KNAMAX™ Seafood / KNAMAX™ Vibrio Control by INTABIOTECH

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KNAMAX™ Seafood / KNAMAX™ Vibrio Control

EXECUTIVE SUMMARY

For shrimp and prawn from Ecuador destined for the EU and Spain, **there is currently no harmonised EU microbiological limit for *Vibrio* spp.** under Regulation (EC) 2073/2005. The regulation itself acknowledges that the scientific evidence did not support specific criteria for *V. vulnificus* and *V. parahaemolyticus* in fish and seafood, and AESAN confirms that Regulation 2073/2005 does not include specific criteria for *Vibrio* spp. in fishery products.

That said, **Spain does apply border control criteria**, especially for *Vibrio cholerae* in imported fishery products, including frozen prawns and shrimp. AESAN states that at border inspection posts a criterion of **zero tolerance: absence in 25 g for *V. cholerae*** is applied, with no distinction between serogroups. This document analyses the current regulatory framework, the critical points for the Spanish market, and INTABIOTECH's technological proposal for risk mitigation.

Applicable Limits and Criteria in Practice

The absence of a harmonised threshold at European level does not mean the absence of operational risk. Each microorganism in the *Vibrio* genus presents a different regulatory and risk profile that the operator must understand precisely before importing or marketing Ecuadorian shrimp in Spain.

Microorganism	EU Harmonised	Spain / Border / Practical Criterion	Practical Interpretation
Vibrio spp. total	No harmonised EU limit	No general limit as "total *Vibrio*"	It is not enough to say "Vibrio spp."; the species and pathogenicity must be specified.
V. cholerae	No criterion in 2073/2005	Absence in 25 g; AESAN records zero tolerance without distinguishing serogroups.	For Ecuadorian shrimp, this is the most sensitive point. A detection can block or reject the batch.
V. cholerae O1/O139 or ctx+	No specific EU criterion; considered high risk	AESAN 2024 recommends absence in 25 g for O1/O139 and strains carrying ctx.	Absence and serogroup/ctx gene characterisation should be required.
V. cholerae non-O1/non-O139 ctx−	No harmonised EU criterion	AESAN 2024 notes that the overall risk is low; in enhanced controls, any detection may be declared non-compliant.	Legally, it may trigger non-compliance, an alert or detention.
V. parahaemolyticus	No harmonised limit in 2073/2005	AESAN 2010: ≤10^2 cfu/g, plan n=5, c=0, m=M=10^2 cfu/g for border controls.	Prudent specification: <100 cfu/g and absence of tdh/trh positive strains.
V. vulnificus	No harmonised EU limit	AESAN 2010 recommends monitoring in risk areas; in RTE, require absence as a preventive criterion.	Advisable in cooked product, peeled product or product destined for demanding retail.

⚠ The absence of a harmonised numerical limit does not equate to the absence of operational risk. In the context of Spanish border controls, any detection of *V. cholerae* can lead to detention, RASFF alert and rejection of the batch.

Pivotal Point: Ecuador and the Real Operational Risk

⚠ BORDER RISK

There is no distinct «special Ecuador limit» different from that applicable to third countries, but **Ecuador appears repeatedly in RASFF notifications for *Vibrio cholerae* in shrimp and langoustine**. Notifications were recorded in 2022, 2023, 2024, 2025 and 2026 relating to *shrimps/prawns from Ecuador*, placing this origin at the centre of official import controls in the EU and, in particular, in Spain.

Therefore, although EU rules do not set a harmonised number for *Vibrio*, the real operational risk at the border is **high if *V. cholerae* is detected**, even in frozen product. AESAN reminds us that freezing may reduce the pathogen, but does not guarantee its elimination.

Frozen raw shrimp

Cooking at **70 °C for 2 minutes** at the core of the product guarantees the elimination of *V. cholerae*. Without a prior kill step, the surface risk persists up to the final consumer.

Cooked ready-to-eat product

The main risk is not residual pathogen presence, but **post-cooking recontamination**. Good hygiene practices and proper HACCP implementation are critical.

RASFF history in Ecuador

5 consecutive years (2022–2026) with active notifications for *V. cholerae* in Ecuadorian shrimp/langoustine, increasing the likelihood of reinforced controls at the Spanish border.

Recommendation for Purchase Specification and COA for Ecuadorian Supplier

To import or supply Ecuadorian shrimp to Spain and the EU with sufficient guarantees of control over the risk posed by *Vibrio*, the supplier should be required to meet precise analytical criteria, with species identification, an accredited method, a sampling plan and, where applicable, virulence markers. The minimum recommended specification is set out below.

1

Vibrio cholerae

Absent in 25 g, n=5, c=0, ISO 21872-1 method or equivalent accredited method, with **identification of serogroup O1/O139** and **determination of the ctx gene**. This is the most sensitive criterion for the Spanish market.

2

Vibrio parahaemolyticus

<100 cfu/g, n=5, c=0, and additionally **absence/non-detection of tdh+ / trh+ strains**. Quantification alone, without virulence analysis, is insufficient for a robust export specification.

3

Vibrio vulnificus

Not detected in 25 g, especially if the product is cooked, peeled, ready to eat or intended for a retail customer with exacting requirements. There is no harmonised EU limit, but it is prudent as a preventive commercial specification.

4

Do not accept generic COAs

Reject COAs that only state **“Vibrio spp. negative”** without specifying species, method, analytical unit, sampling plan, quantitative result and, for *V. cholerae* and *V. parahaemolyticus*, documented virulence markers.

ⓘ The purchase specification should be incorporated as a contractual requirement for the supplier and verified through documentary and analytical audit on each shipment, with particular attention during periods of higher risk (warm seasons in Ecuador).

Practical Conclusion: The Criterion That Must Be Documentally Secured

For shrimp from Ecuador destined for Spain and the EU, the critical criterion **is not a harmonised numerical limit for «Vibrio»**, because no such limit exists in Regulation (EC) 2073/2005. What must be documentally secured is the set of operational specifications summarised below, together with the appropriate process intervention strategy.

V. cholerae	*V. parahaemolyticus*	*V. vulnificus*
Absence in 25 g — Spanish border tolerance-zero criterion, with no distinction between serogroups.	Prudent operational maximum: 10^2 cfu/g and absence of tdh/trh-positive toxigenic strains.	Active monitoring and absence as a preventive specification, although no harmonised EU limit has been established.

⊗ Critical INTABIOTECH precision: **it is not technically correct or regulatorily defensible to promise the "elimination of Vibrio" through an added ingredient.** The correct approach is to propose a validatable process intervention, aimed at reducing the *Vibrio* load before freezing/glazing and avoiding recontamination. This distinction is essential in any commercial or technical communication.

Main Product: KNAMAX™ Seafood / KNAMAX™ Vibrio Control

INTABIOTECH TECHNOLOGICAL PROPOSAL

The most defensible option for INTABIOTECH is a specific version of KNAMAX™ for the shrimp and prawn process: an **alkaline technological process aid** for washing waters, immersion, pre-glazing or treatment prior to freezing. The correct positioning is not as a preservative, biocide or antimicrobial additive in the final product, but as:

> ***«Alkaline technological intervention system for the reduction of microbiological load in process waters and shrimp surfaces, with a particular focus on mitigating risk from Vibrio spp., subject to validation by challenge test and analytical verification by batch/process.»***

The technical logic is sound: *Vibrio* is an aquatic microorganism, sensitive to process barriers such as temperature, hygiene, washing, freezing, heat and inactivation technologies. AESAN indicates that washing, icing and freezing can reduce the concentration of *V. cholerae*, although they do not guarantee complete elimination. Heat treatment at **70 °C for 2 minutes at the centre of the product** does guarantee elimination of the pathogen.

Intervention in process waters

Application in washing, immersion and pre-glazing baths to reduce surface load before freezing.

Not a preservative or biocide

Technological aid with no technological function in the finished product and no antimicrobial declaration on the label.

Validation by challenge test

Any log reduction claim must be supported by validated tests and analytical verification by batch and process.

KNAMAX™ Seafood Processing Aid: Application in Raw Frozen Shrimp

APPLICATION 1

Application Specifications

Recommended product: KNAMAX™ Seafood Processing Aid

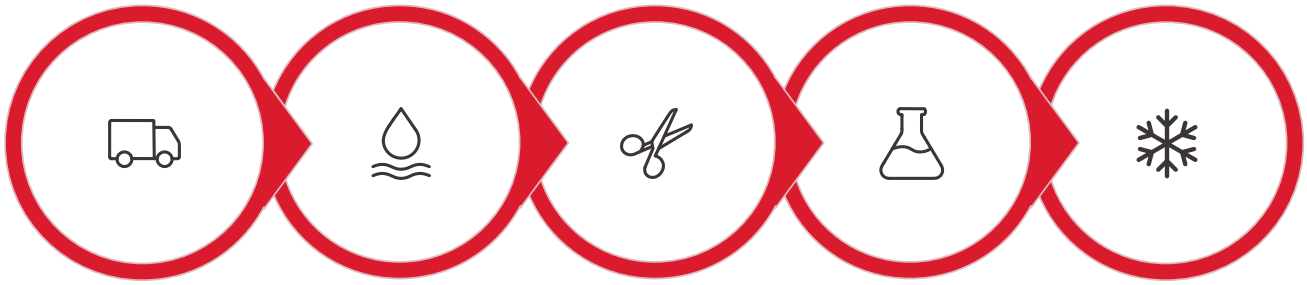
Point of application: Process bath prior to freezing or glazing, after washing, deveining and peeling according to the plant flow.

Technical objective: Reduce the surface load of *Vibrio* spp., especially *V. cholerae*, *V. parahaemolyticus* and *V. vulnificus*, before IQF or block freezing.

Limit of the Commercial Proposition

KNAMAX™ Seafood Processing Aid **is not marketed as an absolute guarantee of absence in 25 g**. The sanitary specification still requires analytical validation at the regulatory boundary and in the operator's self-monitoring.

Spain applies a **absence in 25 g criterion for *V. cholerae*** at border control. AESAN also identifies toxigenic *V. parahaemolyticus* and *V. vulnificus* as relevant in official controls. Treatment with KNAMAX™ is an additional process barrier, not the only control within HACCP.



The diagram illustrates the optimal insertion point of KNAMAX™ Seafood Processing Aid in the raw frozen shrimp process chain, as a controlled alkaline intervention immediately before rapid freezing.

KNAMAX™ + EcoBind™ Shrimp: Cooked Frozen and Ready-to-Eat Shrimp

APPLICATION 2

In cooked frozen shrimp and ready-to-eat products, the focus changes significantly. The true **«kill step»** must be cooking. KNAMAX™ would make sense before cooking or in process auxiliary waters, but the main risk in cooked shrimp is **post-process recontamination**. AESAN explicitly indicates that, in cooked ready-to-eat prawns, the risk is associated with contamination after cooking, so hygiene good practices and HACCP are critical.

KNAMAX™ Seafood Hygiene Processing Aid

Applied in process waters, **not as a final preservative**. Alkaline intervention in pre-cooking stages and in auxiliary process waters in the cooked area.

Process Hygiene Programme

Control of water, glazing, surfaces, operators, temperature and **strict raw/cooked segregation** as an indispensable complement to treatment with KNAMAX™.

EcoBind™ Shrimp

Carbonate/bicarbonate/salt-type blend for **hydration, texture, yield, water retention and ionic stability**. It is not presented as the main anti-*Vibrio* solution, but as a complementary functional barrier.

Combined commercial proposal: «KNAMAX™ + EcoBind™ Shrimp Program: Safety, Yield & Texture System for Export Shrimp.» KNAMAX™ = microbiological process barrier. EcoBind™ Shrimp = functional barrier for hydration, texture and yield.

Pilot Protocol
Phase 1: Problem Diagnosis

PILOT PROTOCOL | PHASE 1 OF 2

Before commercialising the product or launching a plant trial, it is essential to carry out a rigorous diagnosis of the actual microbiological problem at the Ecuadorian customer's or supplier's facility. Without this diagnosis, any technological intervention lacks a technical basis and a solid commercial rationale.

The aim of the diagnosis is to determine whether the problem originates in the aquaculture environment, in the plant water, in handling, in insufficient cooking, or in post-process recontamination. This distinction completely determines the intervention strategy with KNAMAX™.

Species identification

V. cholerae, *V. parahaemolyticus*, *V. vulnificus*. For *V. cholerae*: O1/O139 serogroup and determination of the **ctx gene**. For *V. parahaemolyticus*: determination of the **tdh/trh genes**.

Product type

Complete characterisation: raw, cooked, peeled, whole, IQF, block, glazed. Each type implies a different matrix and a different intervention strategy.

Detection point

Process water, equipment surfaces, final product, border control, internal self-monitoring, RASFF notification, or customer complaint. Identify the point of failure in the process.

Source of contamination

Determine whether contamination is of aquaculture origin (culture water), due to handling in the plant, from uncontrolled process water, or from post-cooking recontamination. Each source requires a different response.

Pilot Protocol
Phase 2: Intervention with KNAMAX™

PILOT PROTOCOL | PHASE 2 OF 2

Once the problem has been diagnosed, the plant trial is carried out under three controlled conditions. The experimental design makes it possible to compare the current process against two levels of alkaline intervention with KNAMAX™, while simultaneously measuring microbiological efficacy and sensory and technological impact on the product.

Trial	Treatment	Objective
Control	Current process without modification	Measure the true starting load as a baseline
KNAMAX™ low	Mild alkaline bath (pH ~10.5–11.0)	Reduction in load without appreciable sensory impact
KNAMAX™ high	Intensified alkaline bath (pH ~11.0–11.8)	Maximum reduction compatible with product quality

Process Parameters to Measure

- Bath pH and final pH of the shrimp
- Bath temperature (ideally 0–4 °C)
- Contact time (indicative range: 1–5 minutes)
- Water renewal and organic load of the bath
- Conductivity and residual sodium/potassium

Quality and Microbiology Parameters

- Texture, colour, odour, exudate, glazing and yield
- *Vibrio* spp. count before and after treatment
- Aerobic mesophiles, enterobacteria and psychrotrophs as auxiliary indicators

⚠ **Regulatory argument / precaution:** In fishery products, the use of substances to eliminate surface contamination is not unrestricted. The regulatory defence of KNAMAX™ must be based on: (1) a technological processing aid, not a final preservative additive; (2) no residual technological function in the finished product; (3) no direct antimicrobial declaration on the label; (4) validation of the absence of residual effect; (5) control of pH, sodium, potassium and residues; (6) prior consultation with the local regulatory authority where applicable. Working at pH 13–14 in shrimp is not recommended unless the trial is very tightly controlled, given the risk of soapy texture, protein modification and regulatory issues.

Commercial Proposal: KNAMAX™ Seafood Vibrio Control Program

> ***«Technological solution for imported shrimp/prawn from risk areas, aimed at reducing the load of Vibrio spp. through controlled alkaline treatment in process water, integrated into HACCP, validated by challenge test and analytical verification in accordance with EU/Spain border criteria.»***

1. KNAMAX™ Seafood

Alkaline process intervention for washing, immersion and pre-glazing. Validatable reduction of surface load of *Vibrio* spp. before freezing.

2. EcoBind™ Shrimp

Functional system for hydration, texture and yield. Not sold as the main antimicrobial, but as a technological barrier for product quality.

3. INTABIOTECH Analytical Plan

V. cholerae absence/25 g, O1/O139, ctx; *V. parahaemolyticus* tdh/trh; *V. vulnificus*; counts of auxiliary microbiological indicators.

4. Documentary Validation

Report on log reduction, sensory impact, residues, final pH, stability in freezing and compatibility with EU requirements. Full support for importer and authority.

Conclusion: INTABIOTECH's Proposal

The best commercial and technical proposal from INTABIOTECH combines **KNAMAX™ Seafood** as a process technological aid for the validated reduction of *Vibrio* in shrimp, with **EcoBind™ Shrimp** when the aim is also to optimise yield, hydration and texture of the final product for export. This combination offers an integrated value proposition oriented towards the EU/Spain market.

Correct formulation

«Validated reduction of *Vibrio* risk in process» through controlled alkaline intervention, integrated into HACCP and supported by analytical validation through challenge test.

Incorrect formulation

«Eliminates *Vibrio* and guarantees legal absence in all batches» — this statement is technically inaccurate, not defensible from a regulatory standpoint, and exposes INTABIOTECH to commercial and legal liability.

The distinction between these two formulations is the core of the entire technical and commercial communication strategy for KNAMAX™ Seafood. Every sales argument, technical data sheet, validation protocol and COA must align with the correct formulation to maintain regulatory credibility and the import customer's trust.

3

Vibrio species covered

V. cholerae, *V. parahaemolyticus* and *V. vulnificus*

5

Years of RASFF alerts

Consecutive notifications 2022–2026 for Ecuadorian shrimp

25g

ES border criterion

Absence in 25 g for *V. cholerae*, zero tolerance at the Spanish border control

70°C

Thermal kill step

2 minutes at the centre of the product for guaranteed elimination of *V. cholerae*

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