ALP science No. 545 | June 2013

Date	04.02.2013		
Assessor	BLK		
Product	Milk	Product x H	lazard x Processing ->
Contaminant	Aflatoxin M1	FLEXIBILI	ITY
Intended use / processing	Cheese production		
Factor		Weighting	Comments, remarks
Quality of agent	chemical		
Agent impact on human health	environmental contaminants, natural toxins	0.0025	
Dissemi bio	low proliferation / transfer /pathogenicity in human and animal	4	
1 Human Health &	farm & processing	2	
6 Exposure Criteria	basic food/feed, daily to weekly consumption	3	
Ch. Ig	accumulation	3	
Spread of hazard / IISK	international (import / export)	3	necessity to specify cheese type
Regulatorycontrol options	known and regulated	→ 1	
Other legitimate criteria	new and not regulated known and regulated known but not regulated	0.54	
media interest (extrapolation)	protection from fraude, illegal activity, misuse, bad practice headline coverage (i.e. due to fraud, political debate, scandal)	3	
cons	no	2	
Other Legitimate Criteria:	good knowledge and no research need	1	
a relevant for value chain	general population	3	
\setminus		18	
	Total priority points TPP	9.72	Rating transfer in data base

Figure 1: User friendly interface of the proposed framework for the evaluation and prioritization of food and feed safety hazards and related research needs (R. Imhof).

PRACTITIONER FRAMEWORK FOR THE EVALUATION AND PRIORITIZATION OF FOOD AND FEED SAFETY HAZARDS AND RELATED RESEARCH NEEDS

Technical-scientific information

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1. Introduction

Priorities of Agroscope Liebefeld-Posieux Research Station ALP-Haras are foods of animal origin, feed production and control as well as food and feed safety and nutrition. Limitations concerning budget and stuff do not allow the realization of all planned research at the same time. Moreover, contacts to and needs of the food and feed sector, e.g. on the farm, production and import / export level confront ALP-Haras with questions related to the quality and safety of foods and feeds and their impact on animal and human health. As is the case with nutritional imbalance, i.e. unfavourable dietary composition, overweight and starvation, the different microbiological, chemical and physical risks may result in different long and/or short term health implications. Up to date, there exist different risk prioritization efforts for specific risks, e.g. for microbiological and chemical risks in foods. On the other hand, no practical concept relating the different risk classes and allowing for their prioritization exists (1). Of course, the relevance for human health is the first and most important safety criteria concerning food, feed and nutrition. But a ranking of food related risks remains difficult. Subsequently, the proposed framework, notably far from perfect and subject to very many future changes, is presented and discussed. Figure 1 shows a first version of the user friendly interface.

2. Aims

For chemicals, different chemical risks with acute and long term end points may neither be properly counted nor balanced. A comparison between microbiological and chemical risks is not yet possible. Nevertheless, methods to do so are under development (2). Most probably, they will be based on "matrix – contamination" couples. Estimations of illnesses and deaths as well as related costs due to the ingestion of pathogenic microorganisms and biological agents differ widely (2, 3). The same holds true for deficient or excessive food intake and imbalanced diet. Reasons for these facts mainly are differences originated in regional versus global focus and a failure to efficiently analyze and correct for systematic underreporting, which is seen typical for most food borne diseases (4, 5).

The ranking system is a risk management tool. Such a tool must be of simple and fast use for decision making without the need to perform scientific risk assessment while using it. If the outcome of the ranking indicates a problem, then the risk manager will order for clarification, data, research or complete risk assessment. Therefore, the incidence and severity of adverse health effects must show up within the "relevance for human health"- criteria without the need for answering specific expert knowledge-guestions. The same is required for the comparison of the different classes of hazards: (micro-)biological, chemical, physical, nutritional. In synthesis, applied criteria need to stay within an expectable horizon of knowledge and experience of risk managers in general. Criteria must be clear, sub-criteria must be intuitively understandable and the wording chosen must reflect them correctly. Moreover, no overlapping of meaning and significance should occur, neither between criteria, nor between sub-criteria.

Besides rather scientific criteria, there is a series of other legitimate criteria leading to decisions, including e.g.: precaution, (past) experience, political awareness, media and social interest. These criteria are listed separately in a subdivision of the ranking tool. Here, the criteria and sub-criteria were chosen in accordance to existing recommendations on risk communication (6). The division allows for a separate treatment of scientific and other legitimate criteria, i.e. by scientists and the risk managing entity, respectively. For the final rating, each sub-criterion is given its numerical value according to the respective importance. Afterwards, these figures are summarized or multiplied to the final rating value. This one is automatically classified by colors, whereby green means low prioritization and low research need, yellow is medium on both terms and red highlights possible food and feed safety hazards with research needs of high prioritization.

3. Building of the framework

A) Comparison of different food borne hazards

In most nations, including Switzerland, data on food consumption with related intake of contaminations and health consequences is at best partially available. A recent report concerning Western European food and health outcomes is from the Netherlands (7). The relevance for human health is expressed as health loss due to illness and death cases. The overall health loss caused by an unhealthy diet is measured in DALYs (Disability Adjusted Life Years). DALYs are a summary measure which combines death and illness, using a disability weighting factor for the seriousness of the disease). The annual health loss due to an unhealthy diet is between 300`000 and 400`000 DALYs in the whole population of the Netherlands. This figure includes 245`000 DALYs caused by unfavourable dietary composition and an unknown proportion of the 215`000 DALYs which are due to overweight.

Thus, unfavourable dietary composition in combination with overweight - understood as nutritional imbalance causes most of the food related human health problems. Interestingly, unfavourable dietary composition is about 1.5 times as bad as is overweight.

Foodborne infections attributable to (micro-)biological agents cause between 300'000 and 700'000 reported cases of gastroenteritis and several hundreds of other cases of serious illness. Moreover, they account for 20 to 200 deaths per year. The overall annual health loss is estimated to be 1'000 to 4'000 DALYs. So, the human health risks arising from (micro-) biological agents in food is 100 to 400 times smaller, i.e. 0.25 to 1 per cent of the combined value of unfavourable dietary composition and overweight.

Chemical contamination, e.g. pesticides and naturally occurring chemical compounds - understood as toxins and contaminants - as well as allergens finally are estimated to cause 1`500 to 2`000 DALYs of health loss per year. So, the human health risks arising from chemical contamination in general is 0.375 to 0.5 per cent of the combined value of unfavourable dietary composition and overweight. Herein, allergens are seen as the most important category of agents. The respective health loss was estimated to be in the order of 1,000 DALYs or 0.25 % of the combined value of unfavourable dietary composition and overweight. The overall health loss due to the presence of natural toxins is smaller than that due to allergens. Here, the estimated theoretical annual health loss is in the order of 500 to 1,000 DALYs or 0.125 - 0.25 % of the combined value of unfavourable dietary composition and overweight.

Another possibility to balance chemical, (micro-)biological and nutritional food borne risks is given by Siebert (8). The human health risks are based on rather crude estimates of severity, incidence and onset of biological symptoms. These estimates in combination with the comparison of the principal categories of food hazards lead to the following conclusion: (micro-)biological human health hazards were considered in first place, followed by nutritional imbalance, understood as excess and deficiency. Nevertheless, a comparison between these two classes of hazards is lacking.

In order to close this gap, newer data was used (5): the data allow for an estimate of health risks as well as financial costs: it is stated, that the USA annually presents approximately 5`000 food related deaths, of whom 1`800 (36 %) are related to known pathogens. These figures show fewer deaths and more illness cases than previously estimated. The total costs of overweight and obesity in the year 2000 amounted to US\$ 117 billion, whereas the total cost of food borne illnesses amounted to an estimated US\$ 6.5 – 34 billion (5.5 – 29 % of the total costs of overweight and obesity). This higher value concerning food borne illnesses is in good relation to estimates of 50 % of death children < 5 years due to malnutrition in third world countries (4). So, even modern societies do first suffer from nutritional imbalance, followed by (micro-)biological food borne diseases at a magnitude of up to 30 %. In Switzerland, the observed prevalence for obesity was rising from 5.4 % (1993) to 8.1 % (2007) and projections over the next 15 years are expected to remain stable at this level. It was estimated, that the costs due to overweight and obesity sum up to approximately 80 % of the total Swiss health costs (9). Therefore, a share of 20 % remains for all other diseases. It is suggested to initiate estimates within the proposed framework with 5 % because of underreporting and Swiss people's preference for traditional raw or low processed foods.

According to the balance between the different classes of hazards given in (8), environmental contaminants and natural toxicants might cause about 1/1000th (0.1%) of the cases due to nutritional imbalance. Finally, pesticide residues and food additives might be responsible for about 1/100th (0.001%) of the cases due to natural toxicants. As it happened in the past, long term risks arising from chemicals appear underestimated. Both comparisons of the different hazards and their respective figures are summarized in Table 1 and a synthesis is suggested in Table 2. The synthesis includes a term unwanted highly or moderately hazardous chemicals that may be useful for food and feed contaminations entering the food chain for reasons of fraud and negligence. Such a special positioning will have to be discussed further.

Table 1:

Criterion Relevance for human health of different food borne hazards at the example of the Netherlands (based on DALYs) and the Example of USA and Australia (based on fatalities and costs).

Hazard	Netherlands, DALYs based factors	USA/Australia, Fatalities/ costs based factors
Unfavorable dietary composition and overweight	1	1
(micro-) biological agents	0.0025 - 0.01	0.05 - 0.3
Chemical contamination: pesticides, naturally occurring chemical compounds, toxins and contaminants including allergens	0.00375 – 0.005	
Allergens alone	0.0025	
Environmental chemicals and natural toxicants	0.00125 – 0.0025	0.001
Pesticide residues and food additives		0.00001

Table 2:

Suggestion for the synthesis of the criterion relevance for human health of different food borne hazards.

Type of Hazard	Hazard	Factor
Nutritional	unfavorable dietary composition and overweight	1
Biological	(micro-) biological agents	0.05
Chemical	Environmental contaminants, natural toxins	0.0025
Chemical	unwanted highly and moderately hazardous chemical	0.01
Chemical	Pesticide residues and food additives	0.001
Biological or chemical	allergens	0.0025
Physical	radionuclides	0.001

Some hazards and their relevance for human health, i.e. their comparisons and respective figures are set somewhat arbitrarily. Specific regional and national situations, as well as national and local events will determine the comparison of the hazards. Nevertheless, this basis relies to measurable descriptors, either as DALYs or as illness and death cases in a population. The spread within the comparison of the hazards is up to thousand fold. For this reason, the relevance for (human) health of different food borne hazards is by far the most important criterion. All other applied criteria at most vary by a factor of 5 and therefore just modulate or refine this criterion of outstanding importance. Of course, the criterion highly depends on an obtained national public health standard with related food and feed laws, regulations, monitoring and testing.

B) Criteria for the modulation of the different food borne hazards

A first part of criteria consider rather scientific aspects like type of the agent, its transfer, proliferation or pathogenicity, the exposure to the hazard as well as existing regulation (and control). Possible criteria and sub-criteria with their respective figures are summarized in table 3 and subsequently reasoned in brief.

Table 3:

Scientific criteria used in the framework for the evaluation and prioritization of food and feed safety hazards and related research needs

Category	Criterion	Sub-criteria	Numerical values
Health relevance	Quality of agent	Important for animal and human health	
		Important for human health	
		Important for animal health	
Health relevance	Type of agent	Chemical	
		(Micro-)biological	
		Physical	
		Nutritional	
Health relevance	Dissemination of agent	High proliferation / transfer / pathogeni- city in human and animal	5
		High proliferation / transfer / pathogeni- city in animal only	2
		Unknown	3
		Low proliferation / transfer / pathogeni- city in human and animal	4
		Low proliferation / transfer / pathogeni- city in animal only	1
Health relevance	Entry to food chain	Retail and consumer	3
		Farm and processing	2
		Environment and field	1
Relevance for exposure	Importance of food / feed ingestion	Basic food/feed, daily to weekly consump- tion	3
		Normal food/feed, weekly to monthly consumption	2
		Speciality, monthly to yearly consumption	1
Relevance for exposure	Changes due to food processing	Accumulation	3
		Unknown	2
		No change	1
		Reduction	0.1
Relevance for extent of occurrence	Spread of the hazard	International (import/export)	3
		National	2
		Local	1
Relevance for regulation	Control options	New and not regulated	4
		Known but not regulated	3
		Fraud, negligence	2
		Known and regulated	1

The sub-criteria of the criterion quality of agent might be used to switch on or off the appropriate criteria selection for separate food and feed hazard prioritization. The definition of the type of agent, i.e. if the hazard is of chemical, microbiological, physical or nutritional nature, selects the appropriate sets of sub-criteria for the selected type of hazard. The dissemination describes the agent's capacity of reaching living beings (humans, animals). The criteria entry to the food chain assumes contaminations to be more hazardous when present in the food or feed near consumption because there remains less possibility for its detection and minimization. The importance of food or feed ingestion associates the probability of ingestion with the ingested amount. The criteria changes due to food processing informs about the amount of hazard expected in the final product. The spread of the hazard defines the

area of influence. Herein, an international area with imports and exports of a product across the border(s) might represent a "switch on" criteria for statistically relevant numbers of regulatory sampling. Finally, known and regulated (and controlled) hazards imply a reduction of hazards present in foods and feeds towards acceptable levels.

A second part of criteria deals with the perception of risk related to a certain hazard. From experience in risk communication it was learnt, that factors different to mere science may heavily influence the public perception of risk. Such other legitimate factors may as well be considered by risk managers and were therefore built into the framework (Table 4).

Table 4:

Other legitimate criteria used in the framework for the evaluation and prioritization of food and feed safety hazards and related research needs

Category	Criterion	Sub-criteria	Numerical values
Perception of risk	Media interest (extrapolation)	Headline coverage (i.e. due to fraud, political debate, scandal)	3
		Little or medium coverage	2
		No coverage	1
Perception of risk	Consumer control over hazard	no	2
		yes	1
Institutional risk communication	Data gaps	No knowledge and high research need	3
		Basic knowledge and medium research need	2
		Good knowledge and no research need	1
Health relevance for consumers	Affected persons	General population	3
		Subpopulations (YOPI)*	2
		Sensitive individuals	1

* Young, old, pregnant, immune-compromised

The criteria related to the perception of risk widely depend on individual risk estimations and evaluations. Media coverage on risks heavily influences the public perception of risks. Therefore, the appreciation of a possible future media interest makes sense, especially when trying to avoid scandals e.g. due to fraud or insufficient controls and when trying to avoid loss of trust. Other mayor qualitative characteristics of risks and their influence on risk perception have already been outlined (6): consumers may show increased risk tolerance, when they exert personal control over a risk, when the risk is voluntarily taken, when it is familiar or when there exists institutional control by a confident institution. Last but not least it is of importance, how many persons might be affected by a certain risk and, in especial, if appealing persons like children or mothers are affected.

4. Discussion

The described prioritizations always are applied to triplets formed by a product matrix (food or feed), it's processing resulting in a possible change of an inherent hazard as well as the respective inherent hazard. This proceeding allows for flexibly applying the framework to typical local or national food and feed hazards.

The scientific criteria lead from a minimal reduction factor of 0.1 to a maximal multiplication factor of more than 3000 over the initial factor set by the relevance for human health criterion. Herein, the spread within the factor of the hazards is up to ten-thousand fold. For this reason, the criterion relevance for (human) health of different food borne hazards is by far the most important criterion. All other applied criteria at most vary by a factor of five and therefore just modulate or refine the factor set by this criterion of outstanding importance.

The four criteria related to the perception of risk lead to a maximal multiplication factor of 72. This factor, even if small in comparison to the maximal multiplication factor of the scientific criteria, may clearly influence the prioritization of a hazard present in a food or feed. It may even give rise to a change within the initial factor set by the relevance for human health criterion. Thus, the factors separating the principal categories of food hazards may be passed or changed. At first sight, this seems to be enough influence for the criteria grouped under perception of risk. If desired, their influence on the outcome of the prioritization might be enhanced by appropriate weighting factors. All chosen criteria and sub criteria remain within an expectable horizon of knowledge and experience of risk managers in general, e.g. lieders of food and feed enterprises and food and feed safety enforcement officials. There is, in difference to the risk assessment based iRISK 1.0 model, no need for qualified assumptions to be taken on doseresponse as well as consumption models and on severity of the health outcomes (11).

Apart of some renaming of criteria and sub-criteria, a discussion with the authors of the proposed draft guidance for governments on prioritizing hazards in feed (10) revealed the following suggestions: A separation of food and feed hazard prioritization is desired. As an equivalent to the relevance for human health criteria, OIE data on animal health should be incorporated. Other criteria dealing with food and feed, e.g. the importance of food / feed ingestion and the category relevance for regulation might be separated and automatically switched on/off when choosing the relevance for human or animal health criteria. Instead of weighting like numerical values given to sub-criteria, normalization should be performed and a separate weighting of problematic constellations of subcriteria should lead to a high priority. A group of experts should validate the system. A glossary of terms must be incorporated. The incorporation of existing data on food and feed contamination incidence is desirable. These data might be obtained from the Swiss Cantonal Chemists. Special thanks are expressed to R. Imhof from ALP-Haras for the development of the user friendly interface in an Excel spread sheet. In the future, a conversion to an access

database might become necessary.

5. Zusammenfassung

Zu Beginn des Jahres 2010 gab es in der Schweiz kein System, welches die verschiedenen (mikro-)biologischen, chemischen, physikalischen und ernährungsbedingten Gefahren aus Lebensmitteln gegen einander abwägt. Deshalb wurde auf Excel ein generisches Programm zur Priorisierung von Gefahren aus Lebens- und Futtermitteln erstellt. Dabei stellt die Relevanz für die Humangesundheit natürlich bei Weitem das wichtigste Sicherheitskriterium für Lebensmittel, Futtermittel und Ernährung im Allgemeinen dar. Andere ausgewählte Kriterien, wie zum Beispiel die Art der Kontamination, ihr Übergang und ihre Ausbreitung sowie ihre Fähigkeit zur Erregung von Krankheiten, die Exponiertheit der Leute wie auch existierende Gesetzgebung und Kontrollen, modulieren dieses wichtigste Kriterium lediglich.

Ein Ranking-System ist ein Instrument zur Risikosteuerung. Es muss einfach und schnell sein in der Anwendung für die Entscheidungsfindung und soll nicht die Durchführung einer wissenschaftlichen Risikobewertung voraussetzen. Aus diesem Grund müssen Entscheidungskriterien klar sein sowie Unterkriterien intuitiv verständlich und mit korrekt umschreibenden Begriffen versehen sein. Dabei sollten keine Überschneidungen in Interpretation und Bedeutung auftreten.

Neben wissenschaftlichen Kriterien existiert eine Anzahl anderer legitimer Kriterien, die ebenfalls zur Entscheidungsfindung führen können. Diese umfassen zum Beispiel das Vorsorgeprinzip, (vergangene) Erfahrungen sowie das Interesse von Medien und Gesellschaft. Entsprechende Kriterien wurden nach existierenden Empfehlungen aus der Risikokommunikation ausgewählt und separat in einer Subdivision des Ranking-Systems eingebaut. Diese Trennung ermöglicht die unabhängige Bearbeitung wissenschaftlicher und anderer legitimer Kriterien jeweils durch Wissenschaftler und die entsprechenden Risikomanager. Zum Rating gelangt man, indem den einzelnen Subkriterien Zahlenwerte entsprechend ihrer jeweiligen Bedeutung zugewiesen und diese zusammen multipliziert werden. Die gegenwärtige Version kann dem vorgeschlagenen Entwurf zur Anleitung für Regierungen zur Priorisierung von Gefahren in Futtermitteln angepasst werden (10).

6. Résumé

Au début de l'année 2010, il n'existait en Suisse aucun système de comparaison des divers risques de nature (micro) biologique, chimique, physique des denrées alimentaires et en lien avec l'alimentation. Un programme générique de priorisation des risques liés aux denrées alimentaires et aux aliments pour animaux a donc été mis au point au moyen d'Excel. Il va de soi que l'importance pour la santé humaine représente de loin le critère de sécurité le plus important pour les denrées alimentaires, les aliments pour animaux et l'alimentation en général. D'autres critères sélectionnés, par exemple, le type de contamination, sa transmission et sa propagation, sa pathogénicité, l'exposition des consommateurs au risque, la législation y relative et les contrôles existants ne font que modifier ce critère essentiel.

Un système de catégorisation est un instrument indispensable pour la gestion des risques. Il doit être simple et rapide d'emploi lorsqu'il s'agit de prendre une décision et ne doit pas présupposer la réalisation d'une évaluation scientifique des risques. Pour cette raison, les critères doivent être clairs, les sous-critères compréhensibles de façon intuitive et tous deux dotés de termes les décrivant correctement. Aucune ambiguïté ni mésinterprétation ne doit subsister en ce qui concerne l'interprétation et la signification des critères.

A côté des critères scientifiques, il y a d'autres critères légitimes qui peuvent aussi contribuer au processus de décision, par exemple le principe de précaution, les expériences (passées) de même que l'intérêt des médias et de la société. Des tels critères ont été sélectionnés selon des recommandations issues de la communication sur les risques et intégrés séparément dans une subdivision du système de catégorisation. Cette séparation permet le traitement individuel des critères scientifiques et d'autre nature par des spécialistes et les personnes chargées de la gestion des risques. On parvient à la catégorisation définitive d'un risque donné en attribuant aux différents souscritères une valeur numérique selon leur importance et en multipliant celles-ci. La présente version peut être adaptée au projet de guide proposé aux gouvernements en vue de prioriser les risques liés aux aliments pour animaux (10).

7. Summary

At the beginning of 2010, no practical concept relating the different (micro-)biological, chemical, physical and nutritional hazards existed in Switzerland. Therefore, a generic hazard prioritization framework was constructed using Excel® as a tool. Of course, the relevance for human health by far is the most important safety criteria concerning food, feed and nutrition in general. Following other criteria were chosen to modulate this criterion: entry of the hazard into the food chain, importance of food ingestion, change of the hazard due to processing, expansion of hazard, and regulatory concern.

A ranking system is a risk management tool. It must be of simple and fast use for decision making without the need to perform scientific risk assessment while using it. Therefore, criteria must be simple, sub-criteria must be intuitively understandable and the wording must reflect them correctly. No overlapping of meaning and significance should occur.

Besides scientific criteria, there is a series of other legitimate managing criteria, which may lead to decisions, including e.g.: the precautionary principle, (past-)experience, media, and social interest. Such criteria were selected in accordance to existing recommendations on risk communication. They were built-in separately in a subdivision of the ranking tool. The division allows for separate work on scientific and other legitimate criteria by scientists and the risk management, respectively. For the final rating, each sub-criterion is given its numerical value according to the respective importance and the values are multiplied to the final rating value. The present version might be adapted to the proposed draft Codex guidance for governments on prioritizing hazards in feed (10).

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