Introduction

The Swiss Federal Veterinary Office (SFVO) is responsible for monitoring the health and welfare of animals in Switzerland and protecting the public from diseases transmitted by animals or through animal products. Risk analysis methods are used in the fields of disease control and food safety in accord with international standards laid down by the Office International des Epizooties (OIE)[1] and in the FAO/WHO’s Codex Alimentarius[2]. Analysis results are used to formulate import regulations for animals and goods, to check the effectiveness of control measures and to set up monitoring programmes for animal diseases and food contamination. Information gained from literature searches and expert opinion is evaluated according to established scientific criteria. Gaps in data, limitations on its use and uncertainties are identified and documented. Risk is then assessed on the basis of structured information and is expressed in terms of the likelihood of an adverse event occurring and the magnitude of the consequences. Results are usually given in report form (qualitative risk analysis). An analysis of the potential health risks to the population from consuming milk and dairy products is used here to demonstrate the steps involved in qualitative risk analysis and the advantages of the method.

Risk profile

After inspections by the European Union’s Food and Veterinary Office in Switzerland it was recognised that a programme of risk-based inspections of manufactured milk and dairy products, supported by official random sampling, was required to ensure products were fit for
export to the EU. In co-operation with risk managers, risk analysts drew up a risk profile establishing the reason for the assessment, identifying the hazards to be investigated, the tolerance values and a detailed questionnaire. The likelihood of high levels of contamination occurring in raw milk, consumer milk and twelve milk product groups leading to rejection of the products (contamination above tolerance values or above threshold limits) was investigated.

**Hazard identification**

Hazard identification is an important part of a risk assessment in which all potential hazards are identified including those that will not actually be studied, in this case *Listeria monocytogenes, Salmonella spp., Staphylococcus aureus* and its toxins, *Escherichia coli, Bacillus cereus* and its toxins and Aflatoxin M1. No assessment was made of the risk from campylobacter, *Yersinia enterocolitica, Vibrio cholerae* and Central European encephalitis. Cattle, goats and sheep have been officially declared free of *Mycobacterium bovis* and *Brucella spp.* so no assessment was made for these pathogens.

**Risk network**

After all the potential hazards and their origins were identified, a risk network for milk and dairy products was drawn up, as shown in Fig. 1.

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Fig. 1: Risk network, origin and identification of hazards in dairy product manufacture
The chain of production, manufacture and sale of milk and dairy products was divided into four stages. Animal health, water, feed, animal housing, milking hygiene and staff hygiene are all factors that influence the quality of raw milk during milk production. Refrigeration and hygiene are crucial during transport. Each manufacturing process used for dairy products has an influence on any potential hazards. A qualitative assessment was made of each process stage and each was categorised. Pasteurisation and sterilisation completely eliminate pathogens. Lowering the pH value and high processing temperatures reduce contamination risk to “medium”. Long maturation periods of more than 60 days reduce contamination substantially. Adding water and other supplements during the process may cause pathogens to multiply. During storage and distribution to points of sale, quality is influenced by staff and equipment hygiene. Twenty potential factors that could cause a detrimental effect on the end product quality were identified in the risk network. Expert opinion was obtained to assess the probability of occurrence for each factor and the consequences for the end product. The probability of occurrence was defined as less than 1%, less than 10% and less than 25% and the consequences were classified qualitatively as “negligible”, “low”, “medium” and “high”.

**Risk assessment**

Various product groups were categorised according to risk, on the basis of the probability of tolerance limits being exceeded. This is an indication of the exposure risk to consumers. For dairy products the likelihood of contamination occurring was estimated by combining available data and on the basis of expert opinions and was defined as “negligible”, “low”, and “medium”. The products posing the greatest risk were raw milk and fresh and soft cheeses while the risk from pasteurised milk, cream, butter and hard cheese was seen to be negligible.

**Recommendations for random sample planning and risk managers**

The expected probability of tolerances being exceeded was defined as less than 1% for a “negligible” risk, less than 2.5% for a “low” risk and less than 5% for a “medium” risk. The number of random samples required was calculated using the usual formulae. Based on the results of the risk assessment and the experience of the authorities, risk-based monitoring of end products was introduced throughout Switzerland in the autumn of 2002.
Advantages and disadvantages of qualitative risk assessment

Establishing a risk profile and characterising the hazards in the initial phase of a risk analysis is always a qualitative process. A risk network is indispensable to both the qualitative and quantitative method. Often, while the network is being established, it is seen that the required data or data quality is unavailable. Qualitative evaluation of expert opinions is much simpler than quantitative evaluation.

Drawing up a qualitative risk assessment to determine whether there is in fact a risk is the first requirement before proceeding with a quantitative risk assessment. If sufficient high quality data is available, models can be created and all risk paths can be quantitatively assessed. In practice, risk assessments are comprehensive projects that can keep whole institutes and organisations occupied over many years. The qualitative assessment of health hazards in milk and dairy products described in this paper was completed in less than 7 months.

In qualitative risk assessments the risk can be described in terms such as “negligible”, “low”, “medium”, and “high”. However, assigning risks to qualitative categories is done subjectively and there is no standardised method. The transition between “negligible” and “non-negligible” is defined subjectively by risk managers. International standards could be reached by a broad discussion of terminology leading to more meaningful risk assessments and improved acceptance of the method.

Usually the information provided by qualitative assessments is adequate for risk managers for decision making. In most cases management measures are general in nature and concern import requirements, monitoring and control regulations or require yes or no decisions. These have to be implemented in any case and do not take account of fine shades of risk.

Risk communication between risk managers and stakeholder groups is simplified when the results of a qualitative assessment is available. No special mathematical knowledge is needed to determine the risk paths and to evaluate the data. Complex quantitative models such as dose-effect relationships, simulations, etc., are usually hard to understand and may be difficult to communicate.

Statistics’ part in qualitative risk assessment

Qualitative risk assessments make use of descriptive statistical evaluations. Probability calculus is used to calculate prevalent risks, their development and the effect of risk reduction measures. It is difficult, if not impossible, to compare risk assessments made in different countries or by different analysts because risk definition and categorisation are subjective. Statistical methods could help standardise assessments and make comparison possible.
Statistics’ role is to provide high quality data resulting in more accurate risk assessments. Inaccuracies are possible in all assessments because of data gaps and variability. High quality data compensates for lack of knowledge and increases the accuracy of such assessments. Well-planned and evaluated studies are needed to obtain such data. Corresponding data from different studies may be combined by means of a meta-analysis. This method improves the data quality and minimises uncertainty resulting from incomplete knowledge.