Food and Agriculture Organization of the United Nations

Cefas

VIRTUAL REGIONAL WORKSHOP ON BIVALVE MOLLUSCS SANITATION

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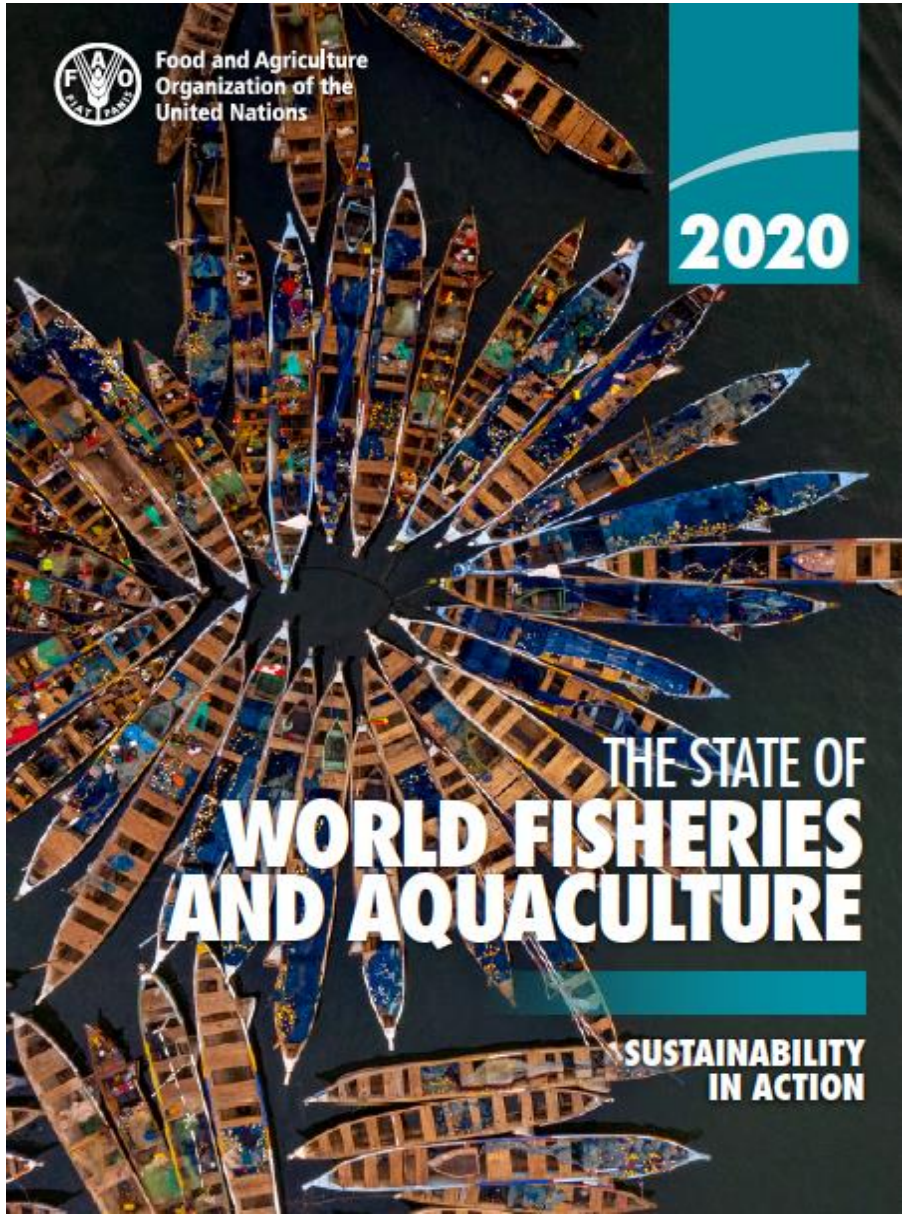
Global bivalve production



Global bivalve production by aquaculture in 2018 – 17.7 million tonnes valued at $34.6 billion.

Filter feeding organisms – non-fed aquaculture
Utilises environmental wastes

MAJOR GLOBAL AND REGIONAL AQUACULTURE PRODUCERS WITH RELATIVELY HIGH PERCENTAGE OF BIVALVES IN TOTAL AQUACULTURE PRODUCTION OF AQUATIC ANIMALS

	Total production	Bivalves production	Share of bivalves
	(thousand tonnes, live weight)		*(percentage)*
China	47 559.1	13 358.3	28.1
Chile	1 266.1	376.9	29.8
Japan	642.9	350.4	54.5
Republic of Korea	568.4	391.1	68.8
United States of America	468.2	181.1	38.7
Spain	347.8	287.0	82.5
Taiwan Province of China	283.2	75.8	26.8
Canada	191.3	43.2	22.6
France	185.2	144.8	78.2
Italy	143.3	93.2	65.0
New Zealand	104.5	88.2	84.3

SOURCE: FAO.

Global bivalve trade – 2019 (Source: FAO Globefish)

Bivalve group	Volume in international trade in 2019 (tonnes)	Marjor producers and importers
Mussels	370,000	Chile major producer – exported 76,000 tonnes EU major importer – 216,000 tonnes
Oysters	70,500	France major exporting country
Clams	291,000	China major exporter, Korea and Japan main buyers
Scallops	170,000	China major importer and exporter

Global bivalve trade in 2018 valued at US$ 4.26 billion and fresh, live chilled form accounted for US$ 1.44 billion

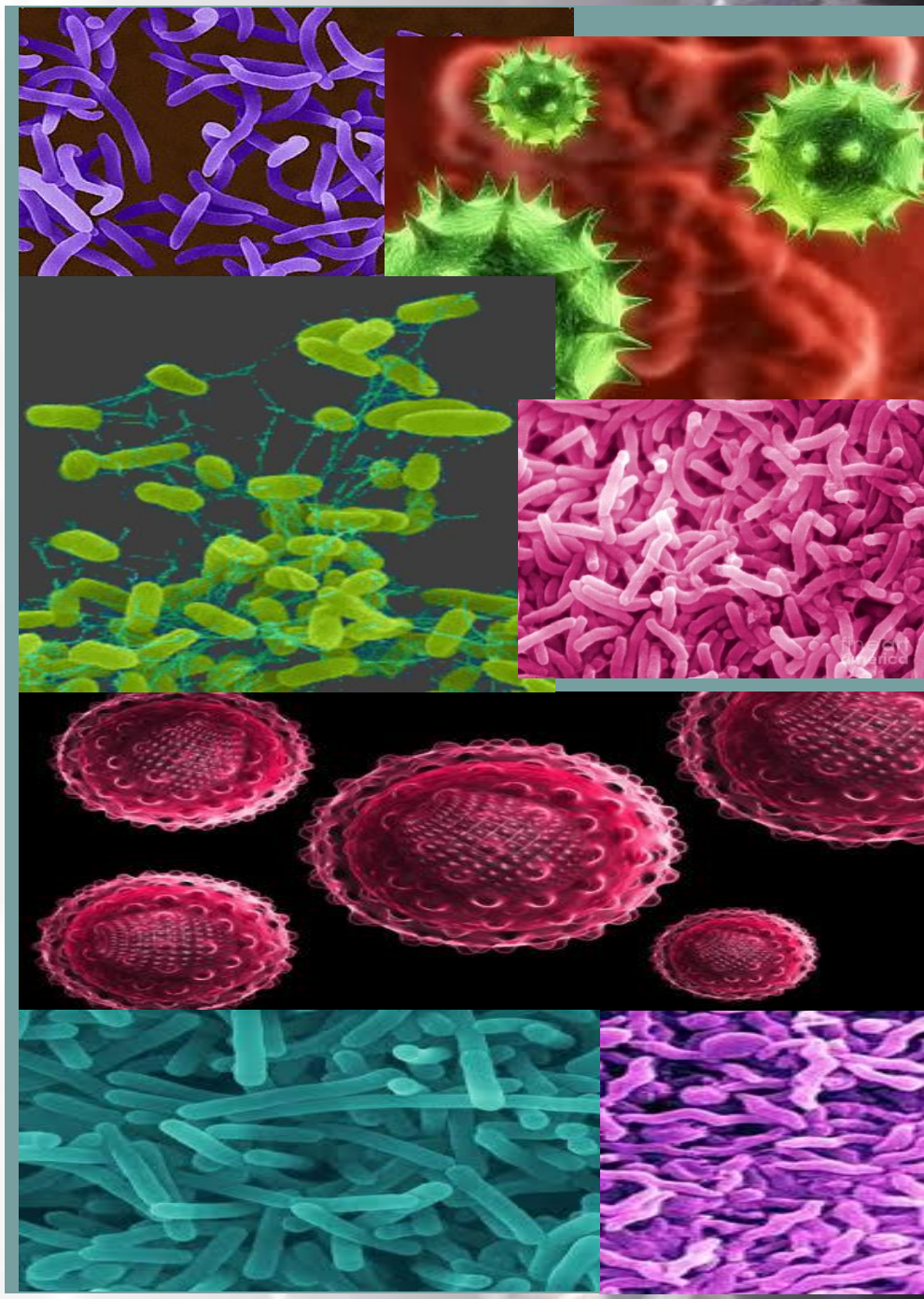
Importance for public health

Pathogens and biotoxins associated with raw shellfish consumption

- ***Frequent and/or severe illness***: Norovirus, *Vibrio parahemolyticus* , Hepatitis A*, V. vulnificus, PSP, DSP, ASP, NSP*

- ***Infrequent illness:***
- *V. cholerae, Salmonella, Campylobactor, Listeria*

Norovirus is leading cause of foodborne illness in US (Canada, others)



Relevant Codex Standards and guidelines

- **Codex Code of Practice for Fish and Fishery Products – Section 7**
- **Standard for live and raw bivalve molluscs** (Codex Stan 292 – 2008 Rev 2015).
- Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* Species in Seafood (CAC/GL 73-2010) - **Annex on control measures for *Vibrio parahaemolyticus* and *V. vulnificus* in bivalve molluscs**
- Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CAC/GL 79-2012) - **Annex on Control of Hepatitis A Virus (HAV) and Norovirus (NOV) in bivalve molluscs.**

Standard for live and raw bivalve molluscs (Codex Stan 292 – 2008).

- I-6. HYGIENE
- I-6.1 It is recommended that the products covered by provisions of this standard be prepared and handled in accordance with the appropriate sections of the **General Principles of Food Hygiene (CAC/RCP 1 – 1969)**, the **Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)** and other relevant Codex Codes of Hygienic Practice and Codes of Practice.

- I-6.2 The products should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CAC/GL 21-1997).

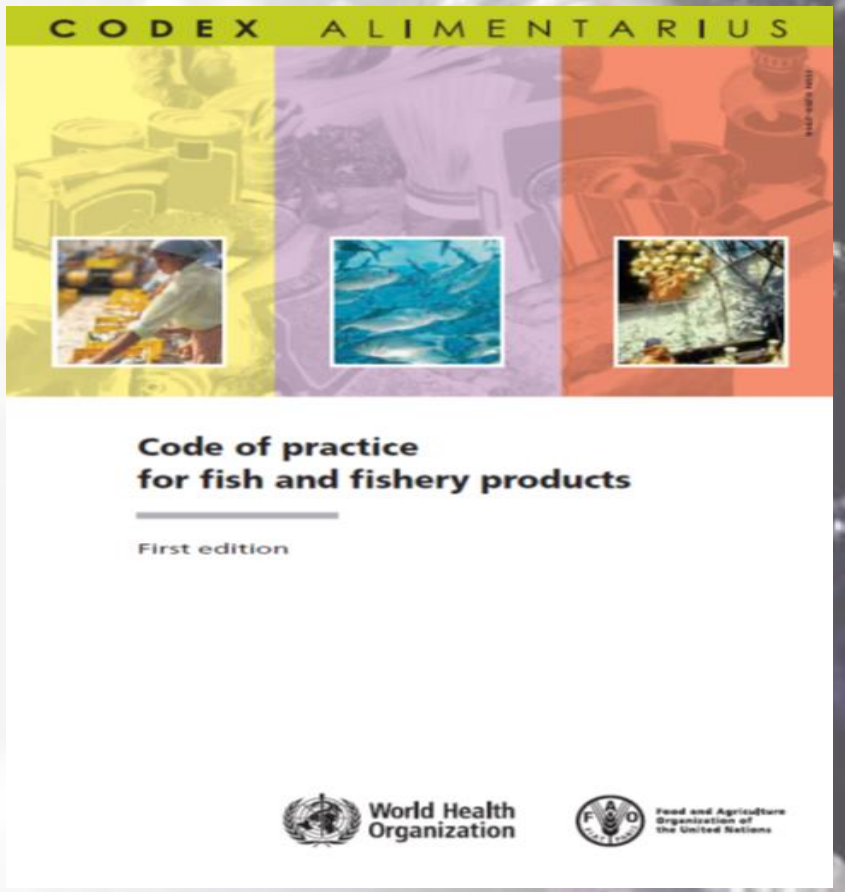
Microorganism = *Escherichia coli* n=5 c=1 m=230 M=700 3 Class Plan

where ‘n’= the number of sample units, ‘c’= the number of sample units that may exceed the limit ‘m’, and ‘M ’is the limit which no sample unit may exceed.

Codex Code of Practice for Fish and Fishery Products

- Section 7 – Processing of Live and Raw Bivalve Molluscs

- Very general and broad guidance; lacks details
- Insuffecient for countries to start a new programme on their own (not targeted at export market)



Basis for the work towards developing Technical Guidelines

- Recommendations of the 2nd International Workshop on Molluscan Shellfish Sanitation, requested FAO/WHO to develop “scientific and technical guidance on the application of shellfish sanitation systems within the framework of Section 7 of the Codex Code of Practice for Fish and Fishery Products”.

- Endorsement of work by the Codex Committee on Fish and Fisheries Products (CCFFP) and the FAO Committee on Fisheries sub-committee on Fish Trade

- Issued a call for data through Codex contact points

- Data received and data from other sources made available for a meeting of Core Group of experts held in Rome, November 26-28, 2014.

Core group of Experts

- Developed the framework and outlines of the guidance document
- Provided oversight and advice throughout the process of drafting the document

Stakeholder consultation at ICMSS-2015

- The scope and contents of the Guidelines were discussed with a group of experts participating in ICMSS 2015 through a Round Table Session.
- Feedback from consultation used for further development of Guideline
- Field testing in some countries in Southern Africa through project funded by Africa Solidarity Trust Fund Project.

Food and Agriculture Organization of the United Nations

World Health Organization

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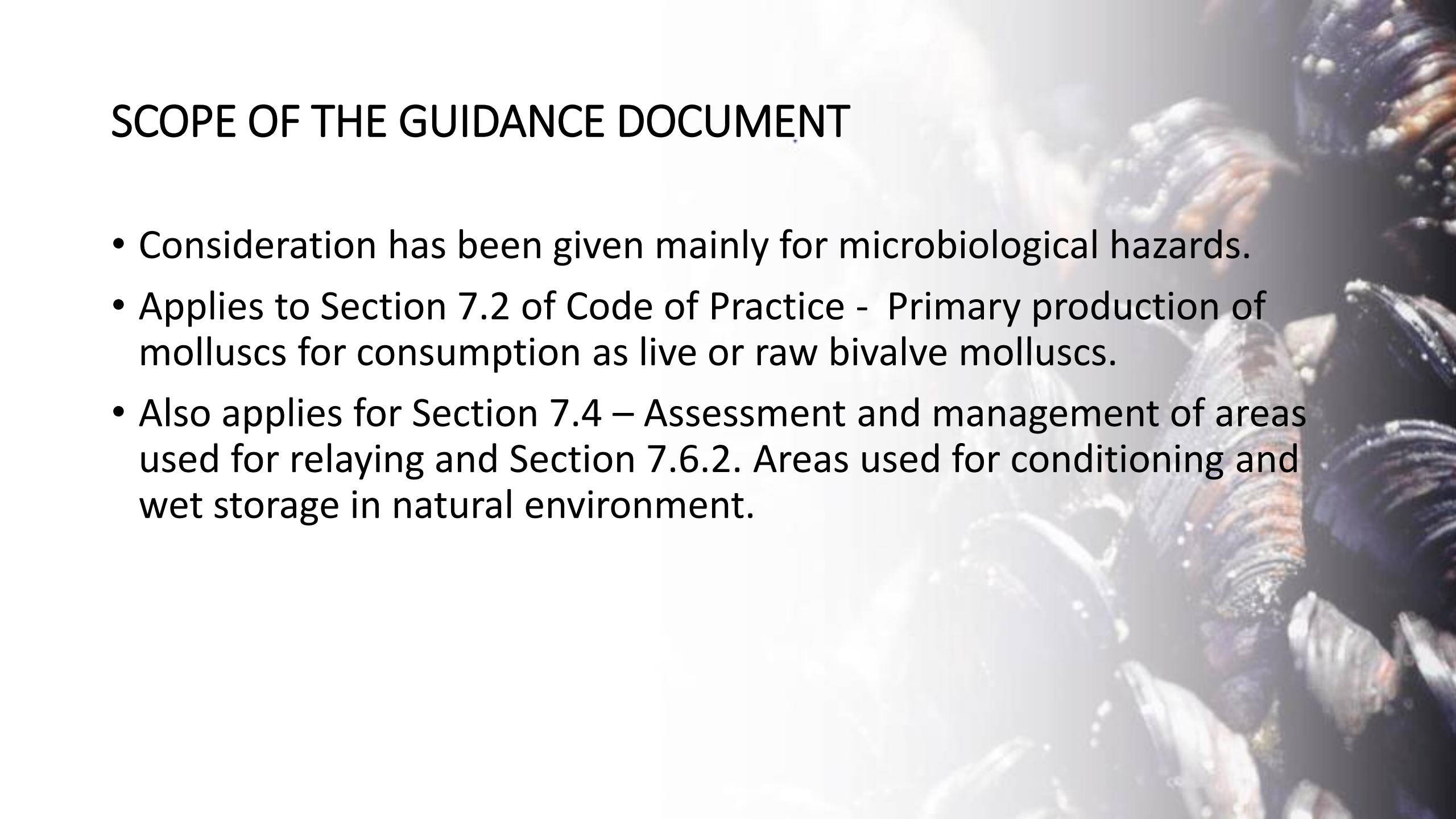
FOOD SAFETY AND QUALITY SERIES

ISSN 2415-1173

TECHNICAL GUIDANCE FOR THE DEVELOPMENT OF THE GROWING AREA ASPECTS OF BIVALVE MOLLUSC SANITATION PROGRAMMES

SCOPE OF THE GUIDANCE DOCUMENT

- Consideration has been given mainly for microbiological hazards.
- Applies to Section 7.2 of Code of Practice - Primary production of molluscs for consumption as live or raw bivalve molluscs.
- Also applies for Section 7.4 – Assessment and management of areas used for relaying and Section 7.6.2. Areas used for conditioning and wet storage in natural environment.



FAO
FISHERIES AND
AQUACULTURE
TECHNICAL
PAPER

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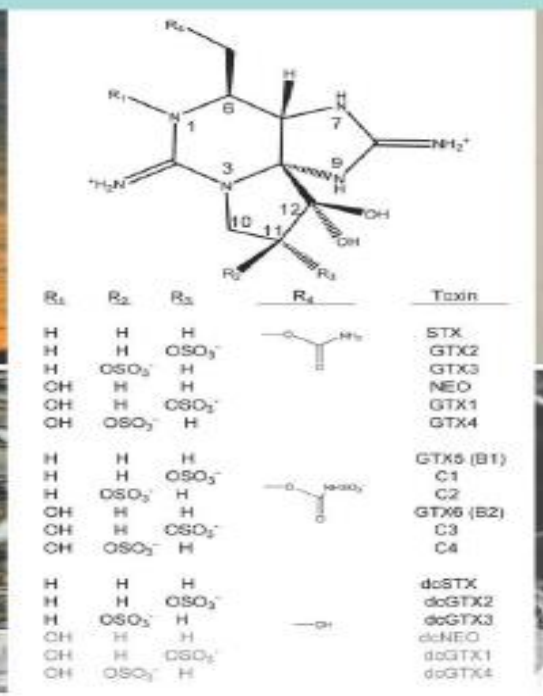
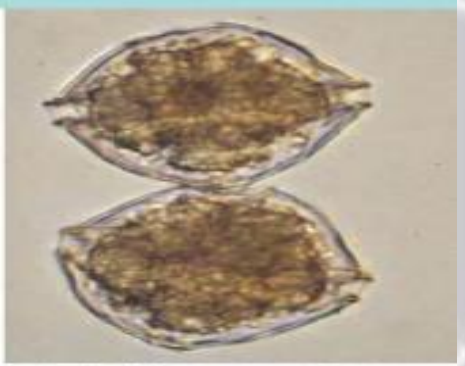
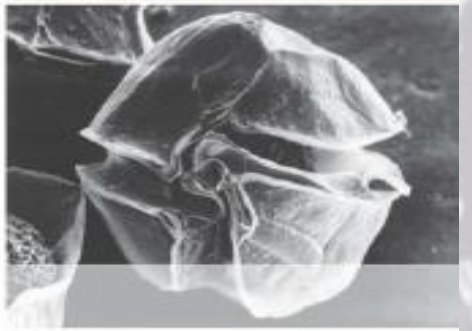
Assessment and management of biotoxin risks in bivalve molluscs



R_1	R_2	R_3	R_4	Toxin
H	H	H		STX
H	H	OSO_3^-		GTX2
H	OSO_3^-	H		GTX3
OH	H	H		NEO
OH	H	OSO_3^-		GTX1
OH	OSO_3^-	H		GTX4
H	H	H		GTX5 (B1)
H	H	OSO_3^-		C1
H	OSO_3^-	H		C2
OH	H	H		GTX6 (B2)
OH	H	OSO_3^-		C3
OH	OSO_3^-	H		C4
H	H	H		dcSTX
H	H	OSO_3^-		dcGTX2
H	OSO_3^-	H		dcGTX3
OH	H	H		dcNEO
OH	H	OSO_3^-		dcGTX1
OH	OSO_3^-	H		dcGTX4





JOINT FAO/WHO

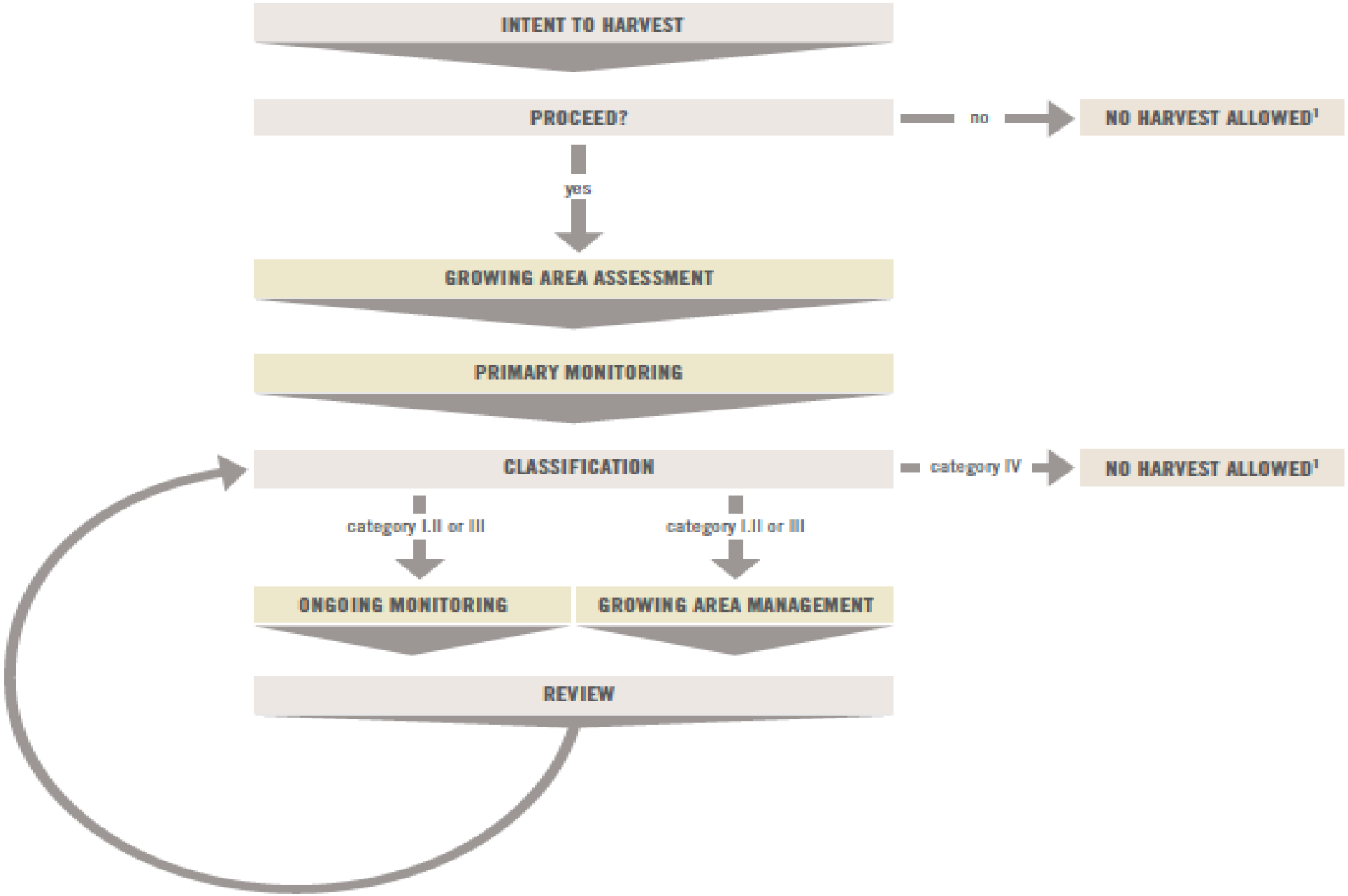
TECHNICAL PAPER

Toxicity Equivalency Factors for Marine Biotoxins Associated with Bivalve Molluscs

Food and Agriculture Organization of the United Nations

World Health Organization

FIGURE 1.1 **PROCESS FLOW CHART FOR A GROWING AREA PROGRAMME**



CHAPTER 2
GROWING AREA RISK PROFILE 7

2.3.2 JURISDICTIONS, RESPONSIBLE AUTHORITIES

Recommendation

Identify and record which official body(ies) is(are) responsible for the application of the sanitation programme and associated monitoring and enforcement activities.

Other considerations

Responsibility within national programmes may be divided between a number of national authorities. For example, there may be a separation between primary responsibility for policy and implementation of the overall programme, growing area monitoring activities and growing area enforcement. Divisions in responsibility may be between different bodies at the national level (e.g. Ministries) or between one or more national bodies and local authorities. Where such divisions of responsibility occur, it is not only important to identify them but also to determine how they will affect the programme at the specific growing area level (responsible local offices, contact details, etc.).

Explanation

It is important to be clear as to which official bodies are primarily responsible for the application of a sanitation programme for a growing area and whether any other bodies also have responsibilities under the programme. In addition, in many countries, responsibility for the application of food safety regulations is split between national, regional and/or local authorities. Again, it is important to document the separate responsibilities and any implications for the programme at the specific growing area level.

HAZARDS TO BE CONSIDERED

TABLE 2.1 **PATHOGEN MATRIX**

HAZARD RANKING	PATHOGEN	EVIDENCE OF BIVALVE-ASSOCIATED ILLNESS	FREQUENCY OF BIVALVE-ASSOCIATED ILLNESS[1]	SEVERITY OF ILLNESS[2]	LIKELY SOURCES OF CONTAMINATION TO THE AQUATIC ENVIRONMENT
Primary hazards	Norovirus (also Sapovirus and Aichi virus)	Y	Common[4]	Usually not severe	Human faeces
	Hepatitis A virus	Y	Moderately common in endemic areas[4]	Moderately severe[5]	Human faeces
	Salmonella typhi and *Salmonella paratyphi*	Y	Moderately common in endemic areas	Severe	Human faeces
	Other *Salmonella* serotypes	Y	Moderately common	Usually not severe	Human or animal[3] faeces
	Vibrio parahaemolyticus	Y	Moderately common	Usually not severe	Autochthonous
	Vibrio vulnificus	Y	Rare	Severe	Autochthonous

HAZARD RANKING	PATHOGEN	EVIDENCE OF BIVALVE-ASSOCIATED ILLNESS	FREQUENCY OF BIVALVE-ASSOCIATED ILLNESS[1]	SEVERITY OF ILLNESS[2]	LIKELY SOURCES OF CONTAMINATION TO THE AQUATIC ENVIRONMENT
Secondary hazards	Toxigenic *Vibrio cholerae*	Y	Moderately common in endemic areas	Severe without proper medical support	Human faeces, sometimes autochthonous
	Other *Vibrio* species	Y	Moderately common	Usually not severe	Autochthonous
	Campylobacter spp.	Y	Rare	Usually not severe	Human or animal faeces
	Listeria monocytogenes	Y (smoked bivalves)	Rare	Usually not severe[5,6]	Animal faeces
	Giardia intestinalis	Y	Rare	Usually not severe[5]	Human or animal faeces
Potential hazards	Hepatitis E virus	N	N/A[7]	Moderately severe[5]	Animal faeces (pigs, wild boar, deer, rats)
	Yersinia enterocolitica	N	N/A	Usually not severe	Animal faeces
	Microsporidia	N	N/A	Usually not severe[5]	Animal faeces
	Cryptosporidium parvum	N	N/A	Usually not severe[5]	Human or animal faeces
	Toxoplasma gondii	N	N/A	Usually not severe[5,8]	Animal faeces (primarily cats)

1. Frequency expected in the absence of an appropriate sanitation programme. The frequency will vary markedly by continent, country and even region. It may also change with time.
2. Expected severity in immunocompetent persons without other underlying disease. This does not apply to *V. vulnificus*, which usually only causes symptomatic illness in persons who are immunocompromised or have underlying illness.
3. The term animal is used to cover mammals and birds. However, some enteric pathogens (e.g. some *Salmonella enterica* serovars) can be carried by cold-blooded animals such as reptiles.
4. The frequency of norovirus and hepatitis A infection will only be partly reduced by a programme based on faecal indicator bacteria.
5. These pathogens may produce severe and/or chronic illness in some patients.
6. May be severe in immunocompromised patients and may have severe consequences for the foetus if a pregnant woman is infected.
7. N/A = Not applicable.
8. *Toxoplasma gondii* can result in severe consequences for the unborn baby if infection occurs in a pregnant woman.

FIGURE 3.1 **COMPONENTS OF THE GROWING AREA ASSESSMENT**

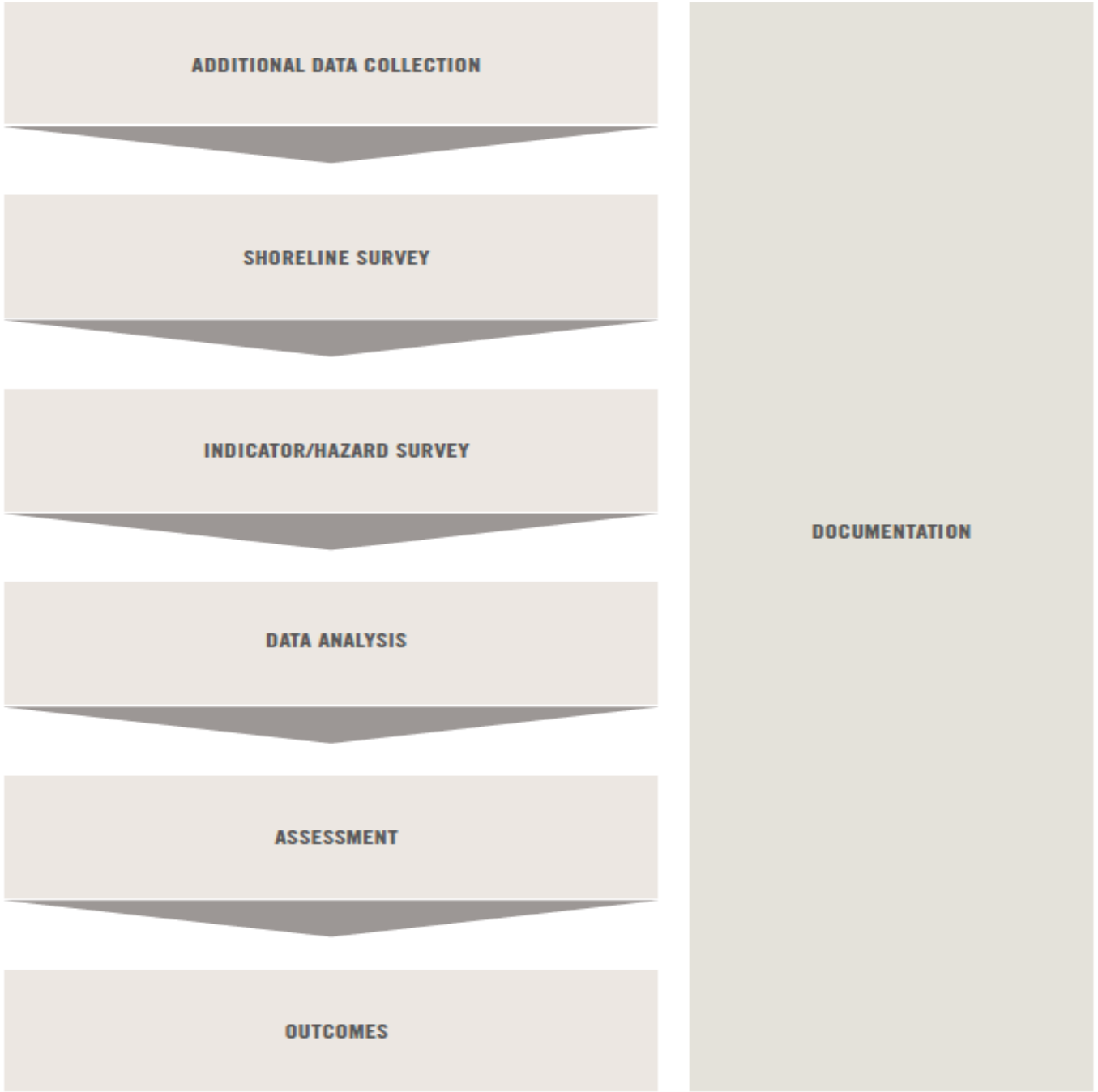


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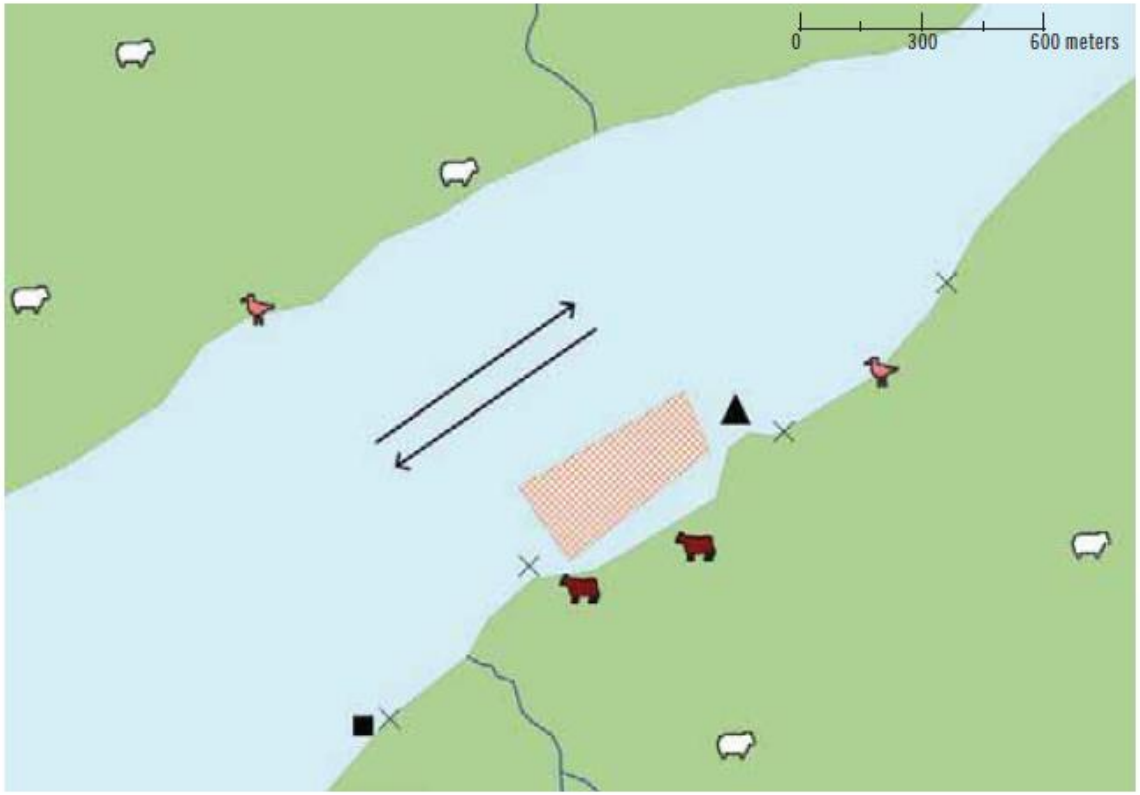
FIGURE 3.2 **PRINCIPAL SOURCE AND FACTOR CONSIDERATIONS FOR THE MAJOR HAZARD GROUPS**

HUMAN ENTERIC PATHOGENS	ANIMAL ENTERIC PATHOGENS	MARINE VIBRIOS	BIOTOXINS	CHEMICAL CONTAMINANTS
Continous sewage discharges	Farm animal polpulations	Concentration of potentially pathogennic species	Occurrence of potentially toxic phytoplankton	Industrial effluents
Intermittent sewage discharges	Animal waste storage locations	Proportion of pathogenic strains	Occurrence of biotoxins in bivalves	Landfill sites
Private sewage discharges	Slurry spreading locations	Seawater temperature	Seawater temperature	Mining
Direct defecation to land	Terrestrial wild animal populations	Seawater salinity	Seawater salinity	Shipping & boating
Sewage sludge spreading	Marine wild animal populations			Marine waste disposal sites
Rainfall-dependent discharges (or run-off)	Wild bird populations			Geological sources
Shipping & boating	Rainfall mediated run-off			Contaminated sediments

Hydrography

FIGURE 3.3 **EXAMPLE MAP FOR A QUALITATIVE ASSESSMENT**



ESTIMATED TRANSPORT DISTANCE
over a single spring tide

WATERCOURSES

WILD BIRD SITES

SHEEP FARMS

CATTLE FARMS

INTERMITTENT SEWAGE DISCHARGES

CONTINOUS SEWAGE DISCHARGES
by dry weather flow (m3/day)
500 to 2 000
0 to 500
by treatment level
secondary
tertiary

BIVALVE ROSOURCE

SEA

LAND

CHAPTER 3
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CHAPTER 4
GROWING AREA MONITORING 83

Monitoring water or bivalves ?

The benefits of both matrices with respect to microbiological monitoring may be obtained by a base monitoring programme using water samples supplemented with more targeted monitoring of bivalve molluscs. There are two possible approaches with such a mixed programme:

- base water programme and targeted bivalve monitoring, with both undertaken for faecal indicator bacteria; or
- base water programme undertaken for faecal indicator bacteria and targeted bivalve monitoring, undertaken for additional indicators (e.g. MSC) and/or pathogens (e.g. norovirus, hepatitis A, but dependent on the hazards identified for the area).

Further to the advice given in CAC (2010a), where the risk profile has identified that *V. vulnificus* and/or *V. parahaemolyticus* may be hazards relevant to the growing area, monitoring of bivalve molluscs at harvest for the levels of total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* should be conducted to determine the regional and seasonal variation.

4.3.4.2 Bivalve numbers

Recommendation

For faecal indicator bacteria, a sample for a single analysis should be comprised of at least 12 to 15 individual animals in order that at least 10 viable individuals can be tested on receipt at the laboratory. For small bivalve species, it may be necessary to collect a greater number of individual animals per sample in order to yield sufficient flesh for testing. For MSC or pathogens, the numbers should be as defined by the method, allowing for up to 20 percent of animals to become moribund prior to receipt at the laboratory.

Other considerations

For individual bivalve species, the required number of animals per sample should be determined in conjunction with the testing laboratory.

Explanation

The concentration of a hazard or indicator will vary markedly between individual animals and ensuring that at least 10 animals are tested reduces sample to sample variability. Use of a smaller number of animals should be supported by a demonstration that the variability of results obtained for the hazard or indicator is not significantly greater than that obtained with the recommended number. It is preferable to collect more animals than required for the test in order that the minimum specified number for analysis is still satisfied if a proportion become moribund or die during transit.

TABLE 4.1 **RECOGNIZED MICROBIOLOGICAL METHODS**

MATRIX	TARGET ORGANISM	METHOD
Bivalve molluscs	Sample preparation for all bacteriological methods	ISO 6887-3
	Preparation of dilutions of homogenized samples for all bacteriological methods	ISO 6887-1
	E. coli	ISO 16649-3 (5 tube format)
	MSC	EURL generic protocol (EURL 2007) FDA MSC Method
	Salmonella spp. (detection)	ISO 6579-1
	Salmonella spp. (quantification)	ISO 6579-3
	Pathogenic vibrios	See FAO/WHO (2016)
	Hepatitis A virus and norovirus (quantification)	ISO/TS 15216-1
	Hepatitis A virus and norovirus (qualitative detection)	ISO/TS 15216-2
Water	Faecal coliforms and presumptive *E. coli* by membrane filtration	ISO 9308-1
	Faecal coliforms and presumptive *E. coli* by Most Probable Number (MPN)	ISO 9308-2
	MSC	ISO 10705-1
	Standard Methods for the Examination of Water and Wastewater (APHA, 1985)	APHA

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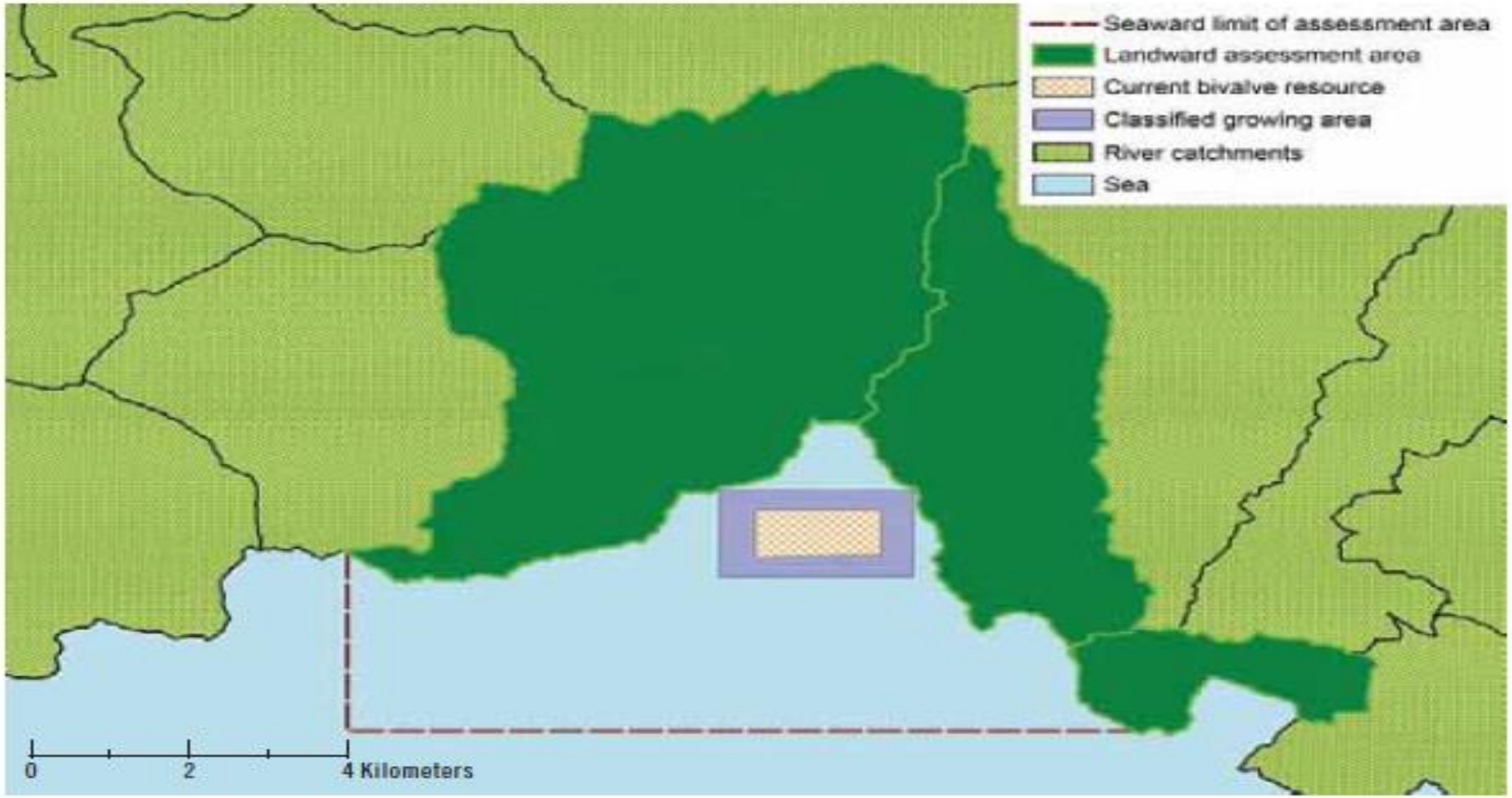
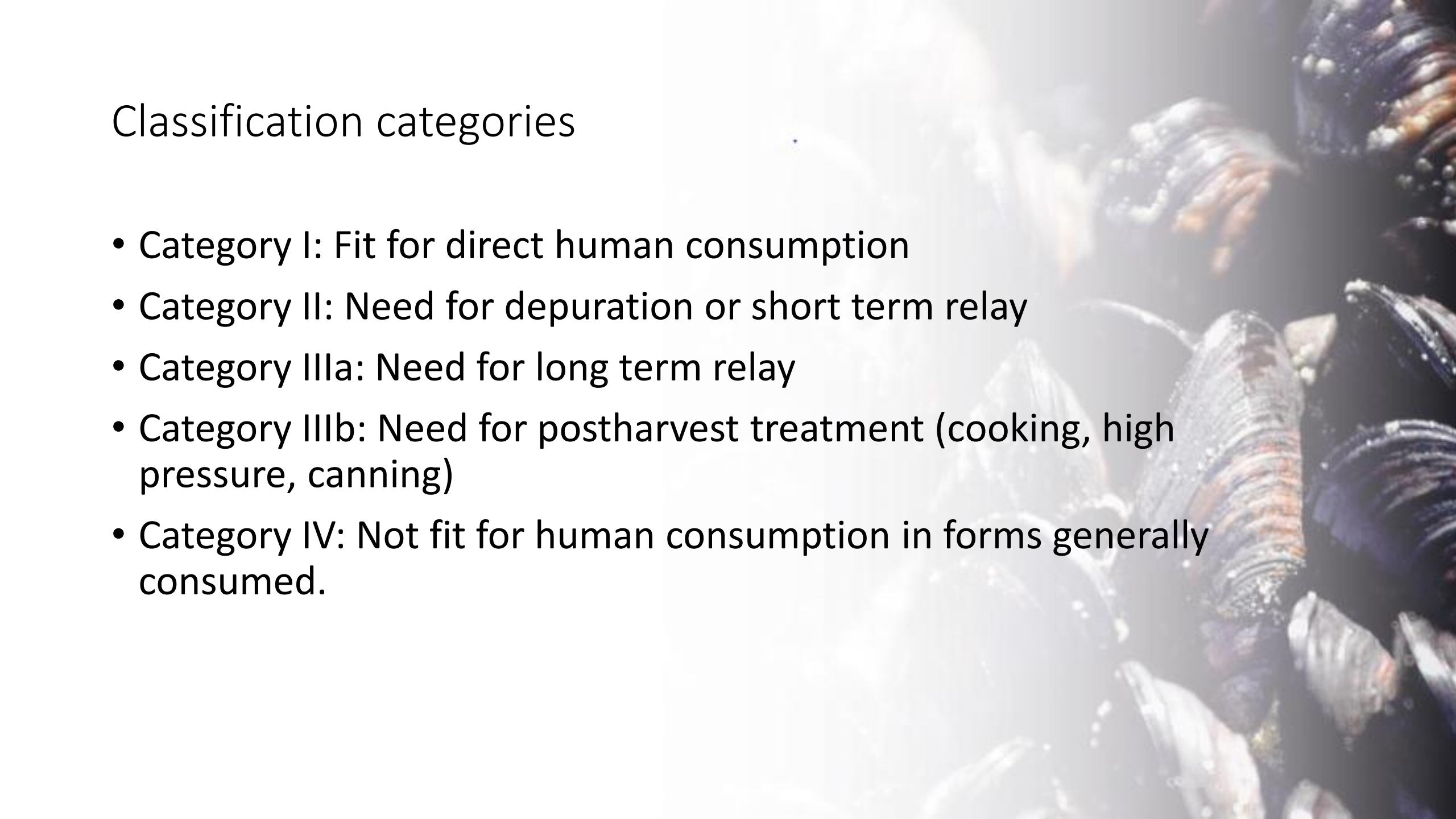
CLASSIFICATION 109

FIGURE 5.1. **EXAMPLE MAP SHOWING THE RELATIONSHIP BETWEEN ASSESSMENT AREA, GROWING AREA AND BIVALVE RESOURCE**



Classification categories

- Category I: Fit for direct human consumption
- Category II: Need for depuration or short term relay
- Category IIIa: Need for long term relay
- Category IIIb: Need for postharvest treatment (cooking, high pressure, canning)
- Category IV: Not fit for human consumption in forms generally consumed.



Classification: Criteria

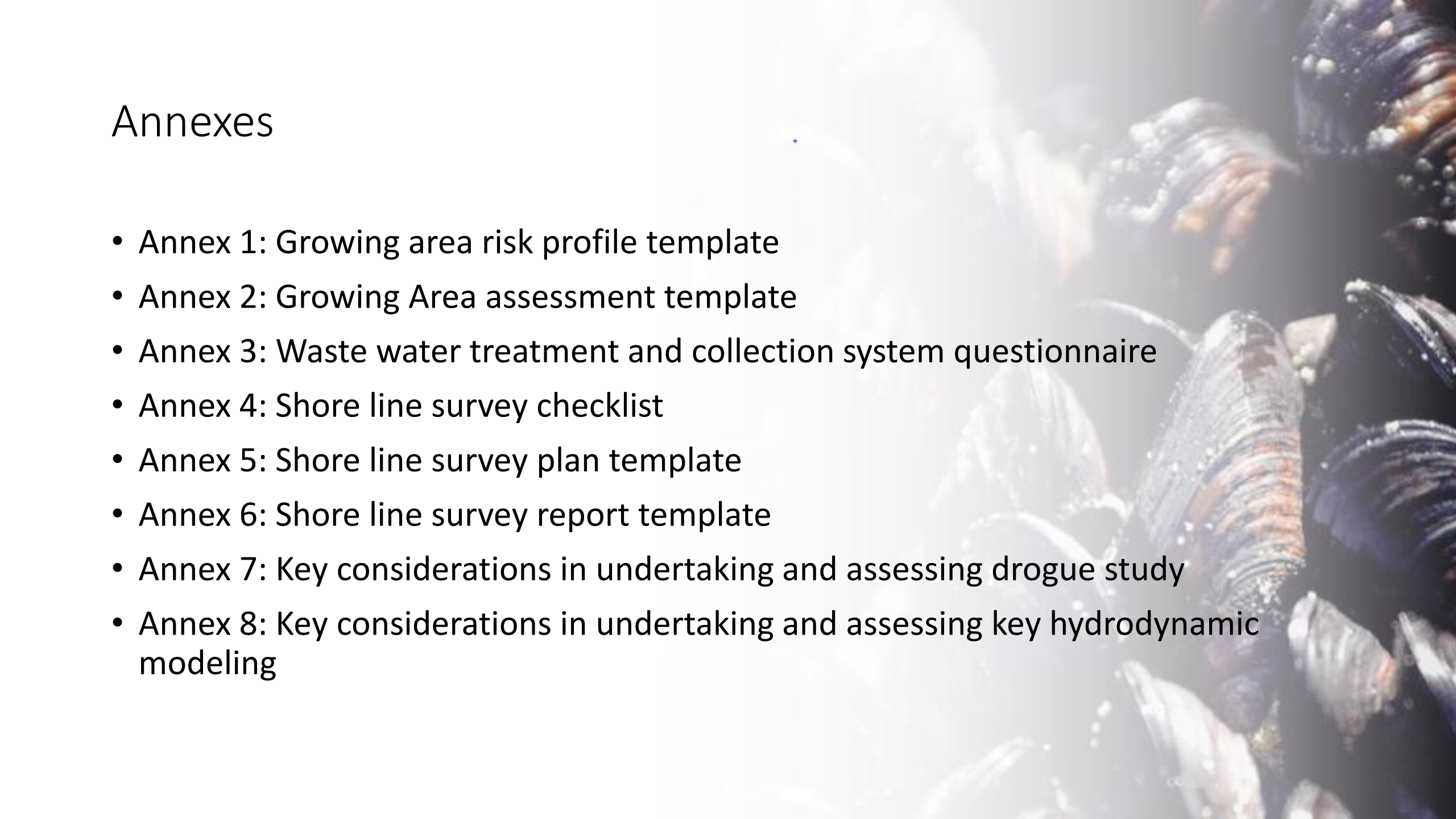
- Category I : Meets Codex microbiological criteria - Microorganism = *Escherichia coli* n=5 c=1 m=230 M=700 3 Class Plan.
- Category II: In the absence of regulatory requirements – (a) From risk profile, identify microbial hazards that need to be addressed by depuration or short term relay (b) Determine depuration kinetics of the process (FAO, 2008) (c) Determine maximum concentration of hazard that can be handled by the process (d) Determine 90^{th} percentile of fecal indicator concentration that relates to maximum concentration of the hazard (e) Review the results of depuration/short term relay to confirm meeting Category I requirements.
- Alternatively use EU category B or US NSSP criteria for restricted areas.

TABLE 6.1 **EXAMPLES OF UNEXPECTED EVENTS**

EVENT	HAZARD GROUP TO BE CONSIDERED
Abnormal weather conditions — severe storms (hurricanes, tornadoes, typhoons, etc.)	Bacterial (including vibrios), viral and protozoal pathogens, chemical contaminants associated with sediments
Abnormal weather conditions — exceptionally warm weather	Vibrios, possibly other bacterial pathogens, biotoxins
Abnormal weather conditions — exceptionally cold weather	Norovirus
Failure of sewage treatment plants, breakdown in sewage pumping stations, breakage of sewerage system	Bacterial, viral and protozoal pathogens of human enteric origin
Spills of animal waste (e.g. from slurry storage systems)	Bacterial, viral and protozoal pathogens of animal enteric origin
Outbreaks related to established (*Salmonella*, *Vibrio*, virus) or "novel "or emergent pathogens (e.g., *Cryptosporidium parvum*)	Pathogen associated with outbreak (reaction to the event may need to proceed before, or in the absence of, confirmation of the causative pathogen)
Illness associated with biotoxins	Biotoxin group associated with illness
Oil spill or discharge containing other chemical contaminants (e.g. spill from industrial plant, spill of water from mine)	Associated chemical contaminant(s)
Elevated indicator or hazard result, e.g. *E. coli* result above the limit for the current classification of the growing area or above some other predefined action limit	Depends on the indicator or hazard that has given the high result.

Annexes

- Annex 1: Growing area risk profile template
- Annex 2: Growing Area assessment template
- Annex 3: Waste water treatment and collection system questionnaire
- Annex 4: Shore line survey checklist
- Annex 5: Shore line survey plan template
- Annex 6: Shore line survey report template
- Annex 7: Key considerations in undertaking and assessing drogue study
- Annex 8: Key considerations in undertaking and assessing key hydrodynamic modeling

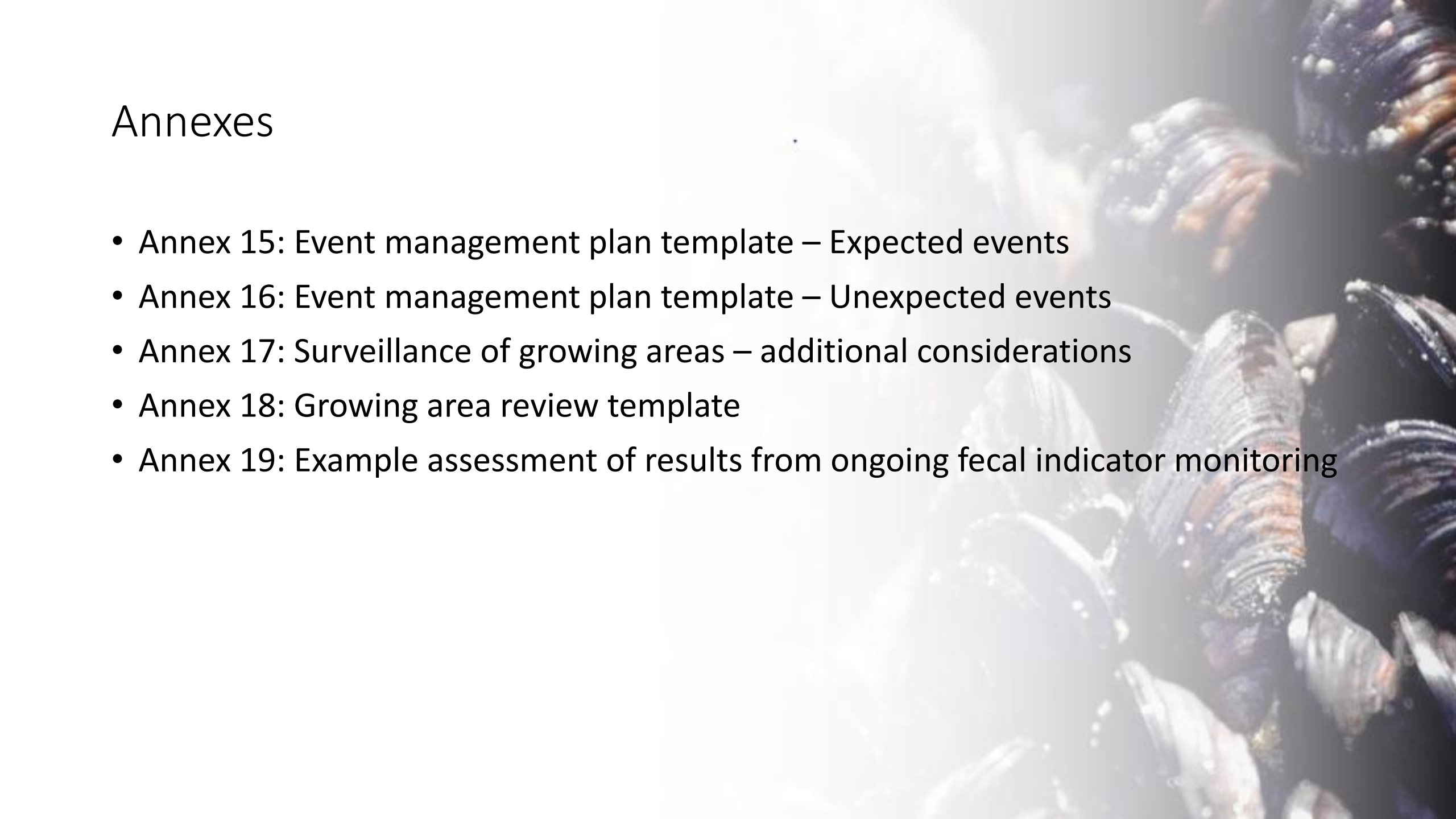


Annexes

- Annex 9: Key considerations in undertaking and assessing dye study
- Annex 10: Buffer zone determination with respect to enteric viruses
- Annex 10a: Recommended dilution rations for sewage treatment works buffer zones
- Annex 11: Guidance on use of male specific coliphage
- Annex 12: Example sampling protocol
- Annex 13: Example sample transport protocol
- Annex 14: Example analysis of results from primary fecal indicator monitoring

Annexes

- Annex 15: Event management plan template – Expected events
- Annex 16: Event management plan template – Unexpected events
- Annex 17: Surveillance of growing areas – additional considerations
- Annex 18: Growing area review template
- Annex 19: Example assessment of results from ongoing fecal indicator monitoring



Acknowledgements

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  - The members of the FAO/WHO Secretariat
  - All of the members of the expert working group
  - Consultants, Policy and technical staff involved in the Southern African pilot trials

THANK YOU