Table 7.1 Summary data used in the derivation of the ARfD, as well as derived and current guidance levels, and Codex maximum level in the Standard for live and raw bivalve molluscs (Codex Stan 292-2008)

	LOAEL (μg/kg bw)	Safety factor	Provisional ARfD	Derived guidance level (mg/kg Shellfish Meat)	Level implemented in some countries in 2004 (mg/kg Shellfish Meat)	Codex maximum level/ kg of mollusc flesh
Azaspiracid	0.4	10 (human data)	0.04 μg/kg 2.4 μg/adult	0.024 (1) 0.0096 (2) 0.0063 (3)	0.16	≤0.16 mg
Brevetoxin	NA	NA	NA	NA	0.8 mg/kg SM as PbTx-2	≤200 mouse units or equivalent
Domoic acid	1,000	10 (human)	100 μg/kg 6 mg/adult	60 mg/kg SM (1) 24 mg/kg SM (2) 16 mg/kg SM(3)	20 mg/kg SM	≤20 mg domoic acid
Okadaic Acid	1	3 (human)	0.7 μg/kg 42 μg/adult	0.2 mg/kg SM (1) 0.08 mg/kg SM (2) 0.05 mg/kg SM (3)	0.16 mg/kg SM	≤0.16 mg of okadaic equivalent
Saxitoxin	2	3 (human)	0.33 μg/kg 21 μg/adult	0.42 mg/kg SM (1) 0.17 mg/kg SM (2) 0.11 mg/kg SM (3)	0.8 mg/kg SM	≤0.8 mg (2 HCL) of saxitoxin equivalent

In the Derived guidance level (mg/kg Shellfish Meat) column, (1), (2) and (3) level were derived based on the assumption of consumption of 100, 250, and 380 g molluscs per one meal, respectively

- As appropriate, make recommendations on the validation of methodology (e.g. such as identifying other international organisations that are working in this area);
- As appropriate, make recommendations on possible changes to the Proposed Draft Standard for Live and [Raw] Molluscs and the section of the Code on Live and [Raw] Bivalve Molluscs arising from the expert advice and other issues arising from the deliberations of the pWG.

The FAO/IOC/WHO expert consultation utilized existing chemical, single exposure based risk assessment approach, which is similar to risk assessments of pesticide residues, and they tried to establish a provisional acute reference dose (ARfD). Table 7.1 shows the outcomes of risk assessments, regulatory levels implemented in some countries in 2004, and established Codex maximum levels of each toxin per kg of mollusc flesh.

With regards to azaspiracid (AZA), the expert consultation established a provisional ARfD of 0.4 μg/kg body weight (bw), based on the Lowest Observed Adverse Effect Level (LOAEL) of 23 μg per person in humans and a bw of 60 kg, using a tenfold safety factor because of the small number of people involved. Insufficient data on the chronic effects of AZA prevented the establishment of a Tolerable Daily Intake (TDI). As shown in Table 7.2, the consumption of 100, 250 or 380 g shellfish meat by adults would result in a derived guidance level of 0.0096 mg/kg shellfish meat (SM) and 0.0063 mg/kg SM respectively.

At the pWG in Canada in 2006, the expert consultation report was reviewed. Given the data available, the existing history of regulatory programs and the level of consumer protection provided by those programs, the pWG agreed that the action level of 0.16 mg/kg implemented in 2001 in Europe, New Zealand and Norway should be maintained (Codex 2006b).

According to the pWG report, the basis of the European action level was based on a risk assessment carried out by the Food Safety Authority of Ireland, which suggested a regulatory limit of 0.12 mg/kg following the first recorded outbreak of food poisoning linked to AZAs in 1995. However, the sensitivity of the mouse bioassay was insufficient to detect the toxin at this level. It was subsequently determined that the mouse bioassay threshold for detecting AZA was 0.16 mg/kg. Consequently, the regulatory limit for this toxin group was set at this level. Finally the WG recommended that the Codex standard (section 1.5) should identify an action level for AZA of 0.16 mg/kg (Codex 2006b).

During the discussion at the 28th session of the CCFFP, a Reevaluation of AZA was requested from FAO/WHO because there was a large difference between the guidance level for AZAs recommended by the Expert Consultation and the limit in the Proposed Draft Standard (Codex 2006a).

With regards to the brevetoxin group, based on a reported incident in humans with a 60-kg body weight who consumed an estimated 100–150 g shellfish at 120 μg PbTx-3 equivalents/100 g, an exposure of 2–3 μg PbTx-3 equivalents/kg bw was estimated. However, uncertainty existed in the accuracy of this dose estimate because of a possible underestimation of the toxin levels actually present in shellfish, and because the metabolites were not reliably extracted by the method used for

regulatory monitoring. The WG decided that the data were insufficient to complete the risk assessment. The relevant brevetoxins and their metabolites need to be identified and estimates of their oral potencies are needed before an ARfD can be established (Toyofuku 2006).

At the pWG, the pWG concurred with the WG's decision that there was currently insufficient evidence to complete the risk assessment of brevetoxins. However, despite the WG's decision regarding the available evidence for a risk assessment, the WG recognized the body of knowledge resulting from the existing history of regulatory programs (e.g. in the US, Mexico and New Zealand) and the absence of human illness in commercially harvested shellfish, where these programs are implemented. Finally the WG recommended (Codex 2006b) that the Codex standard identified an action level for the brevetoxins of 20 Mouse Units or equivalent (conditional on the equivalence information becoming available). During the discussion at 28th CCFFP, a request was made to FAO/WHO to re-evaluate brevetoxins because there was no brevetoxin limit recommended by the WG (Codex 2006a).

Regarding domoic acid (DA), the results of the first outbreak of amnesic shellfish poisoning that occurred in 1987 in Canada provide the best basis for developing an acute reference dose (tolerable single day intake, acute TDI). During this outbreak, a dose- related increase in the severity of signs and symptoms was observed in patients consuming between 1 mg/kg bw (the LOAEL) and 5 mg/kg bw. Studies in rodents and cynomolgous monkeys have generally supported these findings. To cover the full spectrum of human susceptibility, and account for the fact that 1 mg/kg bw was a LOAEL, this value was divided by a safety factor of 10, to derive a provisional ARfD of 0.1 mg/kg bw. This value seems reasonable, as one person who consumed 0.33 mg/kg bw did not become ill. The provisional ARfD of 0.1 mg/kg bw provided the basis for the establishment of the maximum residue limit (MRL) for DA by Canadian authorities, which on the basis of an intake of 250 g shellfish and a body weight of 60 kg, was 24, rounded down to 20 μg DA/g shellfish. If instead of 250 g shellfish, a value of 300 g shellfish was used, the MRL would be exactly 20 μg DA/g shellfish.

Very few animal studies have been conducted on the subchronic and chronic toxicity of DA, and these limited data suggest that cumulative effects of low doses of DA are unlikely. In this regard, studies based on subacute mouse studies revealed no differences in behavioral toxicity scores upon re-exposure to DA compared to a single dose (i.e., behavioral equivalent of kindling). The available data indicate that chronic sequelae, such as epilepsy and memory deficit, were observed only in those patients who had suffered severe acute neurological effects (examined up to 3.5 years post-event) after they had ingested a single high dose of DA. It is therefore unlikely that people who habitually consume small amounts of DA (exposures less than 0.1 mg DA/kg bw) would experience any chronic effects. Thus, this ARfD also may be considered a provisional chronic TDI. As shown in Table 7.1, the consumption of 100, 250 or 380 g shellfish meat by adults would lead to a derived guidance level of 60, 24 or 16 mg DA/kg shellfish meat, respectively (Toyofuku 2006). The pWG noted that the action levels derived in the report support the current

level identified in the draft Codex Standard (20 mg/kg), and the WG agreed that the level of 20 mg/kg is appropriate (Codex 2006b). No further discussion was noted in the report of the 28th CCFFP (Codex 2006a).

With regards to the okadaic acid (OA) group of toxins, OA and dinophysistoxins (DTXs) possess tumour-promoting activity; OA also possesses genotoxic and immunotoxic activity. These effects raise questions as to the human health risks of (sub)-chronic exposure to low levels of these compounds. A pressing problem was the lack of sufficient quantities of purified toxins to perform sub-chronic animal toxicity studies. The pWG determined that no TDI could be established because of insufficient data on the chronic effects of OA, and established a provisional ARfD of 0.33 μg OA equ/kg bw, based on the LOAEL of 1.0 μg OA/kg bw. A safety factor of 3 was chosen because of documented human cases involving more than 40 people and because DSP symptoms are readily reversible. The consumption of 100, 250 or 380 g shellfish meat by adults would lead to a derived guidance level of 0.2, 0.08 or 0.05 mg OA equivalent/kg shellfish meat, respectively (Toyofuku 2006). The pWG discussed the action levels used in various countries and the level of consumer protection which they have provided to date. The current standard, its practical application and demonstrated results indicate that the level of 0.16 mg/kg provides adequate protection for consumers (Codex 2006b).

With regards to the saxitoxin group (STX) of toxins, the pWG established a provisional ARfD of 0.7 μg STX equivalents/kg bw, based on an LOAEL of 2 μg STX equ/kg bw. A safety factor of 3 was chosen because documented human cases included a wide spectrum of people (occupation, age, and sex) and mild illness is readily reversible. The Expert Consultation determined no TDI could be established because of insufficient data on the chronic effects of STX. As shown in Table 7.1, the consumption of 100, 250 or 380 g shellfish meat by adults would lead to a derived guidance level of 0.42, 0.17 or 0.11 mg STX equ/kg, respectively (Toyofuku 2006). The pWG considered that the long-standing enforced tolerance limit of 0.8 mg/kg STX.2HCl equiv., established for consumer protection, was considered to be successful (over nearly 50 years), with no human illnesses from commercially harvested product (Codex 2006b).

The CCFFP during the 28th session agreed to advance the Proposed Draft Standard for Live and Raw Bivalve Molluscs to Step 5 for adoption by the 30th Session of the Commission. The sections on hygiene (including biotoxin level) would be sent to the CCFH for endorsement. At the 38th session of the CCFH, the CCFH was of the opinion that these provisions on marine biotoxins should be considered under the section on contaminants in the draft Standard and that consideration of these issues were outside the competence of the CCFH. The CCFH was of the view that the matter of marine biotoxins should be sent to the Codex Committee on Contaminants in Food (CCCF) for their advice and endorsement, if necessary (Codex 2007a). At the 2nd session of the CCCF in 2008, the representative of WHO noted that the levels proposed by the CCFFP were different to those proposed by the expert consultation and expressed concern that the current proposed levels might exceed those of the ARfD for several marine biotoxins at normal consumption levels. The WHO representative also expressed

the view that further review of the proposed levels would be necessary, but that data may currently be limited. Some delegations were of the view that it would be difficult to endorse the levels without some understanding on how the levels had been reached in the CCFFP and supported the concern of the WHO with regard to potentially high exposure to biotoxins. Because the Expert Consultation had been unable to complete a risk assessment on brevetoxins due to the lack of sufficient data, one delegate requested clarification on how the CCFFP had set a level for this biotoxin. In reply, it was clarified that the CCFFP had agreed to the level of 200 mouse units/kg in view of the knowledge resulting from the existing history of regulatory programmes and the absence of human illness in commercially harvested shellfish where these programmes were implemented. After some discussion the CCCF agreed to provisionally endorse the proposed levels, with the recommendation that the levels would require complete review in the coming few years with a view to revising these levels where necessary, when more data became available (Codex 2008a).

Salmonella *in Bivalve Molluscs*

The CCFFP, at the 29th session, discussed the sampling plans for *Salmonella* in the draft Standard for Live and Raw Bivalve Molluscs. It was pointed out that the criteria proposed for *Salmonella* was not based on a risk assessment as required in the *Principles for the Establishment and Application on Microbiological Criteria for Foods* and general requirements for Codex food safety standards. As a result, it was proposed either to ask for a specific risk assessment in order to justify the use of these criteria, or transfer to the Code of Practice. It was also pointed out that when testing for *Salmonella* in the areas where the occurrence was known to be high, the number of samples should be much higher (50 or 60) but that for routine testing five samples could be used. A proposal was made to prepare a table with the different sampling levels that could be used according to the prevalence of *Salmonella*. The CCFFP agreed that the number of samples would depend on the incidence of *Salmonella* but recognized that it was not possible to develop such a table at this stage. After some further discussion, the CCFFP agreed to retain the text referring to five samples, as mentioned above, and to ask for scientific advice from FAO and WHO on the following question:

> In the context of harvesting area monitoring for faecal contamination and lot contamination, estimate the risk mitigation for *Salmonella* in bivalve molluscs when different sampling plans and microbiological criteria are applied (Codex 2008b).

At the 30th session of the CCFFP, the Representative of FAO informed the CCFFP that the estimation of risk mitigation required risk assessment and, since there were currently no national or international risk assessments available for *Salmonella* in bivalve molluscs, the FAO/WHO had requested Codex members to provide data on sampling plans and *Salmonella* detection from their shellfish

harvesting area monitoring programmes and epidemiological data linking outbreaks of *Salmonella* to bivalve molluscs. The data showed that most countries do not monitor shellfish harvesting areas for *Salmonella*, but rely on monitoring faecal contamination using indicator bacteria in shellfish meat or surrounding water.

Epidemiological data showed that bivalves have rarely been involved in outbreaks of salmonellosis, suggesting that there was no particular public health problem associated with *Salmonella* in bivalve molluscs. The FAO Representative indicated that most studies on *Salmonella* in bivalve harvesting areas have used single samples (n = 1) and there were very limited data using multiple samples and, therefore, data are inadequate for the evaluation of sampling plans. The CCFFP was further informed that the International Commission on Microbiological Specifications for Foods (ICMSF) did not recommend microbiological criteria for *Salmonella* in bivalve molluscs and that the Codex Guidelines on Sampling (CAC/GL 50-2004) recommends sampling plan classification according to the nature of the problem. Relating epidemiological data to these guidelines would suggest continuation of currently recommended (n = 5; c = 0, m = non dateable in 25 g) sampling plan, when there is a need for testing for *Salmonella*. In this two class sampling plan, n means the number of sampling units to be drawn independently and randomly from the lot, c means the maximum allowable number of sample units that yield unsatisfactory test results, and m separates good quality from non-acceptable or defective quality. Therefore, the current two-class sampling plan in the *Standard for Live and Raw Bivalve Molluscs* need not be changed.

Then a question was raised whether there was a need for criteria for *Salmonella* in the Standard, especially taking into account the guidance for the development of criteria given in the *Principles for the Establishment and Application of Microbiological Criteria for Food* (CAC/GL 21-1997) which stated that criteria should be developed only when there was a need for such criteria and that such criteria are meaningful for consumer protection.

The CCFFP agreed to request that FAO/WHO undertake a risk assessment to determine whether there was a significant public health risk of exposure to *Salmonella* associated with consumption of bivalves. FAO/WHO were also asked to evaluate whether criteria for *Salmonella* are meaningful in ensuring adequate consumer health protection. FAO/WHO agreed to retain the current criteria for *Salmonella* and the associated sampling plan as their recommended advice until the result of this assessment became available (Codex 2009).

At the 31st session of the CCFFP, the FAO representative presented the work done by FAO/WHO through an electronic Expert Group. The latter noted that the current Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) recommends control of harvesting areas by monitoring faecal coliforms and *E. coli* and does not recommend pathogen testing for routine monitoring of harvesting waters. Available data on the prevalence of *Salmonella* from bivalves indicate differences in levels of prevalence in areas which are controlled by monitoring faecal indicator bacteria (1 % prevalence in areas where bivalves go directly to

Table 7.2 The numbe
contamination in a lot

Acceptable proportion contaminated samp
≤1 in 10
≤1 in 100
≤1in 1,000
≤1 in 10,000
≤1 in one million

Adapted from (Codex

market and 2–15 %
bivalves go for a pu
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few locations where
were not commonly
of *Salmonella* in co
serving size and the
ability to make any

Epidemiological
live bivalve mollusc
in some countries, t
group on the perfor
at a 1 % level of pr
monitoring) with 95
samples would be ab
of a lower number
molluscs from these
unlikely to reach ma
present sampling pla
shows the number o
detect different frequ
(Codex 2011b).

Based on these
current criteria for *S*
concluding that it m
the Standard. It was
the availability of th
provide their advice
Standard for Live an
Group (Codex 2011a

Table 7.2 The number of samples required, for a given level of confidence, that the frequency of contamination in a lot is below the specified level

	Confidence required that the result is correct				
	50 %	90 %	95 %	99.9 %	99.9 %
Acceptable proportion of contaminated samples	*Number of samples that must be tested:*				
≤1 in 10	7	22	29	44	66
≤1 in 100	69	229	299	459	688
≤1in 1,000	693	2,301	2,995	4,607	6,906
≤1 in 10,000	6,932	23,025	29,957	46,050	69,080
≤1 in one million	693,148	2,302,594	2,995,750	4,605,202	6,908,723

Adapted from (Codex 2011b)

market and 2–15 %, depending on geographical location and season, in areas where bivalves go for a purification step before marketing). Studies at market level show a *Salmonella* prevalence of <1–3.4 %. Diverse serovars have been observed at a few locations where *Salmonella* in bivalves was investigated. Many of the serovars were not commonly found in human outbreaks. Lack of quantitative data on levels of *Salmonella* in contaminated molluscs, and data on human consumption, such as serving size and the proportion of the population consuming live bivalves, limits the ability to make any realistic exposure assessment.

Epidemiological data indicates that outbreaks of salmonellosis associated with live bivalve molluscs are very rare and, even considering the underreporting factor in some countries, the current model over-estimates the risk. The work of the expert group on the performance of a sampling plan indicates that to detect *Salmonella* at a 1 % level of prevalence (seen in areas controlled by faecal indicator bacterial monitoring) with 95 % confidence level, 299 samples need to be tested. Testing of 60 samples would be able to detect only 45 % of a contaminated batch. Although testing of a lower number of samples may be adequate for areas with higher prevalence, molluscs from these areas would have higher levels of indicator bacteria and are unlikely to reach market without purification with the current practices. Thus, the present sampling plan would have little value in public health protection. Table 7.2 shows the number of samples required, when all samples are negative, to be able to detect different frequencies of contamination and for particular levels of confidence. (Codex 2011b).

Based on these findings, the CCFFP discussed whether or not to retain the current criteria for *Salmonella* in the Standard for Live and Raw Bivalve Molluscs, concluding that it might be necessary to remove the criteria for *Salmonella* from the Standard. It was agreed to discuss this issue further at the next session pending the availability of the final report. The CCFFP also agreed to request the CCFH to provide their advice on whether the criteria for *Salmonella* should be retained in the Standard for Live and Raw Bivalve Molluscs based on the final report of the Expert Group (Codex 2011a, c).

At the 43rd session of the CCFH, the CCFH considered this issue and again discussed whether the criteria for *Salmonella* should be retained in the Standard. Some delegations were of the view that the criteria should be removed from the Standard as it was inconsistent with the *Principles for the Establishment and Application of Microbiological Criteria for Food* (CAC/GL 21-1997) and that the criterion provided little or no added protection for salmonellosis, above that achieved by risk management strategies, such as sanitary surveys and faecal indicator monitoring. Other delegations were of the opinion that the criterion should be retained, as it was widely used in their jurisdiction, especially due to the high consumption of live and raw bivalve molluscs which were not submitted to any treatment to reduce the level of *Salmonella* contamination. The CCFH agreed to a proposal, which provided a level of flexibility to the application of the criterion by indicating that it could be implemented by competent authorities taking into account the epidemiological situation and based on environmental monitoring as well as other surveillance. Noting that this type of provision was more appropriate to a code of practice, the Committee agreed to recommend to the Committee on Fish and Fishery Products (CCFFP) to remove the criterion for *Salmonella* (Section I-6.5) from the Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008) and to include in the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003), Section 7.2.2.2, the following: "When appropriate, taking into account the epidemiological situation as indicated by the results of environmental monitoring and/or other surveillance, the competent authority may decide to implement a criterion for *Salmonella*." (Codex 2011d).

Vibrio parahaemolyticus *in Seafood*

At the 38th session of the CCFH, the CCFH agreed to request FAO and WHO to use the risk assessment on *Vibrio parahaemolyticus* in seafood, which they are developing to provide scientific guidance to the Codex Committee on Fish and Fishery Products, to follow up on the recommendations of the CCFH regarding the hygiene provisions in the Proposed Draft Standard for Live and Raw Bivalve Molluscs. The following risk management question is proposed:

- Estimate the risk reduction from *V. parahaemolyticus* when the total number of *V. parahaemolyticus* or the number of pathogenic *V. parahaemolyticus*, ranges from absence in 25 g to 1,000 cfu or MPN per gram (Codex 2007a).

At the 39th session of the CCFH, FAO and WHO presented the work which considered the impact of three different limits for *V. parahaemolyticus*: 100, 1,000 and 10,000 cfu/g. These limits were considered to be applied when the products were cooled after harvesting, or when the population of *V. parahaemolyticus* had stabilised (i.e., when the temperature becomes too low for further growth but not so low that die-off occurs).

Table 7.3 Reduction
haemolyticus, togethe

Specified target	Redu of pr Aust (sum
100 cfu/g	99
1,000 cfu/g	87
10,000 cfu/g	52

Adapted from (Codex

An estimation of
such levels was deve
New Zealand and Ja
surrogate data from t
that all (100 %) harv
baseline distribution
presented include an
amount of product re
the specified target (C

The impact of thr
10,000 cfu/g was eva
sidered to be applied
population of *V. para*
too low for further g
of the risk reductio
developed, based on
and Japan. The varia
countries highlights t
of *V. parahaemolytic*
that the establishmen
greater impact on pro
100 cfu/g implies reje
product, but would h
percentages in the nur
the limit of 10,000 c
Japanese oysters, res
illnesses are 52 and 9C

As a result, both G
Hygiene to the Contro
Bivalve Molluscs cont
species in seafood.

Table 7.3 Reduction in illness, based on meeting specified target numbers of *V. parahaemolyticus*, together with commensurate rejection of product for raw consumption

	Reduction (%) in the number of predicted illnesses			Product (%) rejected to achieve these reductions in illness		
Specified target	Australia (summer)	New Zealand (summer)	Japan (autumn)	Australia (summer)	New Zealand (summer)	Japan (autumn)
100 cfu/g	99	96	99	67	53	16
1,000 cfu/g	87	66	97	21	10	5
10,000 cfu/g	52	20	90	2	1	1

Adapted from (Codex 2007b)

An estimation of the risk reduction associated with the implementation of such levels was developed based on information from three countries, Australia, New Zealand and Japan. However, where the appropriate data was not available, surrogate data from the US was used. The estimation is based on the assumption that all (100 %) harvested oysters meet a specified target limit compared with the baseline distribution of *V. parahaemolyticus* for each of these countries. The results presented include an estimation of both the reduction in human illness and the amount of product rejection that would occur if all market products were to meet the specified target (Codex 2007b).

The impact of three different limits for *V. parahaemolyticus*: 100, 1,000 and 10,000 cfu/g was evaluated by risk assessment methods. These limits were considered to be applied when the products were cooled after harvesting, when the population of *V. parahaemolyticus* had stabilized i.e. when the temperature became too low for further growth but not so low that die-off occurred. An estimation of the risk reduction associated with the implementation of such levels was developed, based on information from three countries, Australia, New Zealand and Japan. The variation in risk reduction and product rejection for each of the countries highlights the relationship between the specific target and baseline levels of *V. parahaemolyticus* in oysters of a particular country, and emphasizes the fact that the establishment of international limit for *V. parahaemolyticus* may have greater impact on product rejection in some countries. For example, the limit of 100 cfu/g implies rejection of 67 % of Australian oysters for consumption as raw product, but would have much less impact on Japanese oysters, while reduction percentages in the number of predicted illness remain the same. On the other hand, the limit of 10,000 cfu/g implies rejection of only 2 and 1 % of Australian and Japanese oysters, respectively, whilst the reduction in the number of predictive illnesses are 52 and 90 %, respectively.

As a result, both Guidelines on the Application of General Principles of Food Hygiene to the Control of *Vibrio* species in seafood, and Standard for Live and Raw Bivalve Molluscs contained no Microbiological Criteria (MC) on pathogenic *Vibrio* species in seafood.

Discussion and Conclusions

For biotoxins the CCFFP should use scientific methods to make risk management decisions and document the reasons why the CCFFP did not accept recommendations from the expert consultation group. Risk management decision should be based on science and other legitimate factors, if relevant. From the *Salmonella* example, the need for risk assessment was highlighted. Some hygienic provisions in the Standards developed by CCFFP need scientific information for decision making. So CCFFP as a risk manager should ask timely and cogent risk management questions, understand the outcomes of risk assessments together with associated uncertainties, and make risk management decisions in a transparent manner.

The *Vibrio* example might be considered as a good example of utilizing the risk analysis framework. CCFH asked a precise risk management question to FAO/WHO, and FAO/WHO replied to the question in a timely manner. As a result, CCFH made a decision which was not to establish microbiological criteria on pathogenic *Vibrio* spp. in seafood.

From these examples, the following policy lessons were drawn:

- Risk management should be based on the results of risk assessments, and decisions on risk management should be clearly documented.
- Risk assessment needs data, resources, expertise, time, etc. Sometimes large data gaps prevent risk assessments; however, even in those cases, risk managers need to make a decision. Therefore, continuous interaction between risk assessment and risk management is needed from the beginning to the end of the risk analysis process, in order to better use risk assessments in the decision making process.
- The risk analysis process should be well planned, coordinated, transparent, and documented.
- In converting the outcomes of risk assessments into mitigations, clear documentation of the process and the reasons for selecting an option are needed.
- Risk managers should be encouraged to understand risk assessment.
- The biggest concern is that risk managers use a hazard based risk management option because of the history of successful implementation of such an option. However, this does not guarantee future successes, because of possible lower sensitivities in previous surveillance systems and/or underreporting factors.
- As indicated in the Criteria for *Salmonella* in bivalve molluscs, some hazard based/microbiological criteria might not be meaningful depending on the prevalence of *Salmonella*. Establishing and implementing MC is a risk management tool; however, such MC should be based on sound science and the MC must protect public health of the consumers.

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