Overview of the Technical Guidance

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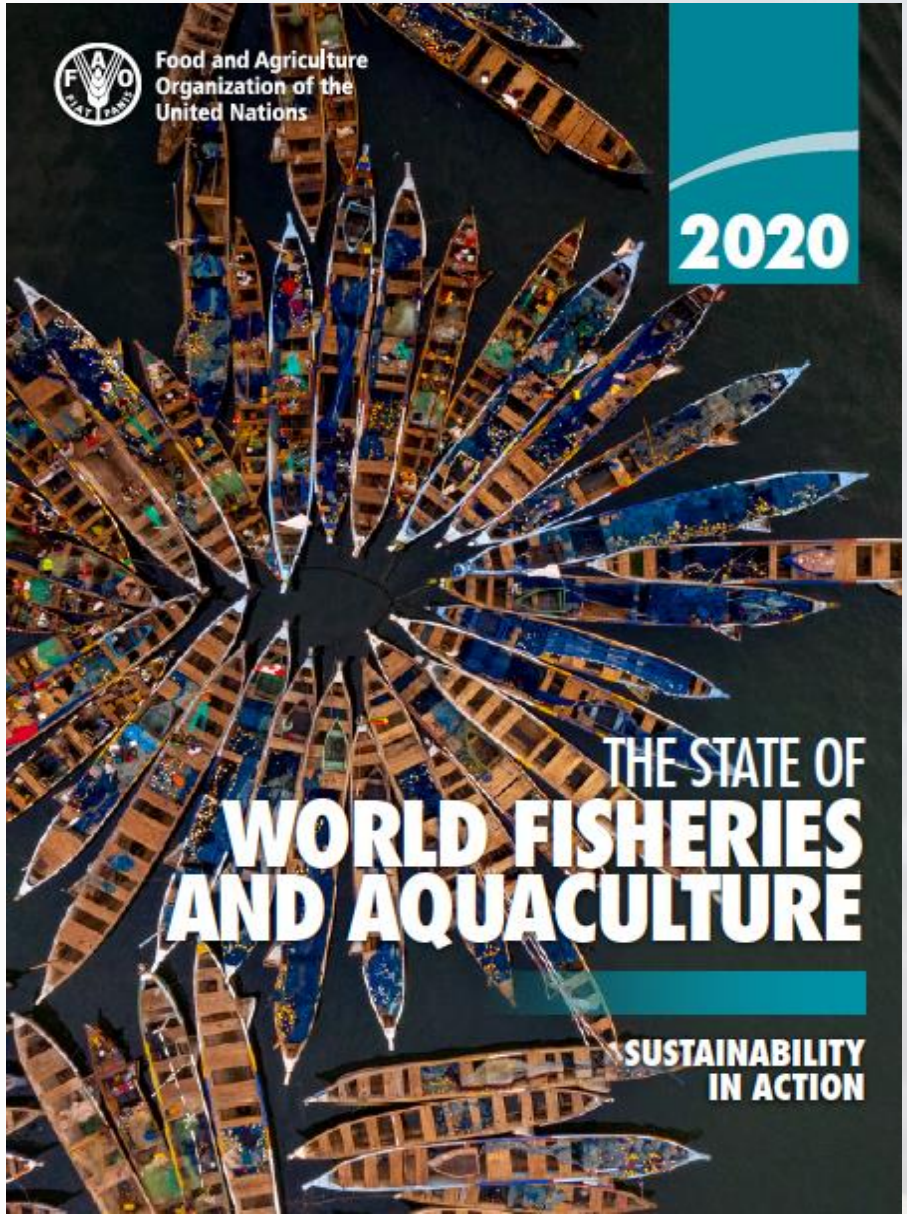
Global bivalve production



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

Global bivalve trade – 2020 impacted by Covid-19 (Source: FAO Globefish)

Global bivalve trade was severely impacted by Covid-19.

Mussels – Imports declined by 15%
France imported 45,500 tonnes, a decline of 21%
Italy imported 35,400 tonnes, a decline of 31%
Chile remained major exporter and even increased exports
Exports from Chile in 2020 reached 88,00 tonnes (14% increase).

Oyster imports in 2020 was 55,000 tonnes compared to 65,000 tonnes in 2019

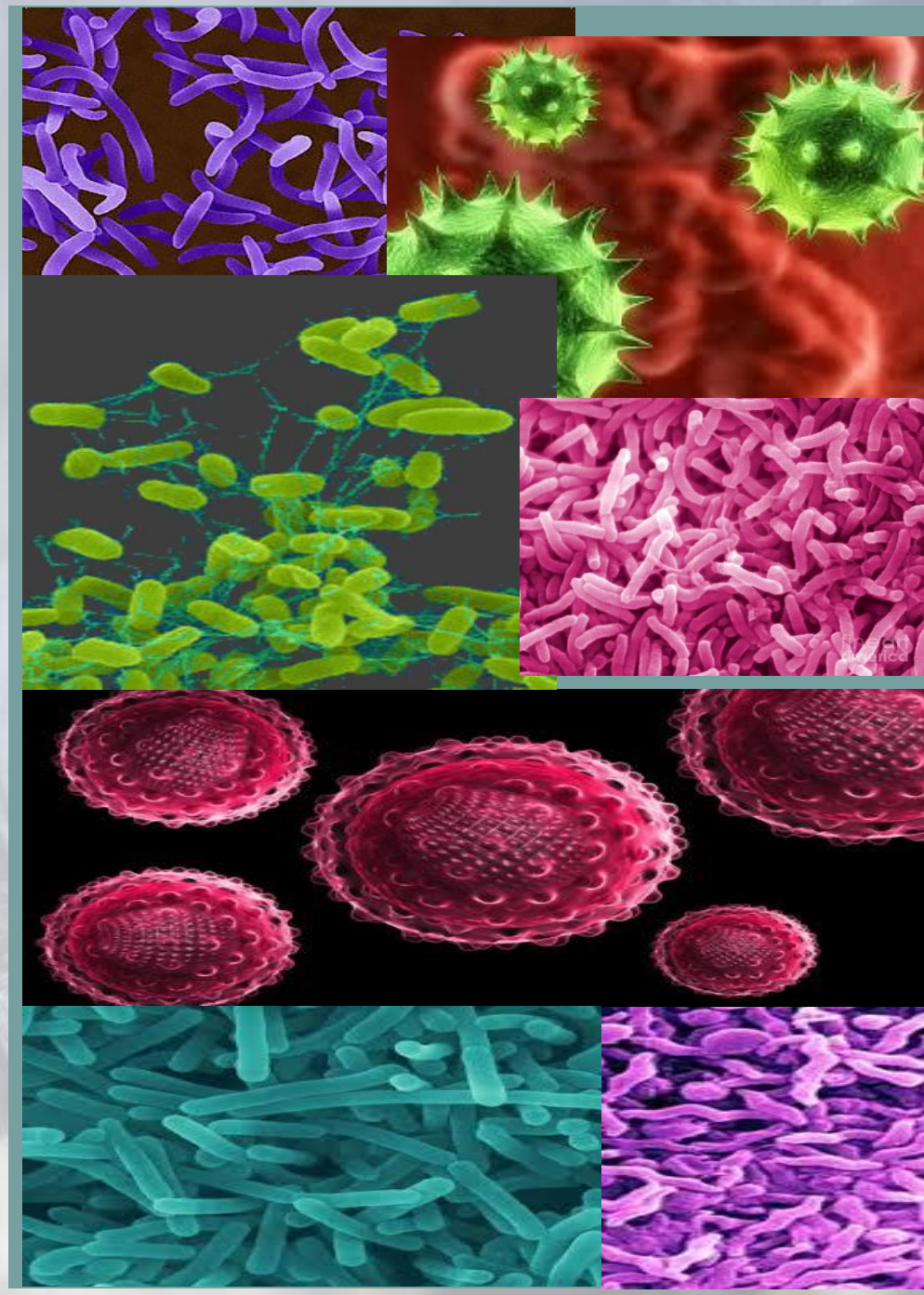
Importance for public health

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).

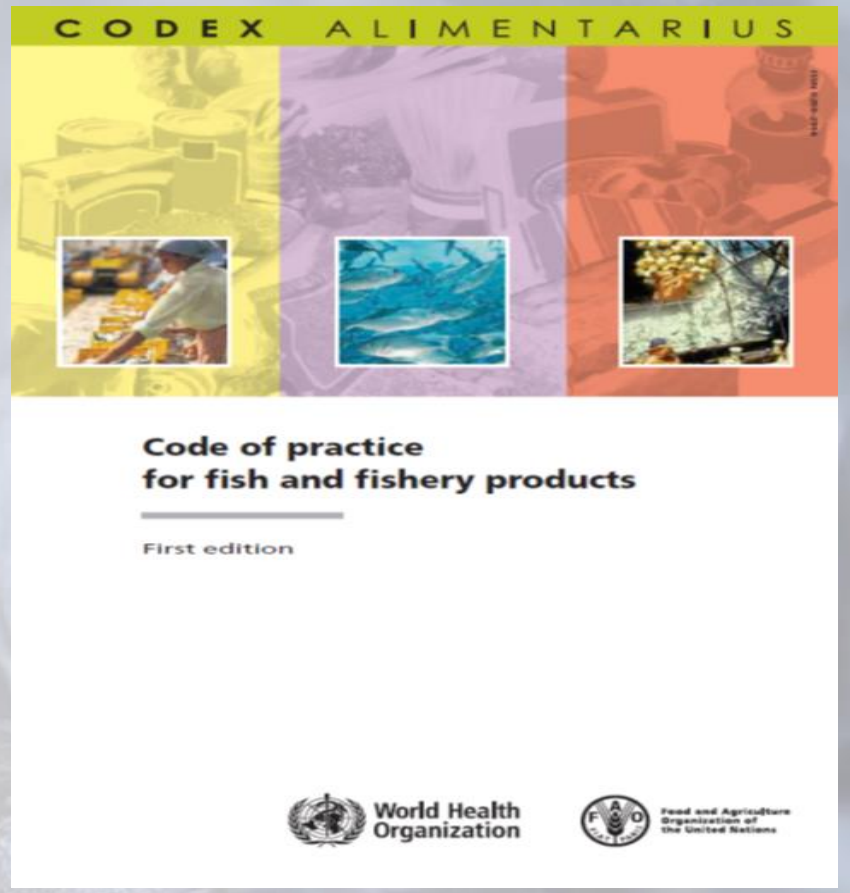
Microorganism = *Escherichia coli* n=5 c=1 m=230 M=700 3 Class Plan

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

5A
FOOD SAFETY AND QUALITY SERIES

ISSN 2415-1173

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

SECOND EDITION

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.

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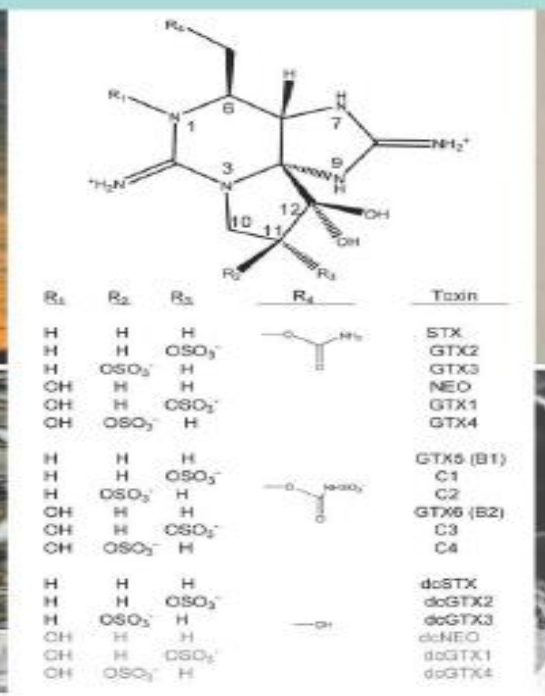
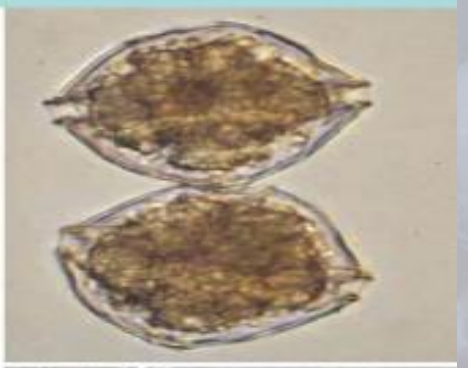
Assessment and management of biotoxin risks in bivalve molluscs



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

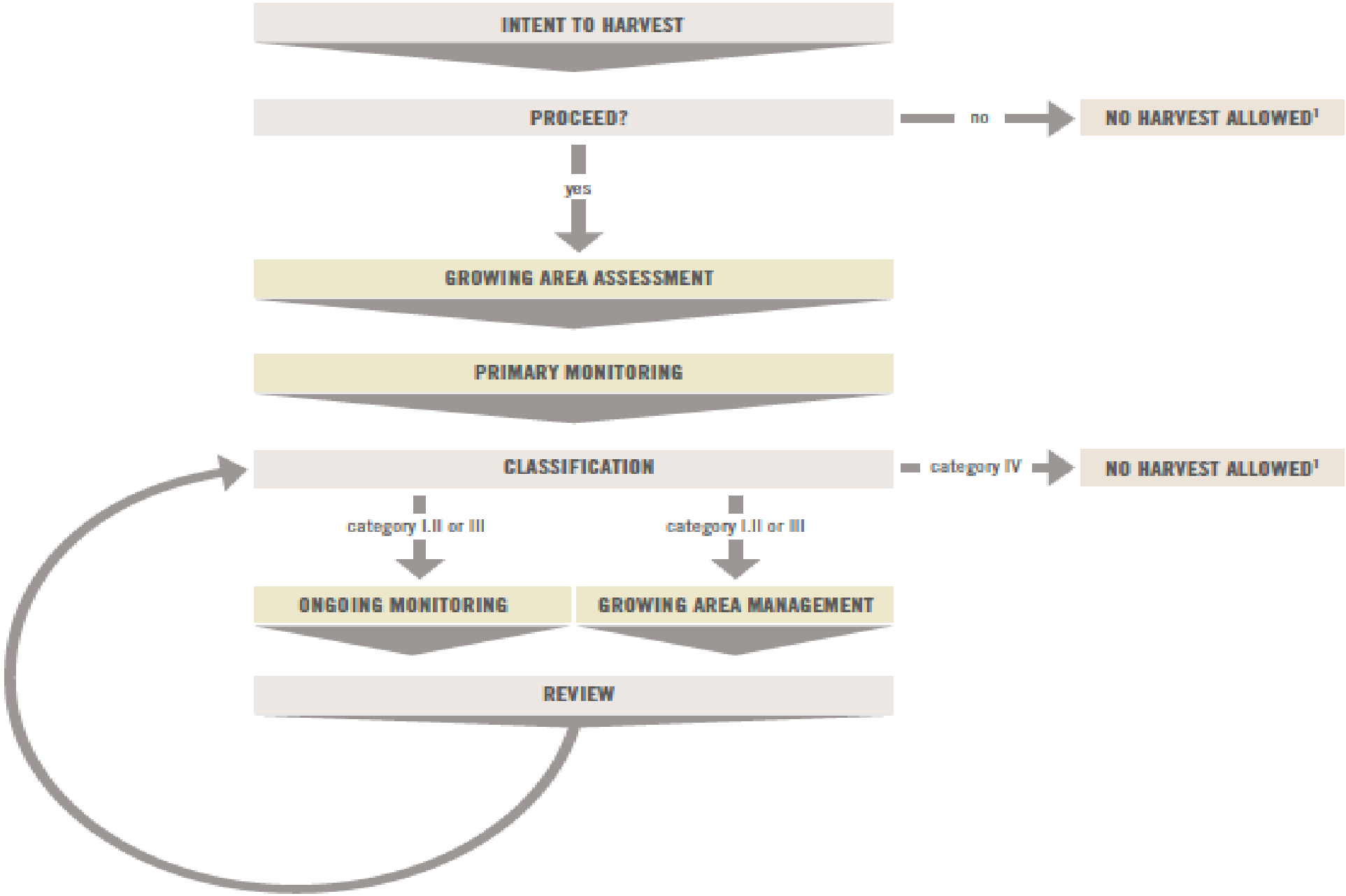
TECHNICAL PAPER

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**



First step – Developing Growing Area Risk Profile

- Outline the scope of risk profile;
- Review existing legal framework, current industry situation, resources available;
- Determine the extent of assessment area;
- Review epidemiological and public health data;
- Consider intended use of products and consuming population;
- Determine hazards to be considered;
- Outline programme capabilities and capacities;
- Perform cost benefit analysis;
- Document Growing Area Risk Profile.

Next step- Growing Area Assessment

- Data collection – sources of contamination, effect of geographical, hydrographical, meteorological and other environmental factors;
- Shoreline survey – planning and conducting the survey;
- Indicator/hazard survey – human and animal enteric pathogens, marine Vibrio spp, biotoxins, chemical contaminants;
- Data analysis and assessment
- Documentation of growing area risk assessment
- Outcomes:
  - Determining the extent of classified growing area
  - Recommendations for primary monitoring
  - Risk management recommendations

Next step- Growing Area Monitoring

- Primary monitoring
  - Defining purpose
  - Selection of sample matrix – water/bivalves
  - Sampling site selection
  - Sampling frequency, strategy
- Ongoing monitoring
  - Basis of ongoing monitoring
  - Indicators/Pathogens to be monitored
  - Number and location of sampling points
  - Frequency of sampling for fecal indicator bacteria
  - Frequency and sampling for other indicators and pathogens
- Documentation

Monitoring water/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.

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.

Growing area management and review

- Growing area management
  - Considerations on the capability of responsible authorities
  - Expected event management
  - Unexpected event management
  - Notification of interested parties
  - Growing area surveillance (patrol and enforcement)
- Growing area review
  - Review period and plan
  - Review of pollution sources
  - Review of on going monitoring data
  - Documentation of review

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

- Thanks to:
  - 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