Annex to: EFSA's BIOHAZ Panel Scientific opinion "Public health aspects of *Vibrio* spp. related to the consumption of seafood in the EU". doi:10.2903/j.efsa.2024.8896

Annex I – Characterisation of relevant (quantitative) microbial risk assessment of *Vibrio* spp. in various types of seafood

Table I.1: Characterisation of selected (quantitative) microbial risk assessment (QMRA) of *Vibrio* spp. in various types of seafood.

Reference	Title
FAO and WHO (2005a)	Risk assessment of choleragenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade
US FDA (2005)	Quantitative risk assessment on the public health impact of pathogenic *Vibrio parahaemolyticus* in raw oysters (FDA-VPRA model)
FAO and WHO (2005b)	Risk assessment of *Vibrio vulnificus* in raw oysters
Anses (2012)	Assessment of the risk associated with *Vibrio parahemolyticus* and live shellfish consumption (mussels and oysters)
BfR (2022)	Bacterial foodborne Vibrio infections: health risk assessment of the occurrence of *Vibrio* spp. (non-cholera vibrios) in food
FAO and WHO (2011)	Risk assessment of *Vibrio parahaemolyticus* in seafood
Phillips et al. (2007)	An evaluation of the use of remotely sensed parameters for prediction of incidence and risk associated with *Vibrio parahaemolyticus* in Gulf Coast oysters (*Crassostrea virginica*)
Yamamoto et al. (2008)	Quantitative modelling for risk assessment of *Vibrio parahaemolyticus* in bloody clams in southern Thailand
Iwahori et al. (2010)	Quantitative risk assessment of *Vibrio parahaemolyticus* in finfish: A model of raw horse mackerel consumption in Japan
Sani et al. (2013)	The risk assessment of *Vibrio parahaemolyticus* in cooked black tiger shrimps (*Penaeus monodon*) in Malaysia
Sobrinho et al. (2014)	A quantitative risk assessment model for *Vibrio parahaemolyticus* in raw oysters in Sao Paulo State, Brazil
Malcolm et al. (2016)	Microbial risk assessment of *Vibrio parahaemolyticus* in bloody clams in Malaysia: A preliminary model from retail to consumption
Huang et al. (2018)	The risk of *Vibrio parahaemolyticus* infections associated with consumption of raw oysters as affected by processing and distribution conditions in Taiwan
Ndraha and Hsiao (2019)	The risk assessment of *Vibrio parahaemolyticus* in raw oysters in Taiwan under the seasonal variations, time horizons, and climate scenarios
Tan et al. (2019)	Preliminary quantitative microbial risk assessment of pathogenic *Vibrio parahaemolyticus* in short mackerel in Malaysia

Kang et al. (2021)	Quantitative microbial risk assessment of *Vibrio parahaemolyticus* foodborne illness of sea squirt (*Halocynthia roretzi*) in South Korea
Oh et al. (2021)	Risk assessment of vibriosis by *Vibrio cholerae* and *Vibrio vulnificus* in whip-arm octopus consumption in South Korea
Ding et al. (2022)	Quantitative risk assessment of *Vibrio parahaemolyticus* in shellfish from retail to consumption in coastal cities of Eastern China
Neetoo et al. (2022)	Prevalence, genomic characterization, and risk assessment of human pathogenic *Vibrio* species in seafood
Takoundjou et al. (2022)	Quantitative risk assessment of *Vibrio parahaemolyticus* toxi infection associated with the consumption of roasted shrimp (*Penaeus monodon*)
Xu et al. (2023)	Risk reduction assessment of *Vibrio parahaemolyticus* on shrimp by a Chinese eating habit
Ong et al. (2023)	Quantitative risk evaluation of antimicrobial-resistant *Vibrio parahaemolyticus* isolated from farmed grey mullets in Singapore
Ndraha et al. (2023)	Modeling the risk of *Vibrio parahaemolyticus* in oysters in Taiwan by considering seasonal variations, time periods, climate change scenarios, and post-harvest interventions

Reference	Scope (part of food chain)	Geographic scope	Approach (type of models, variability/uncertainty)	Hazard(s) and origin of occurrence data	Environmental parameter used	Food(s) and consumption data	Health endpoint (and population)	DR-model	Exposure assessment models (and predictive microbiology models)	Prevention or control measures tested	Risk units
FAO and WHO (2005a)	Harvest to consumption; QMRA model only from the point of entry to consumption	Global; warm-water shrimp produced and processed for the export market; the risk associated with the consumption of imported shrimp in several importing countries	Qual and quant; mean exposure and risk were evaluated analytically and within Monte Carlo simulation of the effect of uncertainty (prevalence and DR)	Vc O1 and O139	None, concentration at port of entry estimated based on prevalence, assuming a Poisson distribution	Warm water shrimp; consumption calculated from production volumes and population size, with a mean serving size of 275 g	Gastro-intestinal illness; general population	Threshold model (qual and semi-quant approach); approximate Beta-Poisson model using data from volunteer studies	Spreadsheet tool (semi-quant); QMRA model: prevalence at the point of entry used to estimate levels assuming a Poisson distribution; no predictive models used but present information on reductions and increases	None, but uncooked (10%) and cooked shrimps (90%) evaluated	Cases per time period, and cases per 10^9 servings
US FDA (2005)	Product pathway: harvest, post-harvest handling, processing, storage and consumption	USA, different regions and seasons	Quant simulation model and what-if scenarios, factors affecting risk and control measures; uncertainty analysis	Pathogenic Vp; different regions in the USA	Occurrence data based on the water T model and the ratio of pathogenic Vp	Raw oysters; national, number of servings based on production volume, number of oysters consumed per meal, and the weight of edible	Illness (GE or septicaemia); healthy individuals or impaired immune systems	DR model developed based on human clinical feeding studies and anchored to epidemiological data	Three modules (harvest, post-harvest, consumption); growth model (> 10°C), during cooling or intertidal harvest; primary Gompertz and three-phase loglinear, and secondary square root a_w and T based on	Presence at harvest (sea water T main factor) and post-harvest growth (t-T at different steps) storage; post-harvest treatments; microbiological standards;	Probability and severity of illness per serving or year

						oyster parts			literature data; inactivation models or estimates from the literature	intertidal harvest	
FAO and WHO (2005b)	Harvest to consumption; evaluate if Vp models could be adapted to Vv	Gulf Coast of USA	The Monte Carlo simulation model addressing variability/uncertainty	Vv; Gulf Coast of USA	Relationship between water T and levels	Raw oysters; USA data, number of oysters per serving and weight per oyster	Septicaemia; susceptible population	Beta-Poisson model developed by fitting estimated consumption; exposure with the number of reported cases	Modules harvest, postharvest-consumption, growth after harvest and during cooling, and storage (three-phase log-linear model); die-off during storage	Different process target levels (3, 30 or 300 Vv per g) which could potentially be achieved by different mitigation strategies (mild heat, freezing, HPP, and icing)	Mean risk per serving and mean number of illnesses
Anses (2012)	Harvest to consumption	France	Monte Carlo simulation model addressing variability/uncertainty	Pathogenic Vp (and info about other non-cholerae vibrios); seven different regions based on SST	Relationship (from a US-FDA study) between seawater T (French data) and Vp levels, pathogenic Vp estimated by proportion from the US-FDA data	Oysters and mussels; consumption (frequency and meal size) over the year from production data and French consumer surveys	Gastroenteritis in the general population	Beta-Poisson model from FDA-VPRA; adjusted beta-parameter was used and uncertainty was estimated by parametric re-sampling (Boot strapping)	Exposure estimated using SST from different regions, the proportion of pathogenic strains, and growth or inactivation depending on T after harvest to direct selling; predictive model Fernandez-Piquer et al. (2011)	The impact of season, increase of SST (2°C) and storage time (12 hours)	Number of cases in France
BfR (2022)	Primary production to	Seafood consumed and/or oysters;	Qual, uncertainties: quant occurrence data, proportion	*Vibrio* spp. including Va, Vm, but focus	Not applicable	Fish, fish products, seafood, oysters,	Illness (diarrhoea and other	Not applied	Not applied	Cooking to internal T of 70°C assumed to	Cases (no cases reported),

	consumption	mussels produced in Germany	eaten raw, and underreporting	is on non-cholerae vibrios; data relevant for consumption in Germany		and mussels; German consumption data	health endpoints); general population and risk groups considered			eliminate all vibrios	results of assessment presented in a BfR risk profile table
FAO and WHO (2011)	Adoption of the QMRA model developed in the USA (FDA-VPRA) to other countries and products (when data missing, USA data was used)	Australia, Canada, Japan and New Zealand (raw oysters); Thailand (bloody clam); Japan (finfish)	Same as FDA-VPRA	Vp; oysters: Australia, Canada, Japan New Zealand, and the USA; bloody clams (Thailand); mackerel (Japan)	For oysters, water T from relevant areas and USA quant relationship; bloody clams and mackerel, small surveys not environmental parameter	Raw oysters; bloody clam (*Anadara granosa*); raw horse mackerel (finfish); local data combined with USA data	GE; general population	Same as in FDA-VPRA	Modular models, different foods did not include all stages, same models as in FDA-VPRA, growth rate in bloody clams estimated from counts harvest and retail, other foods used for oyster growth rates	Target levels (oysters), mackerel (washing or no washing at the port; transportation in clean or contaminated water; washing or no washing of visceral cavity during the preparation; and various combinations of these)	Number of illnesses per year (oysters and mackerel); cases per 1,000 persons and year (bloody clams) Probability of illness per serving (mackerel)
Phillips et al. (2007)	Harvest to consumption but the scope of the study is the remote sensing of parameters to predict	National, Gulf coast of the USA	FDA-VPRA	Vp; remote sensing data of sea water	T, turbidity, chlorophyll to predict Vp in oysters	Raw oysters; same as FDA-VPRA	GE; general population	None	FDA-VPRA	None	Vp per g, colour maps

	Vibrio levels										
Yamamoto et al. (2008)	Harvest to consumption	National, Thailand	Monte Carlo simulation addressing mostly uncertainty of the mean risk	Pathogenic Vp; occurrence from samples in a small survey, assuming lognormal distribution for concentration and Poisson for pathogenic cells	None	Bloody clams; interview of local people	GE; general population	Beta-Poisson model (FDA-VPRA)	Initial occurrence at harvest, growth up to retail and up to home, cooking, consumption; growth rate estimated from survey levels at harvest and retail, inactivation all or none survive, proportion cooking from beta distribution using a small survey	Effect of cooking	Mean number of illnesses per person per year
Iwahori et al. (2010)	Harvest to consumption	Japan	Monte Carlo simulation simulating mostly variability	Vp; Japan	None; based on reported data	Raw horse mackerel; survey data, Japan	GE; general population	Beta-Poisson model, (FDA-VPRA) and a new model with parameters from new feeding studies	Two to three modules; removal-log reductions and growth models (exponential, no lag), secondary from the literature and experiments	Growth at all stages, washing the fish, storage water, and bacterial transfer from the fish to fillets during preparation	Probability of illness per serving
Sani et al. (2013)	Retail to consumption	Malaysia	Monte Carlo simulation simulating mostly variability	Pathogenic Vp; from a previous study in the same area	None	Raw frozen black tiger shrimp; national survey data	GE; general population	Beta-Poisson (FDA-VPRA)	Retail, thawing, cooking, and consumption based on the literature and assumptions	Cooking and t-T control	Number of cases per year, number of cases per 100,000 persons per year

Sobrinho et al. (2014)	Harvest to consumption	National, Brazil	Monte Carlo simulation simulating mostly variability	Pathogenic Vp; sea water T and Vp levels in oysters from Brazil	Sea water T using own regression model	Raw oysters; estimated based on Brazilian data	GE; general population	Beta-Poisson model (FDA-VPRA)	Three modules: harvest, post-harvest, and consumption; growth (FDA-VPRA), reduction due to depuration (this study), inactivation during storage (assumed based on the literature)	t-T, depuration (ozone and UV)	Probability of illness per serving
Malcolm et al. (2016)	Retail to consumption	National, Malaysia	Monte Carlo simulation model addressing variability	Pathogenic Vp; based on a small national study (MPN/g)	None	Bloody clams; national data	GE; general population	Beta-Poisson model (FDA-VPRA)	Two modules: retail and consumption; growth from the broth model (FDA-VPRA) adjusted to oysters; heat inactivation model log reduction from literature data	Impact initial occurrence, and t-T, two types of markets	Probability of illness per serving, number of cases per year
Huang et al. (2018)	Harvest to consumption	National, Taiwan	Monte Carlo simulation addressing variability	Pathogenic Vp; based on a study in Taiwan	None	Raw oysters; the literature and interviews; national survey	GE; general population	Beta-Poisson model (FDA-VPRA)	Three modules: harvest, processing/distribution, and consumption; secondary growth (> 12°C) (FDA-VPRA) and inactivation (< 12°C) secondary square root model developed from experiments	Impact of initial occurrence, t and T during processing and transportation	Probability of illness per serving, cases per 100,000 persons
Ndraha and Hsiao (2019)	Growing, harvest, consumption	National, Taiwan	Monte Carlo simulation addressing mostly variability	Pathogenic Vp; modelled using climate	Water T, and salinity in the US-FDA model	Raw oysters; national data from	GE; general population	Beta-Poisson model (FDA-VPRA)	Four modules: post-harvest, cleaning and packaging, transport, and	Impact of seasons, climate, refrigeration, depuration,	Probability of illness per serving

				factors in Taiwan		Huang et al. (2018)			consumption; growth rate from FDA-VPRA and inactivation data from Huang et al. (2018)	freezing, thermal treatment, heat shock, and irradiation	
Tan et al. (2019)	Retail to consumption	National, Malaysia	Monte Carlo simulation addressing mostly variability	Pathogenic Vp; occurrence data (beta-distribution) from a previous study and levels in whole fish (estimated from levels in different parts of the fish with a modified equation from Iwahori et al. (2010)	None	Short mackerel; consumption from national statistics	GE; general population	Beta-Poisson model (FDA-VPRA)	Growth during storage and transport from FDA-VPRA model, reduction by gilling and gutting, and washing, cooking inactivation from experimental study	Cooking, washing	Number of cases per year, number of cases per 100,000 population per year
Kang et al. (2021)	Market/retail to consumption	National (South Korea)	Monte Carlo simulation addressing variability	Vp survey data from market in South Korea	None	Sea squirt, an edible ascidian (sea pineapple); national consumption data	GE; general population	Beta-Poisson model, same as in Iwahori et al. (2010) based on FDA-VPRA	Stochastic models describing growth during storage and transport; t/T from an interview with a market employee, and home storage from another Korean study; predictive growth models developed in	None	Probability of illness per person and day

									food matrix, and primary Baranyi and secondary square root models		
Oh et al. (2021)	Harvest to consumption	National, South Korea	Monte Carlo simulation addressing variability	Vc and Vv; estimated from market samples	None	Raw whip-arm octopus; national survey data	See respective DR model	Beta Poisson model with parameters from WHO-FAO reports	Occurrence, growth, and consumption; developed polynomial growth and lag phase models	None	Probability of illness per person per day
Ding et al. (2022)	Retail to cooking in the home	China	Monte Carlo simulation addressing variability	Pathogenic Vp; survey, MPN data using PCR	None	Oysters, clams, mussels, and scallop; national dietary survey	GE; general population	Beta-Poisson	Four modules: point of purchase, storage after purchase, preparation stage, and consumption stage	Initial levels, storage conditions	Probability of illness per person per year
Neetoo et al. (2022)	Occurrence to risk	National, Mauritius	Risk estimated from occurrence data using the semi-quant tool Risk Ranger	*Vibrio* spp.; sampling of seafood around Mauritius	None	Wild and farmed finfish and shellfish (oysters and sea urchins); consumer survey	Illness; immuno-competent population	No model	Probability of contamination of raw product and effect of processing control, and preparation (Risk Ranger)	None	Risk score
Takoundjou et al. (2022)	Post-harvest to consumption	National, Cameroon	Monte Carlo simulation addressing mostly variability	Pathogenic Vp; occurrence based on a small study	None	Roasted shrimps; survey on handling and consumption patterns	GE; general population	Beta-Poisson model with adjustment parameter (FDA-VPRA)	Cooking, storage, and consumption; growth: experimental data in shrimps fitted to Baranyi and Roberts model to estimate growth rate and lag; roasting model: experiments	Different roasting/cooking protocols	Cases per million servings, and cases per year

									fitted to a regression model		
Xu et al. (2023)	Market to consumption	National, China	Monte Carlo simulation addressing variability	Pathogenic Vp; assumed range based on the literature	None	Shrimps; national Survey	GE; general population	Beta-Poisson model (FDA-VPRA)	Initial level and reduction via different vinegars; reduction model fitted to experimental data	Mixing of shrimp with vinegars	Probability of illness per serving
Ong et al. (2023)	Farm to consumption and retail to consumption	National, Singapore	Monte Carlo simulation addressing variability	Antimicrobial resistant Vp; based on studies of fish from Singapore	None	Farmed grey Mullet (finfish); national survey data	GE; general population	Beta-Poisson model (FDA-VPRA)	Stages after harvest or retail estimating growth and reduction due to cooking, washing; growth models from FDA-VPRA, reduction from the literature	Cooking and washing of fish cavity	Probability of illness per serving, cases per year
Ndraha et al. (2023)	Harvest to consumption	National, Taiwan	Monte Carlo simulation addressing variability	Pathogenic Vp; modelled using new model and Taiwanese environmental data and levels; proportion pathogenic based on survey data	Levels were simulated applying a new elastic net predictive model using a supervised machine learning approach employing over 20 local climatic factors with fitted coefficients	Oysters; national from the literature and oyster weight from study	GE	Beta-Poisson model (FDA-VPRA)	Growth and inactivation after harvest were modelled based on literature data as part of evaluating interventions	Cooking, icing/refrigeration and T control and cleaning during several stages after harvest, depuration, HPP, salt levels, irradiation, and mild thermal shock; all these under different climate scenarios through effect on T	Probability of illness per serving, probability of illness per year; number of cases per 100,000 population and year

Reference	**Data gaps**
FAO and WHO (2005a)	Quant occurrence data along the food chain; faecal; cross contamination during handling, and post-processes or cross-contamination data; consumption data
US FDA (2005)	Frequency of pathogenic Vp in water and shellfish; growth rates; impact of different harvest and post-harvest handlings and processes; consumption data; DR data; epidemiological data; impact of consumer handling
FAO and WHO (2005b)	Vv-T relationship; oyster species; DR; variation in Vv virulence and human susceptibility
Anses (2012)	National data for SST; relationship between SST and levels based on USA data; air T data based on the relationship with marine SST; post-harvest conditions expert opinion; consumption data; growth of pathogenic Vp; DR data; susceptibility in the French population
BfR (2022)	Levels in food in Germany; consumer habits; epidemiological data
FAO and WHO (2011)	Epidemiological data; incidence and frequency of pathogenic Vp in water, finfish and shellfish; impact of factors on occurrence of pathogenic Vp in the environment, role of oyster physiology and immune status in Vp, DR model; growth rates of within different oyster species at Ts other than 26°C; growth rates in other shellfish and finfish at post-harvest handling and storage; rates of hydraulic flushing (water turnover) in shellfish harvest areas based on levels of freshwater flows; tidal changes, winds and depth of harvesting area, and how these factors may influence pathogenic Vp numbers; consumer handling of oysters; cross-contamination when finfish are prepared for raw consumption; improved global public health surveillance of Vp; knowledge of reporting systems in each country of study
Phillips et al. (2007)	
Yamamoto et al. (2008)	Sensitivities of detection methods; limited occurrence data not covering season and regions, or distributions; proportion pathogenic strains; limited consumption and handling data; epidemiological data; cross-contamination; heat inactivation data; DR; growth rates of pathogenic strains
Iwahori et al. (2010)	Detailed data on initial densities; proportion of pathogenic strains; the uncertainty of the DR
Sani et al. (2013)	DR; occurrence data; food matrix effects; consumer practices
Sobrinho et al. (2014)	Factors affecting growth, e.g. competition, dynamics of environmental variables, maximum population density
Malcolm et al. (2016)	National data; t-T data
Huang et al. (2018)	Impact of cross-contamination; epidemiological data; occurrence of virulent strains; impact of climate change
Ndraha and Hsiao (2019)	
Tan et al. (2019)	Harvest to retail data; storage Ts retail and transport; inactivation during storage; ingredients effect on growth; cross-contamination, effect of different heat treatments; DR model; susceptibility and virulence
Kang et al. (2021)	Not discussed
Oh et al. (2021)	
Ding et al. (2022)	DR; storage conditions; growth model in product

Neetoo et al. (2022)	Concentration data at time of consumption
Takoundjou et al. (2022)	Limited growth data; initial concentration data; DR; proportion of pathogenic Vp
Xu et al. (2023)	Epidemiological data
Ong et al. (2023)	Cross-contamination data; limited data for several of inputs; AMR sequence data
Ndraha et al. (2023)	Number of samples to model; monitoring data in oysters; improve climate effect by extending to other parameters than T; strains virulence; cross-contamination and handling practices; strains survival and VBNC

Abbreviations: a_w, water activity; AMR, antimicrobial resistance; DR, dose response; FDA-VPRA, Risk assessment model of US-FDA (2005) titled "Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters"; GE, gastroenteritis; HPP, high pressure processing; MPN, most probable number; PCR, polymerase chain reaction; QMRA, quantitative microbiological risk assessment; qual, qualitative; quant, quantitative; SST, sea surface temperature; T, temperature; t/T, time-temperature; USA, the United States of America; UV, Ultraviolet; Va, *V. alginolyticus*; VBNC, viable but non-culturable; Vc, *Vibrio cholerae*; Vm, *V. metschnikovii*; Vp, *Vibrio parahaemolyticus*; Vv, *Vibrio vulnificus*.

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