain and valuable information about the complex dynamics of pathogens during food processing. MRA is less accurate in predicting actual public health outcomes, particularly because of the limited availability of dose-response information.

The risk manager, prior to the commissioning of a MRA, considers the available information, particularly from the risk profile, and then identifies questions to be answered by the MRA, such as:

- Quantify relative impacts of specified food safety controls for pathogen x in product y, either alone or in combination, on levels of consumer risk.
- Quantify influence of different levels of hazard control at specified steps in the food production chain on risk estimates.
- Estimate the likely proportions of human foodborne illness z transmitted by food y compared with other food transmission pathways.
- Estimate the efficacy of possible interventions/specified control measures aimed at management of the risk

It is essential that the relevant steps of the production process and current controls, from

farm-to-fork, be adequately described. In addition, this description should include a listing of the controls that can be applied at each of these steps, along with any data regarding the effectiveness of these controls. Consequently, this description should provide a diagrammatic view (flow sheet) of the food safety system and the points at which control can be gained or lost.

Selection of risk assessment type

Food systems are complex and quantitative microbiological risk assessments are mathematical, simplified representations (models) of the food system and their impact on human health.

Risk assessments are often divided into two groups, qualitative and quantitative, the latter that can be further subdivided into deterministic and probabilistic. The differences in design between these two groups result in different forms of output. The type of risk assessment to be used is dependent upon the availability of relevant data and the type of questions to be answered for the risk manager.

Qualitative risk assessments are not based on mathematical models incorporating quantifiable data. Rather, the risk is evaluated in relative terminology such as "high," medium," "low," or "negligible." Such a risk assessment summarizes our knowledge, but does not present a numerical likelihood of an adverse effect.

Quantitative risk assessments are based on mathematical models, incorporating quantifiable data, and emphasize the likelihood of an adverse health effect (e.g., illness, hospitalization, death). In a quantitative microbiological risk assessment (QMRA), the uncertainty associated with the risk estimates is essential information for the risk manager for proper judgement.

The QMRA simulates the impact of the food safety controls on the hazard levels in a food system and the resulting risk level in the population. The various factors in the system can be represented by single numbers (deterministic QMRA) or by distributions of numbers that reflect the variability in the system and/or the uncertainty about the system (probabilistic QMRA)[5]. A key consideration in choosing appropriate models is the level of detail required for the assessment, consistent with the assessment objectives. The type chosen also will have to meet the available data and resources.

In the case of a **deterministic QMRA**, single input values must be chosen to characterize those values that best represent the factors in the food system. Typical choices are the values that represent the most likely value or values that capture a worst-case situation. However, combining the worst-case input values for all factors may lead to overly conservative outputs.

With **probabilistic QMRA**, the input values are distributions that reflect variability and or uncertainty. The advantage of probabilistic QMRA is that it provides more information about the effect on the risk estimate of the variability and uncertainty associated with the risk assessment inputs. This gives the risk manager greater confidence that the risk management options/ measures/food safety controls that are selected will achieve the required level of protection.

Considering these different risk assessment types shows that each type has strengths and weaknesses. The most common factors considered by the risk managers are: (a) time available, (b) resources requirements and (c) resolution of output. Figure 2 gives some indication on when perhaps a particular type of risk assessment may be more suitable, but it should be noted that even if time and resources are available a qualitative risk assessment is still a valid approach.

MRAs can be used to describe the food supply chain under investigation and directly relate the effects of different combinations of control measures on the risk to consumers. An important aspect of the usefulness of an MRA in this regard is the confidence that the risk assessor and the risk manager have in the MRA. This confidence can, for instance, relate to the variability in the food supply chains in practice and how well the MRA captures that variability. It can also relate the uncertainty associated to input values. Both variability and uncertainty carry through into the calculated risk estimate. However, it depends on the type of risk assessment being conducted whether these aspects can be adequately quantified and represented in the outcome of the risk assessment. The choice of the type of MRA and the design of the underlying risk assessment model(s) greatly influences its utility to the risk manager and both the risk assessor and the risk manager should consider this as part of their interactions at the commissioning of a MRA.

[5] A complete description of the characteristics of deterministic and probabilistic QMRA is available in the FAO/WHO Guidelines on Risk Characterization of Microbiological Hazards in Food.

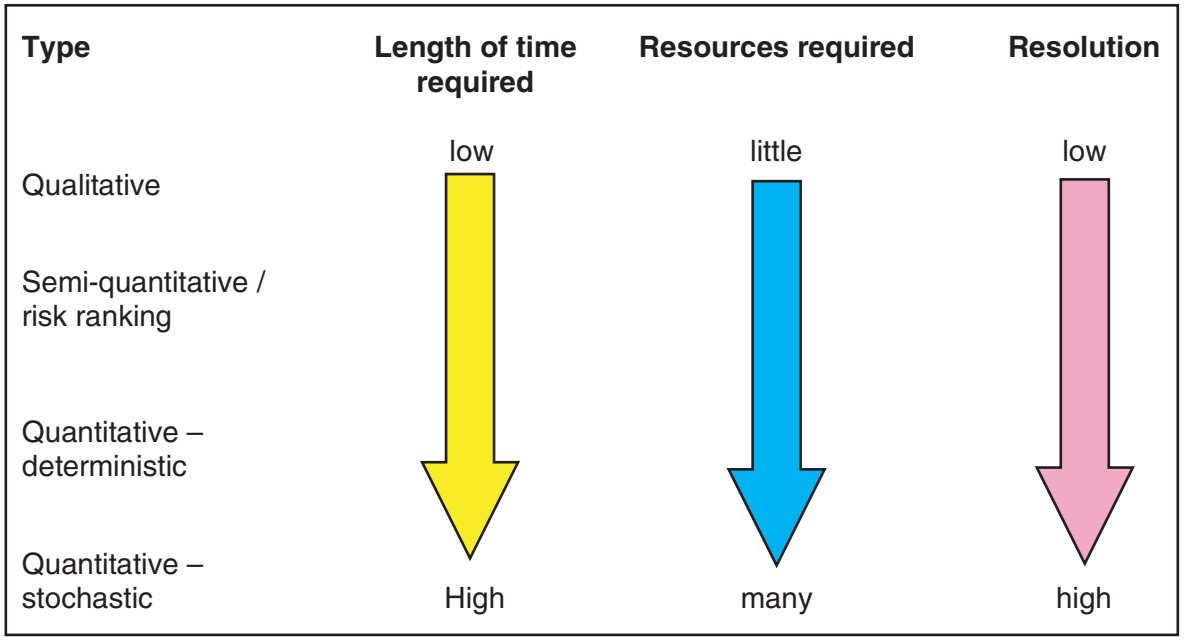

Figure 2. Factors that influence the decision to select a particular type of risk assessment

It is important that risk assessors work with the risk managers such that the risk managers have a very good appreciation of how various risk estimates relate to particular control measure scenarios and understand the impact of variability and uncertainty in the MRA on the risk estimates. It is up to the risk manager then to determine what risk outcome or risk reduction is appropriate and decide which of the scenarios could be taken further to discuss amongst others practical feasibility (involving various stakeholders) and regulatory aspects.

Epidemiology Based Tools

The most widely used public health indicator to quantify the impact of foodborne illness on a population is the (reported) incidence of illness. Many different countries have established some kind of reporting system. The burden of foodborne illness is the sum of all cases of illness for all food categories. There is no direct way to measure this, but incidence of illness associated with foodborne pathogens, followed by attribution of cases of illness to specific exposure routes can indicate food sources. To better control foodborne disease, risk managers require knowledge about the public health impact and relative contribution of possible sources and exposure pathways.

The process of defining this relative contribution is often described as "source attribution". The attribution of cases of human *Salmonella enteritidis* infection to eggs is an example of source attribution. Source attribution analyses support risk managers in evaluating the need for and the effect of food safety interventions. The Codex draft principles and guidelines for the conduct of MRM require relevant epidemiological information to be presented in the risk profile in the preliminary steps of MRM.

Source attribution relies on data collected through surveillance of human illness. Approaches include the analysis of outbreak investigations, analytical epidemiological studies (e.g. case-control studies) and microbial sub typing. The last of these requires data not only from humans but also from animals, food and other potential sources. Risk managers should obtain these data by establishing monitoring programmes along the food chain. Expression of public health goals may range from the general to the specific, depending upon the level of source attribution. A general public health goal could be to reduce the incidence of human *Salmonella enteritidis* infections, and a specific one could be to reduce the incidence of human cases of S. e. associated with consumption of eggs. Goals may be set either as number of cases per 100,000 inhabitants or as percentage reduction in the number of cases.

By analysing data on foodborne disease outbreaks, epidemiologists can determine the most common food vehicles involved. It is suggested that results from outbreak investigations to some extent can also be used for attributing sources of infection that are not related to outbreaks, so called sporadic infections. Case-control studies are studies where data on relevant exposures are obtained from case-patients as well as asymptomatic control persons. Well-conducted case-control studies are important sources of information.

Microbial subtyping involves characterisation of the pathogen by different pheno- or genotypic typing methods (e.g. serotyping, phage typing, antimicrobial susceptibility testing, pulsed-field gel electrophoresis and sequence-based subtyping). This approach requires integrated surveillance of the pathogen in most major food animals, food (including imported food) and humans, providing a collection of representative isolates from the farm-to-fork chain, followed by the use of appropriate discriminatory typing methods.

2.3.2.2. Economic analysis (Cost-benefit analysis)

The risk manager can use economic evaluations to weigh which of the risk management options that provides the necessary level of control in relation to the costs and benefits to stakeholders. While this tool is not currently addressed in the draft Codes principles and guidelines for MRM, it is increasingly identified as an important tool by risk managers.

In undertaking an economic evaluation, a variety of risk management options are generally considered, including doing nothing. Upon completion of the economic evaluation, the risk manager can use this together with the other relevant information such as the outcome of the MRA to select the risk management option(s) that provides the desired public health outcome in relation to the cost to society, including the regulated industry.

2.3.2.3. Monitoring and review

Monitoring of specific steps in a food production system to verify the effectiveness of an individual food safety measure should be part of implementation of food safety measures. Review of risk management strategies and food safety measures is necessary to assess whether or not they as a whole, or one in particular is successful in achieving the desired results and appropriately contributing to consumer protection and identify whether an ALOP or public health goal is achieved. This is also dependent on the frequency at which this level of control is actually achieved, i.e. degree of compliance in a country as a whole.

Risk management options selected for effecting an impact on public health, whether a regulatory change is necessitated or not, is enhanced when an implementation strategy is designed to measure the effectiveness of the risk management option. In some cases, the risk management option needs to be modified, including the enforcement strategy, if public health is not enhanced as a consequence of the risk management action. Enhanced enforcement or education may resolve the problem and the MRA may be reassessed when public health is not impacted as desired. This procedure is also applicable where epidemiological or other data shows that the public health goal is being achieved and an improvement has been measured. In this case, re-evaluation of the stringency or focus of the measure may be warranted.

2.3.2.4. Direct use of MRA in the selection/evaluation of control measures

An MRA associated with a food safety issue of concern can provide the risk manager with new understanding about the issue and the ways the safety level can be influenced throughout the farm-to-fork continuum. If sufficient data are available, MRA models allow a quantitative evaluation and comparison of the effects of different control measures on public health risk to consumers (i.e., risk per servings) or risk to a country (i.e., risk per annum), on an industry wide basis.

One of the case studies evaluated the potential impact of using flock testing as a means of determining how poultry should be slaughtered to mitigate the risk of campylobacteriosis in a human population due to poultry consumption. The model allowed evaluation of the relative risk reductions consequent to flock testing schemes and the impact of likely product segregation.

The recently established risk assessment model for *Enterobacter sakazakii* in powdered infant

formulae includes means for calculating the relative public health risk consequent to a range of possible microbiological criteria with attached sampling plans. This allowed a comparison of the likely impact this would have on the relative risk in the population. The use of "what-if scenarios" has proven to be an effective means of examining risk management options, allowing the risk manager to consider potential interventions in a new way.

It may be possible to directly use the risk assessment to determine the appropriate control measures in situations where the number of potential control measures limited, the segment of the food industry under consideration is highly uniform, the number of individual companies in the industry sector is small, and/or the MRA model is relatively straightforward.

In those cases, the ability to derive control measures from the risk assessment might best be in the hands of a national food safety agency or other competent body that performs the what-if scenarios needed to consider different options proposed.

The direct use of a risk assessment model to derive control measures or make risk management decisions is probably more difficult when the industry is composed of a large number of companies, the companies propose to mitigate that risk at different or multiple sites in the food chain, the individual industries may be using different food safety management systems or at least different control measures, etc.

2.3.2.5. Using MRA to select/evaluate Intermediate Targets

Agencies responsible for food safety have traditionally found it beneficial to articulate to food industry the degree of stringency that needs to be achieved at specific steps along the food chain, in order to deliver a final product that meets an expected level of consumer safety. The expected stringency can be communicated in different ways such as the stipulation of manufacturing requirements, such as microbiological process or product criteria. Such limits provide advantages to both risk managers and the food industry and provide enhanced flexibility, if focusing on the level of control required, not on a specific technology or practice.

These aforementioned limits have been traditionally established through expert advice and related to levels of stringency at specific steps in the food chain, considered being adequate.

With the recent advances in MRA techniques, national governments, Codex Alimentarius, and industry have realized that it is possible to more transparently and objectively relate the establishment of such limits to the intended public health outcome within a risk-based food safety management system.

In the draft guidance provided by Codex on such a system it is proposed to use the terms FSO, PO and PC (Codex Procedural Manual, 15th ed.) to communicate the limits required at specific points in food supply chains in an explicit way to the affected food industry. In the meeting it was agreed to refer to the limits as intermediate targets[6] (see definitions in Fig. 3).

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

Figure 3. The new intermediate targets defined by Codex

[6] The term *intermediate targets* was proposed as these terms form a bridge in the calculation between the public health goals and operational values to manage the risks

It is also proposed that MRA is used for their establishment, which reflects the ongoing international interest by risk managers within competent authorities in being able to specify risk-based food safety requirements at specific points in the food chain that can be more directly related to public health outcomes. Within the food chain, such requirements can be viewed as "intermediate targets" that reflect the ultimate public health outcome targeted at but are particular to the chain concerned.

2.3.2.6. Turning intermediate targets into operational standards

FSO, PO and PC are metrics that are not designed to be actively controlled or verified, but are targets from which to derive appropriate operational standards that can be controlled and verified. Their definitions provide a conceptual framework to establish these intermediate targets, allowing establishing operational criteria, that inform day to day risk management better than targets at the level of public health could do.

The case studies examined, gave examples of differing approaches of interpretation of the various definitions, and how to develop links between intermediate targets such as PO or PC and the ultimate risk of food-borne disease. A common attribute of all case studies was that, while an FSO may be a useful concept to allow risk managers to describe the overall stringency of a food safety system (including the consumer handling of products) PO and PC found wider utility as risk-based targets. PO and PC are easier to relate to the traditional microbiological criteria and the control measures related to them. An important reason for this is that PO and PC can be utilised at points in the food supply chain where control and verification thereof are possible, while this is not the case for the FSO.

Use of deterministic vs. probabilistic QMRA to establish intermediate targets

Evaluation of the case studies highlighted pitfalls that could be encountered in quantifying the linkage between control measures and traditional criteria, or between intermediate risk management targets and the risk to consumers. These pitfalls relate to in which way different types of risk assessment may be used, especially to the application of deterministic versus probabilistic risk QMRA and especially to establish intermediate targets linked to public health goals or ALOPs.

Deterministic QMRA was generally considered simpler, due to the less complex mathematics underlying that type of model. However, this simplicity comes at a cost regarding accuracy and insights into uncertainty. Several problems can arise from the selection of the degree of confidence required as criterion for decision-making. For example, if a PO were selected on the basis of its being the most likely value at a specified step in the food chain, then many values could actually exceed this PO value. This can be overcome by selecting a more stringent value, e.g. one that would require all food products concerned to achieve the PO with for instance a 95% or greater confidence limit. In the latter case a situation may arise where the PO value becomes overly conservative.

For these reasons, a probabilistic approach to modelling would offer the best opportunity for operationalizing intermediate targets and would provide the best insight into the uncertainty underlying the risk assessment. However, to apply probabilistic approaches represents a significantly greater challenge. One advantage of a good deterministic model is the ability to move forwards and backwards in the model to, for example, determine possible values for a PO and the best point in the chain for this PO, considering the hazard dynamics at earlier or later steps in the food chain.

With probabilistic models, one could not typically "back calculate" starting at the FSO or a PO to determine what a PO earlier in the food chain would need to be to ensure achievement of the specific level of control. This does not mean that probabilistic QMRA is not suitable to establish intermediate targets. An adequate procedure would be to estimate the likely value of the earlier PO and then solve the MRA model in an iterative manner until the required value of the later PO and the ultimate target for the risk at population level are achieved at the appropriate confidence level.

2.3.2.7. Using MRA in verifying Compliance

When food safety controls are adequately implemented in practice and achieve the performance projected, it is expected that the level of protection targeted at will be met. Where POs and PCs are used as intermediate targets to articulate the degree of control over a hazard at a specified step in the food chain, again, whether the expected level of control is achieved depends on how well the food safety controls derived from them have been implemented and perform.

The likely impact of choosing different food safety controls or setting different PO or PC values on the resulting risk in the population can be estimated if an appropriately designed MRA is available. However, the actual degree of public health protection achieved is also dependent on the frequency at which this level of control is actually achieved, i.e. degree of compliance. For example, a country could establish a highly stringent PO or PC, but if that limit is met at a frequency of 1%, the overall impact of the PO or PC could be minimal.

For example, the "FAO/WHO Microbiological Risk Assessment on *Listeria monocytogenes* in Ready-to-Eat Foods" (2004) explored the potential level of public health protection expected from two PO values (0.04 and 100 CFU/g) and the observed incidence of disease. The actual incidence of disease was substantially higher than the level predicted if the PO was always achieved. Assuming that the QMRA covered all relevant factors adequately, this indicates that there was a significant degree of non-compliance to a microbiological limit.

The availability of an appropriately designed QMRA can be a highly effective tool for exploring the impact of compliance. In particular, the development of scenario analysis that examines different frequencies and degrees on non-compliance to a microbiological limit can provide the risk managers with advice on how attainment of a public health goal or an ALOP could be confounded.

POs or PCs are achieved by implementation of suitable control measures, where necessary, managed through appropriate operational criteria as part of the management system. Food control systems need to undergo systematic evaluations to verify that the system is functioning continuously as intended. This verification activity is done by industry or by a competent authority as part of a formal auditing program. Ideally, quantitative means would be used as the basis of verification. There may be many direct and indirect means to conduct verification, including chemical or physical characteristics of the food, processing records or raw material data. There may be instances where qualitative approaches such as inspection of farms and factories for adherence to GAPs and GHPs can be indicative of an operation achieving a specified level of control. Microbiological testing is regularly a component for verifying compliance against a particular control measure, a microbiological limit, or even a complete food safety system.

Risk managers might face practical questions such as: where should they verify the compliance with higher priority, how frequently should they verify, or how confident do they need to be in the reliability of the verification results?

The availability of a QMRA and ability of to perform scenario and sensitivity analyses can provide the risk manager with insights into viable verification approaches.

2.4. Conclusions and recommendations

2.4.1. Conclusions (abbreviated)

It was concluded that:

- Quantitative microbiological risk assessment (QMRA) tools are highly desirable for risk managers and industry and allow the definition of intermediate targets to derive operational food safety control measures.
- QMRA facilitates the establishment of a quantitative relationship between exposure through consumption of contaminated food intake and its health impact (illness) and also facilitates the evaluation of the effectiveness and feasibility of possible control measures and can be used in two ways to inform risk management.
- The direct use of QMRA implies that "what-if" scenarios are implemented in a model to simulate the effects of possible control measures on public health and to evaluate if a public

health target will be met in the future or whether an ALOP is being currently met.

- The indirect use of QMRA facilitates the establishment of targets at various points along the food chain. QMRA may be limited in risk management for a sector of the food industry that is using different (combinations of) control measures. In such situations, intermediate targets are desirable to define the necessary level of hazard control at specific steps in the food chain.
- The case studies provided examples of multiple approaches for establishing intermediate targets using MRA. Most case studies required an operational adaptation of the strict Codex definitions of FSO/PO/PC to establish a limit and a required degree of confidence.
- The likely compliance to limits can greatly impact on the level of public health protection achieved by control measures.
- Epidemiology based tools have an important role to play in MRM, there is a need to use epidemiology to its full utility.

2.4.2. Recommendations (abbreviated)

The meeting made the following recommendations.

1. Governments should invest resources in strengthening food safety programmes, to collect, interpret and use available data, particularly in the area of monitoring and surveillance.
2. Codex and member countries should make it a priority to improve the synergy between quantitative risk assessment approaches and quantitative epidemiological analyses.
3. Governments, the scientific community and the food industry should strengthen technical co-operation and capacity building to enhance risk assessment and epidemiological capabilities at national and international level with the assistance of FAO and WHO.
4. The Consultation recognized that MRA should continue to be used as a practical means to establish food safety controls.

   Having noted that:

   - an effective use of PO and PC is constrained by the wording of the definitions as currently adopted,
   - the FSO is a specific case of the PO that is at a point where control and verification is not possible while,
   - PO and PC are at points in the food chain that can be controlled and verified and also can be linked to risk (ALOP) through use of a quantitative QMRA,

   it is recommended to provide explicit guidance on the interpretation in practice of these definitions in the Codex MRM document that is currently under development.
5. Evaluations should be undertaken to provide greater insight into the means for linking these risk management tools particularly FSO/PO/PC, to the level of public health protection and facilitate the provision of practical guidance.
6. Having noted from practical experience that there is more emphasis on a role of PO/PC as intermediate targets from which food safety controls are derived than on FSO, it is recommended to CCFH to consider amending the existing MRM document to reflect this new emphasis.
7. FAO/WHO should consider providing practical guidelines in distinguishing the use of microbiological testing as a control measure versus its use in verifying the performance of food safety systems.
8. Development of practical plain language guidance on how to implement risk management options should remain a priority for FAO, WHO and Codex.

ANNEX 1: Food safety management in practice

As food safety management approaches have evolved there has been a move towards a food chain approach. This recognizes the many contributors to ensuring food safety all along the food chain. From a management perspective it highlights the needs for collaboration of different institutions and ministry's at national or government level. To be successful in food safety management the importance of collaboration between there different sectors is well recognized and well designed risk based management systems can provide the mechanism for such collaboration.

A food supply chain can be composed of many different steps in the farm-to-fork continuum. Even for the same product, there can be a wide variation in individual steps in terms of technologies, ingredients, and logistics. To control potential hazards, various steps in the chain may need to have provisions that manage the level of a pathogen, when present, such that the ultimate food product is safe. Sometimes these provisions relate to one specific step but more often they reflect the integrated controls of all steps prior to a specific site in the food chain. The level of control at a designated step in the food chain must be sufficient to take into account of the likely dynamics of the hazard in subsequent steps. Generalizing, the provisions for hazard control are collectively referred to as the food safety management system.

Food safety management systems exert their control through the control measures that are put in place. In primary production, for instance of meat, control measures would be focussed on the selection of raw materials or hygiene during slaughtering. For food processing industries, typical control measures are physical (e.g. heating, cooling, aseptic filling provisions), chemical (e.g. preservatives, pH, a_w), operational (e.g. good hygienic practice, inspection), etc. For some control measures, process criteria and product criteria can be useful as operational parameters. Process criteria might, for instance, specify the time and temperature needed for a heat treatment to achieve a particular inactivation of possible pathogens. Similarly, product criteria might, for example, define the type and amount of acid to be added to a food product and the pH of the food product needed to prevent or minimise growth of a pathogen.

The selection of control measures for a step depends on the food to be produced, what effects previous and subsequent steps in the food chain have on the level of the hazard, technologies available to the food operations involved, and many other aspects. The selection also should take account of the level of control over a hazard that is required at the particular step. This is often referred to as the required "stringency". Whether this stringency is achieved will depend on the proper implementation and performance of the control measures. Therefore, in many steps within food supply chains, the collection of control measures is established within systematic management systems such as GHP and HACCP. These systems help assure that valid control measures are selected, adequately put in place and their performance managed.

One of the potential control measures that can be employed is the implementation of one or more microbiological criteria. Traditionally, microbiological criteria have been defined as a specific control measure wherein testing is used to segregate possibly contaminated and uncontaminated lots. As part of food safety risk management systems such as HACCP, microbiological criteria are being used by producers to verify periodically that a food safety system at specific steps in the chain is performing as expected. However in many instances there will be other means of verifying the performance than using microbiological criteria. Food control authorities use microbiological criteria or related means of measuring performance in a similar manner to verify compliance to regulatory requirements regarding hazard control at a suitable location in a food supply chain.

3. Case Study: *Staphylococcus aureus* in Cheese

C. Heggum[1]

3.1. Introduction

This presentation addresses a case study on practical risk management strategies for the combination *Staphylococcus aureus* and cheese. It must be emphasized that the study is not a risk assessment but was developed only for illustration of the practical use of the new risk analysis regime referred to as the FSO/PO approach.

3.1.1. The risk and the hazard

The risk related to *S. aureus* is *S. aureus* food poisoning, constituting more than 2% of food safety related outbreaks in 51 countries [1]. Cheese is often linked with outbreaks.

What makes *S. aureus* interesting in relation to practical risk management is that the hazard is not the organism itself, but its toxins produced prior to ingestion (i.e. in the food chain).

Only 3 of the 14 types of enterotoxins produced are relevant for food. As *staphylococci* are present in the nasal passages and throat and on the hair and skin of 50% or more of healthy persons, humans are the most likely source. However, *S. aureus* normally occurs in milk as healthy cows are natural reservoirs, in particular for strains capable of producing type C toxins [2].

It has been known for many years that *S. aureus* produces toxins only when levels exceed 10^5 cells/g (=100.000 cells/g). More recent studies indicate that, in milk, 10-fold higher levels are required [3]

In relation to dairy products, it is difficult to identify control measures that reduce toxin levels, once they are present in the product. Heat treatment within practical range in a dairy plant does not destroy the toxin.

3.1.2. Applying FSOs and POs in the cheese chain

The role of **Performance Objectives** ("POs") is to achieve a **Food Safety Objective** ("FSO") through operational targets for steps earlier in the food chain. In practice, POs can be established at each step where an end product is delivered to the next step in the food chain, e.g. after manufacturing and at the farm gate.

To ensure coherence between a PO and the FSO (or another PO later in the food chain), any established PO must relate to the specific conditions that in the subsequent steps affect the hazard levels (increases and decreases).

Therefore, numerical values of a PO for a cheese after manufacture depend on the probability and extent of growth or decrease during storage and distribution through its pre-determined (usually labelled) shelf life. As such conditions differ according to commercial and trade related needs (e.g. different markets, countries), it implies that different POs apply to the exact same cheese manufactured by the exact same food plant.

The value of a PO also depends on the foreseen intended usage of the cheese, which can vary dramati-cally. The cheese can (i) be used as raw material for secondary processing, (ii) be shredded by the con-sumer for pizza-topping after which it is heat treated in the oven, (iii) be sold as a whole cheese (with protecting rind) and/or (iv) pass through a slicing and packaging step that result in the cheese mass being more exposed. The intended usage has significant impact on the microbial contents in the product and consequently, the ability to meet the FSO.

As shown in Fig. 1, PO_1 is established from the FSO, PO_2 from PO_1, and PO_3 from PO_2, using data and knowledge about the effects on the hazard of the technology, conditions and control measures applied between two targets.

---

[1] Chief Consultant, Quality & Food Safety, Danish Dairy Board, Aarhus (Denmark)

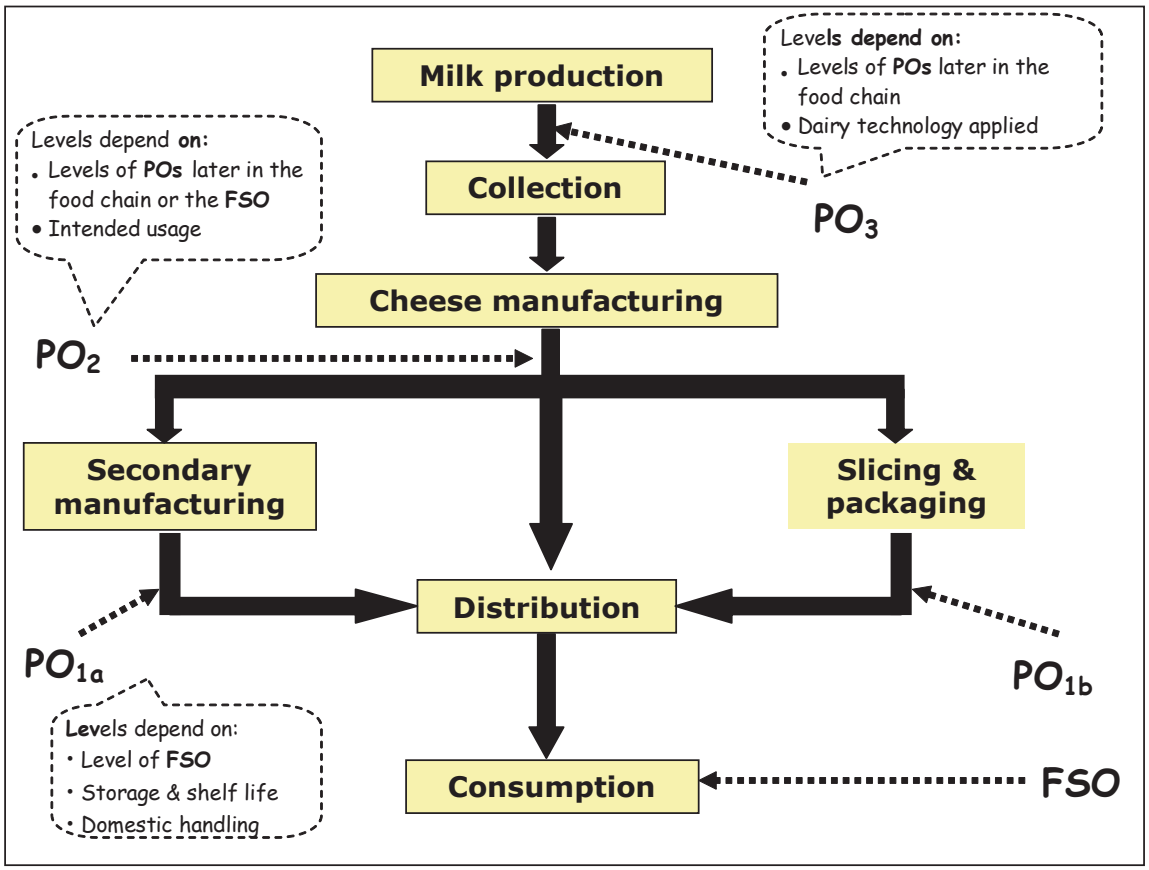

Figure 1. FSO and corresponding POs in the some cheese chains

3.2. Establishing targets - Case study for cheese

3.2.1. FSO for *S. aureus* enterotoxins

No formal ALOPs for *S. aureus* food poisoning has been established yet. Consequently, risk management options are currently limited to retaining status quo, corresponding to an ALOP based on a No Adverse Effect Level strategy.

Dose-response relationships between toxin and illness have not yet been established, yet a dose-effect relation is known: experience shows that toxin dose as low as 1 microgram in food is capable of producing food poisoning symptoms. In the present case study a possible default FSO of max. 100 ng toxin/portion of cheese is used. This value takes into account uncertainty by using a safety factor of 10.

3.2.2. Implementing the FSO

As toxins, once produced, are difficult to remove, the obvious control strategy is to avoid any toxin produc-tion through the whole food chain.

This can be achieved by controlling *S. aureus* contents and ensuring that levels, from the point of the ud-der through to the point of consumption, never exceed the level at which toxin production occur, that is 10^5 cells/g. This level can be referred to as a universal target ($PO_{universal}$) applicable throughout the cheese chain[1].

[1] S. *aureus is* an example of indirect hazard control. S. aureus is not the hazard by itself, but it is used as an indicator for hazard occurrence. Now, HACCP fanatics would probably say that indicators should not be controlled by HACCP systems, but in this case, it is the only practical approach.

In addition the $PO_{universal}$, other POs applicable at specific points in the cheese chain needs to be estab-lished, mainly to enable appropriate design of the food control system during manufacture. These specific POs must each be set at levels that enable the remaining part of the food chain to keep levels below 10^5 cells/g (Log_{10} $PO_{universal}$ = 5). However, despite that subsequent steps in the food chain may involve reduc-tion steps, POs must never be established at higher levels.

Further, the universal target also impacts the order in which control measures are to be applied. For in-stance, if raw milk is subjected to UHT treatment, the milk must never exceed 10^5 cells/g (Log_{10} $PO_{universal}$ = 5) prior to the treatment, despite that the reduction achieved by the UHT treatment will be far below what is needed in order to meet any *S. aureus* specifications.

3.2.3. Setting a specific PO for the (whole) cheese at the point of delivery

When the cheese manufacturer establishes a specific Performance Objective (PO) for a cheese, it is necessary to take into account the expected changes[2] that occur in the cheese after it has left the manufacturers establishment (i.e. after the point at which the PO applies) up to consumption. This can mathematically be expressed as follows:

$$\mathbf{Log_{10}\ PO \leq 5 - \sum Log_{10}\ I + \sum Log_{10}\ R}$$

- where
- **Log_{10} PO** expresses the maximum log concentration of the *S. aureus* cells as a result of the previous steps in the process that will ensure that the universal PO is achieved during the later steps.
- **$\sum Log_{10}$ I** expresses the total log increases in numbers of cells that occur between the point of delivery and the point of consumption.
- **$\sum Log_{10}$ R** expresses the total log decreases in numbers of cells that occur between the point of delivery and the point of consumption

If numbers decline by 2 logs until consumption (e.g. through aging), the *S. aureus* concentration in the fresh cheese prior to any ripening can theoretically be established at 7 logs (or 10^7 cfu/g). However, since such a level would exceed the universal PO of 5, this PO must be set at 5 logs (i.e. equalling the universal PO).

3.3. Achieving the PO - Case study for cheese

Basically, there are two approaches to the practical implementation of a PO:

- a forward approach using Performance Criteria (PC), only
- a backward approach involving the use of specific Performance Objectives (PO) for raw materials

The forward approach is used when the content in raw materials are given, i.e. cannot be changed. This is the situation for most cooperative dairy plants worldwide. The backward approach needs to be used, when technology is fixed, i.e. there is no room for amendments during cheese manufacturing[3]. A combina-tion of these two approaches is, of course, also possible.

3.3.1. The forward approach

The task of the manufacturer is to apply control measure combinations that together deliver a combined performance corresponding to the difference between the specific PO for the end product and the level(s) that occur in the raw milk, while respecting the universal PO of 5 logs. However, between these two points, increases and reductions occur according to the cheese technology applied, such as the temperature and pH profiles applied, development of lactate etc.

---

[2] These changes are partly under control of the manufacturer, to the extent that labelling instructions are provided (storage conditions, usage instructions and shelf life information).

[3] This could, e.g. be the case in the manufacture of certain PGI cheeses.

As these process parameters of technological steps are often fixed, or very limited possibilities for devia-tions exist, controls are primarily done by additional measures (e.g. control of milk storage, heat treatment, etc). The need and intensity of such measures depend on the growth and reductions occurring as a result of the dairy technology used.

The performance required by such additional control measures can be mathematically expressed as fol-lows:

$$\sum PC \geq Log_{10}\, C_0 - Log_{10}\, PO_{end\ product} + \sum Log_{10}\, I - \sum Log_{10}\, R$$

- where
- C_0 expresses the initial concentration of cells in the raw milk
- $Log_{10}\, PO_{end\ product}$ expresses the PO for the fresh cheese, in this case equalling 5
- $\sum Log_{10}\, I$ and $\sum Log_{10}\, R$ express the total log increases and log reductions, respectively, in numbers of cells that occur due to the cheese technology applied (e.g. in the cheese vat, during moulding and brining)

The concentration in milk varies, according to the prevalence of mastitis and farm hygiene. A content of 500 cells/g would typically be a normal level, whereas very high levels can occur in milk from herds with high prevalence of mastitis induced by *S. aureus*. Worst case is *S. aureus* induced mastitis milk (typically about 10^4 cfu/g).

A simple modelling of *S. aureus* development during the manufacture of Danbo (cheese vat) indicates a net increase up to 5 to 6 logs.

If this information is applied to the formula above, and if storage steps for the raw milk are determined not to result in an increase exceeding 0.6 logs (corresponding to max. 30 hrs at 6 °C), then the required PC for a microbiocidal treatment can be calculated. In this example, the required PC is between 4.3 and 5.6 depending on the initial concentration of *S. aureus* in the milk.

It should be noted, that without such a microbiocidal step, numbers would exceed the universal target early in the cheese making process. Therefore, the microbiocidal step must occur prior to cheese making.

So, given that the cheese technology used does not fluctuate from day to day, the PO can be implemented by establishing 2 PCs, one for storage of milk/cheese milk and another for a microbiocidal treatment prior to the cheese making. PCs need be revised, if the technological parameters change significantly.

Where heat treatment constitutes the microbiocidal treatment, D-values expressing the number of seconds to achieve one decimal reduction of *S. aureus* in milk are needed to transform the PCs into process criteria.

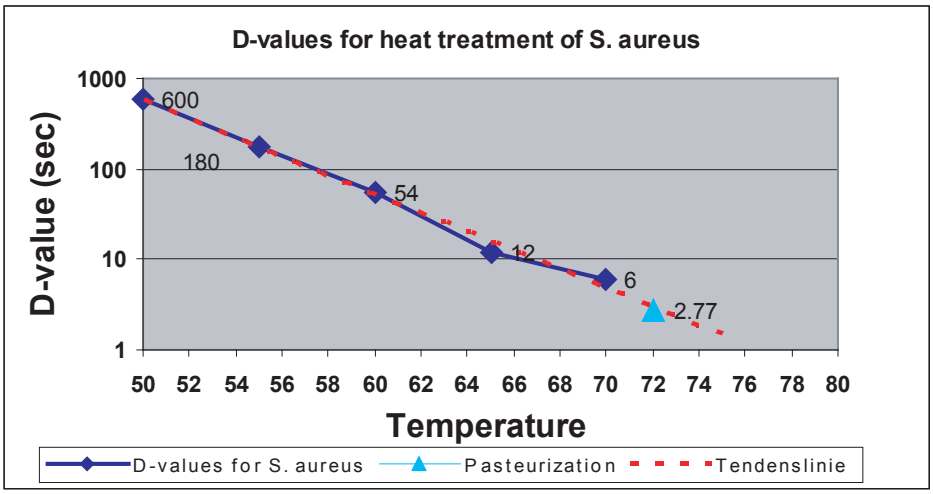

Figure 2. Heat treatment effects on *Staphylococcus aureus* in milk

In the example of Danbo, appropriate sets of process criteria that deliver the PCs required for the various milk quality scenarios can be derived from the linear D-value curve (Fig. 2). Many combinations of holding times and treatment temperatures are possible.

3.3.2. The backward approach

The backward approach needs to be used, when technology is fixed due to other priorities than food safety, i.e. there is no room for amendments during cheese manufacturing. The main regulator to ensure that the PO for the fresh cheese is met is the establishment of a PO for the content of *S. aureus* in the raw milk at farm gate.

Using the same data as used above in the example of Danbo, different control measure combinations result in different POs at farm gate.

Table 1: Examples of using the backward approach to implement a PO for fresh cheese

	Scenario 1	Scenario 2	Scenario 3
Control measures applied to the raw milk	**Trasport:** 10h at 12 °C **Storage:** 30h at 8 °C **Heat treat ment:** 75 °C/21 s	**Trasport:** 10h at 6 °C **Storage:** 30h at 6 °C **Heat treat ment:** 72 °C/15 s	**Trasport:** 10h at 4 °C **Storage:** None **Heat treat ment:** None
Log PO (fresh)	**+ 5.0**	**+ 5.0**	**+ 5.0**
∑Log I (vat)	- 6.0	- 6.0	- 6.0
∑Log R (heat)	+ 12.0	+ 6.1	+ 0
Draft max content at reception	**< + 11.0**	**< + 5.1**	**< - 1.0**
Correction to comply with the $PO_{universal}$	- 6.0	- 0.1	0
Correction max content at reception	**< + 5.0**	**< + 5.0**	**< - 1.0**
∑Log I (storage & transport	- 0.6	- 0.2	- 0
Max log content at farm gate	**+ 4.4**	**+ 4.8**	**- 1.0**
PO (farm gate)	**< 25 000 cfu/g**	**< 63 000 cfu/g**	**< 100 cfu/kg**

Scenario 1 is characterized by relative warm transport and storage conditions within normal time profiles and a heat treatment typically used for cheese milk for Danbo manufacturing. This heat treatment results in a 12-log reduction, thus - in theory - allowing levels in the raw milk of up to 11 log. However, as such high levels exceed the limit of toxin production, correction must be made to ensure that the universal PO (=5 logs) can be met. Taking into account the increase during transportation and storage, the milk at farm gate must never exceed 25 000 cfu/g. Such a level can be established as the PO at farm gate.

Scenario 2 differs from scenario 1 by less intense heat treatment (min. pasteurization conditions) and better temperature control during transportation and storage of the raw milk. The heat treatment results in a 6.1 log reduction, which corresponds to the increase during cheese making. The universal PO is met. Further, scenario 2 shows that no additional benefits (as regards *S. aureus*) occur from using the more intense heat treatment in scenario 1. The more stringent temperature profile during transport and storage allows a slightly higher PO at farm gate.

Scenario 3 differs from the other two scenarios by not involving a microbiocidal step (heat treatment) and by aiming for no growth during storage and transport (temperatures kept below min. temperature for growth of **S. aureus**). If the cheese technology is retained unchanged (i.e. resulting in 6 log increases in the vat), then the PO at farm gate can be set to be below 0.1 cfu/g (or below 100 cfu/kg).

3.4. Conclusions

This exercise shows that the new risk management regime, involving FSOs, POs and PCs can be used, also in the special case of *S. aureus* in cheese, despite the hazard is a toxin and not a microorganism.

The exercise has shown that the existence of dose-response data is not always needed to enable the establishment of an FSO. Although quantitative risk assessment data should always be pursued to im-prove and fine-tune risk management strategies, qualitative risk assessment can work in their absence.

What the food chains need are operational targets in the form of FSOs. Once FSOs have been provided by the authorities, these can be implemented by the individual food business through simple and conser-vative mathematical modelling in support of the hazard analysis applied within in the HACCP approach, for instance, as outlined in the ISO Standard 22000 [5].

However, the development of growth models for milk at relevant temperatures, lactate & CO_2 concentra-tions, and pH conditions will be needed to allow more precise estimates for practical use.

It is important to emphasize that risk managers basing their activities upon the FSO/PO and PC approach must recognize that POs and PC are best established within the exact context of the particular food in the particular food chains, i.e. by the individual food businesses controlling this context. Otherwise, too much uncertainty will have to be built into the modelling.

This means that the key risk management tool for authorities will be to hold the individual business re-sponsible for establishing those POs and PCs that are specific for their products relative to its particular food chain context and to hold the businesses responsible for demonstrating the appropriateness of these targets and criteria. Generally applicable POs and PCs, typically established by food standards, are not related to the actual risk – and will, at best, provide more protection than supported by risk assessments and, at worst, not be effective.

References

1. WHO (2001) Surveillance programme for Control of Foodborne Infections and Intoxications in Europe
2. European Commission (2003): Opinion of the Standing Committee on Veterinary Measures Relating to Public Health on Staphylococcal enterotoxins in milk products, particularly cheese, 26-27 March 2003
3. Fujikawa & Morozumi (2006): Modelling *Staphylococcus aureus* growth and enterotoxin production in milk. Food Microbiology 23, 260-267, 2006
4. Schällibaum, Bachmann & Pfister (2002): Quality and Safety of Swiss Raw Milk Cheese, FAM-INFO No. 446, October 2002, Swiss Federal Dairy Research Station, Liebefield
5. EN ISO 22000:2005 Food safety management systems - Requirements for any organization in the food chain; ISO: Geneva (Switzerland), 2005

4. Efficacy of Preventive Measures and Hurdle Technology by Quantitative Risk Assessment

M. Sanaa[1]

4.1. Introduction

Because of the importance in the rural economy of food made from raw material of animal origin, especially in France, a great deal of effort has been placed on hygiene during production, transformation, and distribution of cheese. The incidence of invasive listeriosis that was divided by 3.1 from 1987 through 1997 can be "at least partly attributed to this effort". As regards raw milk cheeses, the improvement was achieved through improving milking hygiene, rapid detection and elimination of cows excreting *L. monocytogenes*, and selection and sorting of farms that produce milk to the highest level of hygiene.

This communication reports a risk assessment model based on data collected in the years 2000–2005 including 10 traditional camembert cheese plants. Each of these cheeses benefits from a European Protected Denomination of Origin and must be made from raw milk.

Features of the risk assessment model include: milk production, predicted behaviour of *L. monocytogenes* during cheese making, commercial distribution, and at consumers' homes involving the temperature-pH interaction; the reasonable assumption that cell progeny form colonies within the solid cheese matrix instead of spreading as in a liquid broth; and incorporation of the most recent data on the dose-response relationships.

Analysing every step of the full process from the primary source exposing animals to the human host adverse consequences is justified. Today, tools of farming, processing foods, food distribution and marketing, are not simple. Breakdowns at one single step could have directly or indirectly catastrophic consequences. Traditionally, activities and plants are designed and operated by applying references to codes and standards. Now the trend is a more functional system approach where the focus is on what to achieve, rather than on the solution required. Hence, the adequacy of a risk assessment modelling approach could not be assessed by solving a specific problem, but by whether it helps in achieving the goal. The model we developed was designed to answer to specific problem in managing raw milk soft cheese safety.

We developed a comprehensive model to be used as a hazard and risk management tool. It is possible with this model to predict the relative risk reductions that can be achieved through the inclusion of different risk mitigations strategies (e.g. preventive measures at farm level, milk sorting, temperature and storage duration), and estimating the number of foodborne listeriosis prevented. On the other hand, the same tool makes it possible to begin with public health and derive the degree of stringency required to achieve the desired level of protection.

These new capabilities will radically change the level of scientific rigor and transparency associated with the establishment of food safety requirements and/or guidance. Some of the practical questions are: what is the limit of frequency or concentration of *Listeria monocytogenes* in raw milk not to be exceeded in order to achieve the desired level of protection? - How to optimise the sampling frame to monitor the level of contamination in one or several steps of processing?

Our approach is in agreement with the new food safety risk management concepts and metrics, such the Food Safety Objective (FSO), Performance Objective (PO), Performance Criteria (PC), that provide an operational framework for the concepts present in the WTO SPS Agreements.

4.2. Risk assessment model pathway

The present risk assessment of foodborne listeriois covers the whole food chain, from farm to table (Figure 1). Farm animals could be infected by *Listeria monocytogenes*, shed the pathogen

[1] National Veterinary School of Alfort, Epidemiology and Risk Anlysis Unit,
7, avenue du Général de Gaulle 94704 Maisons Alfort, France, msanaa@vet-alfort.fr

and/or carry it in their gastrointestinal tracts, from where they spread to other animals, their primary products and farm environment. Cows with mastitis can shed huge quantities of bacteria in milk and maintain the contamination within the farm via the milking machine. Raw milk may also be contaminated from environmental sources during milking, storage and transport.

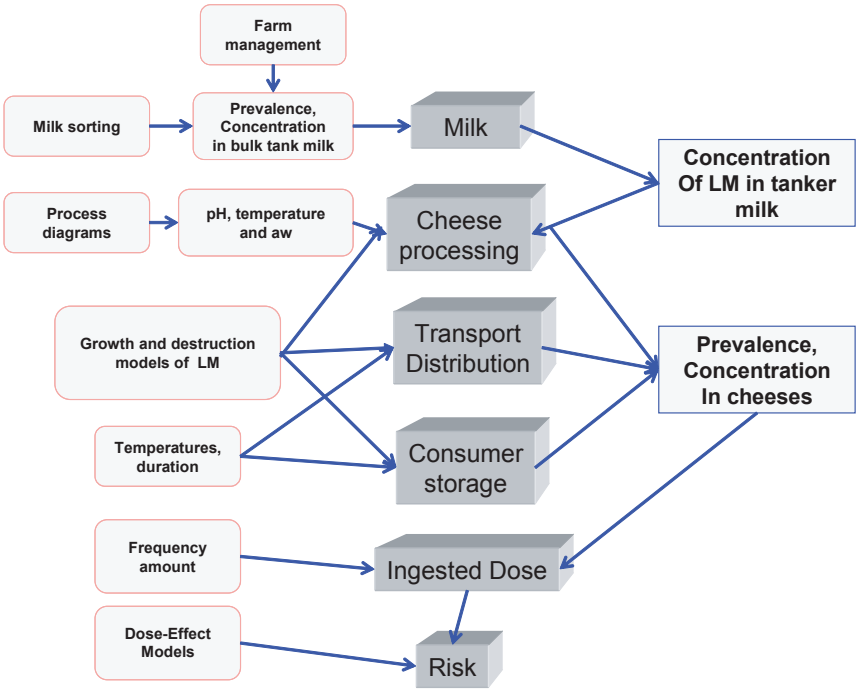

Figure 1. : Quantitative risk assessment model of *Listeria monocytogenes* in Camembert made with raw milk

After the milk leaves the farm, cross-contamination can occur during transportation and processing. It is not unreasonable to control or eliminate the hazard at the source. So far few safety food strategies centre the effort at pre-harvest stage. Risk management of food safety risks paid more attention on implementing harmonized systems such as Hazard Analysis and Critical Control Point (HACCP) mainly focused on processing. In our case it is crucial to identify pre-harvest options for preventing hazards from entering the supply chain. Different options are included in our model: e.g. milk sorting, farm management (housing, feeding, milking hygiene)

Another likely contamination may take place further down the line for the processed food. at the steps following processing and transportation, storage at inadequate conditions and food handling can increase the level of contamination. In addition, consumer behaviour could increase or reduce the risk associated with *Listeria monocytogenes* in cheeses. When a consumer ingests contaminated food, the consequences can have various degrees of severity. The degree of severity depends on the interaction between host factors – pathogen factors and environmental factors. The available dose-response model for *Listeria monocytogenes* could take into account the host susceptibility.

A generic model was implemented as stocked procedures in SAS (Statistical Analysis Software) and a friendly use interface was developed. The simulation model was run for each cheese making plants involved in this project. To run the model specific data are needed:

- Processing data (temperature, pH, water activity, etc. during the different steps of cheese production),
- Farm milk contamination, milk collection and transport data,
- Distribution and retail data, and
- Consumer data

4.3. Main Risk assessment model outputs

4.3.1. Concentration of *Listeria monocytogenes* in milk before cheese making

The model estimates the distribution of Listeria monocytogenes concentration in milk. The influences of relevant factors (i.e. season, sorting strategy etc.) on the concentration are described. This influence study should help the milk quality manager in determining the high-risk season and in optimising the sorting of milk and preventive strategies.

4.3.2. Potential log Growth of *Listeria monocytogenes* during cheese processing

To describe the potential of growth, the model estimates the number of multiplications by 10 after each step of the cheese processing. We use the acronym PLG "Potential Log Growth". For example n PLG means multiplication by 10^n of the initial number of *Listeria monocytogenes* cells. Because the water activities and pH in cheese core and rind differ, the corresponding PLGs were assessed separately. Table 1 gives an illustration of the distribution of PLGs in one specific plant.

Table 1: Example of Potential Log Growth (PLG) in one specific plant

PLGs	percentiles					
	25th	Median	75th	90th	95th	99th
Up to end product delivery						
Core	0	0	0.16	0.49	0.66	0.96
Rind	0	0.16	0.95	1.74	2.2	2.83
Until delivery to the retail shop						
Core	0	0	0.17	0.51	0.69	0.99
Rind	0	0.2	0.99	1.79	2.25	2.88
Until placing on shelves						
Core	0	0.04	0.34	0.76	1.01	1.57
Rind	0.04	0.5	1.35	2.19	2.67	3.43
Until purchase by the consumer						
Core	0.04	0.22	0.63	1.12	1.43	2.04
Rind	0.31	0.9	1.75	2.61	3.1	3.94
Until consumption						
Core	0.11	0.4	0.91	1.46	1.81	2.54
Rind	0.55	1.21	2.1	2.98	3.48	4.41

4.3.3. Concentration of *Listeria monocytogenes* in 27 g cheese serving

The model assesses the distribution of Listeria monocytogenes concentration in a typical cheese serving (27g) (Table 2).

Table 2: Distribution of *Listeria monocytogenes* concentration in a typical cheese serving (27g)

Concentration CFU/g	Percentage of 27 g camembert servings
> 1	2.26%
> 5	1.34%
> 10	0.36%
>100	0.03%
>1000	0.00%

4.4. Model use

In principle, the modelling approach is not only used to assess the risk distribution; it should also provide valuable information on the uncertainty associated with the inputs and control options to be suggested to the risk managers. Sensitivity analysis has to be conducted to identify key contributors to variability and uncertainty in model outputs. In the majority of conducted probabilistic risk assessments, the variability of the output is mainly attributable to variability and/or uncertainty in a small number of inputs. In identifying those inputs we are able to suggest targeting research efforts for the characterization of the uncertainty of a small number of important inputs. In addition to sensitivity analysis, the simulation model could be used to analyze some what-if scenarios, and do formal decision analyses, such as multi-attributes analyses, cost-benefit analysis and utility-based analysis.

Figure 2 shows an example of a what-if scenarios analysis.

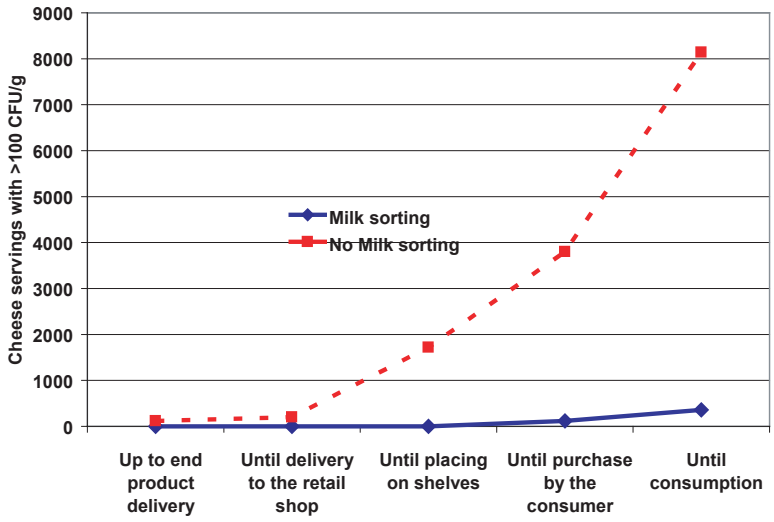

Figure 2. Number of 27 g cheese servings with a concentration higher than 100 CFU/g per one million servings and the impact of milk sorting

In addition to what-if scenarios analysis, the model could be used to establish different quantitative food safety targets: FSO (Food safety objectives), PO (performance objectives), PC (performance Criteria). The oral presentation will give practical examples on the model use.

Acknowledgments

The author is indebted to the members of the Quantitative Risk Assessment Working Group of the French National Interprofessional Centre of the Dairy Economy (CNIEL) and the French Technical Institute of Cheeses (ITFF). This work was funded by CNIEL.

5. Harmonisation and Equivalence in Milk and Dairy Products Standards- Moving towards Regional Trade Blocks: Case Study from East Africa

L.R. Kurwijila[1], C.J.S. Mosha[2], A. Omore[3],T. Lore[3]

Abstract

The dairy industry contributes about 3, 5, and 7% of the GDP of Kenya, Tanzania and Uganda respectively. Milk production is estimated to be about 5 million tons per annum, 60% of which is produced in Kenya. More than 80% of the milk is traded informally as raw milk. The processing industry works at less than 30% of the installed capacity of about 2.8 million litres per day. Except for Kenya, demand for milk and dairy products exceeds domestic production even in years of normal rainfall and the deficit is growing. The gap between supply and demand is filed by intraregional and extra-regional imports which together amounted to 31,555 metric tons in 2003 worth 8.3 million US $.

Intra-regional trade in dairy products is constrained by inadequate milk processing and marketing infrastructure, seasonality of supplies, tariff and non-tariff barriers as well as sanitary and quality standards issues. The paper highlights on the efforts that have been taken by the East African Community (EAC) towards harmonization of standards for milk and dairy products. In view of the predominance of the informal milk trade, dairy regulatory authorities also see training and certification of informal milk trade as a starting point towards quality improvement in the entire dairy value chain and establishment of equivalence in competencies of all key role players through standardized training curricular.

A programme for training and certification of informal milk traders initiated by the Association for Agricultural Research in East and Central Africa (ASARECA) is presented and discussed in that context. Establishment of equivalent or uniform standards and improvements in hygienic handling of milk through enhanced competences of all key dairy value chain role players within the EAC is expected to contribute towards enhancing cross-border trade in milk and dairy products.

Key Words: Harmonisation, milk and dairy products standards and equivalency, East Africa

5.1. Introduction

The three east African countries of Kenya, Tanzania and Uganda cover an area of approximately 1,649,830 square kilometers and have a population of 89.3 million growing at an average of 2.9% per annum. They together form the East African Community (EAC) an economic community re-established in November 1999 to foster integration of their economies, which have long historical ties. Agriculture is the mainstay of the economy contributing about 45-50% of GDP (Table 1).

The dairy industry contributes 3, 5, and 8% of the GDP of Kenya, Tanzania and Uganda respectively. Milk production is estimated to be about 5 million tons per annum 60% of which is produced in Kenya. More than 80% of the milk is traded informally as raw milk.

The processing industry works at less than 30% of the installed capacity of about 2.8 million litres per day. Except for Kenya, demand for milk and dairy products exceeds domestic production

[1] Department of Animal Science and Production, Sokione University of Agriculture, P.O.Box 3004, Morogoro, Tanzania, E-mail: kurwiji@suanet.ac.tz

[2] Head, Agriculture and Food Section, Codex Contact Point Officer, Tanzania Bureau of Standards, PO Box 9524, Dar Es Salaam, Tanzania, E-mail: cjsmoshar@yahoo.co.uk

[3] Veterinary Epidemiologist, International Livestock Research Institute (ILRI), P.O. Box 30709, Nairobi, Kenya, E-mail: a.omore@cgiar.org

even in years of normal rainfall and the deficit is growing. For EAC countries the gap between supply and demand is filed by intraregional and extra-regional imports which together amounted to 31,555 metric tons in 2003 worth 8.3 million US $.

A recent study by the Eastern and Central Africa Program on Agricultural Policy Analysis and USAID sponsored programme on Regional Agricultural Trade Support programme (RATES) established that intraregional trade in milk and dairy products amounted to US $ 20 million over the period 1997 – 2003 compared with dairy imports of selected eleven COMESA/EAC countries (Zambia, Namibia, Congo DRC, Mauritius, Uganda, Madagascar, Sudan, Ethiopia, Malawi, Seychelles and Tanzania) worth US $ 175 million over the same period. Thus intra-regional imports made up a mere 10.25% of the regional dairy import trade. Reasons for low intraregional trade in milk and dairy products include low production, inadequate milk collection, processing and marketing infrastructure as well as a number of tariff, non tariff, sanitary and technical barriers to trade.

To address problems affecting intra-regional trade in general, the EAC has established in January 2005 a customs union (CU) protocol, which provides for reduced import tariffs of 10% and 25% on Kenya's milk exports to Uganda and Tanzania, while the two countries can export to Kenya at zero import rate over a five year period from February 2005 when the Customs union (CU) took effect. Thereafter, dairy trade between the three countries will become zero rated. The CU has also adopted a protective 60% common external tariff on extra-EAC imports. These measures are aimed at promoting intra-regional trade by removing or reducing tariff and related non-tariff barriers (e.g. import licensing, suspended duties; customs clearance, inspections etc).

Another area that is a significant impediment to intraregional trade is lack of uniform or equivalent standards for quality of milk and dairy products. To address these constraints a number of initiatives have been undertaken by several regional organizations. The East and Central African Programme for Policy Analysis (ECAPAPA) of the Association for Agricultural Research in East Africa (ASARECA) working with the International Livestock Research Institute (ILRI) on the one hand and the RATES programmes working with EAC and COMESA initiated independently, parallel studies aimed at promoting dairy trade through harmonization of policies, laws, regulations and standards for the dairy industry in the region. A convergence of the two initiatives culminated in a COMESA/EAC regional dairy trade policy paper which was discussed at a regional meeting held in Nairobi, September 2004.

Given the big role played by informal dairy markets in the region, training and certification of key role players in this segment is seen by dairy regulatory authorities to be part and parcel of efforts aimed at improving the sanitary and quality standards along the entire dairy value chain in the region. Hence, subsequent efforts by ECAPAPA/ILRI are addressing the training and certification of informal milk traders in Kenya, Tanzania, Uganda and Rwanda.

The objective of this paper is to examine the status and progress being made in the area of harmonization of milk and dairy products standards within the EAC countries. Rwanda, which is expected to join the EAC in the not too distant future, has also been included in the ECAPAPA/ILRI programme for the development of the training and certification of informal market traders.

5.2. Definitions

Harmonisation is the bringing together of different approaches, policies, regulations and/or standards used in different countries into a unified system that uses same or similar approaches, policies, regulations, procedures and/or standards that facilitate exchange of information and cross border flow of trade in goods and services.

Rationalisation is the making of changes in the management system of a specific industry or business within a country to increase efficiency and reduce waste.

Equivalence is the "national treatment" or mutual recognition and respect of another country's standard for purposes of exchange of goods and services.

Standardisation is the development, adoption and consistent use of approved procedures, methods, materials and/or processes that ensure provision of high quality and safe (milk and dairy) products.

5.3. Basic information on dairy industry in East Africa

Some key economic indicators:

Within sub Sahara Africa, Eastern Africa has the highest concentration of traditional cattle and improved dairy cattle. Hence, Sudan, Kenya, Ethiopia, Tanzania, Uganda and Somalia are the six top milk producing countries in sub-Sahara Africa accounting for more than two thirds of the total cow's milk on the continent (Muriuki and Thorpe, 2001). Kenya, with over 2.7 million improved cattle accounts for about 75% of improved dairy cattle in Eastern and Southern Africa and about 20% of the estimated 17.9 million litres of milk produced in sub-Sahara Africa in 2003 (FAOSTAT, 2004).

Table 1 shows key geographical, demographic and economic data of the three EAC counties. Endowed with a population of approx. 89 million people and prospects for economic growth, regional integration provides a more practical way of expanding the consumer market that is sufficiently large to attract investment in technologies that is required to further develop dairy industry.

Table 1: Basic economic indicators for East African Community countries (2000)

Parameter	Kenya	Tanzania	Uganda	Total/Av.
Area (Sq. km)	569140	883590	197100	1,649,830
Agricultural land (sq.km.)	258,200 (45.4%)	399,500 (45.2%)	122,720 (62.3%)	780,420 (47.3%)
Land under pasture (sq. km)	213,000 (37.4 %)	350,000 (39.6%)	51120 (25.9%)	614,120 (37.2%)
Human population (mio), 2004	30.7	35.1	23.5	89.3
Human population growth rate (%) 1990-2000	2.7	3.0	3.1	2.9
GDP (2004) (mio US $,real at 1999 prices)	9,876	6,419	7,728	24,023
GDP/capita (US $)	328	191	348	289
Av. GDP growth rate (%), 1999- 2000	1.8	2.8	6.4	3.67
Av. GDP/capita growth rate (%)	-0.7	0.1	3.3	0.9
Contribution of Agriculture(mo US $) to GDP (%)	2533	2679	3115	8,327
Contribution of livestock to GDP (mio US $)	1,366	963	627	2,956
Contribution of dairy to GDP* (%)	3	40	7-9	

Source: *Kasirye (2003), Balikowa, 2003 FAO, 2003; FAO, 2004

East Africa is endowed with considerable natural resources, including highlands whose moderate tropical climate makes them particularly suitable for dairying. Smallholder dairying dominates in the region and Kenya is the major producer, processor and exporter of dairy products in the region (Tables 2 and 3). The dairy industry is growing at 6% per annum in Tanzania and after years of stagnation due to civil strife, is rapidly expanding again in Uganda.

Table 2: Milk Production and processing in the East Africa Community (2003)

Parameter	Units	Kenya [a)]	Tanzania [b)]	Uganda [c)]	Total/Av.
No. Of Cattle	Zebu (x 1000)	10,400	17,700	5,400	33,500
	Improved dairy cattle (x 1000)	3,045	500	300	3,845
Milk production	(x 1000 L/annum)	2,700,000	1,400,000	900,000	5,131,763
Per capita consumption	L/annum	85	33	36-40	44
Milk processing capacity	x 1000 Litres/day	1200[d)]	420	399	2019

Source: [a)] COMESA/EAC (2004); [b)] Ministry of Livestock Development (2006); [c)] Kasirye, 2003; [d)]Kenya airy Board estimates (personal communication, 2006)

Table 3: East Africa's dairy trade statistics (2003)

		Kenya	Tanzania	Uganda	Total/Av.
Milk exports (2003) [a)]	Intra-regional (tons/annum)	363,201	44,729	414,196	822,125
	Extra-regional (tons/annum)	220,492	3,005	93,296	316,793
Milk imports (2003)[b)]	Intra-regional (tons/annum)	?	?	?	?
	Extra-regional (tons/annum)	?	?	?	?
Total imports (2003)	Metric tons/annum)	3,510	20,823	7,222	31,555
Total imports (2003)	US $ (million)	1,775	3,751	2,765	8.3

Source: COMESA/EAC (2004) ? not given; [c] FAOSTAT (2004)

5.4. Milk and dairy products quality standards

Under international trade, product standards fall under the Sanitary and Phytosaniatary measures (SPS) and the Technical Barriers to Trade (TBT) agreements, which allow WTO member states to:

"apply measures necessary to protect human, animal and plant life and health provided that such measures are not applied in a manner which would constitute a disguised restriction on international trade"

Hence within the EAC, government regulatory authorities carry out food inspections and licensing to ascertain that the quality and specification of food imports and exports conform to international food safety requirements and specifications that aim to protect consumers from food safety hazards and risks as defined by the Codex Alimentarius Commission (CAC) and other standards bodies such as the International Standards Organization (ISO), the World Animal Health Organization (OIE), the European Union and others. Licensing of livestock products imports generally requires certification for zoosanitary requirements for contagious or infectious diseases such as Foot & Mouth Disease (FMD), Rinderpest, Contagious bovine pleuropneumonia (CBPP), Tuberculosis, Leptospirosis, Trichomoniasis, Brucellosis, Jones disease (Paratuberculosis) following standards and procedures approved by WHO/OIE/FAO (COMESA/EAC, 2004).

Several epidemiological studies show that there may be cause for zoosanitary concerns as prevalence rates among traditional and/or smallholder dairy herd vary from 0 – 30% for *Mycobacteria bovis* (Kazwala et al, 1998; 2001a; 2001b; Muriuki et al 1997; Koech, 2000; Minja, 1998) and 0 – 20% for *Brucella arbortus* (Mahlu and Hamond, 1962; Msanga et al, 1986; Ndarathi et al, 1991, Swai, 1997).

In this context, Africa governments need to develop the capacity for disease surveillance by extending this task beyond epidemic diseases such as CBPP, Rinderpest, FMD and include control measures for classical zoonoses (Brucellosis and Tuberculosis) which are prevalent in the region. This will promote food safety and help build trust and confidence in regionally traded dairy foods.

With regard to milk and dairy products, the three East African countries have established national standards and are in the process of rationalizing them within their borders and harmonizing at the EAC regional level in order to promote rather than hinder intraregional trade. Dairy industry stakeholders in COMESA member states are also working towards harmonizing dairy standards in order to promote trade (ECAPAPA/EAC/COMESA, 2004). The EAC/COMESA meeting of dairy industry stakeholder recommended that:

- "Standards for all dairy products being produced in the region need to be developed irrespective of whether one or only two countries are the only ones producing such products" and that
- "for commodities where quality standards are in place across the countries, there is need to harmonize them in order to address the divergences observed in the study".

Harmonized draft standards have been formulated by a technical committee of Bureaus of Standards for Kenya, Tanzania and Uganda under the auspices of the East African Community Secretariat and circulated to national technical committees for discussion and eventual approval. They are identical to international standards published by the International Standards Organization (ISO). In effect the harmonized standards will mirror or become the national standards of each member state as well.

Table 4 shows the list of milk and dairy product standards, which have been published by the East African community. They are not comparable to European standards (Table 5). Noteworthy is the standard for raw milk which takes into account the fact that most of the milk produced in East Africa is handled under a partial cold or non-cold chain milk collection system in a warm (20-25 °C) to hot (26 – 33 °C) environment.

Table 4: East African Community product standards for milk and dairy products (2005)

<table>
<tr><th>S/N</th><th>EAC Africa Standard code</th><th>Title</th><th>Main features</th></tr>
<tr><td rowspan="3">1.</td><td rowspan="3">EAS 67:2000</td><td rowspan="3">Specification for unprocessed whole milk</td><td>Gives composition requirements in terms of percent fat (3.3%) and solids not fat (8.5%); s.gr. 1.026 -1.032 g/ml and bacteriological specifications:</td></tr>
<tr><td>Total Plate Count Coliforms</td></tr>
<tr><td>
<table>
<tr><th>Grade</th><th>CFU/ml</th></tr>
<tr><td>Very good</td><td>0-1000,000</td></tr>
<tr><td>Good</td><td>1000,00-2,000,000</td></tr>
<tr><td>Bad</td><td>2,000,000-5,000,000</td></tr>
<tr><td>Very bad</td><td>>5,000,000</td></tr>
</table>
<table>
<tr><th>Grade</th><th>CFU/ml</th></tr>
<tr><td>Very good</td><td>0-1000</td></tr>
<tr><td>Good</td><td>1000-50,000</td></tr>
<tr><td>Bad</td><td>50,000-500,000</td></tr>
<tr><td>Very bad</td><td>>500,000</td></tr>
</table>
</td></tr>
<tr><td>2.</td><td>EAS 70:2000</td><td>Specification for pasteurized milk</td><td>Defines the holder (65 °C, 30 min) and H.T.S.T. methods of milk pasteurization (72 °C, 15 s) and properties such as freezing point -0.525<-0.545 °C; fat content (whole (3.3%; fat reduced (2.2.5%; low fat <2.25%) and a total plate count of not more than 30,000 CFU/ml and absence of fecal coliforms.</td></tr>
<tr><td>3.</td><td>EAS 27:2000 (ICS 67.100)</td><td>UHT - specification</td><td>Defines UHT milk, gives specifications for pH, and titratable acidity variations following 5 days incubation at 55 °C as 0.3 and 0.02% respectively. Total viable bacterial counts max. 30/ml.</td></tr>
<tr><td>4</td><td>EAS 33-1:200</td><td>Yoghurt and sweetened yoghurt - Specification</td><td>Specifies three basic types of yoghurt; Yoghurt (Min. 3% butter fat); Partially skimmed (>0.5% butter fat in multiples of 0.5%) and skimmed yoghurt (0.5% butterfat) all of which may be sweetened with a carbohydrate sugar only and be fermented by typical yoghurt cultures which must be viable and abundant with no other food additives.</td></tr>
<tr><td>5.</td><td>EAS 22:2000 (ICS 67.100)</td><td>Butter and whey-specifications</td><td>Defines butter and gives minimum composition of fat content: 80%m/m; SNF content: maximum 2% m/m; maximum water content 16% m/m.</td></tr>
<tr><td>6.</td><td>EAS 49: 2000</td><td>Specifications for dried whole milk and skimmed milk powder</td><td>Gives requirements for milk powder with respect to eleven parameters and methods for their testing (moisture, total milk solids, fat, titratable acidity, minimum solubility values for roller an spray dried powders, bacterial count, coliform count; pathogenic organisms yeasts and moulds and presence of burnt particles.</td></tr>
<tr><td>7.</td><td>EAS 70:2000 (ICS 67-100)</td><td>Dairy milk ices and dairy ice cream - specifications</td><td>Defines milk ices and dairy ice cream- and minimum fat (3 and 10%) and SNF (8 and 13%) as well as added sugar (13% for both).</td></tr>
<tr><td>8.</td><td>EAS 87: 2000 ICS 67-100)</td><td>Condensed milk-specifications</td><td>Defines full cream and skimmed milk condensed milk and specifies total solids, fat and sucrose content as well as maximum titratable acidity.</td></tr>
</table>

Table 5: Some European standards for milk and milk products (1996)

Product	Plate count (CFU/ml)
Raw milk	<100 000
Raw milk stored in silo at the dairy for more than 36 hours	<200 000
Pasteurized milk	<30 000
Pasteurized milk after incubation for 5 days at 8 oC	<100 000
UHT and sterilized milk after incubation for 15 days at 30 oC	<10

However, in view of the high incidences of mastitis (40-60%) among smallholder and commercial dairy herds (Hamir et al, 1978; Machangu and Muyungu, 1988; Msanga et al, 1989; Shekimweri et al, 1998; Shem et al 2001), concerns have been raised on the need to include standard for somatic cell counts in raw milk. In most countries a cut off point of less than bulk somatic cell count (BSCC) of not more than 300,000 somatic cells/ml has been adopted.

Presence of drug residues in milk above permitted maximum residue limits (MRLs) is also a common problem in East Africa. Some recent work done in Kenya (Ombui, 1994; Shitandi and Sternesjo, 2004a; Shitandi and Sternesjo, 2004b; Shitandi, 2004; Kang'ethe, 2004) have shown the presence of antimicrobial drug residues in 9-16% of marketed milk samples. Higher frequencies (33%) of milk in informal market channels that contain drug residues above MRLs have been reported in Tanzania (Kurwijila et al, 2005).

The presence of antimicrobial drug residues in milk above allowable limits is a serious food safety risk as it may lead to allergies (Oslon & Sanders, 1975; Lee et al., 2000), or drug resistance (Nijsten, et al, 1996) in individuals who may be inadvertently exposed to intakes of such drugs over unspecified prolonged periods of time. The basis for the international regulatory standards (FAO, 1995), which are based on Acceptable Daily Intake (ADI) throughout one's life and a safety factor applied to the no observable effect level (NOEL), have been summarized by Anadon and Martinez-Larranaga (1999). Drug residues also alter the processing qualities of raw milk by inhibiting starter cultures used in preparation of cheese and other fermented dairy products (Katla et al., 2001; Broome et al 2002).

While upper limits for pesticide residues are specified in national standards (COMESA/EAC, 2004), harmonized standards for pesticide and veterinary drug residues is another issue which has to be accommodated in a revised standards for raw milk now under discussion.

In addition to the products specifications, the EAC has also developed and published eight standards for testing and analysis:

- Milk and milk products – sampling – inspection by variable (EAS 165:2000 – ICS 67.100.01)
- Methods of microbiological examination for milk and milk products covering Total plate count, Coliform count, Yeast and moulds and swab tests (EAS 68:2000 – ICS 67.100.10)
- Methods for chemical analysis of butter (EAS 80:2000- ICS 67.100)
- Methods for analysis of milk powders including determination of total solids, fat content (reference method), total nitrogen (by Kjeldahl method), ash, alkalinity, titratable acidity and determination of solubility index (EAS 81:2000 – ICS 67.100)
- Milk and dried milk, buttermilk and butter milk powder, whey and whey powder- Determination of phosphatase activity (EAS 160:2000 – ICS 100.100).
- Milk and milk products - Determination of total solids content – Reference method (EAS 162:2000 – ICS 67.100.10).
- Determination of fat content (Routine method). Describes the determination of fat in milk by the Gerber method for whole milk and partially skimmed milk (EAS 164:2000 – ICS 67.100.10)
- Milk-determination of freezing point- Thermistor cryoscope method (EAST 163: 2000 – ICS 67:100.10).

Other standards under preparation include adaptation of Codex standards for specific cheeses as well as standards for blends of vegetable fat and skimmed milk, evaporated milk or sweetened condensed milk. It is expected that the adoption of these common standards will foster cross-border trade in processed dairy products.

5.5. Improving quality and food safety in the informal sector

In view of the predominance of the informal sectors in the African dairy industry, dairy regulatory authorities have agreed on the need to promote hygiene and food safety through training and certification of producers, traders and small scale processors (ECAPAPA/ILRI, 2006). Through a consultative process facilitated by ECAPAPA and ILRI, minimum competencies for each informal market role players has been defined (Fig 1) and on the basis of these criteria training curricular have been developed and approved for use in Kenya, Tanzania, Uganda and Rwanda.

Minimum areas of competencies required	Dairy chain operative					
	1.Farmers/ milkers/ farm level workers	2. Farmer groups/Coops/ milk collection center operator	3. Hawkers or milk vendors	4. Milk transporters	5. Milk bar operators	6. Small scale milk processors
1. Hygienic milk production	√	√	√	√	√	√
2. Hygienic milk handling (GHPs)	√	√	√	√	√	√
3. Procedures for carrying out basic milk quality tests	√	√	√	√	√	√
4. Hygienic milk storage, preservation and transportation		√	√	√	√	√
5. Maintenance of milk handling and cooling equipment		√	√	√	√	√
6. Dairy effluent management systems						√
7. Code of hygienic practice						√
8. Hygienic processing of specific dairy products (according to need)						√

Figure 1.

5.6. Generic training guides

Based on the above areas of competence, six guides were developed by each national resource person. These were then synthesized by the Regional Resource persons (RRP) into six generic training guides as follows:

Module 1: Hygienic milk production (for farm level workers)
Module 2: Hygienic milk collection and testing (for milk collection/cooling centre operators)
Module 3: Hygienic milk handling and transportation (for milk transporters)
Module 4: Hygienic milk trading (for small-scale milk traders)
Module 5: Hygienic small scale milk processing (for small-scale processors)
Module 6: Fundamentals of marketing and dairy business management (for all dairy chain operators)

The above modules have been approved by dairy regulatory authorities for certification of informal milk traders who successfully undertake the prescribed training and follow the approved code of hygienic practices. They may be adapted to each country's specific situation and circumstances. They are designed to ensure that dairy chain operatives have the minimum competences required to undertake hygienic milk handling and marketing while guaranteeing quality and safety.

In line with current legislation in respective countries, the dairy regulatory authorities are empowered to register and licence dairy industry stakeholders operating in the formal sector.

At the same time quality improvement in the dairy value chain is also a primary responsibility of the regulatory authorities, which include the Dairy Boards, and Government Ministry responsible for Livestock development. Hence, in order to improve and nurture the transformation of the informal value chain operators, licensing and registration should be accompanied by training and certification of the various cadres. The provision of this service should not be confined to public sector dairy training institutions alone. To be more sustainable and reach as many people as possible, the involvement of private Business development service providers (BDS) would be worthwhile. Their involvement could involve training of trainers courses where competence to provide such services is lacking followed by accreditation by regulatory bodies i.e. the national Dairy Boards/Development Authorities.

Business development service providers accredited by national dairy regulatory authorities are expected to offer the required training at a normative fee. Trained informal milk traders will be certified jointly by the BDS and the national dairy Boards/Authorities. Certified informal market role players will qualify for licensing and /or registration as milk handlers, traders and/or processors.

The milk quality assurance scheme to be facilitated by the regulatory authority through privately provided business services would involve the following:

The BDS provider:

- Provides training and other services to milk traders on milk safety and quality control and hygienic handling
- Issues certificates of competence to trained traders
- Reports his/her activities to the regulatory authority

The milk traders:

- Pays cess fee to the regulatory authority upon showing a certificate of competence
- Conducts his/her business within norms accepted and approved by regulatory authority

The regulatory authority:

- Accredits BDS providers based on agreed minimum standards of competence for trainers
- Issues licences to trained traders based on the evidence of a certificate of competence
- Monitors compliance of accredited BDS providers to approved trainers competence level
- Monitors compliance of certified milk traders to approved minimum standards for milk handling. Fig 2 shows the proposed arrangements

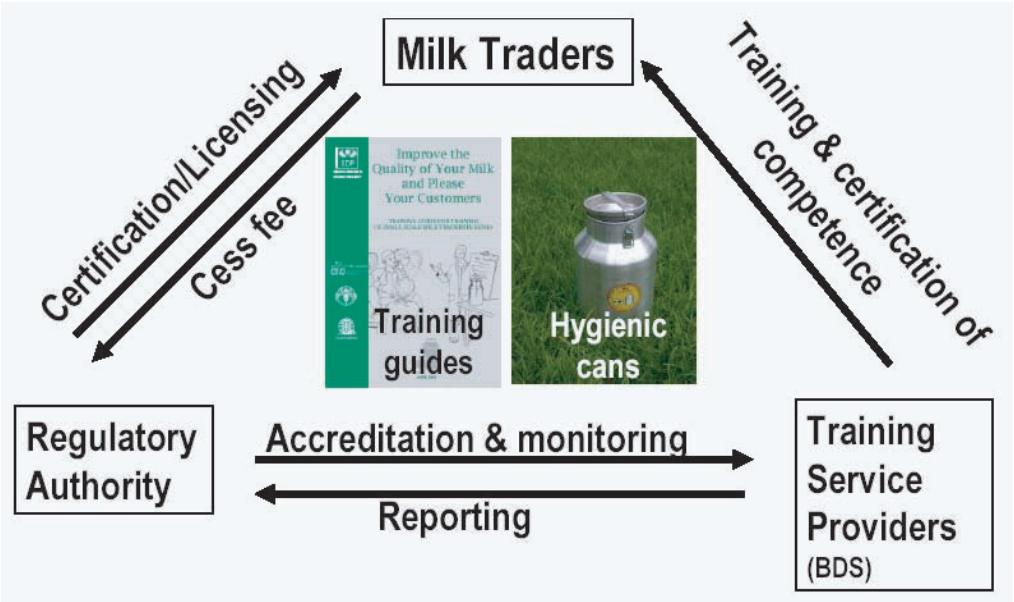

Figure 2. The proposed arrangements for the milk quality assurance scheme

5.7. Conclusions

The East African Customs Union provides an opportunity for integration of the dairy industry of the partner states.

The standards bureaus have made considerable progress in rationalizing and harmonizing standards aimed at promoting intra regional trade.

Zoosanitary concerns remain an obstacle to intraregional trade in live animals as well as dairy commodities.

In view of the predominance of the informal dairy markets, training and certifications in the dairy value chain is necessary for improving the general level of hygienic standards, which is key to establishment of equivalence in milk and dairy products quality and safety across the three countries.

References

1. Anadon and Martinez- Larrnaga.1999. Residues of antimicrobial drugs and feed additives in Animal products. Regulatory Aspects. Livestock Prod. Sci. 59: 183-198.
2. BalikowaD. 2003. Towards a modern, self-sufficient and sustainable dairy industry in Uganda. ACP–EU Technical Training Workshop and Launch of Milk and Dairy StakeholderAssociation for Eastern Africa. Arusha, Tanzania, 23 to 27 June, 2003
3. Broome, C. B. Powell and Limsowtin. 2002. Starter cultures: Specific properties. In Encyclopaedia of dairy Science. Vol. 1. Academic Press. London, 269 -275
4. COMESA/ASRECA, 2004 . Regional Dairy policy paper. Proceedings of Workshop held in Nairobi, September 2004. (also available www.dairyafrica.com.)
5. East African Community. 2005. East African Standard: Butter and wehy butter -Specification. EAS 22:2000 – ICS 67.100 1st Ed. 2005
6. East African Community. 2005. East African Standard: Condensed milk – specification. EAS 58:2000 – ICS 67.100. 1st Ed. 2005
7. East African Community. 2005. East African Standard: Dairy milk ices and ice cream-specification. EAS 70:2000 – ICS 67.100 1st Ed. 2005
8. East African Community. 2005. East African Standard: Methods for the analysis of milk powders. EAS 81:2000 – ICS 67.100.10. 1st Ed. 2005
9. East African Community. 2005. East African Standard: Methods for the chemical analysis of butter. EAS 81:2000 – ICS 67.100. 1st Ed. 2005
10. East African Community. 2005. East African Standard: Methods of microbiological examination for milk for the chemical analysis of butter. EAS 81:2000 – ICS 67.100. 1st Ed. 2005
11. East African Community. 2005. East African Standard: Milk – Determination of fat content (routine Method. EAS 164:2000 – ICS 67.100.10. 1st Ed. 2005
12. East African Community. 2005. East African Standard: Milk – Determination of fat content (routine Method. EAS 164:2000 – ICS 67.100.10. 1st Ed. 2005
13. East African Community. 2005. East African Standard: Milk and dried milk, butter milk and butter milk powder, whey and whey powder- – Determination of phosphatase activity. EAS 160:2000 – ICS 67.100.10. 1st Ed. 2005
14. East African Community. 2005. East African Standard: Milk and milk products- sampling-Inspection by variables. EAS 165:2000 – ICS 67.100.01. 1st Ed. 2005
15. East African Community. 2005. East African Standard: Milk and milk products– Determination of total solids content- Reference method. EAS 162:2000 – ICS 67.100.10. 1st Ed. 2005
16. East African Community. 2005. East African Standard: Specification for unprocessed whole milk. EAS 69:2000 – ICS 67.100 1st Ed. 2005
17. East African Community. 2005. East African Standard: Specification for pasteurised milk. EAS 69:2000 – ICS 67.100 1st Ed. 2005

18. East African Community. 2005. East African Standard: Specification for dried whole milk and skimmed milk powder. EAS 49:2000 – ICS 67.100, 1st Ed. 2005.
19. East African Community. 2005. East African Standard: UHT – Specification. EAS 27:2000 – ICS 67.100 1st Ed. 2005
20. East African Community. 2005. East African Standard: Yoghurt and sweetened yoghurt - Specification. EAS 33-1::2000 – ICS 67.100, 1st Ed. 2005
21. ECAPAPA/ILRI, 2006. Development of Training and Certification Programme for Informal milk Traders in East Africa: Process, achievements and lessons learnt. Report on Rationalisation and Harmonisation of Policies and Standards in Dairy Industry in Eastern Africa Phase II: Training and Certification of Informal Milk Traders.(unpublished)
22. FAO (Food and Agriculture Organisation) /WHO (World Health Organisation). 1995. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Expert consultation. Geneva, Switzerland March 1995. WHO/FNU/FOS/95.3. 38pp.
23. Hamir, A.N., W. Gehring and S.I Muhamed. 1978. The incidence of bovine mastitis in Kenya. Bulletin of Animal Health and Production in Africa. 26:54-61
24. Kagumba, m. and Nandoka, E. (1978). Survey of the prevalence of bovinebrucellosis in East Africa. Bull. Anim.Hlth.pro. Afr. 26 224-229
25. Kang'ethe, E. K., G. O. Aboge, S. M. Arimi, L.W. Kanja; A. O. Omore and J. J. McDermott. 2005. Investigation of risk of consuming marketed milk with antimicrobial residues in Kenya. Food Control, 16 (4): 349-355
26. Kasirye, F.N.M. (2003). Post Harvest Milk Losses in the Small Scale Dairy Sector – Uganda: A Rapid Appraisal . FAO Report on Milk and Dairy Products, Post-harvest Losses and Food Safety in Sub-Saharan Africa and the Near East (unpublished).
27. Katla, A-K, H. Kruse, G. Johnsen and H. Herikstad. 2001. Short communication: Antimicrobial susceptibility of starter culture bacteria used in Norwegian dairy products. International Journal of Food Microbiology. Vol. 67(1-2);147-152.
28. Kazwala, R. R, Daborn, C. J., Sharp, J. M., Kambarage, D. M.; Jiwa, S. F; Mbembati, N. A.; 2001b. Isolation of Mycobacterium bovis from human cases of cervical adenitis in Tanzania: a cause for concern? Intern. J. Tuber. Lung Dis. 5, 87-91.
29. Kazwala, R. R, Kambarage, D. M., Daborn, C. J., Nyange, J, Jiwa, S. F., Sharp, J M.; 2001a. Risk factors associated with the occurrence of bovine tuberculosis in cattle in the Southern Highlands of Tanzania. Vet. Res. Comm. 25: 609-614.
30. Kazwala, R.R., Daborn, C.J., Kusiluka, L.J.M., Jiwa, S.F.H., Sharp, J.M and Kambarage, D.M. 1998. Isolation of Mycobacterium species from raw milk of patoral cattle of the Southern Highlands of Tanzania. Trop. Anim. Hlth and Prod. 30: 233-239.
31. Kazwala, R.R., Daborn, C.J., Kusiluka, L.J.M., Jiwa, S.F.H., Sharp, J.M and Kambarage, D.M. 1998. Isolation of Mycobacterium species from raw milk of patoral cattle of the Southern Highlands of Tanzania. Trop. Anim. Hlth and Prod. 30: 233-239.
32. Koech, R.K.; 2000. Epidemiology of tuberculosis in humans in Narok District with special interest on Mycobacterium bovis. MSc. Thesis, University of Nairobi.
33. Kurwijila,L.R. T. Lore and A .Omore,.2005. Technologies for enhancing the value, quality and safety of milk produced by smallholder farmers in Africa. paper presented at fourth all Africa conference, Arusha, Tanzania (in press)
34. Lee M.H., Lee H.J. and Ryo, P.D. 2000. Public Health risks: Chemical and Antibiotic Residues-Review: Asian-Australian J. Animal Science 14 (3): 402 – 413.
35. Machangu, R..S. and L. Muyungu, 1988. Occurannce of Streptococcocal mastitis in dairy farms in Morogoro Area, Tanzania. Bull. Anim. Health and Production
36. Mahlau, E.A. and Hammond, J.A. (1962) A Brucellosis survey of the Western areas of Tanganyika: Bulletin of Epizootic Diseases of Africa, 10: 511-516.

37. Minja, M. G.; (1998). Occurrence and survival of Mycobacterium species in fermented milk from traditional cattle herds: A case study of Usangu Plains, Southern Highlands, Tanzania. M.Sc. Thesis. University of Agriculture, Sokoine. 91pp.
38. Msanga, J.F., R. Tungaraza, L. M. U Olumu and A. Muhairwa. 1989. Bovine mastitis bacterial isolates from sub-clinical and clinical mastitis in the Lake zone of Tanzania. Tanzania Vwterinary Bull. 9 (1): 13 -17.
39. Msanga, J.F.; Mukanga, D.J.A. and Tungaraza, R. (1986) Bovine brucellosis in the lake zone of Tanzania: the present situation. Bulletin of Animal Health and Production in Africa, 34(4): 230-234.
40. Muriuki, S. M., McDermott, J. J., Arimi, S. M., Mugambi, J. T. and Wamola, I. A.; 1997. Criteria for better detection of brucellosis in the Narok District of Kenya. East Africa Med. J. 74, 317 – 320.
41. Ndarathi, C.M. and Waghela, S. (1991) Brucellosis in Maasai livestock in Kajiado district in Kenya. Indian Journal of Animal Sciences, 61: 156-157.
42. Nijsten R., London N, Van de Bogaard & Stobberingh (1996). Antibiotic resistance among Escherachia coli isolated from faecal samples of pig farmer and pig. *Journal of Antimicrobial Chemotherapy*, 37, 1131-1140.
43. Ombui, J. N. (1994). Antibiotic residues in milk received by dairy cooperatives societies in Kiambu district, Kenya. *East African Medical Journal*, 71, 628 – 630.
44. Oslon J. C. and Sanders A.C. (1975). Penicillin in milk and milk products: Some regulatory and Public Health Considerations. *Journal of Milk and Food Technology*, 38, 630-633.
45. Roundant, G and Moreitain 1990. Sulphonamide residues in milk of dairy cows, following intravenous injection. Food Additives and contaminants. 7: 522
46. Shekimweri, M.T., L.R. Kurwijila and F.O.K. Mgongo, 1998. Incidence, causative agent and strategy of control of mastitis among smallholder dairy herds in Morogoro, Tanzania. Tanzania J. Agric. Sci. 1(1): 28 -36
47. Shem, M.N., J.M.L. Malole, R.. Machangu, L.R. Kurwijila and T. Fujihara.2000. Incidence and causes of sub-clinical mastitis in dairy cows on smallholder and large scale farms in tropical areas of Tanzania. Asian-Aust. J. Anim. Sci. 2001 Vol. 14 (3): 372 – 377.
48. Shitandi , A. and G. Kihumbu. 2004. Assessment of the California mastitis test usage in smallholder dairy herds and risk of violative antimicrobial residues. J. Veterinary Science. 5(1): 5-9
49. Shitandi, A. and A. Sternesjö. 2004. Prevalence of multi-drug resistant Staphylococcus aureus in milk from large and small-scale producers in Kenya. Journal of Food Protection (Submitted)
50. Shitandi, A. and A. Sternesjö. 2004. Research note: factors contributing to the occurrence of Antimicrobial drug residues in Kenyan milk. J. Food Protection . Vol. 67(2):399-402
51. Swai E.M, (1997) Studies on the Prevalence of Bovine Brucellosis and reproductive performance in small scale dairy cattle herds in Dar-es-Salaam and Morogoro regions: MVM. Dissertation Sokoine University of Agriculture (Tanzania) pp 67.

6. The Safety Management of Dairy Industry in China

S. Zhang[1]

Abstract

Recently, the increase of safety awareness of consumers and the appearance of many regulations of food all over the world shows that food safety has become more important, and that producers and consumers will pay more attentions to this fact. Major hazards relevant to milk product processing and consumption include biological hazards, chemical hazards, raw materials of genetic modified organisms, allergens and foreign bodies. Along with the advance of sciences and technologies, and the continuous appearance of new materials and methods, these hazards almost had been actively controlled now in China.

Key words: safety, management, and dairy industry

6.1. Introduction

Recently, the increase of safety awareness of consumers and the appearance of many regulations of food worldwide, shows thatr food safety has become more important, and that producers and consumers will pay more attentions to this fact. Normally, dairy products have been regard as a best food that can provide better nutrition to the consumer. Our research results showed that the expectations of consumers for a quality dairy product could be shown as a pyramid (Fig. 1). We call it Quality Pyramid of Dairy Product.

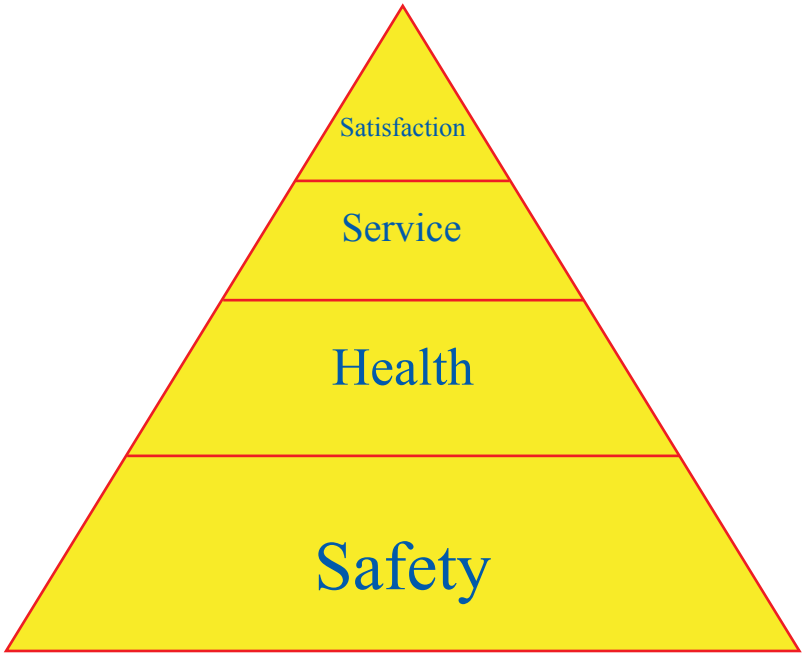

Figure 1. Quality Pyramid of Dairy Product

Based on this quality pyramid, a good dairy product, firstly must be safe, i.e. do not endanger health; also this is most important to consumer. The second requirement is the dairy product

[1] Shanghai Bright Dairy and Food Co., Ltd., 467, Wanrong Road, Shanghai, 200072, China

must be healthy, i.e. can provide appropriate nutrients to consumers to sustain that they stay healthy; the third requirement is a good service and lastly, that there will be satisfaction. The foundation of this pyramid is about the safety of products, which consequently is first to the dairy industry and most important to the consumers.

6.2. Sources and kinds of major hazards

What are the sources of the main hazards in the production of dairy products - from production to consumption - and what kind of hazards do we need to control? To answer these questions, we need to look at the whole processing chain of these dairy products. There are three sources of the major hazards in the processing and consumption of dairy products.

- Upstream: raw milk from farm, ingredients from supplier, packaging materials including gluewater and ink;
- On production sites: state of hygiene, microorganism in the processing environment, manufacturing conditions, equipment and operator, storage facilities;
- Downstream: chilled transports, storages, sales environments, and consumption methods;

Upstream contamination comes from the raw materials and ingredient supplies on the farm. The milking step and conditions for collection of the milk may vary tremendously from region to region in China. Usually, we collect from single farms for main cities such as Shanghai; each farm has about 3000-5000 cattle. In this way we can eliminate or control any adulteration such as the addition of water and other foreign materials to milk. Once the milk is collected you must be aware that the microorganisms grow very quickly and easily multiply and therefore you must put it in a cold environment before it is transported to the plant. At the plant, the milk is processed and finally distributed to the stores. The fresh milk is the raw material. The 100 percent fresh milk itself should have only milk as an ingredient. However, other materials such as the feed used for the cattle (i.e. bean products, potatoes, genetically-modified or transgenic products and packaging materials) may contaminate raw milk. We have to consider the feed and water and how they affect the cows. In packaging, many raise the question about the ink used on the packaging and whether or not it affects the milk. The material used in the packaging is also a consideration, zinc-coated containers for long-term storage, for instance. There is also the issue of internal source of contamination occurring in the storing and processing, transportation environment, and whether they can all meet the hygienic requirements. People are now paying attention also to the contamination caused by building materials, the construction of the plants and factories themselves. The levels of such indoor contamination must also be taken into consideration.

Downstream contamination from the cold storage step is another consideration. Transportation methods must, as well as storage and warehousing, be specifically designated for these types of foods. Salespersons need to understand the requirements of the cold chain because they are really in charge at point of sale. They must visit the supermarket frequently to be sure that the products are kept in the required conditions that control possible sources of contamination. First is chemical pollution through preservatives, second is biological, and certain type of antibiotics. In the industry this constitutes a threat to the production and most importantly if people are taking milk with antibiotics, microorganisms can develop antibiotic resistance.

According to the characteristics and sources, the above major hazards can be classified into four groups:

- Chemical: preservatives, chemical materials, dioxin;
- Biological: coliforms, pathogens, viruses;
- Allergens: antibiotics, medicaments, antibodies;
- Foreign bodies: non-food material.

On production sites, all the hazards can be controlled and are 100% traced in our company.

6.3. Methods for controlling hazards

As discussed above, there are many hazardous points in the manufacturing of dairy products. First of all, we need to identify the hazards and what levels they fall into, whether these are fatal

or can be controlled through normal means. And then we try to identify the source of the hazards and then how to control them. Now, we are talking about control rather than elimination because we can't do that for the moment. With the development of science and technology in the future I am sure that new methods will become available such as high-pressure treatment, and new heat treatment methods, that can eradicate micro-organisms, if residual levels are still present. I am sure that - in the future - there will be some perfect means, like ultra heat treatment. I am certain that this product will be found to contain no micro-organisms. We will reach such a target in the future. Whether it will bring along some other problems like residues of irradiation, for example, remains to be seen. New approaches might be effective but you will need to be continuously following up to see if these give rise to any contamination with the view of the utter elimination of any risk. So currently the consumers are increasing their awareness of food safety.

To control these hazards we have implemented the international standards ISO 9000 and complete HACCP-based QA system in our company. Certainly, people need to develop the HACCP and GMP (Good Manufacturing Process) system most frequently used in the pharmaceutical companies which is now needed in the dairy industry. Not all are using the GMP Principles throughout the production line, as yet. We are implementing parts of the GMP in certain parts of food processing and in packaging. With this tool we try to be close to the requirements of the GMP, to assure the quality of the production and manage the cost. Therefore, if we want to implement GMP throughout all the production lines, quality assurance systems assuring the quality of the production and total quality management systems available.

6.4. 100% Traceability

Besides all these approaches and based on government regulations and work experiences, we believe we have other ways to ensure 100 percent traceability. Several years ago, we started to maintaining records of all the samples in the farm, such as from every cow producing fresh milk, purchased feed, water, vaccination and medicine, and raw materials, ingredients, final products, CIP (acid, alkali and disinfectant). We mention this because there are sometimes problems which occur in the consumption of dairy products, but the hazards are certainly not from the farm or factory. For example, one incident in one school, all those who drank the milk suffered from some problems, yet it could be proven that the milk that left our factories and was provided to the students did not present any quality problem. The raw milk was reliable and the microorganisms and inspections were under control. When the school provides lunch to the students, we provide them with the specific instructions for milk distribution. The above incident occurred because the instructions were not followed. The school kept the milk under unchilled conditions for too long before it was consumed. There are now new practices governing the distribution of milk to students. The milk should not be prepared too early and left at unchilled temperature for a too long time. Therefore the traceability is not just our responsibility. Statistics, inspection results and clinical research are all needed to finally determine the traceability. But this is easier said than done. The food that the cow eats or drinks or the vaccine that is used for it for the ultimate production of milk are all factors. You have to look at all the samples to guarantee that there is 100 per cent traceability.

6.5. Maintaining full records

In order to guarantee the 100 per cent traceability, we need to look at this issue of a full record because the record will ultimately determine whether you have been proceeding according to accepted standards or whether it is acceptable to other parties, whether it satisfies the laws and the regulations from the whole process of manufacturing. This is not as simple as keeping a full record of different types of measures that include feeding, milking, treatment of cow, milk collection, processing, testing, transportation and sales road and area record, but we must keep a full record from milk collection to final consumption. As an example, overseas and in China we have been using the CIP (Cleaning in Place) before and after milk processing. The selection of CIP materials, which may be different in different factories, is very important for obtaining an adequate cleaning result; Likewise are all the conditions of the CIP procedures also are very

important, such as concentration of acid and alkali, temperature and time. So a full record is necessary; As it is not enough just keeping all materials, all the operation records must also be kept in order to prove that the product is safe. Now, CIP is not just in the factory, not just in the production line. At the same time as you collect milk you must look at the dairy manufacturing industry. The collection of milk is only one part. There has been such a trend that the whole system of collection of milk has to be subjected to CIP. Only through this can you guarantee 100 per cent safety.

6.6. Conclusion

Major hazards in the steps of consumption and processing of dairy products include biological hazards, chemical hazards, raw materials of genetic modified, allergens and foreign bodies. These hazards almost had been actively controlled in China. I feel that domestic food safety in China has become an increasingly important issue to all of us. News of this and other food related problems have increased food safety awareness and the Chinese development has resulted in the issuing of quite a number of important documents. So food safety is not just for the manufacturer to guarantee, consumer awareness is a very important driving force for ensuring food safety, and for more nutritious food. Currently we are talking about control rather than elimination of hazards because we can't do that for the moment. Along with the advance of sciences and technologies, and appearance of new materials and methods continuously, we believe that these hazards can be completely avoided in the future.

7. Food Chain Management in Australia

A. Astin[1]

Consumers globally are becoming far more discerning about their foods and supply chains. The interface between foods and medicines is narrowing as consumer demand for foods related to nutritional status, health and wellbeing grows. Expectations that all foods are safe and produced to the highest quality and safety standards are high.

Australia produces a wide variety of dairy products for domestic consumers as well as over 100 countries globally. The dairy industry is a major rural industry in Australia. Based on a farm gate value of production of $3.2 billion in 2004/05, it ranked third behind the beef and wheat industries – and the fourth most important in exports – valued at A$2.6 billion.

Australian dairy farmers operate in a completely deregulated environment; the only government involvement is in the administration of food standards and food safety assurance systems. Australia has developed a comprehensive system of food standards and a system to monitor industry compliance with these standards.

The current food safety operating environment is changing to respond to these changing consumer desires as well as to allow industry to develop innovative foods without compromising public health and safety. As well as general increases in consumerism, there are associated demands by governments for companies to improve standards in health, hygiene, food premises, food security, animal health and welfare, the environment and work safety.

Emerging public debate on issues such as genetically modified foods, food irradiation and health claims perpetuate perceptions and opinions about food safety.

In laboratories, improved analytical and more sophisticated detection techniques for identifying pathogens and chemical residues mean that dairy products and production systems are coming under greater scrutiny. The result is that food borne illnesses no longer have boundaries.

These economic, social and environmental factors are driving the need to change the approach to delivering effective food safety outcomes.

7.1. The food safety vision

The new vision for food safety is based on:

- Maximising public confidence and increasing public awareness about the safety of dairy products they consume. Australia enjoys one of the safest food supplies in the world and will continue to maintain its reputation through improved risk analysis and management and the transparency of its systems.
- Adopting international and national health risk management standards. The adoption of international Codex Alimentarius standards and the recent development of a national primary production and processing standard for milk and dairy products are ensuring Australia's products have to meet the same standards as those produced anywhere in the world.
- Maintaining and developing access to markets. The aim here is to satisfy customer expectations and market assurance needs in a cost effective way for the dairy industry.
- Adopting and implementing HACCP-based food safety programs. Food safety has become the non-negotiable component of industry quality assurance programs that have been or are being introduced through the whole dairy production chain and for all dairy products produced from cows as well as sheep, goat and buffalo milk.
- Industry ownership. The dairy industry is a vertically integrated industry and a "whole of chain" approach has developed as the means to deliver safe milk and dairy products. In this way, both the farm and manufacturing sectors have become dependent on each other to produce safe food.

[1] Dairy Food Safety Victoria, PO Box 548, Richmond Vic 3121, Australia, aastin@dairysafe.vic.gov.au

Historically, food safety has lived in the realms of government through prescriptive standards, inspection systems and end product testing programs.

In Australia, food safety is not the responsibility of a single organisation. All levels of government at federal, state and local levels and across health, agriculture and consumer affairs portfolios participate in food safety policy and standards development.

Policies are developed by a national Food Ministerial Council advised by Food Regulation and Implementation Committees. Standards are established independently by a bi-national organisation, Food Standards Australia New Zealand (FSANZ). Standards Development Committees and comprehensive public consultations as part of a legislated standards development process deliver food standards with a high level of credibility and integrity.

Food Standards Australia New Zealand is required to set food standards that:

- protect the health and safety of consumers
- ensure consumers are informed about the food they buy; and,
- prevent deceptive and misleading conduct.

Food measures should also support an innovative food industry and ensure consistency with international obligations.

Critical to this success is the partnership that has developed between government, the dairy industry and consumers. While government continues to play a critical role overseeing food safety and ultimately is accountable to consumers whether in Australia or overseas, the dairy industry has increasingly taken responsibility for food safety outcomes.

Industry and consumers work together to establish and respond to market trends. Consumers wish to make informed choices about the foods they consume and industry innovates to produce products that are appealing and safe. Government and industry work together in a co-regulatory environment and through the sharing of information for good risk analysis. Government and industry also collaborate in the management of food safety issue and crisis management. Consumer advocacy and education are important partnering activities between government and consumers. The success of this model is the result of effective communication, consultation and an openness and transparency between all parties.

There is a second strategic partnership that is critical to Australia's food safety framework. This is the partnership that exists between the various government organisations with responsibility for food safety outcomes. The Ministerial Council and Food Standards Australia New Zealand are two key federal organisations in the policy and standards setting framework. Other agencies include State, Territory and Local Governments who are responsible for enforcing the standards and the Australian Quarantine and Inspection Service (AQIS),which has responsibility for export certification to overseas markets. Australia has been working towards the harmonisation of domestic and export standards for nearly five years and the partnership between agencies in making this a reality is now being realised.

7.2. The dairy food safety system

Australia's dairy food safety system is based on 3 factors:

- Development, validation and approval of dairy food safety programs consistent with national and international standards;
- Verification of these programs along the whole production and processing chain; and
- Business licensing or accreditation based on performance against the food safety program.

Underpinning the system are industry and government support programs, some of which are regulated while others are industry driven.

The key to the dairy food safety system in Australia is that all milk and dairy products are required to meet standards established by government whether they are destined for domestic or export consumption. These standards are based on sound scientific risk assessment principles and data. The system then provides for flexible and sustainable risk management systems to meet the standards in a way that is specific to each business and is cost effective.

7.3. Food safety programs

All Australian dairy food safety programs are based on the international standards established by Codex Alimentarius. While all food safety programs are based on sound risk assessment and management principles, there is also an emphasis on their practical application. Industry quality assurance programs have been recognised as covering both food safety and quality elements.

On-farm dairy food quality assurance programs cover the same essential elements. These elements were agreed between the dairy industry and government several years ago. The core food safety elements of the programs are:

- The management of physical, chemical and microbiological contaminants,
- Standards in dairy milking premises,
- Standards of hygienic milking practices,
- Water supply and quality,
- Cleaning and sanitising procedures,
- Traceability and record maintenance, and
- The competency of staff who are responsible for milking and the operation of the food safety program on the farm.

In manufacturing and processing establishments, the core elements comprise:

- Pathogen reduction technologies including pasteurisation
- Temperature control
- Processing
- Cleaning and sanitising
- Storage
- Traceability
- Post-pasteurisation hazard management, and
- Post-pasteurisation of raw ingredients and ingredient management.

Food safety programs have integrity because they are underpinned by legislation.

The recognition of the whole chain approach to food safety and an increased understanding of the scientific approach to hazard identification and risk management in the dairy chain have led to the establishment of an outcomes-based system that is flexible for industry and acceptable to consumers.

7.4. Validation of food safety programs

Validation of food safety programs in the dairy industry is undertaken by industry and government to ensure all relevant hazards are identified and can be effectively controlled. It questions and obtains evidence that the elements of the HACCP-based plan are effective. Validation occurs during the development stage, but does need to be repeated and formally reviewed should there be any change in the product or process.

This is a particularly robust process but it is important that government can be satisfied that a proper food safety system is in place and that a dairy company is taking responsibility for its operations.

Industry has accepted these programs as part of good business practice and sees benefits beyond food safety along the whole chain. The validation of food safety programs has resulted in major culture change within the various sectors of the industry. With a more flexible approach to the way in which businesses can achieve food safety standards, these systems can respond more quickly to future emerging complexities in on-farm operations and innovative processing technologies, emerging pathogens, increasing competition for resources and consumer desires for greater choices in convenience foods.

7.5. Verification of food safety programs

Verification of food safety programs is the second element of the system. It is undertaken to ensure that control measures are working.

Increasingly, verification is achieved through regular auditing by companies, regulatory authorities or other third parties such as suppliers and customers.

Companies conduct audits at a frequency determined in the documented business plan. Company staff usually performs these through monitoring and record keeping in an internal verification process.

Regulatory authorities conduct audits to verify that establishments are operating food safety programs satisfactorily. This ensures that:

- Monitoring records are up to date and correct
- Corrective actions are taken in a timely manner and resolved
- Calibration criteria are met
- Testing results are available and within specification
- Changes to systems, procedures, and processes are actioned appropriately.

Auditing is conducted by qualified, competent and accredited auditors directly employed by government or increasingly by auditors approved by the regulatory authority who operate under contract. Where this latter system is operating, regulatory authorities randomly check the contract audit system.

The audit system is again supported by a regulatory system operating in all Australian States and Territories. It is supported by legislative powers designed to protect public health. The scope of the audits is extensive with a focus on the food safety system, including audit standards and auditor competencies and skills rather than traditional inspection.

7.6. Monitoring and surveillance

Monitoring and surveillance of milk and dairy products support verification. Companies undertake individual testing programs and nationally, the Australian Milk Residue Analysis (AMRA) survey provides an independent and credible monitoring tool to assist in the management of agricultural and veterinary chemical use.

AMRA is a government operated chemical residue monitoring program. Dairy Food Safety Victoria co-ordinates and manages this survey for the whole of Australia. The survey has been in operation since the mid to late 1990s.

Milk samples are taken from bulk farm pick-up tankers and tested at government approved laboratories. Laboratories must be accredited to international standards.

If any sample tested exceeds 50% of the maximum residue level, or at any level for antibiotics and aflatoxins, a full investigation is undertaken by government. Increasingly, any detection of a residue is being investigated. Any dairy products produced from the affected milk at the factory are identified - this is known as trace forward - and there is also trace back to the farm.

When the cause is identified, corrective action must be taken and additional testing may be required to ensure that the action taken is effective.

The survey is designed annually. Using a risk based approach, the chemicals selected for analysis are based on chemical use patterns in Australian dairy production or those that are of interest to trading partners. The survey is regularly reviewed by trading partners such as the European Union.

The results show consistently that milk produced in Australia meets the domestic food standard requirements as well as those of all overseas trading partners. It also provides assurance to health authorities that the dairy food safety system has integrity.

7.7. Compliance and enforcement of food safety programs

The third and final element of the dairy food safety scheme is the licensing or accreditation systems that operate in the Australian dairy industry. A dairy licence is a passport to operate in

the industry and demonstrates that holders of licences are aiming to achieve the best in food safety standards. It ensures only properly licensed individuals or organisations are allowed to produce milk or be involved in transport, processing or distribution of milk and dairy products.

The licence offers identity and legitimacy, inhibits unregulated entry to the industry and provides industry protection and security – so important in maintaining industry reputation. The dairy licence is also the link to export certification, which is so crucial not only in providing market access but also in safeguarding that access.

7.8. Support programs

These include a national registration system for agricultural and veterinary chemicals, vendor declaration systems for stockfeed quality and livestock identification, guidelines for the prevention and management of pathogens, particularly *Salmonella spp* and *Listeria monocytogenes* and industry wide surveillance and testing programs.

The national registration system for agricultural and veterinary chemicals is operated by the Australian Pesticides and Veterinary Medicines Authority. This government authority is responsible for the assessment and registration of all agricultural and veterinary chemicals available for sale in Australia. Only chemicals that have been approved by this authority can be used on dairy cows. This government regulated registration system provides confidence that there is an appropriate and independent control system over all chemicals used in the dairy industry.

An industry initiative has developed where milk suppliers must obtain vendor declarations for stockfeed. The vendor declaration provides assurance of the acceptable residue status of the animal feed. The peak stockfeed industry association in Australia has introduced an independently audited HACCP-based, quality assurance program for producers of stockfeed as a condition of membership.

Vendor declaration systems are operating for animal health and residue status and are underpinned by the National Livestock Identification Scheme. This scheme covers both dairy and beef cattle. It provides traceability back to the farm and enhances the integrity of food safety systems generally.

7.9. Conclusion

The whole chain, systems-based approach developed in the Australian dairy industry is delivering significant benefits.

The approach is producing cultural change in the acceptance and approach to food safety management in all sectors involved in the dairy industry with new relationships between government, industry and consumers being established. Industry is accepting greater responsibility for the production of safe food, government is recognising industry programs and consumers perceive industry as a reputable provider of safe and reliable dairy products.

There is increased information exchange between industry and government. The results of this are only starting to emerge, but there is a greater capacity to draw on data that can be converted to knowledge for the benefit of industry and consumers. In future, there will be a shift from being "data-rich and knowledge poor" to being "data-rich and knowledge-rich".

The integrated systems approach offers enormous benefits for future production and processing innovation, the management of emerging food safety risks in dairy and the increasing demands placed on the industry in managing animal health and welfare and environmental regulation.

International trade in food or agricultural products rarely occurs in a truly free market context. Australian goods often compete in markets that are protected or controlled through quotas or tariffs. Issues of food safety and looking to the future, animal health and welfare and environmental sustainability could continue to be associated with an importing country's broader trading policies.

Australia's dairy industry understands that every link in the industry chain must be world class or barriers will be imposed to restrict it from competing in both domestic and export markets.

8. Predictive Microbiology

M. Tamplin[1]

8.1. Introduction

Anticipating the behavior of microbial pathogens in food is an important goal of food safety managers. In this regard, the scientific field of predictive microbiology offers important tools to food safety managers to estimate the consequences of food handling and processing operations on growth, survival and inactivation of foodborne pathogens.

Successful development and implementation of predictive models involves a series of steps that include experimental design, model development, model validation and production of an effective interface between the model and end-user. The net result is a tool that can be used in HACCP plans to define critical control points and critical limits, as well as to determine safe corrective actions when processing deviations occur.

8.2. Phases of Bacterial Growth

The level of bacteria in food is controlled by various factors, including the initial contamination level, the level of nutrients, temperature, pH, water activity, additives, and the presence of other microorganisms. Bacteria can increase in numbers (grow), decrease in numbers (inactivate or die) or remain at the same level (survive). Predictive models can be developed for each of these types of bacterial behavior.

A survey of the literature reveals that many models have been developed for microbial growth compared to inactivation or survival. Also, there are many more models for bacteria in defined microbiological media, such as broth, than for real food. In the majority of cases, microbial growth can be segmented into three different phases: lag phase, growth phase and stationary phase.

8.2.1. Lag Phase (Lag Phase Duration)

Lag Phase can be defined as the amount of time required for a cell to adjust to a new environment prior to replication (growth). Lag Phase is the most unpredictable part of a growth curve compared to Growth and Stationary phases. This is because Lag Phase will be different depending on the previous "history" of the microorganism. For example, the Lag Phase Duration (LPD) of bacteria grown at 37°C (98°F) in culture media and then transferred to raw ground beef at 10°C (50°F) will be different than the LPD of bacteria grown at 21.1°C (70°F) and then transferred to ground beef at 10°C (50ºF). This is because the previous environment of the bacteria will result in different cellular changes that need to be made before the organism can grow in a new environment.

The LPD represents a distribution of lag times for individual cells within the microbial population. As you notice in most growth curves, this produces a curve between the Lag Phase and Growth Phase. Consequently, a portion of this curve is included in the calculated Lag Phase and a portion is included in the Growth Phase.

8.2.2. Growth Phase

The Growth Phase represents the replication (multiplication) of microorganisms. Growth is sometimes described in terms of Growth Rate or Generation (Doubling) Time. The Generation Time is the time (usually stated in hours or days) that it takes for one cell to divide and become two cells. To convert this to Growth Rate, simply divide 0.301 (the $\log_{10}$ value of 2) by the Generation Time. On the other hand, Growth Rate is the change in bacterial numbers over

[1] Director, Australian Food Safety Centre of Excellence, School of Agricultural Science/Tasmanian Institute of Agricultural Research, University of Tasmania, Private Bag 54, 7001 Hobart Tas, Australia, Mark.Tamplin@utas.edu.au

some period of time, typically expressed as $\log_{10}$ per hour or day. To convert Growth Rate to Generation (Doubling) Time, divide 0.301 by the Growth Rate.

For plotting growth data, we typically convert cell numbers to the $\log_{10}$ value and plot this as a function of time. This produces a plot showing a linear growth phase.

8.2.3. Stationary Phase and Maximum Population Density

The terms Stationary Phase and Maximum Population Density (MPD) refer to the maximum (highest) level that bacteria reach in the food. This level can be affected by the presence of other bacteria, such as food spoilage organisms, limiting nutrients, and/or the production of inhibitory factors. In most foods, a typical MPD is 9-10 $\log_{10}$ (1 billion to 10 billion cells per gram or milliliter of food).

8.2.4. Death Phase

Although not always observed, bacteria can die in a food after an extended storage time. This normally occurs after reaching the Stationary Phase.

8.3. Phases of Bacterial Inactivation

Bacteria are inactivated, or killed, when conditions are adverse to bacterial survival. These environmental conditions can cause acute (fast) inactivation as with high temperature, or mild inactivation (slow), as observed with low levels of organic acids. The shape of the inactivation curve may vary, depending on the organism and environment. Conditions may cause an immediate linear (straight line) reduction in cell numbers, or a period of no change in cell numbers followed by a linear decrease.

8.3.1. Linear Phase

For inactivation scenarios, the $\log_{10}$ value of the cell number in normally plotted. In the linear phase of inactivation, the rate (slope of the line) of inactivation depends on the number of cell "targets" affected by the effector (such as heat). As the cell concentration declines, the probability of a "hit" on the cell target decreases, resulting in a proportional linear reduction in cell number.

Inactivation is commonly referred to in terms of the decimal reduction time, or D-value. Although D-values can be expressed for different levels of reduction, the most common representation is the time for the population to decrease by 90% (10-fold or 1.0 $\log_{10}$). The D-value equals the absolute value of the inverse of the rate (slope) of cell reduction.

A common secondary model of the D-value is referred to as the z-value. This term describes the change in temperature that causes in a 90% (or 10-fold) change in the D-value. The z-value is the inverse of the rate of change in the D-value.

The z-value is commonly used to calculate process lethality. Process lethality can be expressed as the F-value, which is an integrated calculation of time-dependent thermal effects on inactivation of cell numbers, and serves to measure the accumulated lethality effects with "come-up" and "come-down" thermal profiles, such as those used in the canning industry.

8.3.2."Shoulders and Tails"

The kinetics of both thermal and non-thermal inactivation may display a lag-like period, sometimes referred to as a "shoulder," that precedes the linear inactivation phase. For thermal inactivation scenarios, this is more commonly observed at lower temperatures and when using higher cell concentrations. It is theorized that this represents a subpopulation of cells that are more thermotolerant, with a greater likelihood of being observed when high inoculum levels are used. In some cases, these shoulders may result from inaccurate measurements of the internal temperature of the matrix during temperature "come-up" time, the use of mixed cultures, cell clumping and cell multiple- hit mechanisms. The Weibull distribution is commonly applied to model such non-linear inactivation curves.

In some instances, the second phase of inactivation indicates a slowing down of the inactivation and eventually can stop in such a way it does not intercept the x-axis, but instead transitions to a curve referred to as a "tail." Such "tails" are more commonly observed with higher inoculum levels. Investigators theorize that "tails" represent a subpopulation of bacteria that are more thermally resistant.

8.4. Primary Factors that Affect Bacterial Behavior

Research shows that temperature, pH and water activity have very pronounced effects on the behavior of bacteria. Consequently, these factors can be adjusted to control both food spoilage and safety. For example, low temperature can be used to inhibit microbial growth during food storage; food pH can be reduced with organic acids to stop growth and cause microbial inactivation; and water activity can be lowered through the use of salts to extend shelf-life.

8.4.1. Temperature

Temperature is an extrinsic factor of food that has a strong influence on the growth and inactivation of bacteria. In general, temperatures less than 5ºC halt the replication of microbial pathogens and retard spoilage, while temperature greater than 54ºC are lethal to pathogens.

In addition, there is a direct relationship among temperature, bacterial lag phase and growth rate, in that lag phase decreases and growth rate increases with increasing temperature.

8.4.2. pH

High levels of acidity inhibit bacterial growth and can lead to the death of vegetative microorganisms. Some acidulants, such as lactic acid, have been shown to be effective inhibitors of *Listeria monocytogenes*.

8.4.3. Water Activity

Water activity is a measure of the amount of water that is not tightly bound to the food matrix and available to support the growth of bacteria, yeasts and moulds (fungi). This value varies from 0 to 1, with most hazardous foods being in the range of 0.85 to 0.99. Water activity is affected by various compounds in food, not simply NaCl.

8.5. Classes of Models

8.5.1. Primary Models

After the experimental protocol is established, time-versus-cell number data are collected for each of the test conditions. Next, curve-fitting programs are used to develop a best-fit line to the data. For growth data, the parameters normally include lag phase duration, growth rate and maximum population density. For inactivation data, parameters may reflect an initial "shoulder", somewhat analogous to the lag phase, a linear reduction in cell count, and possibly a "tail." In cases where probability-of-growth is relevant, such as at the growth/no-growth boundaries, data may be scored simply as growth or no-growth.

8.5.2. Secondary Models

Secondary models are derived from the primary model parameters (e.g., lag time, growth/inactivation rate, maximum population density). Secondary models predict the change in primary model parameters as a function of the environment. An example of a secondary model is predictions of growth rate as a function of temperature, or predictions of growth rate as a function of multiple environmental conditions such as salt, water activity and temperature. The z-value is another type of secondary model that describes the change in D-value as a function of temperature. Secondary models can be simple linear regressions or more complex polynomial models that require sophisticated computational software.

Various secondary models have been used to model growth and inactivation of bacteria. More commonly, lag time and growth rate have been modeled using square-root, gamma and cardinal approaches. The use of probability models for describing the likelihood of a microbial event in food is increasing in the literature. Applications include modeling growth/no-growth interfaces, the length of the lag phase for pathogens in formulated ready-to-eat foods, and the production of microbial toxins. Another model form that is increasingly reported is Artificial Neural Networks.

8.5.3. Tertiary Models

The next step of model development involves expressing secondary model predictions through a primary model. This is commonly done with spreadsheets (e.g., Microsoft Excel) and in stand-alone software, such as the US Department of Agriculture-Agricultural Research Service's *Pathogen Modeling Program* (PMP; http://ars.usda.gov/Services/docs.htm?docid=6786) and the UK Institute of Food Research's *Growth Predictor* (http://www.ifr.ac.uk/Safety/GrowthPredictor/default.html).

Importantly, predictions of microbial behavior are not 100% accurate. Variations and uncertainty are introduced through experimental error, strain variation, and primary and secondary models. Such error is typically expressed as upper and lower confidence levels. For example, model limits that include 95% of the observed data are referred to as 95% confidence intervals.

9. Modeling *Staphylococcus Aureus* Growth and Enterotoxin Production in Milk

H. Fujikawa[1]

Abstract

Staphylococcus aureus growth and its enterotoxin production in sterilized milk were modeled with a new logistic model recently developed by us. The model accurately described *S. aureus* growth at constant temperatures from 14ºC to 36.5 ºC, similar to the Baranyi model. The amount of toxin in milk increased linearly with time from the time the cell population reached about $10^{6.5}$ CFU/ml. The rate of toxin production linearly increased at temperatures between 14 ºC and 32 ºC. From parameter values obtained at the constant temperatures, the model successfully predicted bacterial growth in the milk at a varying temperature. For toxin level estimation, we postulated that the rate of toxin production might be regulated with the temperature after the cell concentration reached $10^{6.5}$ CFU/ml; the time point when the cell concentration reached that value was predicted with our growth model. Introduction of a correction factor in the toxin estimation successfully predicted the toxin level in milk at a varying temperature. These results showed that this prediction system consisting of the growth model and the toxin production algorithm might be a useful tool for modeling bacterial growth and its metabolite production in food.

9.1. Introduction

An extensive *Staphylococcus aureus* food poisoning outbreak among patients who ingested dairy products occurred in Osaka, Japan, 2000 (Asao et al., 2003). The cause was staphylococcal enterotoxin A (SEA) contamination of the products. Exposure of the raw milk to abuse temperatures due to a period of power supply loss during product production may have been the underlying contributing factor that permitted *S. aureus* growth and subsequent SEA production in the contaminated milk. This outbreak reinforced the importance of proper temperature control of foods and/or their ingredients. It also identified the potential utility of having available a mathematical model that predicts *S. aureus* growth and the SEA production in contaminated milk from its temperature history as a tool for preventing the occurrence of such food poisoning outbreaks.

A number of mathematical models and equations for the description of microbial growth in food and culture media have been developed in predictive microbiology so far (Baranyi and Roberts, 1994; Buchanan et al., 1997; Gibson et al., 1987). Historically, various mathematical models, such as the logistic model (Verhulst, 1838; Pearl, 1927), have been used to describe growth of biological systems. It has also been common to describe growth kinetics using a differential equation(s) (Baranyi and Roberts, 1994; Vadasz et al., 2001; Taub et al., 2003). The rate of growth by the logistic model can be written as a differential equation:

$$\mathbf{d}N/\mathbf{d}t = rN\,(1 - N/N_{max}) \qquad (1)$$

where

- ***N***, an arithmetic value, is the population of a microorganism at time t;
- ***r*** is the rate constant, or the maximum specific rate of growth; and
- ***N*max** is the maximum population at stationary phase.

The model describes a sigmoid curve on an ordinary Cartesian plane.

For bacteria, however, the growth curve is generally sigmoidal on a semi-logarithmic plot. The logistic model cannot produce a sigmoid growth curve on that plot; it produces a curve without a lag period (Fig. 1). For this reason, Gibson et al. (1987) proposed a modified Gompertz model

[1] Tokyo Metropolitan Institute of Public Health, Department of Microbiology, 3-24-1, Hyakunin-cho, Shinjuku, Tokyo 169-0073, Japan, Hiroshi_1_Fujikawa@member.metro.tokyo.jp

as an alternate means for describing bacterial growth. Baranyi and Roberts (1994) also reported on an alternative mathematical model for bacterial growth. The modified Gompertz and the Baranyi models have been used widely known to describe bacterial growth kinetics.

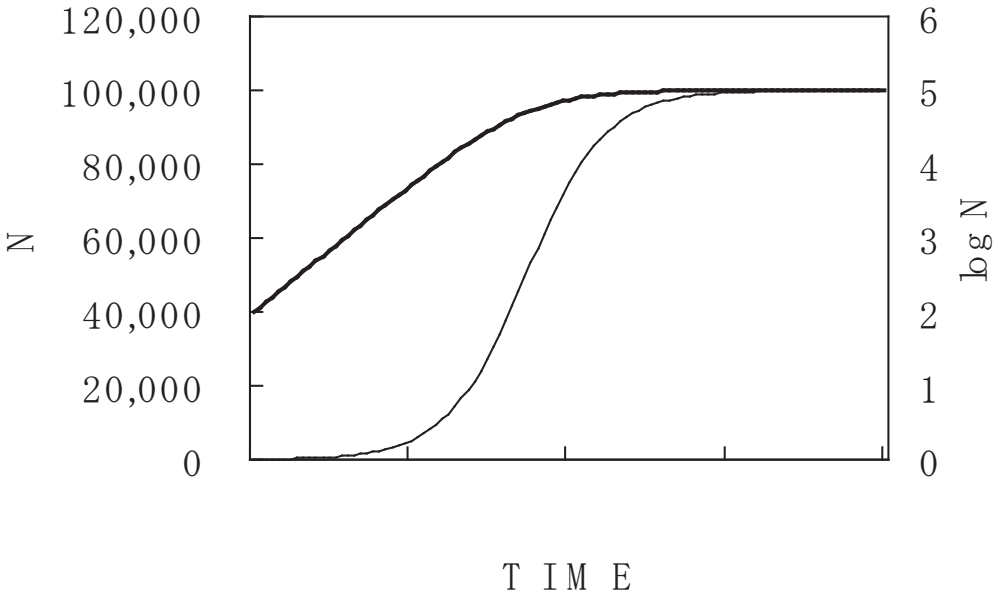

Figure 1. Logistic curves on an ordinary Cartesian plane and a semi-logarithmic plot. A single logistic equation is described on the two plots. A thin line is on the Cartesian plot and a thick line on the semi-log plot. Each arrow shows the corresponding axis.

One of the most important environmental factors that affects bacterial growth in a food is temperature. The temperature history between the production and consumption of food products changes with time. Mathematical models that can successfully predict bacterial growth under non-isothermic environments conditions are needed to adequately describe the changing conditions generally associated with the manufacture and storage of foods. A number of investigators have developed mathematical models for dynamic temperatures, but the models' performances have not always been satisfactory (Taoukis and Labuza, 1989; Fu et al., 1991; Baranyi et al., 1995; Brocklehurst et al., 1995; Van Impe et al., 1995; Alavi et al., 1999; Bovill et al., 2000; Koutsoumanis, 2001).

Recently we proposed a new logistic model, **NLM** (Fujikawa et al., 2003, 2004, Fujikawa and Morozumi 2005). The model contains an additional term that lowers the rate of growth during the lag phase relative to the original model (**Eq. (1)**). We assumed that the growth rate of microbial cells is controlled by a factor related to the minimum cell concentration, N_{min}, which is an "inverse" analog of the term $1- N/N_{max}$ in the original logistic model. N_{min} is set to be slightly smaller than the initial cell concentration (the inoculum size, N_o) of the sample. That is, we assumed that the rate of growth would be proportional to a term, $1- N_{min}/N$. The new growth model, therefore, can be described as follows:

$$dN/dt = rN \{1 - (N/N_{max})^m \}\{1 - (N\text{min}/N)^n\} \quad (2)$$

Where m and n (≥ 0) are adjustment factors.

NLM successfully described growth curves of *Escherichia coli* and *Salmonella* under various initial conditions (Fig. 2) (Fujikawa et al. 2003, 2004, Fujikawa and Morozumi 2005). We, in this study, compared our model with the Baranyi model for *S. aureus* growth in milk at constant temperatures. We also studied *S. aureus* growth and enterotoxin production in liquid milk incubated under several non-isothermal temperature profiles.

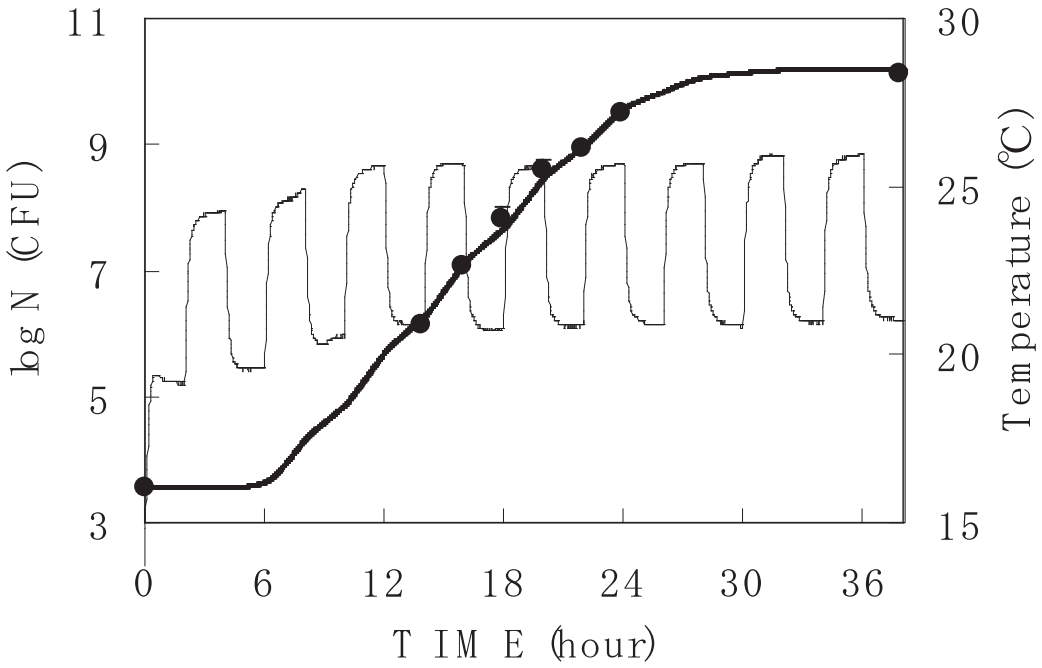

Figure 2. An example of NLM performance (Fujikawa and Morozumi 2005). A periodic line is the temperature of the agar surface. A thick line is a surface growth curve predicted with NLM. Closed circles are experimental.

9.2. Materials and Methods

9.2.1. Bacterial strain

S. aureus strain 12057, which was isolated from a staphylococcal food poisoning outbreak in Tokyo, Japan, was used throughout this study. It was selected because it had growth characteristics that were representative of five strains that were initially compared in preliminary studies under isothermal conditions (data not shown).

9.2.2. Milk

Sterilized liquid milk (Snow Brand Co., Tokyo) was purchased at a retail store. The milk product for study was confirmed to be bacteriologically negative by a standard spread plate count assay and was determined to be SEA-free based on the toxin assay described below.

9.2.3. Inocula preparation

Cell suspensions of strain 12057 were prepared by the method of Fujikawa et al. (2003), with the culture being initial grown on a brain heart infusion agar plate (Difco, Becton and Dickinson) at 35 ºC for 24 h. Cells of several well-grown colonies on the plate were transferred to sterile brain heart infusion broth with shaking at 35 ºC for 24 h. Cultured cells were harvested by centrifugation, washed twice with phosphate-citrate buffer (pH 7.0) and re-suspended in buffer. The cell suspension was diluted to 10^5 CFU/ml with sterile buffer.

9.2.4. Inoculation and Incubation

The diluted cell suspension was added to sterile milk at volume ratio of 1:100 ml, resulting in an initial inoculum of approximately 10^3 CFU/ml. The inoculated milk was then dispensed in 3.5 ml portions to sterile Pyrex glass screw cap test tubes (10 mm in diameter x 100 mm long). The

tubes in a rack were then placed in a controlled temperature water bath (model DH-12, Taitec Co., Koshigaya, Japan) or a programable incubator (model PR-3G, Tabai Espec Co., Osaka) at temperatures higher or lower than the room temperature, respectively. The come-up time of the sample to a designated temperature, as measured with a digital thermometer (AM-7002, Anritsu Meter Co., Tokyo), was taken into consideration for growth experiments at a constant temperature. For non-isothermal trials, the rack of inoculated culture tubes was placed in the temperature programable incubator (Tabai). The temperature of each sample suspension was measured with the digital thermometer every 30 sec throughout the experiment. After each incubation period at a constant or varying temperature, duplicate sample tubes were removed from the bath and cooled in ice water.

9.2.5. Cell counts

Viable cell counts of samples were determined with the spread plate method (three plates per 10-fold dilution). The measured cell counts of the samples were transformed to a base 10 logarithm. Averages and standard deviations of the transformed values were then calculated.

9.2.6. SEA measurement

SEA in milk was measured using an enzyme-linked fluorescent assay, the VIDAS Staph Enterotoxin Test (bioMerieux, Marcy-l'Etoile, France) with the mini-VIDAS automated system. All tests were performed in duplicate. A standard curve was developed using purified SEA (Denka Seiken Co. Ltd., Tokyo) in milk (Snow Brand). When necessary, milk samples were diluted with a dilution buffer (VIDAS) for the SEA measurement in milk. The averages of two measurements were calculated for each data point.

9.2.7. Numerical solution of the model

Eq. (2) was solved numerically with the 4-order Runge-Kutta method using Microsoft Excel (Fujikawa et al. 2003, 2004). For solving the equations, the values of $\boldsymbol{r}$, $\boldsymbol{N_{max}}$, and N_{min} were obtained from experimental data. The adjustment factors, $\boldsymbol{m}$ and $\boldsymbol{n}$, were determined as the value that minimizes the mean of the squared errors between the predicted cell populations and those measured (log unit) at the observed data points (Fujikawa and Morozumi 2005). Here $\boldsymbol{m}$ was fixed to one.

9.2.8. Model Comparison

Bacterial growth data were also analyzed with the Baranyi model using the software program DMFit, kindly provided by Dr. J. Baranyi (http://www.ifr. bbsrc.ac.uk/Safety/DMFit/default.html). Here, parameters ***mCurv*** and $\boldsymbol{h_o}$ in the model were set to be both 10, which are the default values. The rate constant of growth and the lag period were estimated for **NLM** curves and the Baranyi curves described with DMFit.

9.2.9. Statistical analysis

The mean of the squared errors between values predicted with a model and those measured, *MSE*, was defined as a measure of the goodness of fit (Fujikawa et al., 2004). For the cell concentration, the values were transformed into log unit.

9.3. Results

9.3.1. Growth and SEA production at constant temperatures

Growth and SEA production of *S. aureus* in milk were studied at constant temperatures of 14 ºC to 36.5 ºC. Growth curves were sigmoidal and successfully described with **NLM** and the Baranyi model (Fig. 3A, B). The values of *MSE* for cell counts (log units) generated from the models for the whole curves at the constant temperature were all very small. The values of MSE for cell

counts (log units) generated from the models for the whole curves at the constant temperature were all very small; the values of MSE for NLM and the Baranyi model were 0.018 and 0.013, respectively.

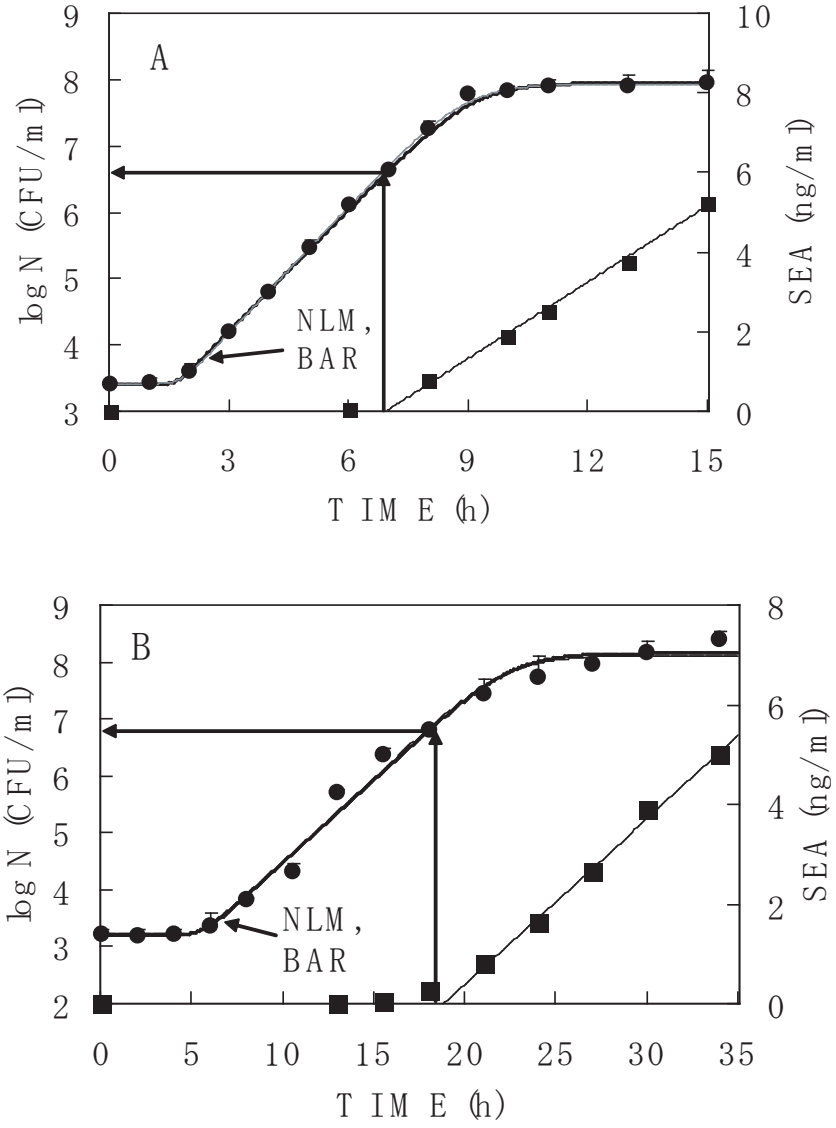

Figure 3. Growth and SEA production of *S. aureus* in milk at constant temperatures of 32 ºC (A) and 23 ºC (B). Closed circles and squares show measured viable cell counts and SEA concentration, respectively. Bars show the standard deviations of the average viable cell counts. Growth curves were described with NLM and the Baranyi model (BAR). Arrows show the cell concentration at the time when the toxin began to be detected.

When values of the rate constant of growth, r (1/h), and the lag period for growth curves generated with the models were compared, the values estimated with the models were very close to the observed values (Fig. 4A, B). The MSE value of the rate constant for NLM (2.11) was smaller than that of the Baranyi model (6.66). The Baranyi model predicted a longer lag period in some cases (Fig. 4B). The MSE value of the lag period for NLM (5.07) was also smaller than that of the Baranyi model (38.0).

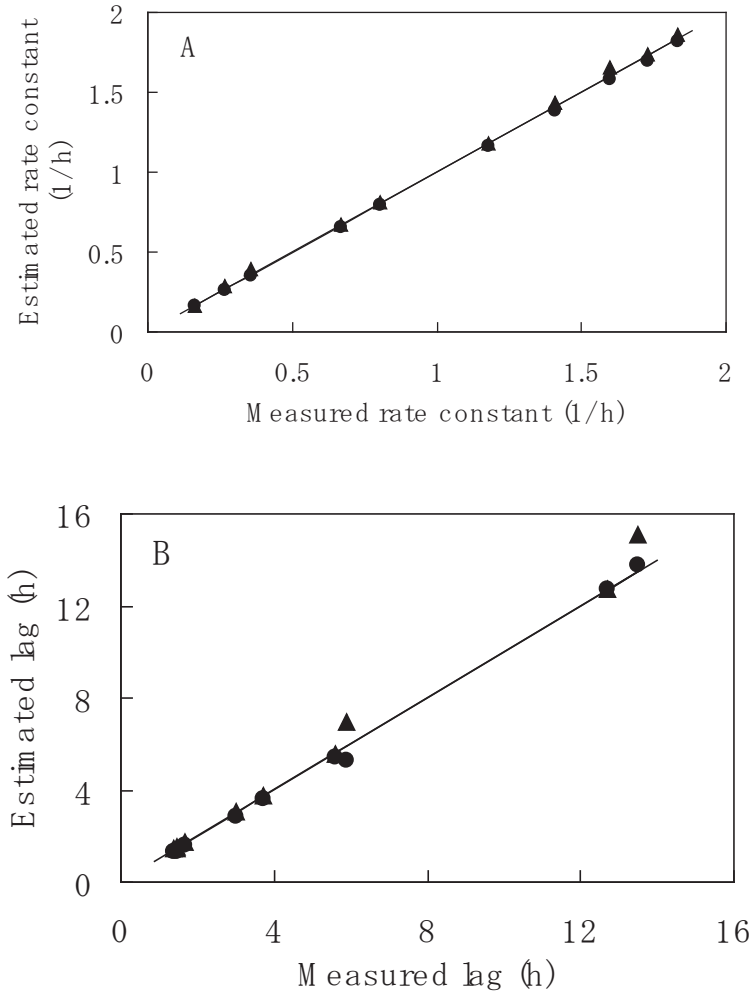

Figure 4. Comparison of the rate constant (A) and the lag period (B) of *S. aureus* growth curves estimated using NLM and the Baranyi model. The straight line is the line of equivalence. Closed circles and triangles show NLM and the Baranyi models, respectively.

The increase in the SEA amount in the milk was linear with time (Fig. 3), thus the kinetics of SEA production could be described as a zero-order reaction (Bailey and Ollis, 1986). The values of the rate constant, ***p***, of SEA production in the milk in Fig. 3 were (A) 0.64 and (B) 0.33 (1/h). Here ***p*** was estimated from the slope of the SEA production curve. With the linear regression analysis of the SEA production curve, the time when the toxin began to be detected corresponded to the cell concentration of approximately $10^{6.5}$ CFU/ml at all temperatures studied. Examples are shown in Figures 3A, B.

9.3.2. Temperature dependency of parameters

The parameters of **NLM** at the constant temperatures were estimated. The rate constant of growth at these temperatures showed a high linearity with the correlation coefficient of 0.997 when plotted with a square root model (Ratkowsky et al., 1982) (Fig. 5). The regression line was expressed as follows:

$$r^{0.5} = 0.0442 \times T - 0.239 \qquad (3)$$

Here ***T*** is the temperature (º C). Using this equation, ***r*** at a given temperature could be estimated. The values of N_{max} over the temperature range examined were almost constant; the

average was $10^{8.15}$ CFU/ml. The values of the adjustment parameter n at the temperatures were independent of temperature, being almost constant with the average of 4.7±1.1.

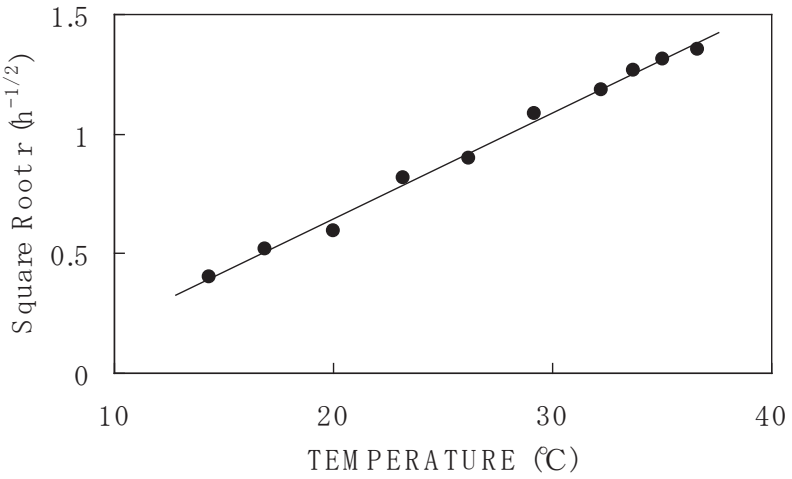

Figure 5. Temperature dependency of the rate constant of *S. aureus* growth. Circles are experimental data. The straight line is the linear regression line.

The temperature dependency of the rate constant, ***p***, of SEA production in the milk was then studied. When the value of p was plotted to the temperatures studied, it showed a high degree of linearity with respect to temperature between 14 ºC and 32 ºC (Fig. 6). The regression line in this temperature range was described as follows:

$$p = 0.0376 \times T - 0.559 \quad (4)$$

The correlation coefficient of linearity was 0.994. The equation indicated that the apparent temperature where ***p*** was zero was about 15 ºC in the present study. At temperatures higher than 32 ºC, the value of p was lowered (Fig. 6).

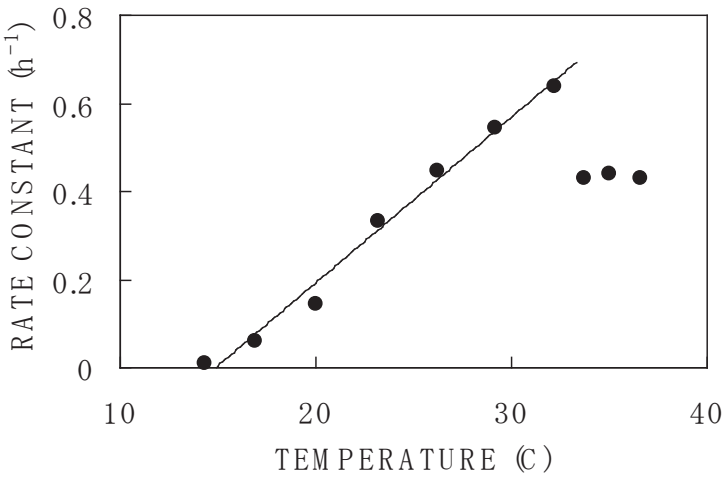

Figure 6. Temperature dependency of the rate constant of SEA production. Circles are experimental data. The straight line is the linear regression line in the range of 14 – 32 ºC. Temperatures above 32 ºC were not included in the linear regression analysis.

9.3.3. Growth and SEA production at a varying temperature

Growth and SEA production of the microorganism in milk was studied at various patterns of varying temperature. The temperature history of the milk recorded for each experiment was embedded into the growth prediction program for **NLM**. For numerically solving the model, the values of parameter ***n*** and ***N*max** were fixed at 4.7 and $10^{8.15}$, respectively, for all experiments. Here ***m*=1**. The value of N_{min} was obtained from measured N_o for each experiment. For toxin level estimation, based on the results at the constant temperatures, we postulated that the rate of toxin production might be temperature-dependent, following a zero-order reaction and that the initial time when the toxin can be detected might be the point that the cell concentration reached $10^{6.5}$ CFU/ml. This initial time was predicted with NLM from the temperature history of the sample. The toxin level was numerically predicted using **Eq. (4)** from the temperature history. The range of temperature variation in the experiment was chosen between 15 ºC and 32 ºC, because the value of ***p*** in this temperature range was positive and expressed using that equation.

Various patterns of varying temperature were studied for the validation of the prediction system. An example is shown in Fig. 7. For these temperature histories, the model successfully predicted bacterial growth; values of *MSE* for growth were 0.030.

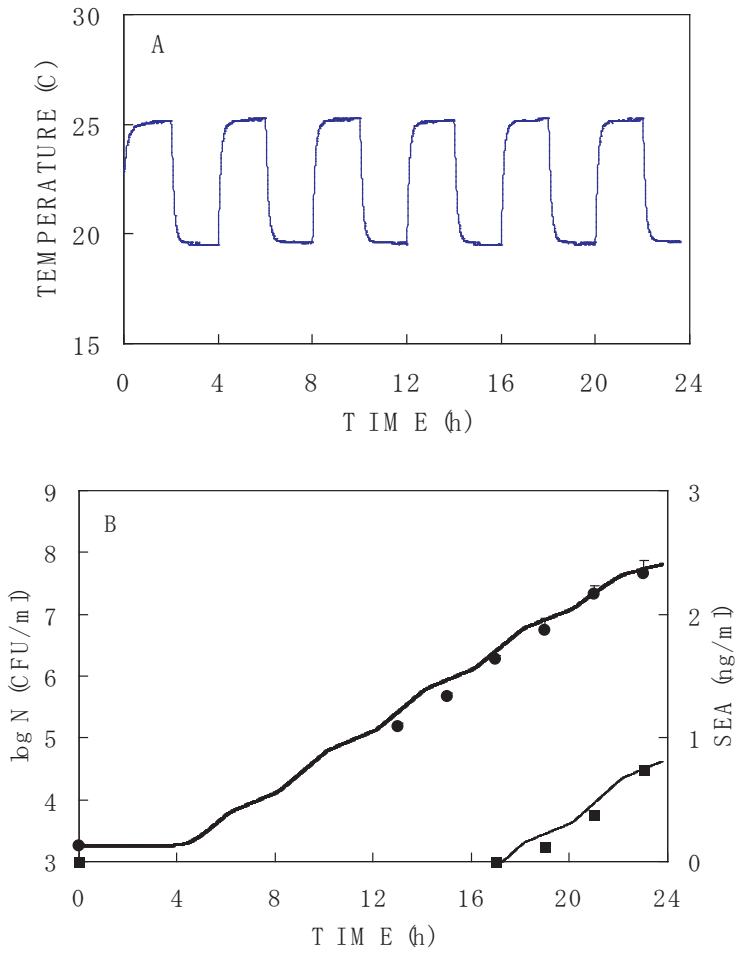

Figure 7. Predictions of *S. aureus* growth and SEA production in milk under a dynamic temperature profile. The periodic curve shows the temperature profile (A). A thick and thin line show predicted bacterial growth and SEA production, respectively (B). The circles and squares represent the observed growth and SEA data. Bars show the standard deviations of the average viable cell counts.

While the growth model accurately predicted, the time when the cell concentration reached $10^{6.5}$ CFU/ml at a dynamic temperature (Fig. 7), the SEA amounts predicted with **Eq. (4)** were about twice higher than the observed values throughout the incubation period (data not shown). Thus, a correction ratio, ***u***, was newly introduced for the toxin prediction; the SEA amount predicted with **Eq. (4)** was corrected by this ratio throughout the incubation period. ***u*** has no apparent biological meaning. The optimal ***u*** values that gave the minimum *MSE* values for the toxin amount were estimated for the experiments. The values of ***u*** were independent of the varying temperature profiles studied, with the average of 0.46 ± 0.059 and thus could be considered to be constant. With this value of ***u***, the SEA production was predicted again at the temperature histories of the experiments in Fig. 7. This value gave good SEA predictions, as shown in Fig. 7; the values of *MSE* for SEA production were 0.0071.

These results showed that this prediction system consisting of **NLM** and the toxin production algorithm might have the potential to predict *S. aureus* growth and SEA production in milk at various temperature patterns.

9.4. Discussion

From the cell concentration of about $10^{6.5}$ CFU/ml, the SEA amount increased linearly with time, even after the cells reached the stationary phase (Fig. 3). Later, the rate of the toxin production gradually decreased to zero to reach a maximum toxin level (data not shown), similar to other bacterial metabolites production in batch (Bailey and Ollis, 1986). At that time, the milk in tubes coagulated, possibly due to metabolites from cells such as organic acids, and the cell concentration in the milk already reached the maximum. Preliminarily, we observed the decrease in pH of the milk during the incubation; pH of coagulated milk was lower than that of the non-inoculated control. The increase in the toxin level followed bacterial growth, not parallel to the cell concentration (Fig. 3). This is sometimes observed in microbial product formations during culture (Bailey and Ollis, 1986, Atkinson and Mavituna, 1991).

While the SEA production was still linear with time at the constant temperatures over 32 ºC, the value of ***p*** was low (Fig. 6). However, the bacterial growth kinetics at those high temperatures was still linear with respect to temperature, as seen in Figs. 4 and 5. Also, the SEA production levels at the dynamic temperatures were lower than expected. At present, we do not know the reasons for these results. The physiological features of cells involved in SEA production under such experimental conditions might have been negatively affected.

On the other hand, it took as long as seven months to complete all experiments in this study and the experiments at the higher and varying temperatures were done at the end of this period. For each experiment, cells were taken from a single stock culture of the original strain. The stock culture was grown in semi-solid medium and stored at 4ºC during the experiments.

Betley and Mekalanos (1985) have found that the gene for staphylococcal enterotoxin A (entA) is encoded by *S. aureus* phages and the phages can carry the gene. It is known that phages embedded into microbial host genome, i.e., prophages, can be removed from the microbial genome by induction and become free. Thus, there is a possibility that during the experiments some cells in the stock culture might have lost the ability of toxin production for this genetic mechanism of induction. It is also experienced in laboratories that the product formation or the physiological characteristics of original microbial strains is decreased during the storage of the strains. Further studies on SEA production of the strain tested should be required to clarify the reasons for the low production results.

The optimal value of parameter ***n*** of our model, which gives the minimum *MSE* between the predicted and observed values, for each temperature-varying experiment gave a growth prediction better than the average value of ***n*** (4.7). Moreover, the optimal ***n*** value specific for each experiment could give the optimal value of ***u*** for SEA production. Generally, however, we could not predict the optimal parameter values of a predictive model for a new experiment. However, we know that a good, practical model can predict microbial behavior using only environmental data such as temperature, without any curve fitting. Here, the parameter estimates used for prediction should be obtained from experimental data already performed. This is just the procedure that we did in this study. That is, although we could make better predictions of growth and SEA production with the optimal parameter values specific for each

experiment in Fig. 7, we predicted using fixed values of the parameters n (4.7) and u (0.46) for the experiments. And those values worked well.

This study clearly demonstrated that the prediction system consisting of **NLM** and the SEA amount estimation algorithm could be useful for microbiological food safety. When the model is embedded into an electronic device such as a time-temperature integrator, it might predict microbial growth and its metabolite production from the temperature history of a liquid food. Also, the prediction system could be also used to quantitatively assess risks to microbial hazards.

This study has been published in the journal of Food Microbiology (Fujikawa and Morozumi 2006).

References

1. Alavi, S.H., Puri, V.M., Knabel, S.J., Mohtar, R.H., Whiting, R.C., 1999. Development and validation of a dynamic growth model for *Listeria monocytogenes* in fluid whole milk. J. Food Prot. 62, 170-176.
2. Asao, T., Kumeda, Y., Kawai, T., Shibata, T., Oda, H., Haruki, K., Nakazawa, H., Kozaki, S., 2003. An extensive outbreak of staphylococcal food poisoning due to low-lat milk in Japan: estimation of enterotoxin A in the incriminated milk and powdered skim milk. Epidemiol. Infect. 130, 33-40.
3. Atkinson, B., Mavituna, F., 1991. Biochemical engineering and biotechnology handbook. 2nd ed. New York: Macmillan.
4. Bailey, J.E., Ollis, D.F., 1986. Biochemical engineering fundamentals. 2nd ed. New York: McGraw-Hill.
5. Baranyi, J., Roberts, T.A., 1994. A dynamic approach to predicting bacterial growth in food. Int. J. Food Microbiol. 23, 277-294.
6. Baranyi, J., Robinson, T.P., Kaloti, A., Mackey, B.M., 1995. Predicting growth of *Brochothrix thermosphacta* at changing temperature. Int. J. Food Microbiol. 27, 61-75.
7. Betley, M.J. and Mekalanos J.J. 1985. Staphylococcal enterotoxin A is encoded by phage. Science. 12, 229 (4709), 185-187.
8. Bovill, R., Bew, J., Cook, N., D'Agostino, M., Wilkinson, N., Baranyi, J., 2000. Predictions of growth for *Listeria monocytogenes* and *Salmonella* during fluctuating temperature. Int. J. Food Microbiol. 59, 157-165.
9. Brocklehurst, T.F., Mitchell, G.A., Ridge, Y.P., Seale, R., Smith, A.C., 1995. The effect of transient temperatures on the growth of *Salmonella typhimurium* LT2 in gelatin gel. Int. J. Food Microbiol. 27, 45-60.
10. Buchanan, R.L., Whiting, R.C., Damert, W.C., 1997. When is simple good enough: a comparison of the Gompertz, Baranyi, and three-phase linear models for fitting bacterial growth curves. Food Microbiol. 14, 313-326.
11. Fu, B., Taoukis, P.S., Labuza, T.P., 1991. Predictive microbiology for monitoring spoilage of dairy products with time-temperature integrators. J. Food Sci. 56, 1209-1215.
12. Fujikawa, H., Kai, A., Morozumi, S., 2003. A new logistic model for bacterial growth. J. Food Hyg. Soc. Japan, 44, 155-160.
13. Fujikawa, H., Kai, A., Morozumi, S., 2004. A new logistic model for *Escherichia coli* at constant and dynamic temperatures. Food Microbiol. 21, 501-509.
14. Fujikawa, H., Morozumi, S., 2005. Modeling surface growth of *Escherichia coli* on agar plates. Appl. Environ. Microbiol. 71, 7920-7926.
15. Fujikawa, H., Morozumi, S., 2006. Modeling *Staphylococcus aureus* growth and enterotoxin production in milk. Food Microbiol. 23, 260-267.
16. Gibson, A.M., Bratchell, N., Roberts, T.A., 1987. The effect of sodium chloride and temperature on the rate and extent of growth of *Clostridium botulinum* type A in pasteurized pork slurry. J. Appl. Bacteriol. 62, 479-490.

17. Koutsoumanis, K., 2001. Predictive modeling of the shelf life of fish under nonisothermal conditions. Appl. Environ. Microbiol. 67, 1821-1829.
18. Pearl, R., 1927. The growth of populations. Q. Rev. Biol. II 4, 532-548.
19. Ratkowsky, D.A., Olley, J., McMeekin, T.A., Ball, A., 1982. Relationship between temperature and growth rate of bacterial cultures. J. Bacteriol. 149, 1-5.
20. Taub, I.A., Feeherry, F.E., Ross, E.W., Kustin, K., Doona, C.J., 2003. A quati-chemical kinetics model for the growth and Death of *Staphylococcus aureus* in intermediate moisture bread. J. Food Sci. 68, 2530-2537.
21. Taoukis, P.S., Labuza, T.P., 1989. Applicability of time-temperature indicators as shelf life monitors of food products. J. Food Sci., 54, 783-788.
22. Vadasz, A.S., Vadasz, P., Abashar, M.E., Gupthar, A.S., 2001. Recovery of an oscillatory mode of batch yeast growth in water for a pure culture. Int. J. Food Microbiol. 71, 219-234.
23. Van Impe, J.F., Nicolai, B.M., Schellekens, M., Martens, T., De Baerdemaeker, J., 1995. Predictive microbiology in a dynamic environment: A system theory approach. Int. J. Food Microbiol. 25, 227-249.
24. Verhulst, P.F., 1838. Notice sur la loi que la population suit dans son accroissement. Corr. Math. et Phys. Publ. par A. Quetelet. TX, 113-121.

10. Modelling of Recontamination

E.D. van Asselt[1], A.E.I. de Jong[2], R. de Jonge[3], M.H. Zwietering[4], M.J. Nauta[3]

The work described in this paper is performed at the Laboratory of Food Microbiology, Wageningen University, the Netherlands (recontamination in industrial setting) and at the National Institute for Public Health and the Environment, Bilthoven, the Netherlands (recontamination in domestic environment).

10.1. Introduction

Pathogenic microorganisms in the food production chain can cause food safety problems. This safety risk can be quantified by applying a Microbial Risk Assessment (MRA). In the exposure assessment part of an MRA all steps up to consumption should be included. Studies on the presence of pathogens in the farm-to-factory part have resulted in predictive models describing growth and inactivation, but quantitative data and models for recontamination are often lacking (2). Recontamination can take place through various routes as depicted in Figure 1.

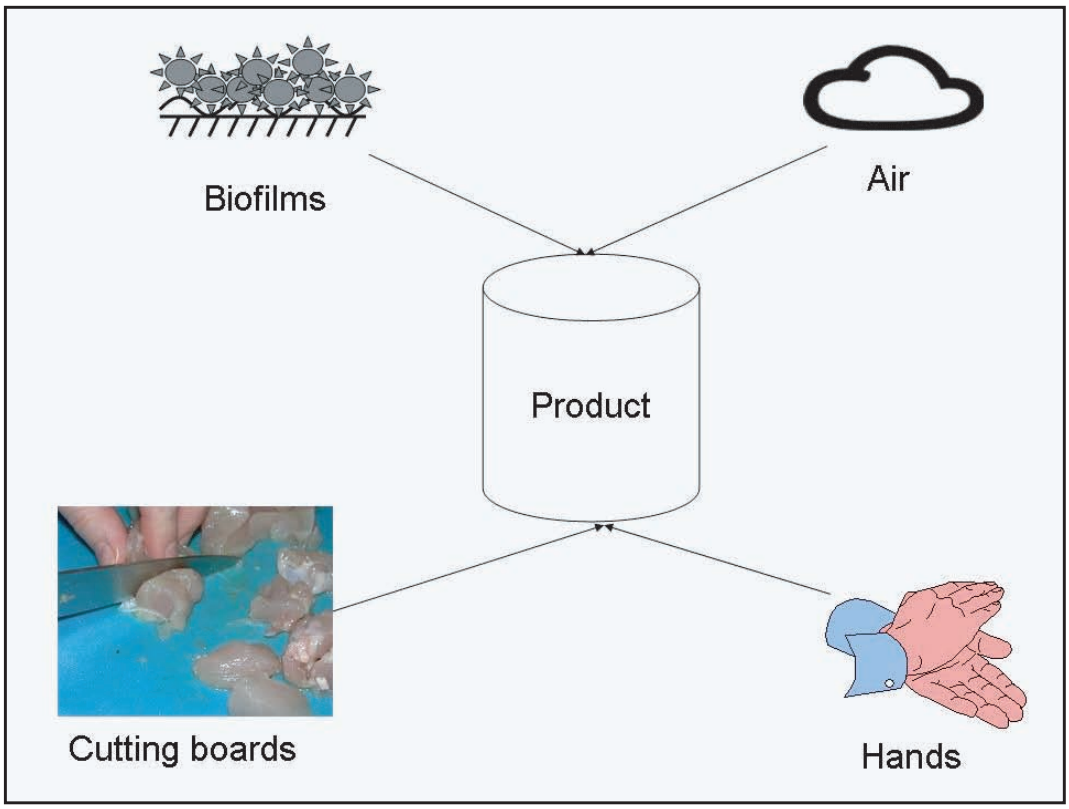

Figure 1. Overview of the various recontamination routes described in this paper.

[1] Current affiliation: Rikilt Institute of Food Safety, Wageningen, the Netherlands
P.O. Box 230, 6700 AE Wageningen. Tel: +31-317-475422, esther.vanasselt@wur.nl

[2] Current affiliation: Food and Consumer Product Safety Authority (VWA), Amsterdam, the Netherlands

[3] Microbiological Laboratory for Public Health Protection, National Institute of Public Health and the Environment (RIVM), Bilthoven, the Netherlands;

[4] Laboratory of Food Microbiology, Wageningen University, the Netherlands

The recontamination routes can be divided in recontamination in an industrial setting (from farm-to-factory, such as air contamination and biofilm formation) and recontamination in the domestic environment (from factory-to-fork such as contamination via hands, cutting boards and cutlery). Quantification of these routes is described below.

10.2. Recontamination in industrial setting

10.2.1. Air contamination

When microorganisms are present on the floor, they can be transferred to the air by e.g. spraying, which causes aerosol formation (droplets of water in the air). Microorganisms are, however, not only on floors, they are on every surface such as cable trays, pipes, light fittings, window ledges, equipment etc. and human skin. These microorganisms can travel through the air while adhering to dust or skin particles. When products are exposed to the air of the product line environment e.g. during assembly or at the filling step, these microorganisms can end up in the product via several routes (3). The number of microorganisms that enter the product via the air depends on the concentration of micro-organisms in the air, the settling velocity and the exposure time and area of the product (7):

$$N_c = C_{air} * v_s * A * t \qquad (1)$$

where:

- N_c expresses the contamination level in the product (cfu)
- C_{air} is the concentration of microorganisms in the air (cfu/m^3)
- v_s is the settling velocity (m/s)
- A is the exposed product area (m^2)
- t is the exposure time (s)

A contamination level of 10^{-3} cfu then means that one out of every 1000 products is contaminated with 1 microorganism.

The settling velocity (v_s) can be calculated by dividing settle plate counts (cfu/m^{2}h) by the airborne concentration (cfu/m^3). Parameter values for equation 1 were collected from literature and industry and probability density functions for air concentration (C_{air}) and settling velocity (v_s) were estimated. Concentration of bacteria in the air (C_{air}) depended on the product produced and could be divided in three groups: low counts (vegetables, dry products and liquid products), solid dairy products (like cheese and butter) and meat products. For each of these groups a normal distribution with the following parameters was used to fit the data (3):

Table 1: Parameters for concentration of bacteria in the air (C_{air}) and settling velocity (v_s) based on total viable counts.

Product group	μ (log cfu/m^3)	σ (log cfu/m^3)
Vegetables, Dry products, Liquids	2.44	0.71
Dairy solid	3.19	0.25
Meat	3.39	0.73
Settling velocity	-2.59 (log m/s)	0.45 (log m/s)

10.2.2. Application of a recontamination model

Once recontamination models are available, they can be incorporated in an exposure assessment in order to quantify the recontamination for a certain food product. As an example, the air contamination model (**equation 1**) is applied for smoked salmon (as described in (1)). The production process of this product is given in Figure 2.

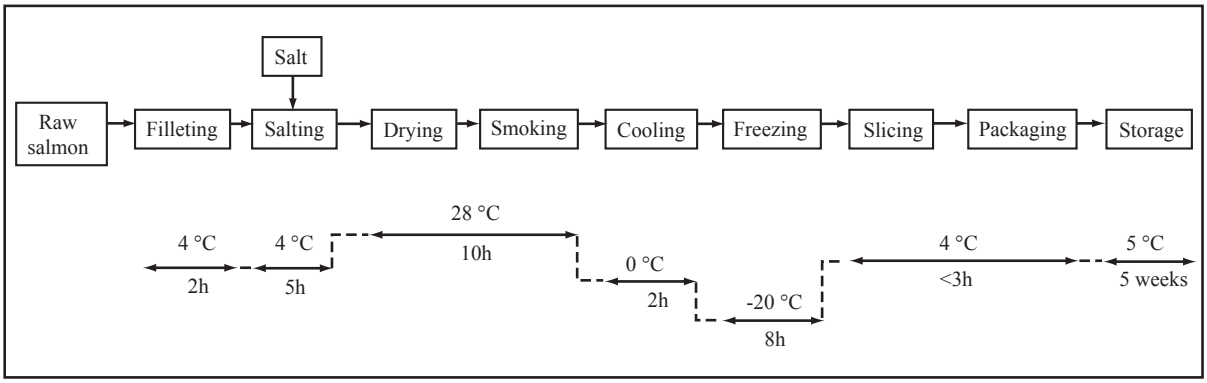

Figure 2. Production process of smoked salmon together with residence times (hours) and temperatures in each step.

In order to assess possible growth in each step, first order kinetics are used:

$$N_i = N(_{i-1})*exp(\mu\tau) \quad (2)$$

where:

N_i expresses the concentration of bacteria at the end of the process step (cfu/g)

$N(_{i-1})$ expresses the concentration of bacteria at the end of the previous process step (cfu/g)

μ is the specific growth rate in product stream (s^{-1}), and

τ is the residence time (s)

The effect of airborne contamination can be evaluated by incorporating the airborne contamination model (**equation 1**) in **equation 2** (3) as:

$$N_i = (N(_{i-1}) + N_c)*exp(v\tau) \quad (3)$$

where:

N_c is the level of recontamination (cfu/g), which can be calculated using the airborne contamination model (**equation 1**).

Using process characteristics (*pH*, temperature (*T*) and water activity (a_w)) and growth characteristics of the pathogen (in this case *Listeria monocytogenes*), the number of pathogens in each process step can be estimated resulting in Figure 3.

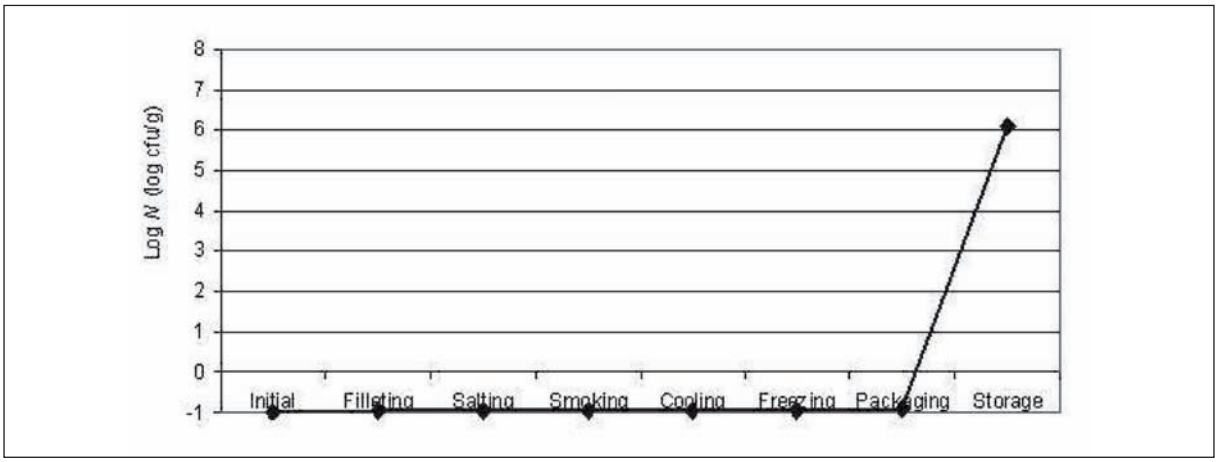

Figure 3. Number of *L. monocytogenes* in each process step in case there is no recontamination and the raw fish is contaminated with 1cfu/10g. It is assumed that growth during smoking does

This figure shows that when *L. monocytogenes* is present on raw salmon at the concentration 1 cfu/10g, it can grow out to high numbers during storage, since this pathogen can grow at refrigeration temperatures.

If air contamination can take place during filleting, salting and packaging this results in an increase at the filleting step of 2 logs (Figure 4). Subsequent contamination at salting and packaging give smaller increases. This shows that the importance of recontamination strongly depends on the number of pathogens already present in the product (this can also be seen in **equation 3**). If a product is contaminated with 10^3 cfu/g, contamination of 1 cfu/g from the air is negligible. However, for sterile products, this contamination may be important, especially if subsequent growth can occur like in the case of *L. monocytogenes*.

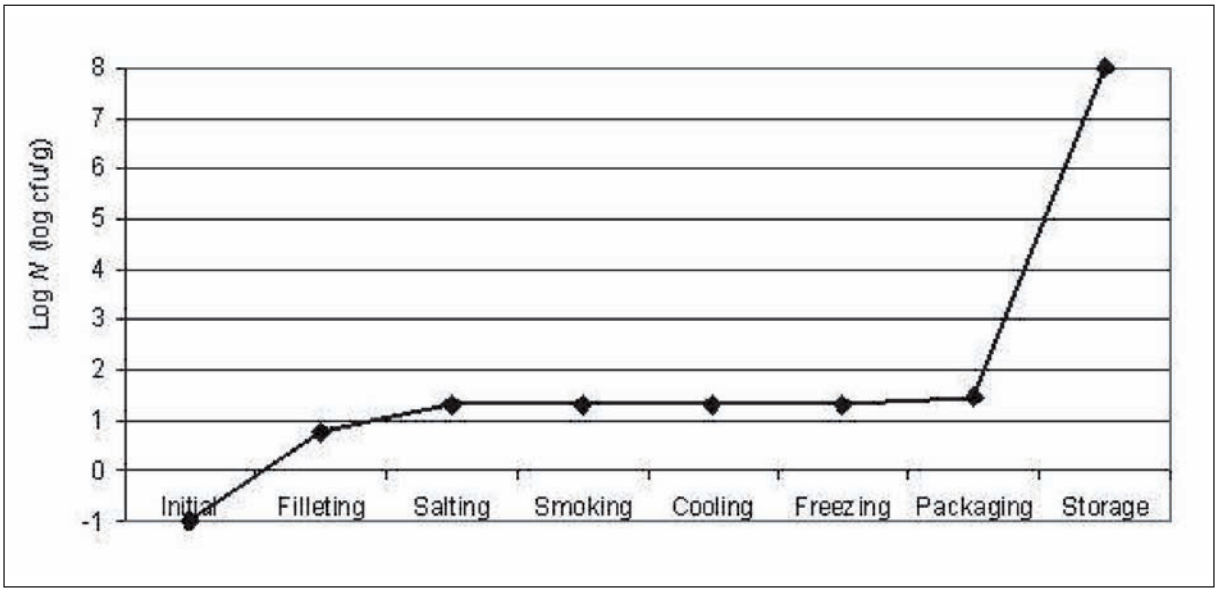

Figure 4. Number of *L. monocytogenes* in each process step in case there is air contamination at the filleting, salting and packaging step.

This example shows that incorporating recontamination models gives insight in the production process and can easily show the most important process steps.

10.2.3. Recontamination via biofilms

When bacteria attach to a surface they can form biofilm, which consist of bacteria and their extracellular products. Bacteria in such biofilm are more resistant to cleaning and disinfection, which makes it more difficult to remove these attached bacteria from food production systems than free living cells. Biofilm can then cause recontamination of products when bacteria detach from the biofilm and end up in the final product. Most biofilm models in literature are designed for aquatic systems for which the focus is on substrate and/or oxygen consumption and where the biofilm is well developed and mature. In the food processing industry, however, biofilm will be much thinner due to regular cleaning of the equipment. Further, the substrate consumption is usually unknown and much smaller than in aquatic systems. Therefore, models based on oxygen and substrate consumption as applied in aquatic systems are less useful for the food industry. Therefore, a 1D model is developed that can be used for the food industry, which consists of a liquid bulk phase (or product phase) and a biofilm phase (Figure 5) (4).

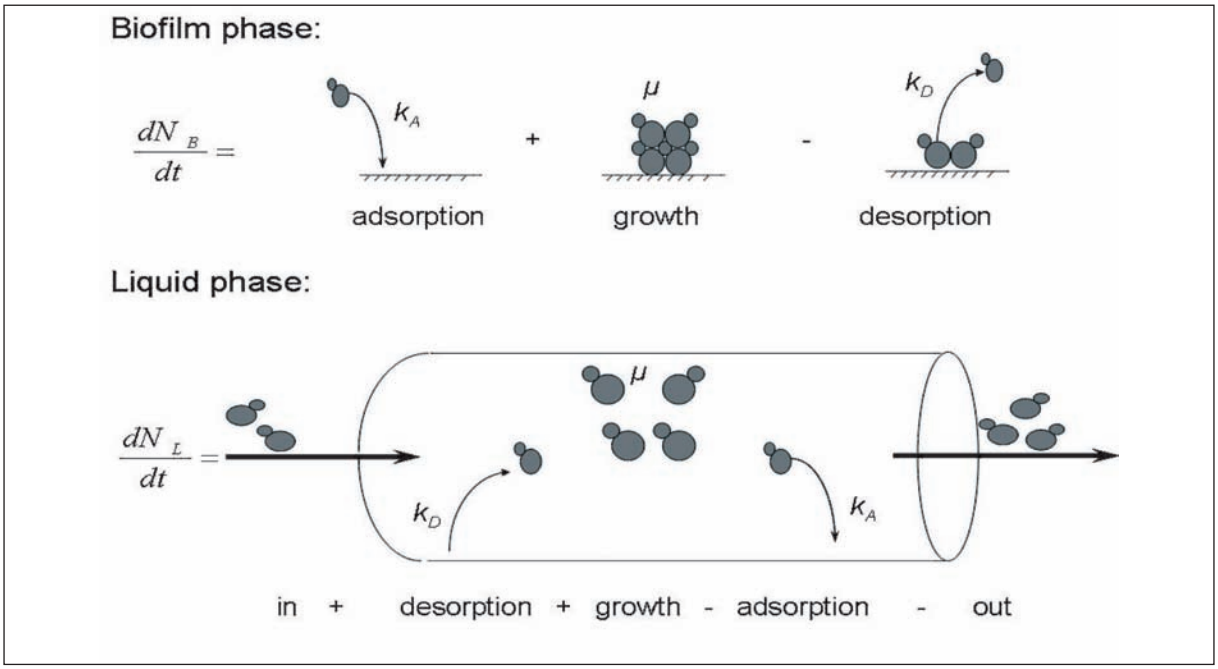

Figure 5. Schematic picture of the biofilm model. The number of cells in the biofilm phase (N_B) depends on the number of cells adhering to the wall (with adsorption rate k_A), the growth of attached cells (μ) and the number of cells detaching from the wall (with desorption rate k_D).The number of cells in the bulk liquid (N_L) depends on the number of cells flowing into the system, the number of cells released from the wall, growth in the bulk liquid, adsorption of cells to the wall and the number of cells flowing out of the system.

Model parameters were obtained in laboratory experiments with Staphylococcus aureus (as described in (4). The results of the model fits are given in Figure 6.

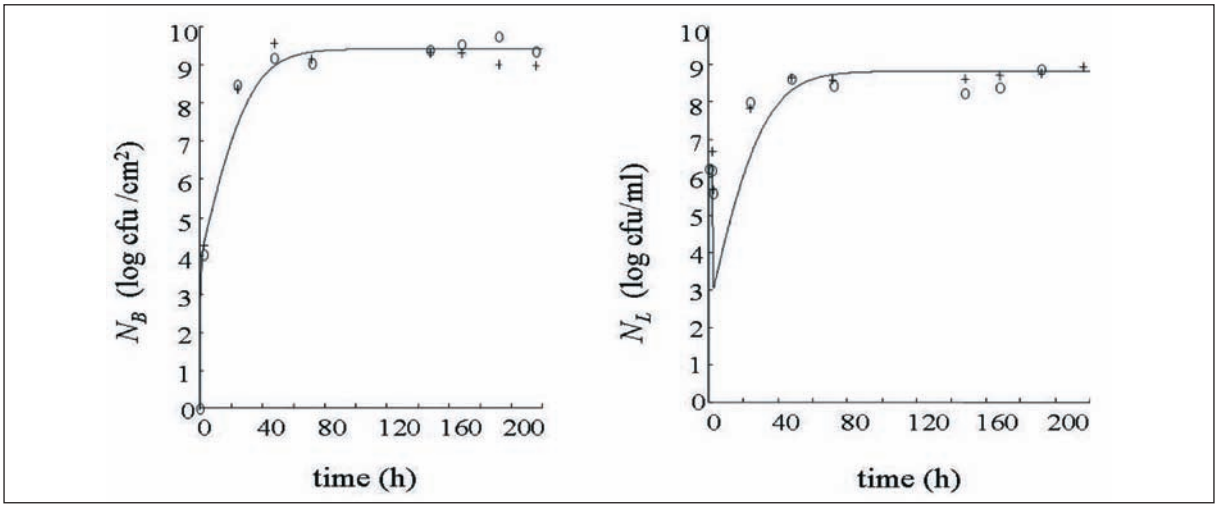

Figure 6. Biofilm formation both the number of attached cells (left picture) and the number of released cells from the biofilm (right picture). The + and o signs depict data points of two separate biofilm experiments with *S. aureus* and the solid line is the description of the model for μ_B = 0.49 h^{-1} and k_D = 0.0048 $m^{0.3}cfu^{-0.15}h^{-1}$.

Since both the biofilm and product phase are described, this biofilm model can be used to assess the importance of recontamination in flowing systems such as heat exchangers.

10.3. Recontamination in domestic environment

Transfer of bacteria to surfaces and subsequent contamination of a product can also occur in the domestic environment. Recontamination in the domestic environment can occur, for example, when consumers prepare a salad with meat. When preparing the meat, various items like cutting boards, cutlery and hands get contaminated potentially resulting in a contaminated salad. The effect of these contamination routes was studied in laboratory scenarios. A chicken-curry salad recipe was studied since this recipe offered possibilities for cross-contamination and undercooking. The salad was prepared as follows: first cut a chicken breast fillet in half (by which the chicken can contaminate various items), then boil it in water for 10 minutes. Cut the chicken to smaller pieces, cut the fruit (apple, orange and pineapple) and add spices and cream. Details of the recipe can be found in (6). The chicken breast fillet was inoculated with *Campylobacter jejuni* and final levels of this pathogen in the salad were determined when making various mistakes during preparation of the salad. In this way, cross-contamination via cutting board, hands and cutlery was studied and the results were used to determine transfer rates for the various contamination routes. In this paper we focus on hand contamination. Results of the other contamination routes can be found in (5) and (6). The hand contamination route with associated transfer rates is depicted in Figure 7.

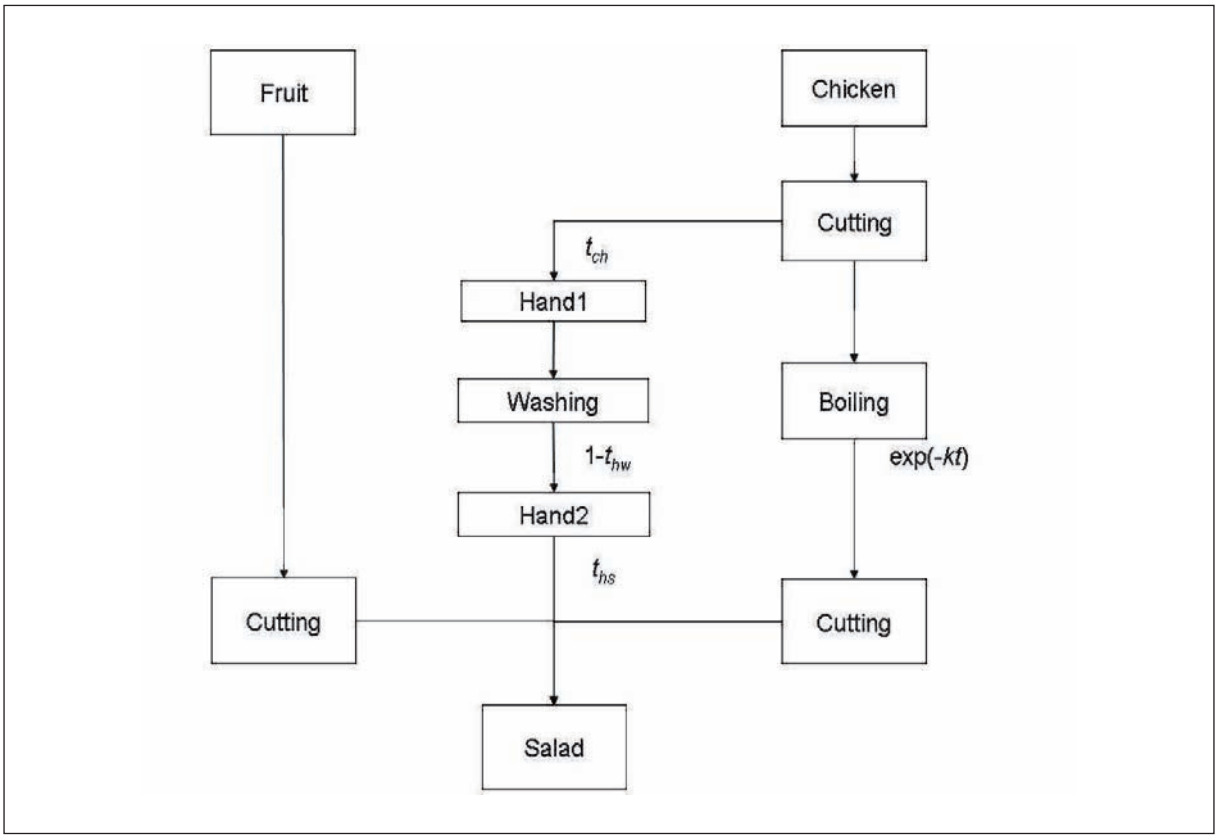

Figure 7. Cross-contamination routes with transfer rates used in the model. t_{ch}: transfer rate from raw chicken to hands, t_{hw}: transfer rate from hands to sink due to washing; t_{hs}: transfer rate from hands to salad.

Figure 8 shows that hand contamination resulted in the same levels of bacteria in the salad as in the worst case scenario (WC) with cooking, where cutting boards, hands and cutlery were not washed after cutting the raw chicken fillet. All contamination routes, thus, were equally important (6).

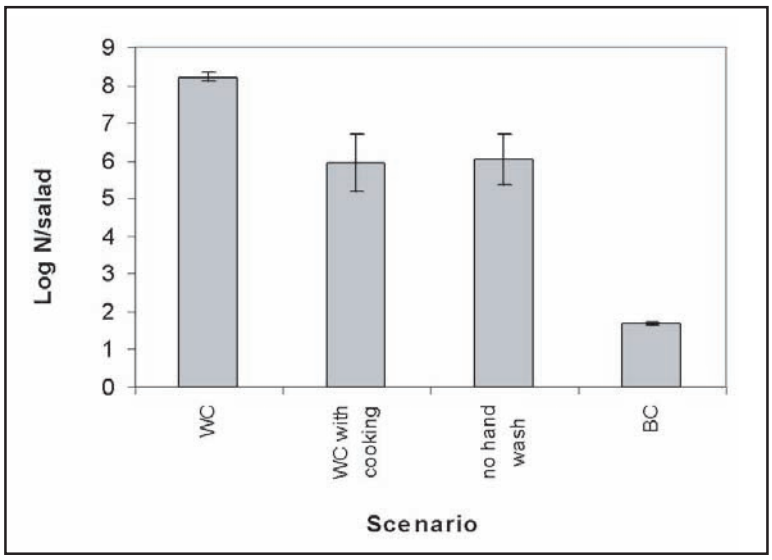

Figure 8. Number of bacteria found in the salad for various scenarios. WC: Worst Case: hands, cutting boards and cutlery were not washed after cutting raw meat and the chicken was not boiled. BC: Best Case: chicken was not touched by hand and new cutting board and cutlery was used for cutting the cooked chicken and fruits.

Based on these scenarios, transfer rates (from chicken via cutting board, hands or cutlery to the final salad) could be obtained by comparing initial levels on the chicken with final levels in the salad. Only overall transfer rates could be estimated, i.e. the multiplication of transfer from chicken to item (t_{ci}) with transfer from item to salad (t_{is}) and not the separate parameter values (5). The obtained transfer rates for hand contamination are given in Figure 9. This figure shows that if hands are not washed (t_{hw} = 0, therefore hand transfer is $t_{ch}t_{hs}$), the number of *C. jejuni* that is transferred from the raw chicken to the final salad ($t_{ch}t_{hs}$) is around 0.5% of the initial level on the raw chicken. If hands are washed with cold water or soap either 1.9% or 0.05% of this 0.5% is transferred to the salad.

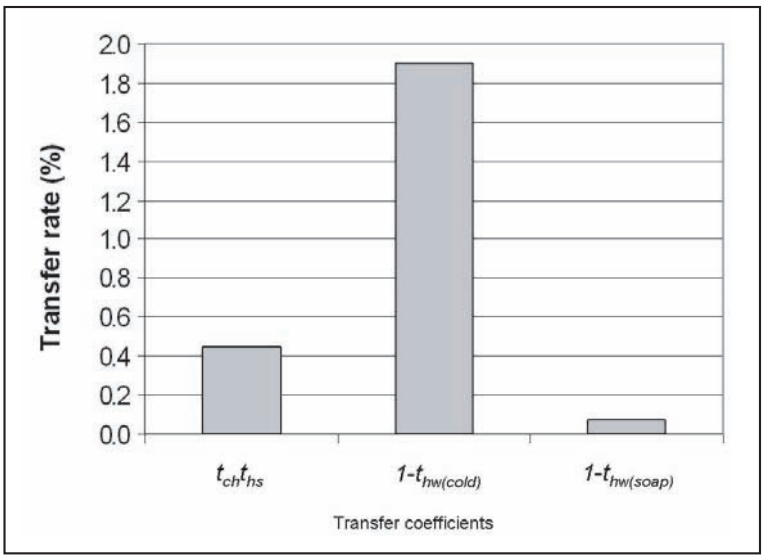

Figure 9. Transfer rates for hand contamination. $t_{ch}t_{hs}$: transfer from chicken to hand and from hand to salad. t_{hw}: transfer from hand to sink due to washing ($(1\text{-}t_{hw})$ is remaining fraction on the hands). "Cold" means washing with cold water and "soap" means washing with cold water and soap.

Van Asselt et al. (5) and de Jong et al. (6) showed that it is important to use separate clean knives and cutting boards for cutting fruits, vegetables and prepared meat after cutting raw meat. Washing alone is no guarantee to remove all bacteria. Furthermore, hand contact should be avoided, but in case hands are used to cut raw meat they should be cleaned thoroughly using soap.

The obtained transfer rates for *C. jejuni* can be used to predict the effect of consumer behavior on the probability of illness from a chicken-curry salad. In order to do this, an observational study needs to be performed to determine what errors are most common in domestic cooking. Data from such a study can be used to validate the developed model. Once the model is validated, the obtained transfer rates for *C. jejuni* can be used in combination with consumer handling practices in microbiological risk assessments to assess the effect of cross-contamination in the kitchen on human health risks (5).

References

1. den Aantrekker, E.D. (2002). Recommendation in food processing – quantitative modelling for risk assessment. Wageningen University, Laboratory of Food Microbiology, Wageningen, the Netherlands
2. den Aantrekker, E.D., R.M. Boom, M.H. Zwietering, and M. van Schothorst (2002). Quantifying recontamination through factory environments – a review. International Journal of Food Microbiology 80(2), p117-130
3. den Aantrekker, E.D., R.R. Beumer, S.J.C. van Gerwen, M.H. Zwietering, M. van Schothorst, and R.M. Boom (2003a). Estimating the probability of recontamination via the air using Monte Carlo simulations. International Journal of Food Microbiology 87 (1-2), p 1-15.
4. den Aantrekker, E.D., W.W. Vernooij, M.W. Reij, M.H. Zwietering R.R. Beumer, M. van Schothorst, and R.M. Boom (2003b). A biofilm model for flowing systems in the food industry. Journal of Food Protection 66 (8), p1432-1438
5. van Asselt, E.D., A.E.I. de Jong, R. de Jong, and M.J. Nauta. Quantifying cross-contamination in the kitchen (submitted)
6. de Jong, A.E.I., L. Verhoeff-Bakkenes, M.J. Nauta, and R. de Jong. Cross-contamination quantifying hygiene measures in the consumer kitchen. (submitted)
7. White, W. (1986). Sterility assurance and models for assessing airborne bacterial contamination. Journal of Parenteral Science and Technology 40(5), p 188-197
8. Zwietering, M.H. (2002). Quantification of microbial quality and safety in minimally processed food. International Dairy Journal 12 (2-3), p 263-271

11. The CRAN Project – Company Risk Assessment Network

C. Heggum[1], E. Borch[2]

The CRAN project is a three-year project (2004-2007), partly founded by the Nordic Innovation Center, aiming at improving HACCP systems in the food industry.

The project is lead by the Swedish Institute for Food and Biotechnology and involves experts from various public and private research institutes, organizations and food companies.

11.1. The objectives of the CRAN project

Today, food businesses perform more or less objective and qualitative hazard analyses when developing their individual HACCP plans.

Currently, the level of objectivity of these HACCP plans is reduced due to difficulties in

- Estimating the severity and likelihood of the occurrence of a specific hazard and
- Quantifying the impact of control measures on these hazards,

This situation creates uncertainty as regards correctly identifying hazards requiring control and the best means of controlling them. In the best case, this leads to the built-in of exaggerated safety margins – in the worst case, it leads to food safety problems.

A substantial improvement of the hazard analysis can be achieved by using a systematic approach similar to quantitative risk assessment. Such improvement will, in particular, be necessary when food safety authorities implement quantitative risk management approaches including the establishment of FSOs, POs etc.

Applying a systematic quantitative approach will enable the HACCP team to optimize the selection of control measures (& combinations), taking the whole food chain into account, and will lead to decisions being made on more comprehensive and balanced facts, and thus lead to control systems that are better documented as regards compliance with legislation, consumer demands.

Such approach is already outlined in ISO 22000, and is followed by the CRAN project. The four-step hazard analysis process stipulated by ISO 22000 is:

3. Hazard identification (Which hazards are likely to be present, and at what frequencies and levels?)
4. Hazards assessment (Which of the identified hazards require control, and to what extent?)
5. Control measure assessment (Which control measures are effective and to what extent?)
6. Combination of control measures (What combination(s) are needed, suitable and sufficient to meet the defined outcome for each of those hazards requiring control?)

11.2. The software

The output of the CRAN project will be:

- Computer-based tools for probabilistic exposure assessment and for fact-based decision making, and
- The establishing a network among food businesses carrying out quantitative hazard analysis.

Three pathogen/product combinations have been chosen for the first version. After closing of the project, subsequent further development of the software will be required.

The software package consists of 4 related programs:

1. Two databases:

[1] Chief Consultant, Quality & Food Safety, Danish Dairy Board, Aarhus (Denmark)

[2] Unit Director, Swedish Institute for Food and Biotechnology, Lund (Sweden)

- Pathogen database containing data collected on prevalence in ingredients, growth/survival rates under various conditions, D-and z-values for treatments, and probabilities for contamination.
- Process database, containing flow diagrams, process & product criteria (time, temperature, water activity, salt, pH, additives) and description of other process parameters (mixing, partitioning, removal)

2. A **simulation program** that enables the user to take the data from the databases to simulate the effect of process and product parameters on the bacterial concentration in the end product. This includes simulations of bacterial growth, reduction, contamination and removal. The effect of variations in the process parameters is evaluated using Monte Carlo simulation.
3. A **decision tool** utilizing simulation outputs in relation to other factors important for decision making

The dataflow is illustrated in Fig. 1.

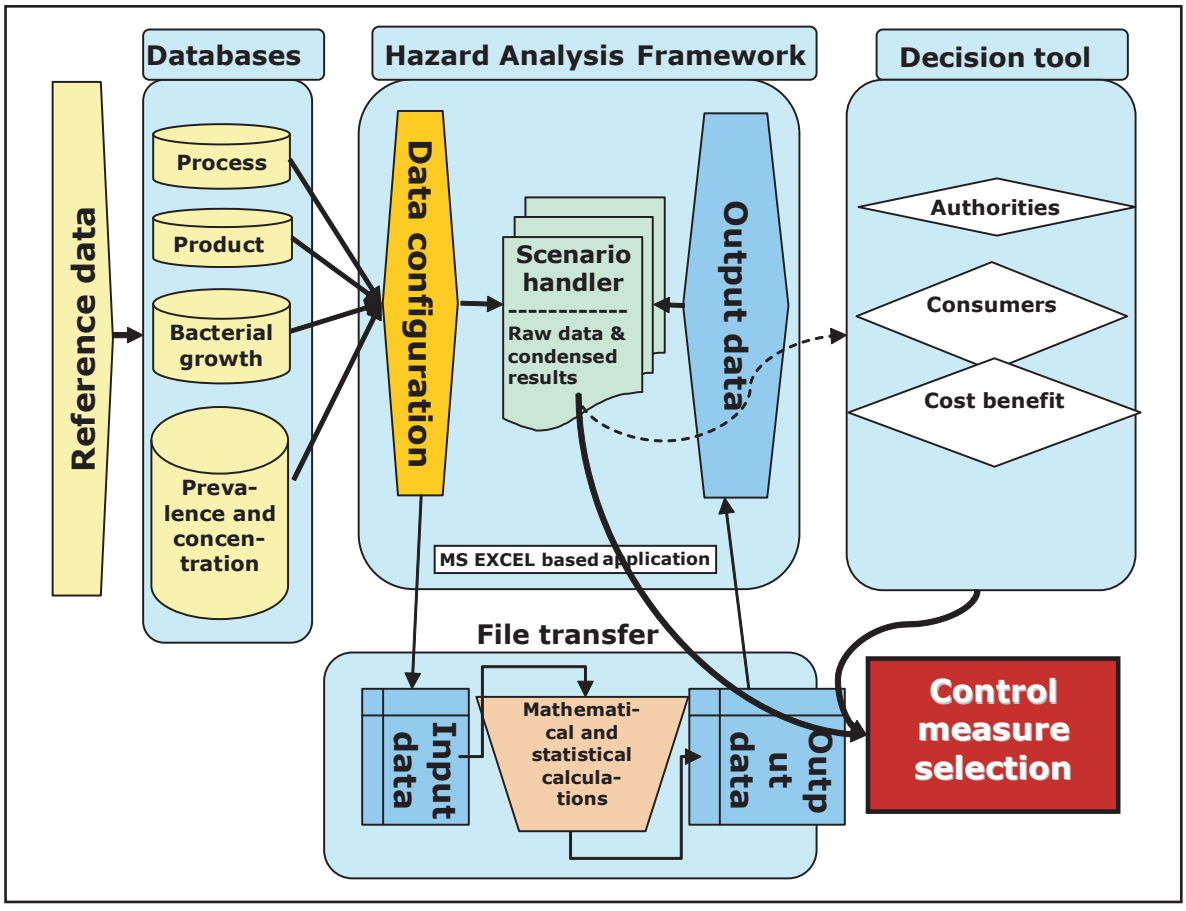

Figure 1. Dataflow in the CRAN calculation program

The databases are developed in Microsoft Access and the simulation/calculation tool is written in Matlab. The user interface is in Microsoft Excel. The decision tool will mainly be built on Microsoft PowerPoint

11.2.1. The probabilistic approach

In reality, there are no true levels or frequencies of hazards in any food nor is any process parameter (e.g. a temperature) functioning at the exact one value. The truth is that all values are distributions of various kinds.

In a bacterial growth model, a number of distributions occur:

- The initial level in the food
- Lag times,
- Growth rates

Together, these three distributions lead to a consequential distribution of the concentration of the hazard in the food at any specific time.

It is impossible to carry out calculations on the basis of distributions, unless software such as Monte Carlo is used. The CRAN software use Monte Carlo simulation and enables simulation on the basis of single value assessments as well as normal, triangle and uniform distributions of parameters included.

11.2.2. The decision tool

In a legal environment in which the principle of equivalence prevails, the individual food business will have full freedom to choose among control measures that are capable of, either alone or in combination with other control measures, to control identified hazards to the extent required to achieve food safety targets.

But it is difficult to make informed decisions among a huge number of alternatives. To assist food busi-nesses in obtaining the full benefits of the simulation results, the CRAN project includes the development of decision assistant tools.

Such tool will be valuable in the planning and designing of cost-effective control measure combinations taking into account control measures applied throughout the food chain

The decision making tool can assist the food business, taking into account the local context, in making choices between, for instance

- Different control measures (e.g. shorter time profile during manufacture versus a microbiocidal treatment,
- Different process parameters (e.g. time/temperature combinations of a heat treatment)
- Different durability scenarios

Further, the information obtained could be focused on various output parameters, such as

- Probability of exceeding a specific target (FSO or PO)
- Probability of detecting the organisms when testing the end product in the laboratory
- Number of expected death, hospitalizations and other defined adverse health effects resulting from the distribution of hazards in the products.

11.3. Networking activities

Part of the CRAN project is to develop networks to enable discussion among food businesses about quan-titative hazard analysis as well as the dissemination of results and sharing knowledge in this field.

Project activities to achieve this involves:

- Training activities

  Until now the project participants have received training in microbial risk assessment to enable them in developing the software, and an open workshop for the food industry was held in 2005. In 2007, a more comprehensive seminar is being planned.
- Establishing a communication framework for exchanging knowledge

  A homepage has been created. A chat page still to be established

Finally, newsletters are issued frequently.

11.4. Perspectives

The dairy sector is probably the most advanced food sector in terms of food safety management. It was therefore felt natural to base the first version of CRAN on dairy examples. It is likely to expect that it also will be the dairy sector that will be in the frontline in developing new food safety management initiatives

Today, we have learned about the current activities of WHO and Codex Alimentarius, which clearly show in which direction food safety management is developing. Microbial risk management, in particular the FSO/PO/PC approach will drive a number of new initiatives, at authority and at industry levels, and will dramatically change the way in which food businesses deal with HACCP.

The drafters of ISO 22000 foresaw this wherefore the ISO standard provides a further developed HACCP approach that enable the practical implementation of quantitative targets.

Incitements to perform quantitative hazard analysis as the basis for designing HACCP plans will certainly grow, and hence there will be a growing demand for software-based tools that assist food businesses in this regard.

Programs such as the USDA Pathogen Modeling Program represent the first generation of assistance tools. CRAN represents the second, but many additional generations will come.

12. *E. sakazakii* – An Update on Risk Assessment Activity

J. Shepherd[1]

12.1. Introduction

Since 1958, approximately 45 cases of *Enterobacter sakazakii* invasive disease in infants have been documented [1]. Although the occurrence of illness is very rare, the disease is of concern because of its severity. A high proportion of infants infected suffer serious developmental sequelae or death.

Some of the cases of illness caused by *E. sakazakii* have been linked to powdered infant formula. This has triggered significant international activity, including risk assessments, creation/revision of documents providing guidance on manufacture and use of powdered infant formula, as well as research into methods, characteristics, sources, pathogenicity and virulence of *E. sakazakii*.

The issue of pathogens and in particular *E. sakazakii* in powdered infant formula was raised at the 35th Session of Codex Committee for Food Hygiene (CCFH) in 2003 [2] by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) which requested a revision of the Recommended International Code of Hygienic Practice for Foods for Infants and Children (the Code) (CAC/RCP 21-1979) [3]. At this same meeting the United States of America and Canada introduced a risk profile for *E. sakazakii* in powdered infant formula for consideration by the Committee [updated version, [4].

A drafting group led by Canada was set up to initiate revision of the Code and the CCFH requested that FAO and WHO convene an expert consultation on pathogens of concern in powdered infant formula.

As a response to this request, the first Joint FAO/WHO expert meeting on microbiological risk assessment (JEMRA) on *E. sakazakii* and other micro-organisms in powdered infant formula was held in Geneva (February 2004) and a risk assessment was subsequently published [5]. The JEMRA meeting considered pathogens (including opportunistic pathogens) of concern in infant formula (defined as a breast milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complimentary feeding). The microorganisms identified as being well-established causes of illness in infants, and therefore the focus of the risk assessment were *E. sakazakii* and *Salmonella enterica*. The drafting group revision of the Code was based on the scientific advice from the JEMRA report.

At the 37th Session of CCFH (March 2005) [6] the Committee agreed to change the title of the Code to Code of Hygienic Practice for Powdered Formulae for Infants and Young Children and FAO/WHO was requested to convene a second Expert Consultation for additional scientific advice to contribute to further revision of the Code. As a consequence the second JEMRA on *E. sakazakii* and other micro-organisms in powdered infant formula was held in Rome, in January 2006 [1]. This assisted with the revision of the Code by the Working Group at its meeting in May 2006 [7].

Other risk assessments have also been published, including the European Food Safety Authority's (EFSA) opinion on microbiological risks in infant formulae and follow-on formulae [8] which provides a risk assessment on *E. sakazakii*. Subsequently the European Union has revised microbiological criteria for foodstuffs to include *E. sakazakii* criteria for infants up to 6 months of age [9].

All the *E. sakazakii* risk assessments have been valuable for defining risk groups, potential sources of the microorganism, and possible control measures and risk reduction strategies. The risk assessments have also identified data gaps, and consequently, have played a part in directing research efforts.

[1] Fonterra Co-operative Group Ltd., Dairy Farm Rd, Private Bag 11029, Palmerston North, New Zealand.
joanna.shepherd@fonterra.com

This paper summarises some key points arising from risk assessments and the application of these by manufacturers, regulators and advisory bodies to minimise the risk to infants from *E. sakazakii* in powdered infant formula.

12.2. Risk Assessments

The risk assessments have brought together and evaluated relevant information from the scientific literature and other reliable sources. Because this paper is a summary, the information has been extracted from the JEMRA and EFSA risk assessments, rather than from the original references. Following are some of the information and key points from the risk assessments that are critical to consider when making risk management decisions.

12.2.1. Population at greatest risk

The different risk assessments agree that those at greatest risk from *E. sakazakii* illness are young infants (neonates). Each of the definitions is given below.

- In the first JEMRA report the infants at greatest risk are defined as "neonates (≤28 days), particularly preterm infants, low birth weight infants or immunocompromised infants."
- The second JEMRA report further refined the definition to "infants less than 2 months of age being at greatest risk, with two distinct infant groups in terms of the syndrome they tend to develop. These are premature infants who develop bacteraemia outside of the neonatal period with most cases occurring in infants less than 2 months of age and term infants who develop meningitis during the neonatal period."
- The EFSA risk assessment defined the group at greatest risk as "neonates (up to ca 4-6 weeks of age), preterm or low birth weight infants and those immunocompromised."

Other age groups have not been covered in the risk assessments because, although there have been documented cases of illness in children and adults, these are extremely rare and have occurred in individuals with underlying diseases, have often been hospital acquired (nosocomial) and have not been foodborne. Additionally, the very small number of cases in children and adults is not remarkable in relation to the general background of nosocomial infections from other microorganisms [10, 11, 12, 13].

12.2.2. *E. sakazakii* characteristics

There are various characteristics of *E. sakazakii* that are important to understand when considering and implementing control measures. These include

- **Growth**. *E. sakazakii* will not grow in powdered infant formula. However, after reconstitution it can grow at temperatures ranging from 8-47oC. When present, *E. sakazakii* can grow well in both breast milk and reconstituted powdered infant formula.
- **Biofilm formation**. *E. sakazakii* is able to form biofilms on silicon, latex and polycarbonate– all materials commonly used for feeding equipment.
- **Osmotolerance and thermotolerance**. *E. sakazakii* is more osmotolerant and thermotolerant than other Enterobacteriaceae. This means that it is more able to persist in warm and dry environments than other Enterobacteriaceae. *E. sakazakii* is also able to persist in the powdered infant formula.
- **Inactivation**. *E. sakazakii* is inactivated by heat treatments equivalent to pasteurisation.

12.2.3. *E. sakazakii* sources

E. sakazakii is ubiquitous. It has been found in a wide range of environments including food factories, households, hospitals and formula preparation equipment and is carried by flies. For the risk assessments, understanding sources that can contaminate powdered infant formula and reconstituted powdered infant formula is important.

E. sakazakii is more difficult to control in manufacturing environments than other Enterobacteriaceae. Consequently, manufacturing plant environments are a recognised source of contamination of powdered infant formula post manufacture, during handling and filling. Sterile powdered infant formula can not be produced using the current manufacturing technology.

Another source of *E. sakazakii* that must not be overlooked is environmental contamination occurring during reconstitution of the powdered infant formula.

12.2.4. Dose-response and exposure

The dose-response and exposure aspects of the risk assessments are difficult to define quantitatively due to the limited data available. The lack of information on the number of organisms that infected infants had been exposed to makes it impossible to develop a dose-response relationship.

It is also difficult to estimate the number of infants exposed to *E. sakazakii* internationally as consumption of infant formula and breastfeeding rates differ from country to country. The concentration that infants consuming infant formula will be exposed to is also difficult to calculate as there is variability and uncertainty in the handling practices of infant formula internationally. Although there is some data on the levels of *E. sakazakii* in powdered infant formula, the levels will have changed over time as awareness has increased and additional control measures have been introduced. Also, various testing protocols were used in the surveys, so there is a need for surveys using consistent methods.

In the JEMRA risk assessments, modelling was used to predict growth of *E. sakazakii* in reconstituted powdered infant formula. This has enabled the relative risk of different preparation and handling practices to be explored and the effectiveness of different control measures such as temperature of reconstitution and time and temperature of storage to be evaluated.

12.2.5. Risk assessment findings

From the first JEMRA risk assessment, the following are some of the key points.

1. The key factors affecting the microbiological risks associated with powdered infant formula include:
   - *The level of contamination in the powdered infant formula*. For example, a reduction in the frequency of contamination from 0.025 (1 in 40) to 0.0001 (1 in 10,000) reduced relative risk by approximately five-fold.
   - *The level of hygiene in the preparation and delivery of the reconstituted formula*. For example, a decrease in environmental contamination from 0.00625 (1 in 160) to 0.0001 (1 in 10 000) was estimated to achieve a 1.24-fold decrease in relative risk.
   - *The inclusion of a bactericidal treatment at the time of preparation*. For example, reconstitution of formula at >70oC could result in a relative risk reduction of 10 000 fold, however, if this is applied only 80% of the time the estimated risk reduction would only be five-fold.
   - *The duration of the feeding period and the temperature*. If reconstituted formula is held for extended times this can greatly increase the relative risk. For example, after 6 hours at 25oC the relative risk increases thirty-fold and after 10 hours at 25oC the relative risk increases 30 000-fold.
2. The two factors that were predicted to produce the greatest reductions in risk were:
   - The duration of the time between reconstitution and consumption, and
   - The inclusion of a bactericidal treatment at the point of rehydration
3. The degree of risk reduction that can be achieved by reducing *E. sakazakii* levels in powdered infant formula is dependent in part on the extent of contamination that is attributable to the presence of the pathogens in the preparation environment
4. Control measures can be combined to achieve a greater degree of risk reduction than that achieved through the use of any single control measure

The second JEMRA risk assessment extended the modelling by using a larger number of more specific preparation and handling parameters to assess relative risk. Some additional key points from this risk assessment are:

- The temperature of reconstitution has a significant impact on the relative risk. Temperatures less than 20°C will have no lethal effect on *E. sakazakii* but will minimise growth. Temperatures between 20 and 60°C will have little or no lethal effect and if the formula is not consumed immediately or cooled rapidly there is significant opportunity for growth of *E. sakazakii*. At 70°C significant inactivation occurs.
- Periods of holding reconstituted infant formula increase the risk. Room temperature holding has a greater risk associated with it than formula held at refrigeration temperatures.
- Using large containers to prepare and cool formula increases the risk as a result of the slower cooling rate allowing more time for growth of *E. sakazakii*.

12.3. The Codex Code

The Code is being revised [7] with the objective of providing practical guidance and recommendations to Governments, industry and caregivers of infants and young children, as appropriate, on the hygienic manufacture of powdered formulae and on the subsequent hygienic preparation, handling and use of reconstituted formulae.

The JEMRA risk assessments were undertaken to provide scientific advice to the Working Group revising the Code. The key recommendations from the risk assessments that are addressed in the Code are:

1. For situations where high-risk infants are not breastfed
   - Alert caregivers that powdered infant formula is not a sterile product
   - Provide information on use of powdered infant formula that can reduce the risk
   - Encourage the use of sterile liquid formula or formula that has undergone a point-of-use decontamination procedure
2. Develop guidelines for the preparation, use and handling of infant formula to minimise risk (also being addressed separately by the WHO/FAO)
3. Reduce the concentration and prevalence of *E. sakazakii* in the manufacturing environment and powdered infant formula (including development of appropriate microbiological criteria)

12.4. Control measures

The risk assessments have identified control measures that will contribute to reducing risk to infants consuming reconstituted powdered infant formula. These control measures are being incorporated into the revised Code. The following summarises these control measures and includes some text from the draft Code [7].

12.4.1. Manufacturing

Control measures to minimise *E. sakazakii* contamination of powdered infant formula at the manufacturing level include the use of quality ingredients; zoning of the manufacturing environment and restricting access to high hygiene areas, separation of wet and dry processes (avoiding condensation and water ingress in dry areas) and avoiding recontamination of the final product from air and surfaces during blending, filling and packaging.

Monitoring Enterobacteriaceae in the manufacturing environment verifies that these strict hygiene measures are being successfully implemented. The draft Code contains an appendix on environmental monitoring.

Already, manufacturers of powdered infant formula have been active in implementing appropriate control measures, resulting in reduced prevalence of *E. sakazakii* in powdered infant formula.

12.4.2. Education and labelling

Safe preparation and handling of powdered infant formula is critical and this can be communicated through education and labelling.

The risk to infants consuming reconstituted powdered infant formula can be reduced by ensuring that adequate and accessible information is available to all concerned in the food chain, in particular retail establishments, pharmacists, caregivers of infants in the home, day care and health-care facilities and health-care professionals to enable them to handle, store, process, prepare and display powdered formula safely and correctly. This can be provided through labelling and education.

Caregivers of infants in the home, day care and health-care facilities and health-care professionals should be informed that powdered formula is not a sterile product, and should be provided with sufficient information on food hygiene to enable them to make informed choices appropriate to the health status of the infant and to prevent contamination and/or growth of foodborne pathogens.

More specific control measures can be targeted at the specific situation. For example, for caregivers in the home the most effective control measure is to use the formula immediately after it is prepared. In situations where this does not occur, then control measures that minimise the opportunity for growth of any microorganisms present become important.

Infants in neonatal care units are considered to be at risk of *E. sakazakii* illness. To reduce the risk to these infants, many countries have advised that, where possible, infants in neonatal care units should be fed sterile liquid formula. If this is not possible then control measures such as heat treatment at the time of preparation and minimising storage time and temperature are important. The draft Code contains an appendix on control measures to select from when preparing and using powdered infant formula.

12.5. Microbiological Criteria

Microbiological criteria for powdered infant formula are being reviewed by various groups, the published and proposed *E. sakazakii* criteria are presented in Table 1.

The European Union was the first to publish microbiological criteria for *E. sakazakii* [9]. The food safety criterion has been set for "dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age", and is only required if there is a detection of Enterobacteriaceae in any of the units tested (process hygiene criteria).

In the latest draft of the Code, the Codex Working Group has included *E. sakazakii* criteria that are based on recommendations from the second JEMRA report. The report considered different sampling plans and calculated the probability of rejecting lots of powdered infant formula and the relative risk reduction achieved when different concentrations of *E. sakazakii* were present in powdered infant formula. It was considered that more stringent criteria would not give a significant improvement in risk reduction.

There is continuing debate among member countries on the age groups that the Codex criteria should apply to. Some countries favour applying criteria to the definition of infant[1], which means that *E. sakazakii* criteria would apply to any products manufactured for consumption by infants up to 12 months of age. Other countries favour applying criteria to product definitions. The *E. sakazakii* criteria would apply to infant formula but exclude follow-on formula[2] as this is targeted at older infants[3] that are not part of the group at greatest risk. Also, these older infants will be exposed to *E. sakazakii* from a wide range of sources, not just powdered infant formula. From discussions at the May 2005 Codex Working Group meeting on the Code, there is no intention to require *E. sakazakii* testing for products intended for young children[4].

---

[1] Defined in Codex Stand 72 and Codex Stan 156 as "a person of not more than 12 months of age". [14]

[2] Defined in Codex Stan 156 as "a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children". [15]

[3] Defined by Codex in CAC/GL 8 as "persons from the 6th month and not more than 12 months of age". [16]

[4] Defined in Codex Stan 156 as "persons from the age of more than 12 months up to the age of 3 years (36 months)". [15]

The USFDA proposed rule is open for comment on whether *E. sakazakii* criteria should be required for powdered infant formula (up to 12 months of age) [17].

Any microbiological criteria that are set must include reference to the method used to test for the specified microorganism. The EU specify that the joint ISO/IDF technical specification method (ISO/TS 22964, IDF/RM 210:2006E) "Milk and milk products – detection of *Enterobacter sakazakii*" should be used. Codex has also noted that the joint ISO/IDF method would be used.

Table 1: *E. sakazakii* criteria for powdered infant formula (products requiring testing vary, see the detail in the text)

	n	c	m
Codex (draft) [7]	30	0	0/10 g
European Union*[9]	30	0	0/10 g
USFDA proposed rule**[17]	30	0	0/10 g

*only required if Enterobacteriaceae is detected in n = 10, c = 0, m = 0/10 g (process hygiene criteria)

**comment on whether criteria should be required by 15 September 2006

12.6. Continuing Activity

- The WHO/FAO has drafted guidelines for safe preparation and use of powdered infant formula. These have gone out for comment.
- The next CCFH meeting, 38th Session, to consider the Code is scheduled for December 2006 [18].
- An international working group has been convened to develop an international standard for the detection of *E. sakazakii* based on the ISO/IDF document issued in January 2006.
- Various groups are continuing their research into methods of isolation as well as the characteristics, pathogenicity and virulence of *E. sakazakii*.

References

1. Enterobacter sakazakii and Salmonella in powdered infant formula. Meeting Report, [Joint FAO/WHO Workshop, Rome, Italy 16 – 20 January 2006]. Advance pre-publication copy 2 May 2006. ftp://ftp.fao.org/ag/agn/jemra/e_sakakazii_salmonella.pdf
2. Report of the Thirty-fifth Session of the Codex Committee on Food Hygiene. Orlando, Florida, United States of America, 27 January - 1 February 2003. Alinorm 03/13A. http://www.codexalimentarius.net/web/archives.jsp?year=03
3. Codex Alimentarius Commission. Recommended International Code of Hygienic Practice for Foods for Infants and Children. CAC/RCP 21-1979 ftp://ftp.fao.org/es/esn/jemra/CAC_RCP21.pdf
4. Risk Profile of Enterobacter sakazakii and Other Microorganisms in Powdered Infant Formula. Codex Committee on Food Hygiene, Thirty-Sixth Session, Washington D.C., United States of America, 29 March – 3 April 2004. Agenda Item 11(A), Prepared by the United States of America and Canada. CX/FH 04/12, January 2004. ftp://ftp.fao.org/codex/ccfh36/fh04_12e.pdf
5. Enterobacter sakazakii and other microorganisms in powdered infant formula: Meeting report [Joint FAO/WHO Workshop, Geneva, 2-5 February 2004]. Microbiological Risk Assessment Series 6. FAO/WHO 2004 (ISBN: 92 5 105164 X). http://www.fao.org/ag/AGN/jemra/enterobacter_en.stm http://www.who.int/foodsafety/publications/micro/enterobacter_sakazakii/en/

6. Report of the Thirty-seventh Session of the Codex Committee on Food Hygiene. Buenos Aires, Argentina, 14 – 19 March 2005. Alinorm 05/28/13.
http://www.codexalimentarius.net/web/archives.jsp?year=05
7. Codex Committee on Food Hygiene, Thirty-eighth Session, Provisional Agenda. Houston, Texas, United States of America, 4-9 December 2006. CX/FH 06/38/1July 2006
http://www.codexalimentarius.net/download/report/671/fh38_01e.pdf
8. Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the microbiological risks in infant formulae and follow-on formulae. The EFSA Journal (2004)113, 1-34
http://www.efsa.europa.eu/en/science/biohaz/biohaz_opinions/691.html
9. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on Microbiological Criteria for Foodstuffs. Official Journal of the European Union, 22.12.2005, L338.
http://europa.eu.int/
eur-lex/lex/LexUriServ/site/en/oj/2005/l_338/l_33820051222en00010026.pdf#search=%22EC%202073%2F2005%20microbiological%20criteria%22
10. Chang W.N., Huang C.H. & Chuang Y.C. (2000) Mixed infection in adult bacterial meningitis. Infection, 28(1): 8-12.
11. Chotpitayasunondh T. (1994) Bacterial meningitis in children, etiology and clinical features, an 11-year review of 618 cases. The Southeast Asian Journal of Tropical Medicine and Public Health, 25(1): 107-115.
12. Janicka G., Kania I., Ulatowska B., Kruszynska E. & Wojda M. (1999) The occurrence of the Enterobacter genus rods in the clinical materials and materials taken from hospital environment. Wiadomosci Lekarskie., 52(11-12): 554-558.
13. Jarvis W.R. & Martone W.J. (1992) Predominant pathogens in hospital infections. Journal of Antimicrobial Chemotherapy, 29(Suppl. A): 19-24.
14. Codex Alimentarius Commission. Codex Standard for Infant Formula. Codex Stan 72-1981. Amended 1983, 1985, 1897), currently under revision at step 6 of the Procedure (Appendix IV of Alinorm 05/28/26, Codex Committee on Nutrition and Foods for Special Dietary Uses)
http://www.codexalimentarius.net/download/standards/288/CXS_072e.pdf
http://www.codexalimentarius.net/web/archives.jsp?year=05
15. Codex Alimentarius Commission. Codex Standard for Follow-Up Formula. Codex Stan 156-1987, amended 1989.
http://www.codexalimentarius.net/download/standards/293/CXS_156e.pdf
16. Codex Alimentarius Commission. Guidelines on Formulated Supplementary Foods for Older Infants and Young Children. CAC/GL 08-1991.
http://www.codexalimentarius.net/download/standards/298/CXG_008e.pdf
17. Department of Health and Human Services, Food and Drug Administration. 21 CFR Parts 106 and 107 [Docket No. 1995N–0309] (formerly 95N–0309) RIN 0910–AA04. Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Reopening of the Comment Period
http://www.fda.gov/OHRMS/DOCKETS/98fr/E6-12268.pdf#search=%22FDA%20proposed%20rule%20sakazakii%20register%202006%22
18. Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (at Step 3). Codex Committee on Food Hygiene, Thirty-eighth Session CX/FH 06/38/7 September 2006.
ftp://ftp.fao.org/codex/ccfh38/fh38_07e.pdf

13. Antimicrobial Resistance - Prevention through Integrated Food Chain Management

H. Dornom[1], J Manners[1], R Condron[1]

Minimisation of antimicrobial resistance is a current and future challenge for human health professionals. The decline in the release of new antibiotic drugs and the increasing use of available antibiotics has resulted in the emergence of multi- resistant bacterial pathogens in the human health system. The consequences of the resistant pathogens are severe leading to failure of previously effective treatments, prolonged hospitalisation resulting in fatal outcomes in some instances and a greater risk for the wider community to be exposed to resistant strains.

There is debate about the potential for antimicrobial resistance to develop from the use of antimicrobials in animals. Although it is generally accepted that increases in resistance are primarily driven by use of antimicrobials in human medical practice and other factors including declines in local infection control practices [1] some international and government agencies believe there is evidence for:

- the emergence of resistant bacteria in humans and animals following antibiotic use
- the spread of resistant bacteria from animals to humans
- the transfer of antibiotic resistance genes from animal bacteria in animals to human pathogens and
- resistant strains of bacteria from animals causing human disease [1,2]

Under certain conditions such as confined spaces, resistant bacteria may spread from animal to animal. It has been suggested that other avenues for spread of resistant bacteria from animals to humans are via food or water that has not been adequately treated.

The risk related to toxicity affects and the disruption of human intestinal flora from antibiotic residues in food is considered to be very low. However the risks related to the emergence of resistant bacteria is considered to be high. [2]

The dairy industry needs to be mindful of the issues of antimicrobial resistance firstly for the potential impact it may have for the treatment of animals and hence cause productivity and animal welfare concerns but also for the potential in the future for antimicrobial resistance to be traced to the use of antimicrobials in dairy animals and potential damage to the reputation of the dairy industry.

The prevention of transmission of antimicrobial resistance through an integrated food chain requires positive action and cooperation by regulators, pharmaceutical companies, veterinarians and farmers. Across the world, these partners are working together to minimize the development of antibiotic resistance. The partnerships are in varying states of maturity however all parties are mindful of the importance of the challenge of preventing resistance.

13.1. Registration of drugs

Many countries require registration of all antimicrobial drugs used for food production. The registration is usually performed by a government agency. In a recent survey by the International Dairy Federation (IDF) [3] all twenty countries that responded (100%) reported the supply and sale of antimicrobial drugs was regulated by legislation. The responsible agencies were a combination of health and agriculture agencies.

In Australia the Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for approving the use of antibiotic products and regulating the sale of these products to wholesale level. The purpose of these laws is to allow the use of antibiotic products to treat sick animals but also to prevent their overuse or misuse. The APVMA must be satisfied that the

[1] Dairy Australia, Locked Bag 104, Melbourne, Victoria Australia

use of the product will not result in residues on or in the food that would be an undue risk to the safety of people consuming that food [4]. Reports from other parts of the world about specific issues are monitored on an ongoing basis to ensure that appropriate decisions are made about permitting the ongoing registration of antimicrobial treatments.

The IDF survey found that many countries have prohibited the use of certain antimicrobials in dairy animals. For example the European Union under directive ED 2201/82JEC has excluded chloramphenicol, nitrofurans, tilmicosin and all compounds where there is no MRL, erythromycin and other antimicrobials. In USA, approval to use nitroimidazoles (including dimetridazole, metronidazole and ipronidazole), sulfonamide use in adult dairy cattle, clenbuterol dipyrone, fluoroquinolones (examples enrofloxacin and danofloxacin), glycopeptides (example vancomycin) and nitrofurans has been removed. [3]

Other countries have taken action to remove specific antimicrobial treatments from the list of approved treatments. It is expected this will be an ongoing trend as more is learnt about antimicrobial resistance and sources of the resistance.

13.2. Risk assessment prior to registration

In the process of approving antimicrobials for use on animals, more regulatory agencies are conducting a risk assessment on the potential use of the drugs. The risk assessment includes consideration of the potential for development of antibiotic resistance during animal treatment that will impair the efficacy of antibiotics for human or animal use.

In Australia, the risk assessment is initially qualitative with applicants being asked to provide scientific evidence to support the claims. Specific information required includes:

- antimicrobial activity of the antibiotic,
- antimicrobial resistance mechanisms and genetics
- occurrence and rate of transfer of antimicrobial resistance genes
- occurrence of cross resistance
- occurrence of co-resistant/co-selection
- in vitro mutation frequency studies
- pharmacokinetic/pharmacodynamic profile of the active constituents after administration of the products
- antimicrobial activity in the intestinal tract

The risk assessment includes consideration of the following:

- ***Hazard characterisation*** i.e. the potential for antibiotic-resistant micro-organisms or their resistance transferable genetic elements (that have the potential to transfer to humans) to occur within an animal species, arising from the use of an antibiotic in an animal species and the potential exposure of gut flora to the antimicrobial (or its metabolites).
- ***Exposure characterisation*** The amount and frequency of exposure of susceptible humans to antibiotic-resistant micro-organisms (or their transferable genetic elements) from animal sources
- ***Impact characterisation*** The evaluation of infections (caused by antibiotic-resistant pathogens of animal origin) in susceptible humans. Here the antibiotics are rated against perceived and known clinical importance of the antibiotics to humans. For example a high rating is nominated when the antibiotic is regarded as essential for treatments of infections in humans and there are no or few alternatives treatments. Other factors considered include severity of antibiotic resistant disease, expected numbers of infections and deaths, probability of infection developing in susceptible humans.
- Assessment of the ***uncertainty of the data*** used in the risk assessment
- ***Benefits of use*** of the antibiotics in Australian animal health
- ***Risk characterisations*** i.e. the probability of disease due to infection in susceptible humans after exposure of humans to antibiotic-resistant micro-organisms (or their transferable genetic elements) of animal origin and the severity of the impact of exposure on susceptible humans [5]

After the initial qualitative assessment, companies may be required to submit quantitative evidence to support their claims.

Other countries have introduced risk assessment approaches when considering the suitability of antibiotics for registration. [6]

To assist the development of a common approach to risk assessment of antimicrobial resistance in veterinary treatments, working groups of the World Organisation for Animal Health (OIE) have been developing guidelines to risk assessment. [7]

13.3. Establishment of maximum residue limits and withholding periods

Maximum residue limits (MRL) and withholding times prior to consumption of the product are also established by the regulatory agencies. The MRL is recognized as the maximum level of antibiotic after use following recommended and legal guidelines for use. Nineteen countries reported that MRLs were in place for antibiotic treatments used on dairy cattle and withholding periods between treatment and entry into the food chain were nominated [3]. The IDF survey noted a high degree of commonality in the MRLs across responding countries [3].

Given that many countries have established MRLs for antimicrobials used in dairy animals and have withholding periods between treatment and inclusion in the food chain, the likelihood for consumption of milk containing antibiotic residues is considered to be very low.

Antimicrobial residues are further degraded during heat treatment by pasteurisation and by metabolism in the gut. [8]. Consequently it has been considered highly unlikely that antimicrobial residues in food would lead to the development of resistance [8].

13.4. Requirements for labelling

Pharmaceutical companies are required by regulators to include on the label, information relating to restrictions on use, expiry date for the antimicrobial and storage conditions. This information must be able to be interpreted by veterinary practitioners as well as sellers and farmers.

Government agencies monitor the conformance of labels to these requirements.

13.5. Exclusion of antibiotics for use in animals

Certain antimicrobials such as chloramphenicol, fluoroquinolones, tilmicosin have been prohibited for therapeutic use on food animals by veterinarians [3]. These antibiotics are regarded as critical for use in human health treatments.

The use of antibiotic drugs in agricultural food industries for disease prevention or as so-called *growth promoters* in intensive animal industries has been widespread for many years. However in recent years, this practice has been questioned as part of the debate on minimisation of antimicrobial resistance. The European Council of Agricultural Ministers in December 1998 voted to withdraw authorisation of the use of growth promotants bacitracin zinc, spiramycin, virginiamycin and tylosin phosphate as feed additives [9]. The therapeutic or treatment uses of these products were not affected as they were regulated separately. From the end of 2005, the use of antibiotics for growth promotion in food animals has been banned in an attempt to protect public health based upon the precautionary principle.

Other countries have followed suit in withdrawing approval to use selected antimicrobials. For example Australia has reviewed the use of antibiotics used for growth promotion in some species and has commenced phasing out antimicrobials that are:

- ineffective in livestock production under Australian farming conditions,
- frequently used for treating infections in humans or animals,
- considered critical therapy for human use, and
- likely to impair the effectiveness of prescribed antibiotics through the development of resistant strains of bacteria.

Decisions in Europe to remove selected antimicrobials from animal feed have had significant impacts on the poultry and swine industries. Farming and animal husbandry practices have had

to be reviewed to establish new commercial practices and advice provided to farmers about the changed practices. Therapeutic use of antibiotics has reportedly increased. [10]. Further work to develop vaccines and other treatments is required to assist these industries to address the increased rates of animal health problems.

13.6. The Veterinary Surgeon

Many countries require the use of antimicrobials and treatment of animals to be managed by veterinarians. [3]

As in the human medical sector, veterinary medicine educators are placing increased emphasis on antibiotic resistance, factors impacting on it and measures practising veterinarians need to take to ensure effective treatment of animals. This may include increased use of pathological testing to assist in diagnosis and selection of the appropriate antimicrobials for treatment.

Continuing professional development programs have been launched in many countries to ensure practising veterinarians are aware of the challenges and recommended actions to minimise the risks.

The *Get Smart When Antibiotics Work on the Farm campaign* [11] is an example of a program designed to increase awareness and knowledge within the USA veterinary profession. This program has a number of aspects including an interactive web based program combining aspects of microbiology, pharmacology, infectious disease and public health to promote appropriate use of antimicrobials by veterinarians. Topics covered include: mechanisms of resistance development; diagnostic tools and tests; guidelines for empirical treatment; client education; alternatives to antibiotics, and public health risks of the use of antimicrobial treatments in food animals and in companion animals. This material can be used for undergraduate study and for continuing professional development of registered veterinarians.

Professional veterinary bodies have been monitoring the discussion about antimicrobial resistance and in many countries have revised existing guidelines or have published new guidelines for use of antimicrobials in dairy cattle [12]. These guidelines cover the background on the growing challenge of antimicrobial resistance, general principles relating to preventive action to avoid disease, selection of antimicrobials and alternative options for treatments.

13.7. Farmers

In many countries, veterinarians oversee the use of antibiotics on farms. Farmers are expected to follow their instructions. The availability of antimicrobials is limited to issue through prescriptions from veterinarians and purchase through prescribed retail outlets such as pharmacies. [3]

More countries, states and companies are introducing on farm quality assurance or food safety programs. This is consistent with moves across all parts of the international food supply chain to have food safety plans developed using a risk assessment approach.

On farm quality assurance programs outline the minimum food safety outcomes that a dairy farm operator should be managing. The *on farm* program requires a farmer to document their management system for the prevention of food safety issues and to demonstrate the system works effectively. The program is based on a risk assessment of the farming practices used in the operation. Appropriate use of veterinary drugs, control and prevention of chemical contamination and effective identification and traceability of product are part of the program. [13]. Records of drug usage, withholding periods, treatment details and identification of animals treated are kept. Stock food purchased from external suppliers is included in the on farm program. On farm QA programs are audited by a combination of regulators, second or approved third party bodies.

As the knowledge of resistance development increases, opportunities will be taken to review current animal husbandry practices to reduce the spread of disease and the potential for antimicrobial resistance being associated with dairying operations. These changes will be incorporated into *on farm* food safety management systems.

Some countries are developing communication plans to farmers explaining the significance of antimicrobial resistance and the importance of following label directions for use on antibiotics and instructions of veterinary practitioners.

Farm extension programs, like Countdown Downunder in Australia, also promote responsible use of antibiotics to treat animal health issues like mastitis.

13.8. Monitoring by dairy companies and regulators

For many years, milk samples have been tested by dairy companies for the presence of antibiotic residues. If residues are detected, follow up samples are taken and if the samples are still positive, financial penalties applied to the supplier. The sampling generally occurs at milk tanker level however farm milk supplies may be sampled and tested on a monthly or weekly basis. [3]

Analytical techniques to detect non-penicillin residues at or below generally accepted MRLs have been developed. This has provided testing agencies with techniques to detect antibiotics commonly used for the treatment of dairy cattle.

Monitoring by regulatory agencies varies from direct testing of farm supplies on a predetermined basis to annual surveys of food samples from the retail level. [3]

Many purchasers of milk and milk products include requirements for absence of antibiotic residues in their purchasing specification.

13.9. Heat processing of dairy products

The manufacture of dairy products routinely involves heat processing, or alternative microbiocidal treatments, to meet food safety requirements. This processing, which eliminates microorganisms in dairy products, helps to ensure there is no transfer of antibiotic resistant bacteria to humans.

13.10. Surveillance of antimicrobial resistance

Regulators, researchers and pharmaceutical companies play an important role in the monitoring of the frequency of antibiotic resistance within regions, nations and internationally. Potential sources of resistant microbes or avenues of contamination are identified through these programs. A number of surveillance programs operate around the world. These include:

WHONET: This monitoring system was developed by the World Health Organisation to track global trends in antimicrobial resistance. WHONET provides computer software to laboratories and medical centres to assist the systematic entry of antibiotic resistance results. Some 30 countries use the system. [14]

Sentry: Commenced in 1997 by the University of Iowa College of Medicine the SENTRY program conducts surveillance of hospital and community acquired infections through a global network of over 100 medical centres and outpatient centres across the world. Researchers from the Eijkman – Winkler Institute for Microbiology Infection and Inflammation at the University of Utrecht are partners in the program

Sentry provides useful data for evaluating the extent of current resistance threats among human pathogens and any potential correlation or link between the use of antibiotics in animals and the extent of emerging antibiotic resistance in humans. The program routinely tracks and investigates by molecular methods unusual "cluster" infection outbreaks that can have disastrous consequences. [15]

13.11. National Antimicrobial Resistance Monitoring System – Enteric Bacteria

The National Antimicrobial Resistance Monitoring System – Enteric Bacteria (NARMS) was established in 1996 as a collaborative effort between the Food and Drug Administration's Center for Veterinary Medicine (FDA CVM), U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC). The NARMS program monitors changes in antimicrobial drug susceptibilities of selected enteric bacterial organisms in humans, animals, and retail meats to a panel of antimicrobial drugs important in human and animal medicine. Bacterial isolates are collected from human and animal clinical specimens, from healthy farm animals, and

raw product from food animals. Retail meats collected from grocery stores have been added to NARMS sampling. [16]

Other surveillance programs have been established on a national basis or collaboratively with medical or research centres in other countries.

Pharmaceutical companies contribute to the funding of these surveillance programs as well as government funds. [15,16]

13.12. Summary

In summary, various partnerships of regulators, pharmaceutical companies, veterinarians, farmers and dairy companies are working together across the world on the current and future challenge of minimizing the development of antibiotic resistance. The common strategy can be simply described as

- prudent use of antibiotics through registration of approved drugs and forms of treatment,
- education of veterinarians and farmers,
- research into improved forms of animal husbandry and antimicrobial treatments,
- surveillance of the use of antibiotics, antibiotic residues in milk and dairy products, and
- monitoring resistance patterns. This information is being used for further improvements in the use of antimicrobials for treatment of disease in animals and humans.

Antibiotics are an important tool in the treatment of animal disease and the prevention of animal welfare issues. While the use of agricultural and veterinary medicines is not a significant contributor to the development of antimicrobial resistance in pathogens of humans, the dairy industry must remain vigilant about the use of antimicrobial treatments on dairy farms. Changes may need to be made to current practices in the supply chain as further information becomes available about antimicrobial resistance.

References

1. Alliance for the Prudent Use of Antibiotics. The Need to Improve Antimicrobial Use in Agriculture Ecological and Human Health Consequences. Clinical Infectious Diseases 34 Supp 3 p73- 75 (2002)
2. FAO/OIE/WHO. Expert Workshop on Non – Human Antimicrobial Usage and Antimicrobial Resistance; Scientific Assessment. Downloaded from http://www.who.int/foodsafety/publications/micro/nov2003/en/ September 11 2006 (2003)
3. International Dairy Federation 1304/SCRCC Survey unpublished (2005)
4. Australian Pesticides and Veterinary Medicines Authority. Maximum Residue Limits. Fact Sheet Canberra downloaded from http://www.apvma.gov.au/residues/mrl6.pdf September 11 2006 (2005)
5. Australian Pesticides and Veterinary Medicines Authority. Manual of Requirements and Guidelines for Veterinary Applications vol 3, part 10 Special Data: Antibiotic Resistance Canberra downloaded from http://www.apvma.gov.au/MORAG_vet/MORAG_vet_home.shtml September 11 2006 (2006)
6. US Food and Drug Administration Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern. Guidance for Industry Number 152 downloaded from http://www.fda.gov/bbs/topics/NEWS/2003/NEW00964.html September 11 2006 (2003)
7. The European Agency for the Evaluation of Medicinal Products. Veterinary Medicines and Inspections. Guidance on pre - approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance VICH Topic GL27, European Medicines Agency, London (2004)

8. Australian Government National Health and Medical Research Council. Antimicrobial (Antibiotic) Resistance. Fact Sheet Canberra downloaded from http://www.nhmrc.gov.au/about/committees/expert/eager/aar.html September 11 2006 (2005)
9. European Union Council Directive. 70/524/EEC, Bulletin EU 4-1998 Agriculture (5/16), European Union, Brussels, Belgium (1998)
10. World Health Organization International Review Panel. Impact of antimicrobial growth promoter termination in Denmark, WHO/CDS/CPE/ZFK/2003.1, p 6-8, WHO (Denmark) 2002
11. US Department of Health and Human Services Centers for Disease Control and Prevention. National Antimicrobial Resistance Monitoring System GET SMART: Know When Antibiotics Work on the Farm, downloaded from http://cdc.gov/narms/get_smart.html September 11 2006: 2006
12. American Veterinary Medicine Association. Judicious Use of Antimicrobials for Dairy Cattle Veterinarians. Downloaded from http://www.avma.org/scienact/jtua/cattle/jtuadairy.asp September 11 2006 (2006)
13. Australia New Zealand Dairy Authorities' Committee. Guidelines for Food Safety Dairy Farms. Dairy Food Safety Victoria, Hawthorn, Australia (2006)
14. World Health Organization. Surveillance standards for antimicrobial resistance. WHO/CDS/CSR/DRS/2001.5 downloaded from WHO/CSR site http://www.who.int/emc September 11 2006 (2001)
15. Bell,J. and Turnidge, J. SENTRY Antimicrobial Surveillance Program Asia – Pacific region and South Africa, Comm Dis Intell 27 Suppl: S61 – S66 (2003)
16. US Food and Drug Administration Center for Veterinary Medicine. National Antimicrobial Resistance Monitoring System Enteric Bacteria. Downloaded from http://www.fda.gov/cvm/narms_pg.html September 11 2006 (2006)

14. Benefits and Potential Risks of the Lactoperoxidase System of Raw Milk Preservation

A. Bennett[1]

14.1. Summary

The lactoperoxidase system operates by the reactivation of the naturally present enzyme lactoperoxidase, by the addition of a source of peroxide and a source of thiocyanate. The effect of the system is considered to result in an overall bacteriostatic effect in raw milk.

Although the system was adopted by Codex Alimentatius in 1991 it was mentioned in the Codex Alimentarius Commission (CAC) meeting that the system was "not to be used on milk and dairy products intended for international trade". This created some confusion among member countries as to whether the system was safe but could not be used for products intended for international trade. Codex agreed that "The use of the lactoperoxidase system for milk and milk products in international trade will be re-examined by the Committee on Food Hygiene (CCFH) after completion of an expert review by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of available data and considering the FAO Lactoperoxidase Expert Group report on the benefits and potential risks of LP-system. It was agreed that CCFH will then review the issue in 2006".

In response to this request from CCFH, and in line with the FAO/WHO guidelines for the provision of scientific and technical advice, FAO and WHO organised a technical meeting on the issue in December 2005. This started with a literature review, followed by a global "Call for Data and Experts" in July 2005. Nine independent experts, supported by FAO and WHO staff were involved in the FAO/WHO technical meeting on ***"Benefits and potential risks of the Lactoperoxidase system of raw milk preservation"***, held in FAO HQ from 28 November to 2 December 2005.

The meeting report recommended that Codex remove the current provision regarding the restriction on the use of the LP-s in milk or dairy products intended for international trade as the meeting found no scientific or technical basis or economic justification for the provision.

14.2. Background

Lactoperoxidase is an enzyme which is naturally present in raw bovine and other milks. The Lactoperoxidase system (LP-s) consists of three key elements - the enzyme lactoperoxidase, sodium thiocyante and sodium percarbonate. The LP-s operates by the reactivation of the naturally present enzyme lactoperoxidase, by the addition of a source of peroxide (recommended as sodium percarbonate) and a source of thiocyanate (recommended as sodium thiocyante).

The enzyme oxidizes thiocyanate ions in the presence of hydrogen peroxide to convert the thiocyanate to hypothiocyanous acid which, at the pH of milk, is dissociated and exists mainly in the form of hypothiocyanous ions. It is these ions which react with specific sulphydryl groups, thereby inactivating vital metabolic bacterial enzymes, thereby blocking their metabolism and ability to multiply. As raw milk contains very few sulphydryl groups the reaction of this compound in milk is quite specific and is directed against the bacteria present in the milk (1). The effect of the enzyme in sufficient quantities and with a sufficient substrate is therefore considered to result in an overall bacteriostatic effect in raw milk. This effect decreases once the milk is produced (i.e., milking takes place) and the effect of LP-s is normally not registered in raw milk two to three hours after milking.

With smallholder farmers as our main target groups, member countries and FAO are interested in the system due to the following three key advantages:

[1] Dairy and Meat Officer - Animal Production Group - Animal Production and Health Division, Food and Agriculture Organisation of the United Nations, Viale delle Terme di Caracalla, anthony.bennett@fao.org

1. Extends the shelf life of raw milk unrefrigerated
2. Time–temperature dependent
3. Increased milk collection possibilities

The Guidelines for the Preservation of Raw Milk by use of the Lactoperoxidase system were adopted by the Codex Alimentarius Commission in 1991. Although the system was adopted by Codex in 1991 it was mentioned in the Codex Commission meeting that the system was "not to be used on milk and dairy products intended for international trade" (2). This created some confusion among member countries as to whether the system was safe but could not be used for products intended for international trade.

This source of confusion culminated in the "27th Session of the Codex Alimentarius Commission in July 2004 at which concern from the 36th Session of the Codex Committee on Food Hygiene (CCFH) regarding the Draft Code of Practice for Milk and Milk Products in which the LP-system was listed as a 'microbiostatic'. The Commission agreed to add the following text to the end of footnote 9 of Appendix II of the draft Code: "The use of the lactoperoxidase system for milk and milk products in international trade will be re-examined by the Committee on Food Hygiene (CCFH) after completion of an expert review by FAO and WHO of available data and considering the FAO Lactoperoxidase Expert Group report on the benefits and potential risks of LP-system. It was agreed that CCFH will then review the issue in 2006" (3) (4).

FAO/WHO play an important role as an independent broker in the gathering and provision of scientific advice and technical opinions. *Scientific advice* can be defined as the conclusion of a skilled evaluation taking account of the scientific evidence, including uncertainties. The purpose of scientific advice is to help risk managers, policy makers and others in decision making. Advice may take many different forms, from a response to a specific question, or provision of scientific information related to specific needs, to a full quantitative risk assessment. Depending on the degree of uncertainty, advice may range from a clear conclusion on risk to a recommendation to obtain additional data. It can for example include:

- To provide the relevant Codex Committees with:
  - Sound scientific advice as a basis for standards, guidelines and recommendations
  - Answers to specific risk management questions on hazard - commodity combinations
- To provide FAO and WHO member countries with:
  - "Adaptable" risk assessments and modelling tools to use in conducting their own assessments
  - Risk-reduction-based advice on which to establish interim risk management decisions.

Hence, in response to the above request from CCFH, FAO and WHO started the process of organising the technical meeting. Firstly FAO/WHO initiated a literature review. The literature review included both peer reviewed scientific journals and grey literature/other reports e.g., FAO field reports. A Call for Data and Experts was then prepared. In line with the guidelines for the provision of scientific and technical advice it was considered essential to include:

- An appropriate level of information and involvement of countries
- An open call for data and experts
- The identification of key areas to be addressed identified
- The independent role of consultation e.g., declaration of interest is obligatory
- Adequate regional representation for global issues

The Call for Data and Experts was distributed via the established system of Codex contact points and FAO mailing lists, and to research, industry and consumer groups e.g., for milk issues such as IDF, in July 2006. Relevant data was then collected and independent experts from the five regions screened and selected by FAO/WHO to cover the four key areas which the technical meeting was designed to address:

- Microbiological effects and performance of the lactoperoxidase system
- Human health and nutrition
- Processing and technology
- Economic value and trade

Following this, a total of nine independent experts, supported by FAO and WHO staff were involved in the FAO/WHO technical meeting on ***"Benefits and potential risks of the Lactoperoxidase system of raw milk preservation"***, held in FAO HQ from 28 November to 2 December 2005.

14.3. Results and recommendations of the report

The results of the report and recommendations made by the meeting are provided hereunder by each of the four key areas:

14.3.1. Microbiological effects and performance of the lactoperoxidase system

- Applied to raw milk to halt proliferation of milk spoilage and pathogenic micro organisms.
- Considered as part of a programme to improve milk hygiene and safety along the milk chain, owing to its bacteriostatic effect.
- Consideration be given to the application of the LP-s to complement cooling in order to extend the keeping quality of raw milk.
- Codex consider expanding the guideline for the application of the LP-s with regard to temperature of application to also include the temperature range from 31 to 35 ºC for 4–7 hours and down to 4 ºC for 5–6 days.
- Monitoring for the development of resistance be undertaken to detect the development of any resistant micro organisms.

14.3.2. Human health and nutrition

- The LP-s can be considered safe, when used according to the Codex guidelines, for use in situations when technical, economical and/or practical reasons do not allow the use of cooling facilities and that it be applied as part of an integrated programme to improve milk production and quality.
- Milk consumption should be promoted because of its value in human nutrition for healthy development and growth.
- Measures to rectify iodine deficiency should be implemented in recognised Iodine Deficiency Disease areas accompanied by appropriate monitoring of its prevalence.

14.3.3. Processing and technology

- Use of the LP-s does not preclude the need for pasteurization and does not negatively impact on, or interfere with, subsequent processing.
- Efficient alternative for preservation of raw milk that will be subjected to further processing.
- Used alone when refrigeration is not available, or in synergy with cooling or chilling
- Considered as suitable to extend milk collection distances particularly in developing countries and thereby increase the amount of milk available
- Can improve the quality of processed products - bacteriostatic effect from milk collection to processing.

14.3.4. Economic value and trade

- Small-scale dairying be promoted - household nutrition, food security, and poverty alleviation.
- Codex Alimentarius develop milk and dairy product standards that can be easily adopted at regional or national level.
- Active participation of a representative range of country members should be supported in the development of standards.
- The current Codex limitation related to the use of LP-s in milk or dairy products intended for international trade be removed.

14.4. Next step

The report (5) is to be submitted for consideration by the Codex Committee on Food Hygiene in November 2006 at the 38th Session to be held in Houston, Texas, USA.

References

1. CAC 1991. Guidelines for the preservation of raw milk by use of the lactoperoxidase system (CAC GL 13/91). Available at http://www.codexalimentarius.net/download/standards/29/CXG_013e.pdf
2. CAC 1991. Report of the nineteenth session of the Codex Alimentarius Commission, Rome 1-10 July 1991. Rome, Italy.
3. CAC 2004. Report of the twenty seventh session of the codex Alimentarius Commission. 28 June – 3 July 2004, Geneva Switzerland. Document no. 04/27/41. Available at http://www.codexalimentarius.net/download/report/621/al04_41e.pdf
4. CAC 2004. Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004). Available at http://www.codexalimentarius.net/download/standards/10087/CXC_057_2004e.pdf
5. FAO/WHO 2006. Benefits and potential risks of the lactoperoxidase system of raw milk preservation: report of an FAO/WHO technical meeting, FAO headquarters, Rome, 28 November – 2 December 2005. Available at ftp://ftp.fao.org/docrep/fao/009/a0729e/a0729e00.pdf

HYGIENE AND FOOD SAFETY OF DAIRY PRODUCTS AND FOOD STANDARDS FOR INTERNATIONAL TRADE

ABSTRACT

Proceedings of the Conference on Hygiene and Food Safety of Dairy Products and Food Standards for International Trade, at the IDF World Dairy Congress in Shanghai (CN), October 2006. The publication contains the conference papers covering : Recent Developments in Risk Management, introducing the new approach to quantitative risk management; Practical Food Safety Management, providing examples of developments in food safety management in various geographical regions; Predictive Modelling in Decision Making, providing an update on new tools and models; Emerging Food Safety Issues, addressing specific food safety issues under debate on the international scene.

Keywords: hygiene, milk, milk products, predictive modelling, risk management, safety

97 pp - English only

Bulletin N° 430/2008 - 89 Euro (electronic) - Date: 2008

INTERNATIONAL DAIRY FEDERATION
INSTRUCTIONS TO AUTHORS

Submission of papers

Submission of a manuscript (whether in the framework of an IDF subject on the programme of work or an IDF event) implies that it is not being considered contemporaneously for publication elsewhere. Submission of a multi-authored paper implies the consent of all authors.

Types of contribution

Monographs; separate chapters of monographs; review articles; technical and or scientific papers presented at IDF events; communications; reports on subjects on the IDF programme of work.

Language

All papers should be written in English.

Manuscripts

- Files to be sent electronically on CD-ROM, diskette or by e-mail.
- Final document in Word 2000 or later.
- All tables/figures included in final document to be sent also in separate Word, Excel or PowerPoint files, in colour format. Pictures to be sent in tif or eps format (resolution 300 DPI)
- All files to be named with author's surname plus title of paper/tables/figures.

References

- References in the document to be numbered and placed between square brackets.
- Reference lists at the end of the document to contain the following:
  * Names and initials of all authors;
  * Title of paper (or chapter, if the publication is a book);
  * If the publication is a journal, title of journal (abbreviated according to 'Bibliographic Guide for Editors and Authors', published by The American Chemical Society, Washington, DC), and volume number;
  * If the publication is a book, names of the publishers, city or town, and the names and initials of the editors;
  * If the publication is a thesis, name of the university and city or town;
  * Page number or number of pages, and date.

Example: 1 Singh, H. & Creamer, L.K. Aggregation & dissociation of milk protein complexes in heated reconstituted skim milks. J. Food Sci. 56:238-246 (1991).

Example: 2 Walstra, P. The role of proteins in the stabilization of emulsions. In: G.O. Phillips, D.J. Wedlock & P.A. William (Editors), Gums & Stabilizers in the Food Industry - 4. IRL Press, Oxford (1988).

Abstracts

An abstract not exceeding 150 words must be provided for each paper/chapter to be published..

Address

Authors & co-authors must indicate their full address (including e-mail address).

Conventions on spelling and editing

IDF's conventions on spelling and editing should be observed. See Annex 1.

ANNEX 1 **IDF CONVENTIONS ON SPELLING AND EDITING**

In the case of native English speakers the author's national conventions (British, American etc.) are respected for spelling, grammar etc. but errors will be corrected and explanation given where confusion might arise, for example, in the case of units with differing values (gallon) or words with significantly different meanings (billion).

" ..... Usually double quotes and not single quotes
? ! ..... Half-space before and after question marks, and exclamation marks
± ..... Half-space before and after
micro<u>o</u>rganisms ..... Without a hyphen
Infra-red ..... With a hyphen
et al. ..... Not underlined nor italic
e.g., i.e.,... ..... Spelled out in English - for example, that is
lit<u>re</u> ..... Not liter unless the author is American
ml, mg,... ..... Space between number and ml, mg,...
skimmilk ..... One word if adjective, two words if substantive
sulfuric, sulfite, sulfate ..... Not sulphuric, sulphite, sulphate (as agreed by IUPAC)
AOAC <u>I</u>nternational ..... Not AOAC<u>I</u>
progra<u>mme</u> ..... Not program unless a) author is American or b) computer program
milk and milk product ..... rather than "milk and dairy product" - Normally some latitude can be allowed in non scientific texts
-ize, -ization ..... Not -ise, -isation with a few exceptions
Decimal comma ..... in Standards (only) in both languages (as agreed by ISO)
No space between figure and % - i.e. 6%, etc.
Milkfat ..... One word
USA, UK, GB ..... No stops
Figure ..... To be written out in full
1000-9000 ..... No comma
10 000, etc. ..... No comma, but space
hours ..... ø h
second ..... ø s
litre ..... ø l
<u>t</u>he Netherlands
Where two or more authors are involved with a text, both names are given on one line, followed by their affiliations, as footnotes
for example A.A. Uthar[1] & B. Prof[2]
[1] University of .....
[2] Danish Dairy Board .....
IDF does not spell out international organizations

INTERNATIONAL DAIRY FEDERATION / FEDERATION INTERNATIONALE DE LAITERIE
Diamant Building, Boulevard Auguste Reyers, 80 - 1030 Brussels (Belgium) - http://www.fil-idf.org