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A Qualitative Risk Assessment Approach for Swiss Dairy Products: Opportunities and Limitations

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Impacts

In the context of food safety surveillance of dairy products in Switzerland, the risk assessment presented in this work exemplified the following:

- Qualitative risk assessment is a useful and accessible tool for decision-making in a food safety context.
- Risk assessment can be used for the design of risk-based food safety surveillance to ensure appropriate and cost-effective data collection.
- Based on a risk assessment, recommendations can be made to orient further research and to guide or improve public health interventions.

Keywords:
Qualitative risk assessment; risk-based surveillance; food safety; dairy products

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Summary

Switzerland implemented a risk-based monitoring of Swiss dairy products in 2002 based on a risk assessment (RA) that considered the probability of exceeding a microbiological limit value set by law. A new RA was launched in 2007 to review and further develop the previous assessment, and to make recommendations for future risk-based monitoring according to current risks. The resulting qualitative RA was designed to ascertain the risk to human health from the consumption of Swiss dairy products. The products and microbial hazards to be considered in the RA were determined based on a risk profile. The hazards included *Campylobacter* spp., *Listeria monocytogenes*, *Salmonella* spp., Shiga toxin-producing *Escherichia coli*, coagulase-positive staphylococci and *Staphylococcus aureus* enterotoxin. The release assessment considered the prevalence of the hazards in bulk milk samples, the influence of the process parameters on the microorganisms, and the influence of the type of dairy. The exposure assessment was linked to the production volume. An overall probability was estimated combining the probabilities of release and exposure for each combination of hazard, dairy product and type of dairy. This overall probability represents the likelihood of a product from a certain type of dairy exceeding the microbiological limit value and being passed on to the consumer. The consequences could not be fully assessed due to lack of detailed information on the number of disease cases caused by the consumption of dairy products. The results were expressed as a ranking of overall probabilities. Finally, recommendations for the design of the risk-based monitoring programme and for filling the identified data gaps were given. The aims of this work were (i) to present the qualitative RA approach for Swiss dairy products, which could be adapted to other settings and (ii) to discuss the opportunities and limitations of the qualitative method.

Introduction

Up to one-third of the population of developed countries may be affected each year by food-borne diseases caused by chemical and biological hazards (FAO, 2006). Food safety has been challenged in the last years by changing global patterns of food production, international trade, new technologies and higher public expectations. To face those changes, food safety has taken a preventive, integrated and science-based approach addressing the farm-to-table continuum. In this context, risk analysis is increasingly being used as a science-based tool to help managers better understand the risks and to evaluate the options available for their control (Vose, 2008). Risk analysis can also be used for the design of risk-based surveillance to ensure appropriate and cost-effective data collection (Stark et al., 2006).

Dairy production represents 22% of the Swiss agricultural production value (FOAG, 2007). Almost half of the commercialized milk is manufactured into cheese and thereof around 30% (50 945 tonnes) is exported, mostly to European countries. To facilitate trade of agricultural products, Switzerland and the European Union have acknowledged through bilateral agreements the equivalence of their respective food safety legislation (Anonymous, 1999). Within this frame, Switzerland established a risk-based monitoring programme for dairy products. Based on a qualitative risk assessment (RA) performed in 2001, the programme was launched in 2002 by the Federal Veterinary Office (FVO), the Swiss Association of Cantonal Chemists (VKCS), and the Federal Research Institute for Animal Products (Agroscope Liebefeld-Posieux, ALP). The monitoring programme aimed (i) to describe the prevalence of microbial hazards in Swiss dairy products, (ii) to identify high-risk products and practices, and (iii) to give recommendations to improve the safety of dairy products.

The initial RA estimated the likelihood of exceeding a microbiological limit value set by law in the final products taking into account the influence of the manufacturing process on the hazards considered (*Salmonella* spp., *Listeria monocytogenes*, Aflatoxin M1, *Bacillus cereus* spores and toxin, and *Staphylococcus aureus* toxin). The risk-based monitoring targeted each year different combinations of hazards and products according to the RA and the results of previous years. A pre-determined number of samples of dairy products from all Swiss regions were collected and analysed. The sample frame included licensed dairies, which were those processing >10 000 kg milk per year, or >3000 kg for alpine dairies. The proportion of dairies sampled was set considering technical and logistic constraints (accessibility, seasonality of production, available resources). Dairies were sampled at random; further dairies with unsatisfactory results in the previous year campaign were also included in the sample. The samples of products collected were analysed in the cantonal laboratories according to the methods of the Swiss Food Manual (Schweizerisches Lebensmittelbuch; http://www.slmb.bag.admin.ch). The results were published and distributed among the concerned parties every year. The first RA, as well as the monitoring programme, has been further described in the literature (Brülisauer et al., 2005; Hauser et al., 2007). In 2007, FVO and ALP requested to update that RA in light of the available monitoring results, and to develop it further by considering production data and the possible consequences for consumers' health.

The aims of this work were (i) to present the qualitative RA approach developed for Swiss dairy products, which could be adapted to other settings and (ii) to identify and discuss the opportunities and limitations of the qualitative approach. Technical details on the RA can be requested from the Swiss Federal Veterinary Office.

Materials and Methods

Risk assessment approach

A qualitative RA was designed to assess the risk to human health from the consumption of Swiss dairy products. A risk profile was drawn up by risk managers and risk assessors to document the need and objectives of the RA, to define clearly the question to be addressed, the microbial hazards and the products to consider, and to identify involved stakeholders. The question to be addressed was: 'What is the risk to human health from the consumption of Swiss dairy products taking into account the kind of product consumed and the type of dairy where it was produced?'.

The microbial hazards considered included *Campylobacter* spp., *L. monocytogenes* (LM), *Salmonella* spp., Shiga toxin-producing *Escherichia coli* (STEC), coagulase-positive staphylococci (CPS) and *S. aureus* enterotoxin (SE). Swiss legislation defines microbiological limits (threshold values) beyond which a product is considered hazardous for human health. Until January 2006, the limit values in dairy products were 'not detectable in 25 g of the product' for *Campylobacter* spp., LM and *Salmonella* spp.; 10^4/g for CPS; and 'absence' for SE. The equivalence with the European legislation led to changes in the Swiss food safety regulations that affected those thresholds. Nevertheless, the old limit values were considered in our work because available monitoring data had been gathered before implementation of those regulatory changes. A limit value for STEC was not described in the regulations; its presence was considered to affect human health negatively due to the low infectious dose described

in the literature (Blackburn and McClure, 2002). Results on SE of previous monitoring campaigns were not available; it had only been tested in case of exceeding the limit value for CPS. For the purpose of this RA, it was assumed that exceeding the limit values could potentially cause adverse health effects. This assumption represented a rather pessimistic scenario, as depending on hazards' pathogenicity and immune status of the host, the real infectious dose might be higher.

Only dairy products made of cow milk were considered due to the minor role of sheep and goat milk production (Anonymous, 2007). Following products were taken into account: milk, cream, hard cheese, semi-hard cheese, soft cheese, fresh cheese, butter, yoghurt, ricotta, melted cheese and milk powder for direct consumption. Raw milk was not included because, according to Swiss legislation, milk is suitable for consumption only after being heat-treated (at least pasteurized). Some products manufactured in very low quantities (fermented milk products other than yoghurt, condensed milk), destined to further industrial transformation (most of milk powder, dehydrated milk fat), or products where milk is mixed with many different ingredients (soft drinks, desserts, puddings, etc.), were excluded from this RA.

The legislation in force until 2006 classified Swiss dairies into types depending on their nature and the amount of milk processed: alpine dairy, artisanal dairy, industrial dairy, milk farm with dairy processing (farm dairy) and plant for cheese ripening and pre-packaging. Alpine dairies are located in alpine pastures, which are sometimes difficult to reach, and have a seasonal production over the summer months. After regulatory changes in 2006, these types of dairy were no longer defined in the legislation and only those dairies processing above 100 000 kg milk per year were obliged to have a licence. This would mean a reduction of approximately 50% of the sampling frame if only licensed dairies were to be sampled for the monitoring programme; many small dairies (mostly alpine and farm dairies) would no longer be sampled.

The RA followed the standard procedures for risk analysis at the FVO (http://www.bvet.admin.ch/gesundheit_tiere/00315/index.html?lang=en; Breidenbach et al., 2004), which are based on OIE (OIE, 2004, 2008) and Codex Alimentarius guidelines (CAC, 1999, 2004). The steps followed were hazard identification, release assessment and exposure assessment. Consequences could not be assessed because the information needed was not available; therefore, the risk could not be estimated either. These steps were applied qualitatively; a quantitative approach was not feasible due to the data requirements and the multiple combinations of hazards/products/types of dairy. Available quantitative data were categorized and included qualitatively in the RA. Risk is defined as the likelihood of the occurrence of an adverse event (in our work, contamination above the microbiological limit value) and the likely magnitude of its consequences. Likelihoods were categorized as being negligible, very low, low, medium, high or very high. The uncertainties associated with the estimated likelihoods were categorized as low, medium or high depending on the reliability and agreement of the data sources (Hauser et al., 2007). Experts from ALP (http://www.agroscope.admin.ch), the Institute for Food Safety and Hygiene (http://www.ils.uzh.ch), the Federal Office for Public Health (http://www.bag.admin.ch), as well as the dairy industry, provided data and checked the progress of the RA. The final draft was externally peer-reviewed by the Austrian Agency for Health and Food Safety (http://www.ages.at).

Hazard identification

Hazard identification is an essential step that must be conducted before any RA (OIE, 2008). In this work, it involved identifying the pathogenic agents that could potentially cause adverse consequences associated with the consumption of dairy products. The hazards to consider were determined according to the risk profile. Information on physiological, clinical and epidemiological characteristics (growth, inactivation and survival parameters; disease features; habitat, transmission, occurrence in humans, animals and dairy products) was gathered for each one of the hazards from scientific literature, epidemiological reports and consultation with experts (list of references available upon request). Such information contained elements of release, exposure and consequence assessment and constituted a generic hazard profile (Bassett and McClure, 2008).

Release assessment

The release assessment considered the influence of consecutive steps along the food chain on the presence/absence of contamination and its magnitude until the products reached the consumers. These steps were (i) the prevalence of the hazards in bulk milk, (ii) the manufacturing process, and (iii) the influence of the type of dairy. The release likelihood (RL) was estimated as the generic likelihood of exceeding the microbiological limit value in the final product for each combination hazard/product/type of dairy.

Prevalence of the hazards in bulk milk

The prevalence of the hazards in Swiss bulk milk was ascertained from the literature: 0% for *Salmonella* spp. (Stephan and Buehler, 2002) and *Campylobacter* spp. (Bachmann and Spahr, 1995; Stephan and Buehler, 2002), 0.4–0.6% for LM (Bachmann and Spahr, 1995; Stephan

and Buehler, 2002), 2.5% for STEC (Rusch, 2005) and 62% for *S. aureus* (Stephan et al., 2002). The uncertainty associated with this estimate was considered low due to the reliability of the data sources and the coincidence with experts' opinion.

Influence of the manufacturing process

Process parameters such as temperature, pH, water activity and ripening length, and the possible interaction with starter cultures influence the survival/growth of microorganisms or the production of their toxins. The inhibitory effect of one of those parameters on the microorganisms may be small, but the overall inhibitory effect of several parameters acting simultaneously may be very large, even lethal; this is known as 'hurdles concept' (Sinell, 2004).

Depending on the heat treatment of the milk, Swiss legislation defines three types of cheese: cheese made of raw milk (heat treatment below 40°C), cheese made of thermized milk (heat treatment above 40°C and below pasteurization) and cheese made of pasteurized milk (or curd; heat treatment at 72°C for at least 15 s or equivalent). Thermization can decrease the number of spoilage microbes, extend the shelf life of milk and inhibit or reduce the number of pathogen microorganisms depending on the time/temperature applied. As time/temperature may vary largely, thermized and raw milk cheeses were both considered to be made of raw milk for the RA. This assumption represented, however, an overestimation of the likelihood of contamination (LC) for cheeses made of thermized milk.

A flow chart of the manufacturing process containing the relevant process parameters was drawn for each dairy product on the basis of technical publications (Kessler et al., 1998; Knüsel et al., 2000; Salvadori-del-Prato, 1998), information published on ALP webpage (http://www.agroscope.admin.ch) and consultation with experts. The software ComBase (http://www.combase.cc) was used to model the behaviour of the hazards during milk storage. All this information was then used to estimate the generic LC above the microbiological limit value in the final product for each combination hazard/product. The uncertainty associated with this likelihood was considered low for most of the combinations, but medium for SE in cream, butter, ricotta and melted cheese because of missing information on the initial contamination of the materials these products are made of (cream, whey and different cheeses).

Influence of the type of dairy

Field experience and previous monitoring campaigns pointed out that the frequency of non-conformity with the microbiological limit values depended on the type of dairy where products were manufactured (FVO, 2004–2007, 2008), probably due to differences in size, situation, equipment, degree of specialization, staff education, quality management, etc. To account for these differences, a 'type factor' was estimated based on the prevalence of transgressions of the limit values for each type of dairy observed between 2004 and 2006 (Table 1). Data from 2002 to 2003 were discarded due to unsatisfactory data quality. The type factor was then combined with the LC estimated in the previous step to obtain the RL. An observed prevalence of transgressions <0.1% was considered negligible and this type factor did not modify the LC; ≥0.1–1% was a very low-type factor and increased the LC by one level; ≥1–10% was a low-type factor and increased the LC by two levels. The values used for the prevalence of transgressions were point estimates from the available data. The type factors derived from them were, however, robust, e.g. when using the confidence limits of the point estimates, the type factor changed only for farm dairies from low to very low (lower confidence limit). The validity of the prevalence estimates could have been affected by several facts: (i) the hazard/product combinations sampled were not the same each year; (ii) the testing methods applied were not fully harmonized among the cantonal laboratories, even if they were according to the Swiss Food Manual; and (iii) data on

Table 1. Type factor: estimation from the prevalence of transgressions of the limit values for each type of dairy (2004–2006)

Type of dairy	Transgressions of limit value (*n*)	Number of samples	Prevalence of transgressions (range)* (95% CI) (%)	Type factor
Alpine dairy	36	1083	3.3/(0–11.2)/(2.2–4.4)	Low
Farm dairy	8	490	1.6/(0–3.6)/(0.5–2.8)	Low
Artisanal dairy	22	3511	0.6/(0–2.0)/(0.4–0.9)	Very low
Industrial dairy	0	1212	0/(0–0)/(0–0)	Negligible
Ripening plant	0	293	0/(0–0)/(0–0)	Negligible
Unknown	1	18	na	na

CI, confidence interval; na, not assessed (number of samples < 30).
*Range between the product with the lowest prevalence of transgressions and the product with the highest prevalence of transgressions.

the tests' characteristics were not found. Nevertheless, as the type factor was plausible and in agreement with previous work and experts' opinion, the uncertainty associated with RL was kept equal to that of the previous step.

However, this approach presented limitations. It assumed that the frequency of non-conformity was the same for all products within a same type of dairy, when in reality it might vary. This led to an over- or underestimation of RL for certain hazard/product/type of dairy combinations. For instance, LC for hard cheese was estimated as being negligible or very low depending on the hazard considered. Even if no transgression of the limit value had been found in hard cheese from alpine dairies, their type factor (low) led to a RL low or medium depending on the hazard considered. Similarly, the non-stratified RL was higher for yoghurt from farm and artisanal dairies, fresh cheese from farm dairies, and milk, cream and ricotta from artisanal dairies. It was lower for butter from alpine dairies and soft and fresh cheese from artisanal dairies. A type factor stratified per product could not be estimated due to the low number of samples analysed (<30) for several product/type of dairy combinations. This low number was the consequence of the risk-based sampling, changes in the sampling schema (hazard/product to sample) and the specialization of dairies in the manufacture of certain products.

Table 2. Distribution of the percentage of production (in kg) per dairy product and type of dairy (2006)* used for the qualitative risk assessment of Swiss dairy products

	Type of dairy				
Product	No licence†	Alp dairy	Farm dairy	Artisanal dairy	Industrial dairy
Milk	<0.1	<0.1	<0.1	2.4	50.4
Cream	<0.1	<0.1	<0.1	0.1	7.2
Hard cheese	<0.1	0.3	<0.1	7.6	0.5
Semi-hard cheese	<0.1	0.2	<0.1	2.9	2.3
Soft cheese	<0.1	<0.1	<0.1	0.2	0.5
Fresh cheese	<0.1	<0.1	<0.1	<0.1	4.2
Butter	<0.1	<0.1	<0.1	0.1	3.2
Yoghurt	<0.1	<0.1	<0.1	0.5	14.9
Ricotta	<0.1	<0.1	<0.1	<0.1	0.1
Melted cheese	0	0	0	0	2.0
Milk powder‡	0	0	0	0	<0.1
Total	0.1	0.5	<0.1	13.9	85.4

*No production in ripening and pre-packaging plants; data on flow of products not available.
†Dairies processing <10 000 kg milk (<3000 kg in alp dairies) per year, according to the regulations in force until 2006.
‡Only milk powder for direct consumption.

Exposure assessment

Exposure assessment was based on production data corresponding to 2006, which were obtained from associations of producers, and classified per product and type of dairy. For each product/type of dairy combination, the proportion over the total production was then calculated and assigned a qualitative value representing the exposure likelihood (EL), that is, the relative likelihood of consumer's exposure to a certain product from a certain type of dairy. A relative production <0.1% was assigned a negligible EL, ≥1–1% very low, ≥1–10% low, ≥10–25% medium, ≥25–50% high and ≥50% very high. Most of the production was concentrated in few large dairies (Table 2). The uncertainty associated with EL was considered low.

The production data available had several gaps. Data regarding the flow of products in ripening and pre-packaging plants are not reported and therefore, the EL for this type of dairy could not be assessed. Production data from non-licensed dairies, which had not been sampled in previous monitoring campaigns, were available. These dairies processed each <10 000 kg milk per year (or <3000 for alpine dairies), but on the whole, their production was higher than that of farm dairies. In Switzerland, majority of hard cheese and a significant amount of semi-hard and soft cheeses are made of raw milk, but detailed data on their quantity are not available. After experts and associations of producers were consulted, it was assumed that those cheeses were made of raw milk in alpine and farm dairies and of pasteurized milk in industrial dairies. In artisanal dairies, it was assumed that hard cheese was made of raw milk; for semi-hard and soft cheeses, both scenarios (raw versus pasteurized milk) were modelled. For other dairy products, the heat treatment was at least equivalent to pasteurization. These assumptions would represent a pessimistic scenario for alpine and farm dairies, and an optimistic one for industrial dairies. Nevertheless, their impact on the results of the RA would be limited by the likely few exceptions to it.

Combination of release and exposure likelihoods

The estimated RL and EL were combined to obtain the final likelihood (FL) for each combination hazard/product/type of dairy (Table 3). FL was defined as the relative likelihood of consumers' exposure to a product contaminated above the microbiological limit value. The following rules of combination were applied:

1 If RL was negligible, FL was also considered negligible.
2 For other levels of RL, FL was equal to RL if EL was negligible, very low or low.
3 FL was one level higher than RL if EL was medium or high.
4 FL was two levels higher than RL if EL was very high.

Table 3. Combination table of release (RL) and exposure (EL) likelihoods to obtain the final likelihood (FL)* used for the qualitative risk assessment of Swiss dairy products

Final likelihood	Exposure likelihood					
Release likelihood	Negligible	Very low	Low	Medium	High	Very high
Negligible	n	n	n	n	n	n
Very low	vl	vl	vl	l	l	m
Low	l	l	l	m	m	h
Medium	m	m	m	h	h	vh
High	h	h	h	vh	vh	vh
Very high	vh	vh	vh	vh	vh	vh

n, negligible; vl, very low; l, low; m, medium; h, high; vh, very high.
*The combinations of RL and EL likelihoods that were found are shadowed.

5 If EL was negligible, FL was not automatically considered negligible because certain product/type of dairy combinations with negligible RL have been pointed out as possible causes of food-borne outbreaks.

Not all possible combinations of RL and EL were found. The uncertainty associated with FL was low or medium, similar to that for the RL.

Consequences assessment and risk estimation

Information regarding the incidence and prevalence of food-borne disease, risk groups in the human population, disease complications, hospitalization and mortality rates, notification procedure and estimated underreporting in Switzerland and other Western countries was gathered for the assessment of consequences. However, they could not be assessed due to lack of epidemiological link between cases, aetiological agents and Swiss dairy products as the food vehicle. Therefore, the risk could not be estimated either.

Results

Ranking of final likelihood

The results of the RA were expressed as a ranking of relative FL for all combinations hazard/product/type of dairy:

Very high FL: not found

High FL: CPS in soft cheese from alpine and farm dairies

Medium FL:

From alpine and farm dairies: LM and SE in hard cheese; LM, STEC, CPS and SE in semi-hard cheese; LM, STEC and SE in soft cheese

From artisanal dairies: CPS in soft cheese made of raw milk

Low FL:

From alpine and farm dairies: other hazard/product combinations

From artisanal dairies: LM and SE in hard cheese; LM, STEC, CPS and SE in semi-hard cheese made of raw milk; LM in semi-hard cheese made of pasteurized milk; LM, STEC, SE in soft cheese made of raw milk; LM in soft cheese made of pasteurized milk

Very low FL:

From artisanal dairies: other hazard/product combinations

From industrial dairies: LM in semi-hard and soft cheeses

Negligible FL: other hazard/product combinations from industrial dairies

Final likelihood depended largely on the type of dairy: for most of the combinations, it was low in alpine and farm dairies, very low in artisanal dairies and negligible in industrial dairies; it could not be assessed for ripening and pre-packaging plants.

Recommendations to the risk managers

Based on the RA process and the ranking of FL, two kinds of recommendations were made to the risk managers: those for the design of the national monitoring programme of dairy products, and those for the future improvement of the RA.

Within the first group, it was recommended to sample all types of dairy, including those not licensed, to reinforce sampling in the types of dairy with the highest FL, and to sample targeted hazard/product combinations depending on the type of dairy. Even if no longer anchored in the regulations, keeping the classification of dairies in different types seemed to be reasonable, as they could be considered risk groups. It was further suggested that sampling of many alpine and artisanal products could be simplified by taking the samples in ripening and pre-packaging plants, where most of those products come to. For this, information on the flow of products in this type of dairy should be made available. Data on the heat treatment of the milk should be collected, and data collection should be further standardized to improve data quality. Alternate instead of annual testing was deemed sufficient for *Salmonella* spp. and *Campylobacter* spp. because these hazards had been detected neither in bulk milk nor in dairy products in the previous years. Testing for SE instead of CPS was recommended because the absence of CPS or its presence below the limit value does not exclude the presence of SE. The description of the sensitivity and specificity of the testing methods and their harmonization among the laboratories involved were further encouraged to enhance accuracy and comparability of monitoring results. Regarding the limit values and taking into account the new regulatory framework, it was recommended to reconsider them in light of the current

diagnostic possibilities and the intended food safety objectives. It has to be noted that official interventions are only justified in case of exceeding the limit values; those are currently defined for *Salmonella* spp. and LM only.

The recommendations for future RAs aimed to fill identified data gaps. It was recommended to intensify epidemiological investigations of food-borne outbreaks (sporadic and collective) to identify the food vehicles and to investigate the food consumption patterns of the Swiss population. It was further suggested to extend the RA to other hazards and to products made of sheep or goat milk, the importance of which is on the rise, and to obtain representative baseline data on the prevalence of hazards for those product/type of dairy combinations less sampled.

Discussion

This work describes a qualitative RA for microbial hazards in Swiss dairy products that considered multiple hazards and products from different types of dairy along the food chain. The results were expressed as a ranking of relative likelihoods representing consumers' exposure to a product contaminated above a microbiological limit value. The consequences, and therefore the risk, could not be assessed due to lack of epidemiological link among food-borne disease cases, aetiological agents and dairy products as the food vehicle. Nevertheless, the RA suited its purpose: the obtained ranking served to make recommendations on the design of the national risk-based monitoring programme of dairy products. Moreover, further recommendations to fill the identified data gaps were made to the risk managers.

Opportunities and limitations of the qualitative risk assessment approach

Animal health risk analysis has traditionally been based on OIE standards (OIE, 2004, 2008), whereas food safety risk analysis has relied on the Codex ones (CAC, 1999, 2004). Despite differences in their original purpose and in nomenclature, both approaches are equivalent, require similar information and share similar principles (Vose et al., 2001). The present study represents an adaptation of the OIE methodology to a domestic food safety RA.

International standards offer a general framework for risk analysis, but risk analysis should remain flexible to deal with the complexity of real life situations, and therefore, no single approach is applicable in all cases (OIE, 2008). The harmonization of the RA methodology suggested by EFSA and other international organizations aims to remove discrepancies between the approaches used rather than to standardize it, and recognizes that differences are probably inevitable due to the diversity of scenarios evaluated (EFSA, 2008a). Moreover, risk management decisions are based not only on RA but also on other legitimate factors of technical, economic, ethical, social and political nature (FAO, 2006; Havelaar et al., 2007). In addition, differences in risk perception by involved stakeholders have been identified as a constraint to policy making (Sargeant et al., 2007). We support that the output of risk analysis is context-specific and therefore care should be taken when attempting to extrapolate their results. Nevertheless, the approach followed in this RA could be adapted to other settings than Switzerland. Local RAs may reflect better any specific situation and may allow a higher degree of involvement of stakeholders in the decision-making process, which in turn would lead to increased acceptability of the policy adopted. This is in agreement with the principle of subsidiarity of the European Community, which is intended to ensure that decisions are taken as closely as possible to the citizens. Large-scale RAs in contrast, may become cumbersome and are challenged by national and regional variations (e.g. prevalence of hazards, nutritional habits, existence of local products) (Hugas et al., 2007).

Risk assessment may be qualitative or quantitative depending on whether the output is expressed in words or in numerical values. Both methodologies are accepted by OIE and Codex, and the latter recommends including quantitative information wherever possible. Qualitative RA provides a means to identify the risk pathway and the available and missing information, and is a first step towards any quantitative approach (Clough et al., 2006). It is less demanding in terms of resources, data or mathematical knowledge, and its output is easier to communicate and usually adequate for decision-making (Hauser et al., 2007). However, assigning qualitative categories or combining them is done subjectively and there is no standardized method, which makes it difficult to compare RAs made in different settings or by different analysts (Hauser et al., 2007). Nevertheless, assumptions and subjectivity also occur in quantitative RA when adjusting probability distributions to expert opinion or sparse data. The results might be then misleading and give a false impression of objectivity. On the other hand, it has been pointed out that qualitative categories may not be informative if they do not succeed in discriminating between different numerical estimates of risk (Cox et al., 2005). Moreover, linguistic uncertainty, which may rise from ambiguity, vagueness, or contextual dependence of the categories used, can lead to misunderstanding (Carey and Burgman, 2008). To minimize these effects, our categorization of quantitative data and the combination table of RL and EL were discussed and agreed with risk managers

and experts. The type factor used could discriminate results on the prevalence of transgressions that were not quantitatively very different among the various types of dairy. A further limitation of the qualitative approach is the lack of standard sensitivity analysis methods, which are still in development (Presi et al., 2008). Sensitivity analysis is used to identify the most influential risk factors, to develop priorities for risk mitigation, to identify important uncertainties for prioritizing additional research and to evaluate robustness of the risk model (Patil and Frey, 2004).

Qualitative risk assessment approach for Swiss dairy products

The present RA updated and extended the RA of 2001 by incorporating the results of monitoring campaigns and the exposure assessment. Moreover, regulatory changes that could influence the monitoring of Swiss dairy products were considered. The RA should be reviewed as new information becomes available. In addition, risk-based sampling should consider low risk products or types of dairy to detect possible changes over time. This was encouraged in the recommendations given to the risk managers.

The lack of data of good quality is a common constraint to many RAs and leads to simplifications in the risk model that may affect the accuracy of the results. For instance, survival and growth of hazards during processing of raw milk are influenced by the interaction with the natural flora of milk. The effect of thermization depends primarily on the time and temperature applied. These are some examples of food safety issues that need to be further researched in cheese production (Berger, 2008). The release assessment could be further improved by updating data on the prevalence of hazards in bulk milk periodically, and by gathering data on prevalence of hazards for specific product/type of dairy combinations.

Exposure assessment usually considers the probability of a contaminated product being consumed, the frequency and amount of consumption, and the concentration of the hazard in the product (Sanaa and Cerf, 2002), but it was simplified in this work by accounting only for production data, as other information was not available. Food consumption data in Switzerland have been scarce and not focused on dairy products (FOPH, 2005; FOAG, 2007; Schaub, 2007), but surveys are envisaged to obtain such information (National Nutrition Survey Switzerland, NANUSS, in development by the Federal Office of Public Health). Consumption data may range from population summary data derived from food production statistics, to detailed information derived from national food consumption surveys (type and amount of food consumed by individuals). However, important data for RA such as the specific type of food, the eating patterns of susceptible populations or the propensity of consuming high-risk food are often not collected (Barraj and Petersen, 2004). Factors that may modify the risk, e.g. whether a product has been made of raw or pasteurized milk, should be reported (Batz et al., 2005; Bahk and Todd, 2007).

Consequences could not be assessed due to lack of epidemiological link among food-borne disease cases, aetiological agent and dairy products as the food vehicle. In Switzerland, diagnosed infections caused by *Salmonella* spp., *Campylobacter jejuni*, enterohaemorraghic and enteropathogene *E. coli* (STEC and EPEC), and LM are subject to mandatory notification and collective outbreaks are further investigated. A standardized reporting system has been put in place since 2008. From 1994 to 2006, 137 food-borne outbreaks were investigated (FOPH, 2008). The hazards and involved dairy products most frequently identified were SE in artisanal soft cheese (seven times), *Salmonella enterica* non-enteritidis in soft cheese (twice) and LM in soft cheese (once). Seven further outbreaks were suspected to have dairy products or contact with cows as their source. Industrial products were not responsible for any investigated outbreak. These results seem to be in accordance with those of the RA. However, it was not attempted to estimate the attributable proportion of disease due to the lack of standardized reporting over this period and the high underreporting suspected. Austria, a country with a comparable dairy industry structure, reported 438 domestic food-borne outbreaks in only 1 year (Much et al., 2008); dairy products were responsible for only 0.3% of the outbreaks with an identified food vehicle.

Different approaches have been described for identifying the source of food responsible for human disease (microbial subtyping, outbreak investigation, case–control studies, expert opinion), but due to their limitations, a combination of approaches is needed to obtain accurate information on food attribution (Batz et al., 2005; EFSA, 2008b). Data from outbreaks, for instance, may not represent sporadic cases, and data from agents that are typically not found in outbreaks, such as *Campylobacter* spp., are scarce (Batz et al., 2005; Havelaar et al., 2007; FOPH, 2008). Data from microbial subtyping allow identification of animal reservoirs or food sources, but factors along the food chain are not highlighted; for animal sourcing, subtypes must be species-specific (Havelaar et al., 2007). The combination of attribution methods requires increased resources and cooperation among food safety institutions (Batz et al., 2005; EFSA, 2008b). A further source of bias for surveillance of human illness is underreporting, which leads to underestimation of the true incidence. Reasons

for underreporting are mild course of disease (medical attention not sought), presence of underlying diseases, pathogens that have not yet been identified and cannot be diagnosed; person-to-person spread of some pathogens, which masks the food-borne source; and differences in notification and reporting systems (Mead et al., 1999; Havelaar et al., 2007). Underreporting has been estimated to be as high as 1 : 38 for *Campylobacter* spp. or *Salmonella* spp. (Mead et al., 1999). EFSA has acknowledged the need for harmonization and structured categorization of food items to compare data on food-borne outbreaks from different countries (EFSA, 2008b), and has developed a proposal for standardizing data reporting from the member states, which allows the collection of detailed information (EFSA, 2007). Reporting not only aggregate data but also data on individual outbreaks has been encouraged.

The microbiological limit values represented the food safety objectives in force until 2006. As new regulations were implemented, some of them changed (LM), were omitted (*Campylobacter* spp.) or were substituted by performance objectives along the manufacturing process (CPS). This raised the question of which values should be used to interpret surveillance results in future. Keeping the old values would allow for comparison with previous years, but if the limit values are no longer anchored in the legislation, no intervention of food safety authorities would be possible in case of a transgression. In addition, the results of the previous monitoring campaigns had been interpreted as yes/no transgression. Taking into account the development of quantitative diagnostic methods, raw data would provide information on the concentration of hazards, which would be valuable for future RAs. How to interpret laboratory results depends ultimately on the purpose of the programme, which is defined by FVO, ALP and VKCS.

Microbiological testing of end products may be of limited use for food safety, particularly in case of low prevalence of contamination or low infectious-dose pathogens, in which case, the testing procedure may not be sensitive enough to allow detection (Havelaar et al., 2007; Bassett and McClure, 2008). However, the usefulness of testing could be improved by targeting high-risk foods or practices and including a sufficient sample size (Tebbutt, 2007). Prevalence of hazards is low in Swiss dairy products, and some of the hazards considered have not yet been detected by the risk-based monitoring programme. Obtaining further baseline data could help better target sampling and gain data on emerging hazards that could be considered in future RAs. Increasing sample size, however, is constrained by limited resources and could reduce the efficiency of the programme. Nevertheless, the information obtained by the monitoring programme has been used for advising the producers and emphasizing the importance of self-control measures. It has to be noted that sampling is performed in the milk processing dairies. The household level has not been considered, although domestic handling practices may play a role in food-borne disease (Fischer et al., 2005).

Qualitative RA can prove a useful tool for decision-making provided it is timely, informative, consistent, comprehensive, valid, accurate, transparent and well-documented. These characteristics determine the quality of any RA and should be subject to peer review (Alban et al., 2008).

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