



ASEAN REGIONAL GUIDELINE FOR THE IMPLEMENTATION OF INTERNATIONAL STANDARDS RELATED TO SPS MEASURES

GUIDELINE 3 FOOD SAFETY RISK ASSESSMENT

Supported by:



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Implementation of International Standards related to Sanitary and Phytosanitary (SPS) Measures

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Contents

Disclaimer	ii
Contents	iii
Introduction	1
The Sanitary and Phytosanitary Measures Agreement.....	1
Sanitary and Phytosanitary Measures Agreement in ASEAN	1
ASEAN Regional Guideline for the Implementation of International Standards related to SPS Measures.....	1
A risk-based approach to food safety.....	3
What is risk?.....	3
Risk perception	3
Risk analysis in food safety.....	3
Risk assessment.....	3
Risk management	3
Risk communication	4
Interaction between components	4
Differentiating between hazards and risks.....	4
Food safety risk assessment	4
Risk pathway.....	4
The difference between risk assessment and surveillance.....	5
What to do with the results of a risk assessment?	5
Resources	5
Food safety risk assessment overview	6
Four steps of risk assessment	6
Hazard identification.....	6
Hazard characterization.....	6
Exposure assessment	6
Risk characterization.....	6
Hazard prioritization.....	7
Emerging risks.....	7
Variability and uncertainty.....	7
Human resources needed for food safety risk assessment	7
Linking risk assessment to risk management	7
Resources	8
Food safety risk assessment case studies	9
Case study one: Exposure to captan and tolylfluanid.....	9
Data about food consumption.....	9
Data on pesticide residues.....	9
Data about the influence of processing.....	9
Exposure assessment	9
Conclusion.....	9
Case study 2: Cholera from shrimp	9
Hazard identification.....	10

Exposure assessment.....	10
Hazard characterization.....	10
Risk characterization.....	10
Conclusions	10
Case study 3: Roquefort cheese.....	10
Resources	11
Sourcing information for food safety risk assessment.....	12
Guidelines and resources available online	12
Data sources	12
Sourcing peer-reviewed studies	12
The evidence hierarchy	12
Evaluating evidence	13
No need to reinvent the wheel	13
Resources	14

Introduction

The Sanitary and Phytosanitary Measures Agreement

The World Trade Organisation (WTO) recognises each nation's sovereign right to use sanitary and phytosanitary (SPS) measures to protect animal, plant and human health. The Agreement on the Application of SPS Measures (SPS Agreement) is a WTO Agreement that formalises how these SPS measures should be used so that they do not unduly affect trade. The SPS Agreement is necessarily broad and strategic: it outlines the principles to be followed but provides little detail on how to implement these principles. International standards set by the World Organisation for Animal Health (OIE), the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) Commission provide further guidance, including technical details and recommendations for implementation.

The major features of the SPS Agreement include:

- countries may set their own standards and methods of inspecting products
- regulations must be justifiable and based on science
- regulations should be applied only to the extent necessary to protect human, animal and plant life or health—in other words, measures should restrict trade to the least extent possible
- regulations should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail
- countries are encouraged to use international standards, guidelines and recommendations where they exist, but may implement higher standards provided these are scientifically justified based on appropriate risk analysis that is consistently applied.

Members can use two broad approaches in setting SPS measures, consistent with the SPS Agreement:

- implement the normative standards established by the relevant international standards
- implement SPS measures to suit an individual country's risk tolerance based on a defined appropriate level of protection (ALOP), underpinned by a risk analysis and credible scientific justification.

While Members accept that each country can determine its own ALOP, the SPS Agreement seeks to ensure that SPS measures are the minimum required to provide that protection, are consistently applied, are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

Sanitary and Phytosanitary Measures Agreement in ASEAN

In recent years, the volume of trade in agri-foods has grown rapidly in Southeast Asia. However, despite formally adopting SPS Agreement principles, many ASEAN Member States (AMS) face difficulties putting into effect these principles and the relevant international standards, guidelines and recommendations. Among AMSs, there is a high degree of variability in the maturity of SPS systems and capacity to implement. Looking forward, as agri-food industries continue to expand in the region increasing the capacity for AMSs to implement the SPS Agreement is of paramount importance.

ASEAN Regional Guideline for the Implementation of International Standards related to SPS Measures

The ASEAN-Australia-New Zealand Free Trade Area (AANZFTA) Economic Cooperation Support Programme (AECSP) aims to assist ASEAN countries to maximise the benefits of AANZFTA with the aim of enhancing trade within the region and between Australia, New Zealand and AMSs. A crucial

component of improving trade is to enhance implementation of the SPS agreement and international standards by AMSs.

Within this context, AANZFTA developed a project to provide assistance to the AMSs to develop their own national SPS standards based on international standards, guidelines and recommendations, where they exist. The immediate aims of the project are:

- To enhance understanding and recommend solutions about the challenges encountered by AMS in developing national SPS standards based on international standards, guidelines (IPPC, OIE, Codex); and
- To develop a regional guideline to assist AMS in their practical implementation of international standards related to SPS measures

The project is divided into two phases. Phase 1 has already been concluded and was a comprehensive study resulting in a report, titled 'Review Report of the Implementation of SPS Agreement and International Standards in ASEAN Member States'

This guideline is the fourth in a series of guidelines produced as part of Phase 2 of the project. These guidelines are complemented by a collection of e-learning modules. These guidelines are deliberately succinct and written in plain language to facilitate accessibility for a wide audience.

A risk-based approach to food safety

What is risk?

Risk is something we deal with in our daily lives. We are constantly confronting risk. The technical definition of risk is the likelihood of an adverse health event occurring and the consequence/severity of that event occurring.

We identify risks all day: when we cross the road, we may be hit by a car. When we hammer a nail into the wall, we may hit our fingers. When we buy fresh meat from the market, the meat we buy may not be suitable for human consumption. When we approach these risks we immediately and often subconsciously assess them. Will we have time to cross the street? Are my fingers placed carefully around the nail? Does the meat we are buying look fresh? We also manage risk. We go to a pedestrian crossing when we want to cross the road. We place our fingers far away from the head of the nail or we use a separate tool to hold the nail while we are hammering. We go to the market that has a good reputation for selling fresh products. We also communicate that risk. We tell our children when it is safe to cross the road. We tell our partner to place his fingers a bit further away from the head of the nail. We ask the store owner where the meat is from.

Risk perception

When dealing with risk, we also need to deal with the perception of risk by people, countries and cultures. Risk perception is the tendency for people to have different estimates of risk probability and its impact given the same information. For example, how and where pedestrians feel comfortable crossing the street varies widely around the world. Consumer preferences also vary when it comes to where and how to buy fresh products: pre-packed in a supermarket or directly from a market stall. Risk perception can also change over time. For example, medical doctors have believed for a long time that eating a lot of spicy food may cause stomach ulcers. Studies have now shown that eating spicy food does in fact not cause stomach ulcers and therefore nutritional advice for consumers with stomach pain has changed.

It is important to keep in mind that risk is everywhere along the food chain: at primary production, at processing level, during storage or transport. Not all risks are the same. Some risks have more serious health implications than others. It is not possible to eliminate all risks. Zero risk is not possible.

Risk analysis in food safety

Risk analysis is a term used to describe a process consisting of three components: risk assessment, risk management and risk communication. This guideline is primarily focused on risk assessment.

Risk assessment

Risk assessment is defined by Codex Alimentarius as a scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment and risk characterization. It is therefore a method to understand, measure and describe the risks that we are confronted with.

Risk management

Risk management is defined by Codex Alimentarius as 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. It is therefore a coordinated approach of using control measures to mitigate identified risks.

Risk communication

Risk communication is defined by Codex Alimentarius as the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perception, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions. Risk communication is therefore communicating with each other about these risks to learn what is and is not risky and what we can do about them.

Interaction between components

Risk assessors, risk managers and risk communicators need to work together closely, but it is important that the functions are clearly separated. For example, while a risk assessor should understand, measure and describe a food safety risk from a purely scientific and data-driven approach, a risk manager may consider policy priorities or stakeholder interests in addition to the results of a risk assessment when deciding on the appropriate control measures. A risk communicator facilitates the discussion between the risk assessors, risk managers and other stakeholders about the risks, risk management measures and risk perception. As described earlier, this guideline is focused on risk assessment.

Differentiating between hazards and risks

In a risk assessment, it is important to differentiate between a hazard and a risk. A hazard is a biological, chemical or physical agent in, or a condition of, food with the potential to cause an adverse health effect. A risk is the function of the probability of an adverse health effect occurring and the severity of that effect, consequential to a hazard in food.

Some food hazards are essential to maintain human health, even though they can pose a health risk at very low and very high levels of intake. For example, iodine is an essential micronutrient for the production of thyroid hormones. At the same time, an insufficient intake of iodine can lead to mental retardation while an excess intake can lead to an increased risk of developing iodine-induced thyroid dysfunction.

Food safety risk assessment

Food safety risk assessment can be used to address risk questions in the context of import risks, export risks and risk questions concerning products produced for the domestic market. The results of a risk assessment can help us:

- To better understand the strengths and weaknesses of a food safety system
- To determine the impact on public health of a specific food safety hazard
- To compare the impact on food safety of different proposed control measures
- To determine the equivalence of different food safety systems between countries

Any type of risk assessment should be based on evidence. That means that the data used for a risk assessment should be sourced from reputable and up to date published reports, scientific studies, inspection and surveillance results, etc. The risk assessors who are performing the risk assessment should be able to work independently and not be influenced by factors such as political preferences or industry interests. The results of a risk assessment should list all sources of data and information to increase transparency. This will also allow reviewers and interested parties to understand how the risk assessors reached their conclusions.

Risk pathway

A good risk pathway is the basis for any risk assessment. It outlines all steps between the start point of the risk assessment (e.g. a carcass in the slaughterhouse) until the end point of the risk assessment (e.g. the

dinner table of the consumer) and defines all steps that may influence the presence of the hazard along this chain of events.

The difference between risk assessment and surveillance

A surveillance system provides data on the frequency of occurrence of a defined hazard over time, in a certain geographical area and in selected commodities. A risk assessment can combine these surveillance data with information about the relevance of this hazard for public health and the quantity and frequency of exposure of the consumer to the hazard.

What to do with the results of a risk assessment?

A risk manager can use the results of a risk assessment as one factor among multiple to decide on which measures to take to address a food safety challenge. Such measures can include, for example, improvement of the national official inspection systems, work with private industry to improve hygiene systems, implementation of information campaigns for consumers or requests for additional guarantees from international trading partners.

Resources

E-learning module 3.1.

Codex Alimentarius Commission. *Working principles for risk analysis for food safety for application by governments*. Available: <http://www.fao.org/3/a-a1550t.pdf> (accessed 26th Sept 2019)

Food safety risk assessment overview

Four steps of risk assessment

A food safety risk assessment consists of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization

Hazard identification

Hazard identification is the recognition of the agent that is likely to be present in food and is associated with negative health effects. The agent can be microbiological, chemical or physical. Hazard identification is an essential first step. If no hazard can be identified, then no risk is associated with the commodity. For the hazard identification, the assessor must establish if there is enough evidence to consider that a substance is able to cause an adverse health effect.

Hazard characterization

A hazard characterization is the determination of the adverse health effects associated with a hazard. For a hazard characterization, the following should be taken into consideration.

- The pathogen or substance itself: intrinsic characteristics, virulence and pathogenicity, type of disease caused, host specificity, invasiveness and ports of entry, secondary spread, strain variability, antimicrobial resistance, etc.
- The host: age, general health status, immune status, underlying health conditions, genetic background, use of medications, pregnancy, nutritional status, body weight, demographic, social and behavioral traits.
- Disease process: clinical forms of the disease, duration of illness, severity of the disease, physiopathology, epidemiological patterns, secondary transmission, quality of life.
- Influence of the matrix in which the hazard is contained: protection of the hazard against physiological barriers, induction of stress response, effects of transport of the pathogen through the gastro-intestinal tract.
- Dose-response relationships: organism type and strain, route of exposure, level of exposure (the dose), adverse effect to be considered (the response), characteristics of the exposed population, duration or multiplicity of exposure.

Exposure assessment

In an exposure assessment the risk assessor estimates how likely it is that a consumer, or a group of consumers, is exposed to the hazard and how high the level of exposure is. The likelihood of exposure is influenced by several factors including:

- The prevalence of the hazard: with increasing prevalence consumers are more likely to be exposed.
- Dietary habits: the probability of exposure can vary between sub-groups of consumers due to different dietary habits. Consumption data from the population for which the risk assessment is carried out are an important piece of information for an exposure assessment.
- Production, handling and preparation processes: certain processes can increase or decrease the occurrence of the hazard in the food commodity and therefore influence the probability of exposure of the consumer.

Risk characterization

A risk characterization is a collection evidence from the previous steps and an estimation of the likelihood of the adverse health effects. The overall risk can be expressed qualitatively or quantitatively. In a qualitative

risk characterization, the risk estimation is expressed in words. In a quantitative risk characterization, the risk estimation is expressed numerically. Both qualitative and quantitative risk assessments have advantages and disadvantages, therefore for each risk assessment it should be decided which of the two options is most suitable.

Hazard prioritization

It is not possible to consider all possible hazards for a specific commodity in a single risk assessment. Therefore, a risk assessment is sometimes preceded by a hazard prioritization. A hazard prioritization is a structured process through which different hazards are scored based on clearly defined criteria. The sums of all scores can subsequently be ranked to determine the order of priority of the hazards.

Emerging risks

A particular challenge for risk assessment is so-called emerging or re-emerging risks. Emerging risks are new or future hazards that may occur in the food chain and cause potential health problems. Re-emerging risks are hazards that are already known, but for which suddenly new information becomes available. For example, this could be the case when a food safety hazard that is known to occur in meat is suddenly also detected in plant products. One can identify such emerging or re-emerging risks through a regular review of scientific literature, through existing monitoring or surveillance programs or through regular exchange with experts, for example.

Variability and uncertainty

A risk assessment requires a large volume of data, which inheritably has variability and uncertainty associated with it. Variability refers to the natural heterogeneity that exists for a certain parameter. For example, the average consumption of poultry meat per person per year in a country may be 7 kg, but of course within the country there will be people both eating more and less than 7 kg of poultry meat per year. Uncertainty refers to lack of data, incomplete data or incorrect data. For example, there may be estimates of the percentage of the population that buys its meat from informal markets, but these estimates are based on limited surveys done within a single city.

Human resources needed for food safety risk assessment

To perform a risk assessment, a multidisciplinary approach is required. For example, an epidemiologist, a public health expert, a laboratory expert and a food technologist may all be consulted for a risk assessment. Not all people need to be part of the official risk assessment team, some will be consulted as external experts.

Risk assessments can be carried out by a variety of institutions, including government agencies, universities, private companies, and others.

Linking risk assessment to risk management

Based on the results of the risk characterization, the risk manager makes a decision about the need for control measures for a specific hazard. Various surveillance and inspection systems may generate new data about the impact of these measures. These new data can later be used again for a new risk assessment or for an update of the first risk assessment.

Resources

E-learning module 4.2.

- Van der Fels-Klerx HJ, Van Asselt ED, Raley M, Poulsen M, Korsgaard H, Bredsdorff L, Nauta M, Flari V, d'Agostino M, Coles D, Frewer L, 2015. Critical review of methodology and application of risk ranking for prioritization of food and feed related issues, on the basis of the size of anticipated health impact. EFSA supporting publication 2015:EN-710, 106 pp. Available through <http://www.efsa.europa.eu/en/supporting/pub/en-710> (accessed 26 September 2019)
- Lammerding A and Fazil A, 2000. Hazard identification and exposure assessment for microbial food safety risk assessment. *International Journal of Food Microbiology*, 58, 147-157
- FAO/WHO, 2003. Hazard characterization for pathogens in food and water. Microbiological Risk Assessment Series Nr 3. Available through <https://www.who.int/foodsafety/publications/risk-assessment-series/en/> (accessed 26 September 2019)

Food safety risk assessment case studies

Case study one: Exposure to captan and tolylfluanid

This case study is an acute dietary exposure assessment for captan and tolylfluanid in consumers in selected European countries. The assessment was conducted to assess the level of daily exposure that an average consumer in several different European countries has to captan and tolylfluanid through the consumption of various food commodities.

This exposure assessment relied on three important data sources:

- Data about food consumption
- Data about the frequency of occurrence and level of contamination of the food commodities with the hazards
- Data about the influence of any processing steps on the level of contamination of the food commodities

Data about food consumption

In each of the countries considered in this risk assessment, food consumption data were collected in a slightly different manner. For the purpose of comparison between countries, the data from the different countries were harmonized to a standard age group and standard food commodities.

Data on pesticide residues

The data on pesticide residues were obtained from the national pesticide residue monitoring programs. An important hurdle to overcome was that the countries only reported the actual level of contamination when a certain threshold level was exceeded. This threshold value was not standardized between countries. If a country reported that contamination was below the threshold value, the true level of contamination could be anywhere between 0 and the threshold.

Data about the influence of processing

Analyses for pesticide residues are often conducted for raw agricultural commodities, while the consumer eats processed products. Processing affects the concentration of pesticides. In most cases the concentration reduces, but in some cases it can also lead to an increased concentration. Data on the impact of processing on pesticide concentrations were taken from a previously published report.

Exposure assessment

Combining all these data, this quantitative risk assessment calculated the acute dietary exposure of a standard consumer in each of the countries. Subsequently, the risk assessment also determined which food commodities contributed most to the dietary exposure.

Conclusion

This risk assessment was primarily performed to test the function of a new joint database on consumption data. As it was a research project, no risk management followed this assessment.

Case study 2: Cholera from shrimp

This case study is a risk assessment of choleraenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade.

The scope of this risk assessment was to assess risk of acquiring cholera as a result of the consumption of imported warm-water shrimp. The risk associated with the consumption of domestically produced shrimp was excluded. The risk assessment included all four steps of a complete food safety risk assessment:

- Hazard identification
- Exposure assessment
- Hazard characterization
- Risk characterization

Hazard identification

The only causative agents of cholera are cholerae *Vibrio cholerae* O1 and O139. The primary source of cholerae *V. cholerae* is faeces of a infected person. The agent can survive for a long time in fresh water and estuarine environments. There are very few records of isolation of cholerae *V. cholerae* from shrimp.

Exposure assessment

A risk pathway was developed to outline the harvest-to-consumption pathway, which helped to identify points along the pathway that influence the prevalence and level of the hazard in the commodity. There were very little data available to quantify the presence of the hazard throughout the harvest-to-consumption pathway, but it was recognized that various processing steps have a significant impact on reducing the prevalence and quantity of cholerae *V. cholerae* in the final product. Consumption data were not available but were estimated based on import statistics and population statistics.

Hazard characterization

The hazard characterization described the impact of the hazard on human health. Based on the results of a volunteer feeding trial a dose-response curve could be established.

Risk characterization

The risk characterization included both qualitative and quantitative estimates. The qualitative risk characterization concluded that the opportunity was small for cholerae *V. cholerae* to survive processing and therefore be present in shrimp that is finally consumed. Using a first quantitative approach, the risk characterization concluded that depending on the importing country that is considered between 1-2 human cases per decade and 1 human case per 25 years could be expected. A second quantitative approach concluded that 0.009-0.9 human cases per year could be expected as a result of consumption of contaminated imported shrimp, and that the risk of developing disease was 2-9 illnesses per 1000 million (10⁹) servings of warm-water shrimp.

Conclusions

The risk assessment concluded that the qualitative and quantitative approaches were both valid and provided consistent results. A quantitative risk assessment however relies heavily on the availability of numerical data as a basis for the quantitative models. The results of the risk assessment showed that the risk of acquiring cholera through the consumption of imported warm-water shrimps is very small. No risk management measures were implemented in response to this assessment.

Case study 3: Roquefort cheese

This case study describes the process of risk assessment and risk management to decide on the permission to import Roquefort cheese, a semi-hard blue veined French cheese made from unpasteurized ewe's milk. First, the relevant hazards for this type cheese were identified via the hazard identification process. The risk characterization ultimately showed that the overall risk to consumers from consuming Roquefort cheese was low, but that certain sub-groups with reduced immunity could face a higher risk.

Subsequently, several risk management options were identified. These options would have led to specific requirements for the exporting countries, while other options would have been implemented in New Zealand. These options were compared against each other and stakeholders were consulted. The ultimate risk management decision was to implement several measures: 1) certification that Roquefort is produced according to the EU requirements covering microbiological, food safety and process hygiene criteria, 2) monitoring in New Zealand that imported Roquefort meets the criteria for *E. coli* prescribed in the Food Code and 3) providing information to vulnerable consumers about the risks of consuming Roquefort.

Resources

E-learning module 4.3

Boon PE, Svensson K, Moussavian S, Van der Voet H, Petersen A, Ruprich J, Debegnach F, De Boer WJ, Van Donkersgoed G, Brera C, Van Klaveren JD, Busk L, 2009. Food and Chemical Toxicology 47, 2890-2898

FAO/WHO, 2005. Risk assessment of cholerae *Vibrio cholerae* O1 and O139 in warm-water shrimps in international trade. Microbiological risk assessment series Nr 9. Available through <https://www.who.int/foodsafety/publications/mra9/en/> (accessed 26 September 2019)

New Zealand Food Safety Authority, 2010. New Zealand's Food Safety Risk Management Framework. Available through <https://www.mpi.govt.nz/food-safety/food-safety-and-suitability-research/food-risk-assessment/overview/> (accessed 22 November 2019)

Sourcing information for food safety risk assessment

Guidelines and resources available online

Codex, FAO and WHO have developed a number of important resources for food safety risk assessment. These are listed in the resources section below. The Australian government and The European Food Safety Authority have also developed useful resources. Relevant information for ASEAN Member States can also be found on the website of the ARAC, the ASEAN risk assessment centre for food safety.

Data sources

For any risk assessment, finding the right data is crucial. Ideally, a risk assessment is informed by complete data, including peer-reviewed studies, official data on occurrence of food safety hazards and trade and production data. However, in many cases, data are limited. In these cases, expert opinion and less formal data sources are also valuable. Potential data sources include:

- Peer-reviewed studies in scientific journals
- Recent textbooks
- Official government websites
- Expert consultation
- Other sources such as trade statistics, FAOSTAT, RASFF (EU database), ComBase and Food Spoilage and Safety Predictor (FSSP)

Sourcing peer-reviewed studies

Peer-reviewed studies provide strong evidence for risk assessment. However, relevant studies are not always available, particularly for rare hazards, and literature must be recent to ensure knowledge has not become outdated.

Peer-reviewed studies relevant to an assessment can be found by using a bibliographic database—e.g. Web of Science (which can be expensive to access) or Google Scholar (for which access is free, though note that studies returned using this database are not necessarily peer-reviewed).

Some peer-reviewed studies are open access, which means they are freely available to download. In other cases, peer-reviewed studies may need to be purchased or accessed through a licence. Government departments can buy subscriptions to access peer-reviewed studies.

When considering the journals used to provide input into an assessment, there are several indicators of quality. Considerations include:

- the relevance of the journal to the field;
- the journal impact factor, relative to other journals in that field (in some fields, journals are ranked); and
- the general tone and history of the publication.

Recent studies are best, as they should have been designed with relatively up-to-date knowledge of the field of study in mind, and should consider and discuss previous studies relevant to their work.

The evidence hierarchy

Some sources of information provide better evidence than others.

In regards to food safety risk assessment, peer-reviewed literature is considered the best source of evidence, where available. Recently published textbooks and websites from reputable international organisations (such as the WHO and FAO) are considered the next best source of information. Government websites

and expert opinion can make a valuable contribution to food safety risk assessment, but are considered the lowest tier of evidence.

Other sources of evidence may include trade or climate records, or media reports. These sources generally belong in the lowest tier of evidence, though some (e.g. climate records) may justify consideration as higher up the hierarchy.

Evaluating evidence

Information must be evaluated to decide if it is credible for inclusion in an IRA. Alongside consideration of the evidence hierarchy, here are some other factors to consider.

- Peer review: as per the evidence hierarchy, information is considered more credible if it has undergone the peer-review process.
- Quality publications will generally list the author(s) and the organisation they work for: be careful of those that don't. Consider also the credentials of the author, and whether they could be biased.
- If the information has a reference list, or refers to known experts, it is likely to be more credible than information without any references.

No need to reinvent the wheel

Many risk assessments have already been performed and are readily available in the public domain. Reading published risk assessments helps to increase understanding on how to conduct risk assessment. The following organisations publish food safety risk assessments:

- FAO and WHO
- EFSA
- Food Standards Australia and New Zealand
- United States Department of Agriculture
- The Canadian Food Inspection Agency
- The National Institute of Public Health and the Environment of the Netherlands (RIVM)

Resources

- ASEAN risk assessment centre for food safety, ARAC. <http://www.arac-asean.org/>
Codex 2014, *Principles and guidelines for Conduct of microbiological risk assessment (CXG 30-1999)*, last modified in 2014. Available: <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/> (accessed 25th Sept 2019).
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- Codex 2019, *Guidelines for rapid risk analysis following instances of detection of contaminants in food where there no regulatory level (CXG92-2019)* Available: <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/> (accessed 25th Sept 2019).
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- Food Standards Australia and New Zealand. *Publications*. Available: <http://www.foodstandards.gov.au/publications/Pages/default.aspx> (accessed 25th Sept 2019).
- United States Department of Agriculture. Risk assessments. Available: <https://tinyurl.com/y5jcqv33> (accessed 25th Sept 2019).
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