marmade

marine biomass valorization for food and feed innovation

WP1 - Sourcing of biomass from circular processes and sustainable cultivation

D1.2 - Regulatory Review – EU and National Regulations for Marine Biomass Harvesting and Applications (Food & Feed)

Project 101213231 - MARMADE - HORIZON-JU-CBE-2024-RIA-05

Circular Bio-based Europe Joint Undertaking

The project is supported by the Circular Bio-based Europe Joint Undertaking and its members. Funded by the European Union under grant agreement No101213231. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or CBE JU. Neither the European Union nor the CBE JU can be held responsible for them.

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DOCUMENT INFORMATION

Grant Agreement Number	101213231
Project Full Title	MARine bioMass valorisAtion for fooD and fEed innovation
Project Acronym	MARMADE
Horizon Europe Call & Topic	HORIZON-JU-CBE-2024-RIA-05
Type of action	HORIZON JU Research and Innovation Actions
Start Date	1 September 2025
Duration	48 months
EU project officer	Simone Maccaferri
Deliverable number & title	D1.2: Regulatory Review – EU and National Regulations for Marine Biomass (Food & Feed)
Work package number & title	WP1: Sourcing of biomass from circular processes and sustainable cultivation
Dissemination level	Public
Contractual delivery date	31 August 2026
Actual delivery date	30 September 2026
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Reviewer(s)	Serena Gabrielli, UNICAM

DOCUMENT HISTORY

Version	Issue Date	Stage	Changes	Contributor
0.1	01 August 2026	Draft 1	New document	All authors
0.2	15 September 2026	Draft 2	New document	All authors
0.3	17 September 2026	Draft 3	New document	CdC – Biochica
0.4	25 September 2026	Final draft for review	New document	FMcO - Algae Scope
1.0	29 September 2026	Final version	Final review & Submission	All authors

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LIST OF ACRONYMS

Acronym	Description
ABP	Animal By-Product
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AESAN	Agencia Española de Seguridad Alimentaria y Nutrición (Spanish Food Safety and Nutrition Agency)
ATP	Agreement on the International Carriage of Perishable Foodstuffs
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (German Federal Office of Consumer Protection and Food Safety)
CFP	Common Fisheries Policy
CMR	Convention on the Contract for the International Carriage of Goods by Road
COS	Chito-oligosaccharides
CRPMEM	Comités Régionaux des Pêches Maritimes et des Élevages Marins (French regional sea-fisheries and marine-aquaculture committees)
DAFM	Department of Agriculture, Food and the Marine (Ireland)
DDCSPP	Direction Départementale de la Cohésion Sociale et de la Protection des Populations (France)
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DES / NADES	(Natural) Deep Eutectic Solvent(s)
DGAL	Direction Générale de l'Alimentation (France)
DGRM	Direcção-Geral de Recursos Naturais, Segurança e Serviços Marítimos (Portugal)
EEA	European Economic Area
EFSA	European Food Safety Authority
EIA	Environmental Impact Assessment
EU	European Union

Acronym	Description
FBO	Food Business Operator
FSA	Food Standards Agency (UK)
FSAI	Food Safety Authority of Ireland
GDPR	General Data Protection Regulation
HACCP	Hazard Analysis and Critical Control Points
HOSO	Head-On, Shell-On
IAS	Invasive Alien Species
ICNF	Instituto da Conservação da Natureza e das Florestas (Portugal)
MARMADE	MARine bioMass valorisAtion for fooD and fEed innovation (the project)
MMO	Marine Management Organisation (England and Wales)
NVWA	Netherlands Food and Consumer Product Safety Authority
ONSSA	Office National de Sécurité Sanitaire des produits Alimentaires (Morocco)
RGSEAA	Registro General Sanitario de Empresas Alimentarias y Alimentos (Spain)
TRACES	Trade Control and Expert System
VC1 / VC2	Value Chain 1 (Crustacean residues) / Value Chain 2 (Macroalgae biomass)
WP1–WP8	Work Package 1–8

EXECUTIVE SUMMARY

The increasing strain on the planet's limited biomass resources is severe. Agricultural land has been depleted by the overuse of chemical fertiliser, and pesticide pollution and micropollutants in the food system are a significant and growing concern, making new sources of biomass essential to help feed the planet. MARMADE addresses this challenge by pioneering new circular value chains for the future of food and feed ingredients. The project will convert locally sourced European marine biomass, including crustacean residues and macroalgae, into high-value ingredients, such as vitamins, peptides, oligosaccharides, prebiotics, postbiotics, fats, emulsifiers, and digestibility enhancers.

The MARMADE project distinguishes two principal value chains (VCs):

VC1 – Crustacean residues

VC2 – Seaweed (macroalgae)

The regulatory landscape for these crustacean residues, and macroalgae biomass in Europe is complex and fragmented. There is no single EU framework dedicated to their regulation. Instead, operators must navigate a matrix of EU-level regulations (food safety, novel food, animal feed, environmental protection) alongside diverse national and regional permitting systems. Key barriers identified by suppliers include: uncertainty around Novel Food authorisation for new species; lack of harmonised production standards; and specific restrictions on invasive species that limit commercialisation potential.

This deliverable maps the applicable EU and national regulatory frameworks for both value chains, country by country and species by species, and translates these findings into a set of key compliance recommendations to guide sourcing decisions across the MARMADE consortium.

This report is delivered under Work Package 1 (WP1): Sourcing of biomass from circular processes and sustainable cultivation, which pursues four core objectives: to ensure sustainable sourcing of crustacean residues and seaweed for downstream processing; to assess the effects of storage and handling on biomass quality and yield; to address regulatory and administrative requirements for biomass sourcing; and to establish reliable and stable biomass supply chains through Month 30.

In this Deliverable 1.2 Regulatory Review, the MARMADE project seeks to close the loop between the fragmented data on marine biomass, and to promote the circularity in the European blue bioeconomy. By securing sustainable, compliant and stable biomass supply chains, the project builds the foundation on which new marine-derived ingredients can reach the market.

1. Introduction and objectives

The different technical work packages of the project focus on advanced biorefineries for the sustainable processing of marine biomass (WP2), the validation of food and feed ingredient building blocks in targeted market applications (WP3), and the assessment of quality, safety, nutritional and health aspects of the resulting applications (WP4). Environmental and socio-economic assessments, stakeholder engagement, and consumer acceptance are addressed in WPs 5 and 6.

At the basis of the project is WP1: Sourcing of biomass from circular processes and sustainable cultivation, of which the current deliverable represents the second output, following Deliverable 1.1, "Mapping of Available Marine Biomass". The objective of WP1 is to identify, evaluate and support the sustainable sourcing of biomass for the other work packages, in particular WP2. This includes the assessment of biomass availability, geographic distribution, seasonality, storage conditions and implications for composition and extraction yields. This deliverable, D1.2, builds on that work with a preliminary identification of the relevant regulatory and administrative aspects of the selected biomass sources, including safety concerns, aquaculture by-products, genetic resource regulations and residual biomass from invasive species.

D1.2 pursues three specific objectives: to map the EU-level and national regulatory frameworks applicable to each value chain and priority sourcing country identified in D1.1; to identify species-specific and cross-border compliance requirements, including Novel Food, animal by-product and invasive species provisions; and to translate these findings into operational compliance recommendations for WP2 and WP4.

1.2. Biomass value chains and species selection

The MARMADE project distinguishes two principal value chains (VCs):

VC1 – Crustacean residues
VC2 – Seaweed (macroalgae)

1.2.1. VC1: Crustacean residues

VC1 focuses on crustacean residues generated by seafood processing activities, with particular attention to shrimp, Norway lobster and other commercially relevant crustaceans. These residues include heads, shells, tails, legs and other exoskeleton-rich by-products that may become available during peeling, heading, cooking, brining, freezing, repacking or further processing. For MARMADE, this

biomass is relevant because it can support circular biorefinery routes for the production of high-value food and feed ingredients.

VC1 also includes emerging biomass streams from invasive or underused crustacean species. A relevant example is the Atlantic blue crab (Callinectes sapidus), an invasive species native to the western Atlantic that is increasingly affecting European Atlantic and Mediterranean coastal ecosystems, with particular concern for lagoon and shellfish-farming areas (Mancinelli et al., 2017; Tiralongo et al., 2025). This document assesses the regulatory framework applicable to this species for food and feed use.

1.2.2. VC2: Seaweed (macroalgae)

This value chain involves three groups of biomass resources, all sourced within Europe. First of all, there are various green, brown, and red seaweeds from harvesting and from the emerging seaweed cultivation sector. Secondly, green algal blooms, in particular Ulva spp. in connection with intensive finfish aquaculture, that can be considered an aquaculture by-product. And, finally, residues from beach cleaning activities involving the invasive brown alga Rugulopteryx okamurae. This is also an invasive species native to the temperate areas of the Northwest Pacific Ocean. It was first observed in the Mediterranean in 2002 and has been progressively expanding both to the East and to the West, even into the Northeast Atlantic, currently causing significant problems on Mediterranean and Atlantic beaches in Spain, Portugal and France and threatening local biodiversity (Díaz-Tapia et al., 2025). For the extraction and application of macroalgae later in the project, it was decided to focus on a selected number of six species, allowing for an in-depth analysis of compounds and conservation and extraction methods, rather than a more superficial, prospective analysis of many species.

1. **Brown algae:** *Alaria esculenta* (commercial supplier) and *Rugulopteryx okamurae* (invasive, collected by project partner)
2. **Red algae:** *Gracilaria gracilis* and *Palmaria palmata* (both commercial suppliers)
3. **Green algae:** *Codium spp.* (commercial supplier or CTAQUA cultivation) and *Ulva ohnoi* (aquaculture-associated, collected by CTAQUA)

However, for D1.2, the scope was broadened to cover European seaweed regulation more widely, to provide a comprehensive approach that can be used across industrial applications.

2. METHODOLOGY

This report is principally a desk-based study, reviewing published EU and national legislation, regulatory guidance, official technical documents, and recent regulatory developments of relevant sourcing, handling and movement of marine biomass intended for food and feed value chains. The regulatory assessment considers the two MARMADE value chains separately where their legal entry points differ, while maintaining a common analytical framework to allow comparison and integration across the project.

The desk study covers principal regulatory domains relevant to MARMADE Project: (1) Food safety and hygiene; (2) legal status and management of biomass residues and animal by-products (2) Novel Food requirements; (3) Animal feed legislation; (4) Fisheries); (4) Environmental and harvest permitting; (6) invasive alien species provisions; (7) transportation and cross-border movement, (8) and, where applicable, access and benefit-sharing requirements associated with genetic resources.

For transportation, EU ADR/CMR frameworks apply to dry and frozen biomass, with additional national requirements for perishable goods. Then moving on to the national regulatory framework, and species-specific regulations analysis. Followed by the transportation and cross border supply chain analysis and showing some key compliance and recommendations from the MARMADE Project.

Particular attention is given to the distinction between biomass retained within the food chain, animal by-products not intended for human consumption, production residues that may qualify as non-waste by-products, and materials that fall under waste legislation. This distinction is especially relevant to Value Chain 1 (VC1), while cultivation, harvesting and species-specific environmental permissions have greater relevance to Value Chain 2 (VC2).

The regulatory review combines EU-level legislation with national implementation and administrative requirements in the countries identified as relevant sourcing, landing, processing or trade nodes. EU Regulations that are directly applicable across Member States are therefore distinguished from national rules governing competent authorities, permits, registration procedures, fisheries management, waste/by-product qualification and other administrative requirements.

The desk-based review is complemented by information gathered through WP1 supplier mapping, stakeholder contacts and representative interviews conducted across the target supply countries. These interactions are used to validate the regulatory analysis against operational practice and to identify practical compliance

issues, permitting routes, documentation requirements and potential regulatory bottlenecks encountered by operators.

The methodological approach is directly linked to D1.1 - Map of marine biomass sources and hotspots. The D1.1 established the geographic distribution, species composition and value-chain structure of the marine biomass streams considered by MARMADE Project. The present deliverable uses these results as the starting point for identifying the jurisdictions and regulatory pathways that are most relevant to realistic biomass sourcing.

The report proceeds from the EU level regulatory framework to national and species-specific requirements, following the two value chains from biomass sourcing to cross border movement and their interface with downstream food and feed applications. Section 3 presents the EU-level regulatory framework; Section 4 examines national and regional requirements in the priority sourcing and processing countries identified through D1.1; Section 5 addresses species and value chain specific considerations; Section 6 reviews transportation and cross-border movement; and the final sections (Section 7 and the Conclusion) consolidate the findings into compliance matrices, identify key regulatory gaps and implementation challenges, and provide operational recommendations for the project.

These final sections also highlight regulatory aspects that may influence subsequent technical choices in WP2 and the safety, quality and regulatory assessment activities in WP4, including the compatibility of extraction processes and processing aids with food and feed requirements, as well as the availability, or absence, of harmonised analytical standards and quality specifications for selected chemical building blocks.

These issues are not addressed in detail within D1.2 but are flagged as relevant regulatory checkpoints to guide the development and validation activities undertaken in WP2 and WP4.

2.1. Methodology for VC1: Crustacean residues

For VC1 in particular, regulatory relevance is assessed according to the *location at which crustacean biomass is physically processed and residues are generated*, rather than according to trade volumes alone. D1.1 distinguishes between fishing and production areas, landing sites, import gateways, processing hotspots, redistribution hubs and outsourced peeling locations. This distinction is maintained in D1.2 because the applicable regulatory obligations may differ substantially according to where and how the crustacean material leaves, or remains within, the food chain.

The regulatory assessment for VC1 follows the crustacean biomass flows and residue-generation hotspots identified in D1.1. VC1 includes residues from shrimp, Norway lobster, blue crab and other crustaceans generated during operations such as heading, peeling, cooking, brining, freezing, repacking and further seafood processing. The assessment therefore focuses on exoskeleton-rich fractions including shells, heads, tails, legs and related processing residues potentially suitable for subsequent valorisation.

Unlike conventional biomass assessments based primarily on capture or trade statistics, the VC1 methodology adopts a residue-generation approach. For each relevant stream, the analysis first identifies where physical transformation occurs and then determines the regulatory status of the resulting material like by-products or waste or other classifications. This is necessary because a high-volume import country does not necessarily represent a high-availability residue hotspot when crustaceans arrive already peeled or processed. Conversely, processing or outsourced-peeling locations, (i.e. Morocco for several EU countries) may generate significant shell biomass even when they are not major production or landing countries.

The CV1-Crustacean chain assessment is therefore structured around following sequential questions:

Assessment step	Methodological question	Regulatory purpose
1. Biomass origin and species	Which crustacean species and production system generate the biomass?	Identify fisheries, aquaculture, invasive-species and import requirements
2. Processing and residue-generation point	Where are shells, heads or other fractions physically separated?	Identify the competent jurisdiction and the relevant hotspot from D1.1
3. Intended use and legal status	Does the material remain within the human food chain, become an animal by-product, qualify as a production by-product, or become waste?	Determine the applicable regulatory regime
4. Movement and destination	Is the material transported nationally, within the EU/EEA or from a third country?	Identify traceability, health, transport, import and border requirements
5. MARMADE downstream interface	Is the biomass intended for food, feed or another valorisation pathway?	Identify regulatory constraints that must be considered before WP2 processing and subsequent WP4 safety/regulatory assessment

Legal status screening

A core component of the VC1 methodology is the legal-status screening of crustacean residues "*at the point at which they are generated*".

Materials that are maintained as food or food ingredients are assessed principally under the EU food-law framework, including Regulation (EC) No 178/2002, Regulation (EC) No 852/2004 and, for foods of animal origin, Regulation (EC) No 853/2004 (European Commission, 2004). The last one remains in force and establishes specific hygiene requirements for food of animal origin, therefore the crustacean residues.

Where crustacean material is no longer intended for human consumption, the assessment considers the "Animal By-Products framework" established by Regulation (EC) No 1069/2009 (European Commission, 2009) and its implementing Regulation (EU) No 142/2011 (European Commission, 2011). These rules are relevant to animal-derived materials that have left the human-food chain and establish requirements for their classification, handling, transport, processing and permitted uses.

Where a residue falls outside, or is not governed by, the applicable food or animal-by-product regime, the assessment subsequently considers the "Waste Framework Directive 2008/98/EC (European Commission, 2015)". Particular attention is paid to Article 5, which establishes the conditions under which a substance resulting from a production process may be considered a by-product rather than waste, including certainty of further use (i.e., bioenergy, biofertilisers) , with a direct usability subject to normal industrial practice, integral generation within the production process and lawful subsequent use.

This sequence is used throughout the nationals analysis to avoid treating the terms "*processing residue*", "*animal by-product*", "*by-product and waste*" as interchangeable. In the present Deliverable, the neutral terms "*crustacean processing residues*" and "*exoskeleton-rich residues*" are therefore used, unless a specific legal classification has been established.

Geographic and country selection

The countries considered in the VC1 regulatory review are selected according to their functional relevance within the supply chains mapped in D1.1. Priority is given to jurisdictions where crustaceans are physically transformed and residues are expected to be generated, rather than to countries characterised only by high import or export volumes, especially for no European countries.

The EU country-level analysis therefore distinguishes between:

- EU crustacean processing and residue-generation hotspots;
- fishing and landing areas generating local residue streams;
- EU import and redistribution hubs;
- outsourced processing locations outside the EU;
- third-country origin areas supplying crustaceans to EU processors.

This approach is particularly relevant for the cold-water shrimp supply chains mapped in D1.1.

For example, the *Crangon crangon* chain includes EU fishing and landing activities but significant outsourced peeling in Morocco, whereas *Pandalus borealis* from Greenland, Canada, the Faroe Islands and northern waters may enter the EU through Denmark in processed forms. Warm-water shrimp imports may similarly generate residues either in the exporting country or in European processing destinations depending on whether products enter the EU whole, head-on-shell-on, shell-on or peeled.

Accordingly, national legislation is reviewed in detail only where it materially affects biomass sourcing, processing, residue classification or movement. For EU Member States, directly applicable EU Regulations are complemented by national provisions governing competent authorities, implementation procedures and areas in which EU law allows or requires national measures.

Third-country legislation is considered more selectively, with emphasis on the regulatory interface governing the entry of relevant products, animal by-products or derived materials into the EU.

Species-specific screening including invasive species

Species are grouped according to the value-chain structure identified in D1.1 rather than analysed independently where the applicable legislation is identical.

Conventional shrimp processing residues are assessed primarily according to their production mode, processing stage and intended use. Separate attention is given to species for which sourcing itself creates additional regulatory considerations, particularly the invasive Atlantic blue crab, *Callinectes sapidus*, and underused or bycatch associated crab streams such as *Liocarcinus depurator*.

For invasive or management-sensitive species, fisheries and environmental rules are reviewed in parallel with food, feed, by-product and waste legislation.

This enables the regulatory assessment to distinguish between the legality of capturing or removing the organism and the subsequent legality of transporting, processing and valorising the resulting biomass that is particularly relevant for exploitation in chemical building blocks to be used in several sectors, including novel food and nutraceutical.

Cross-border and third-country screening

Cross-border assessment is performed after the legal status of the material has been determined, because the requirements applicable to movement depend on whether the consignment is food, an animal by-product, a derived product, a feed material or waste.

For third-country flows identified in D1.1, the analysis therefore focuses on the EU-entry conditions applicable to the relevant material rather than assuming that EU legislation governs all domestic activities of the exporting country. Where animal-origin products or animal by-products are imported into the Union, the review considers the relevant official-control, certification and border-entry requirements, including (European Commission, 2017), where applicable.

This distinction is particularly important for MARMADE because D1.1 includes non-EU origin and processing nodes that are commercially relevant to European crustacean supply chains (i.e., Morocco) but are not necessarily equivalent to eligible MARMADE feedstock sourcing locations. Feedstock eligibility and sustainability requirements established in the MARMADE Project are therefore considered separately from the broader mapping of international biomass flows.

Interface with downstream MARMADE activities

The purpose of the VC1 methodology is to determine under which legal status and conditions crustacean biomass can be sourced, handled and transferred for MARMADE purposes, like novel food and feed valorisation.

It does not affect the technical optimisation of extraction processes in WP2 or the detailed safety and regulatory assessment of the resulting food and feed ingredients in WP4. Technical and legislative aspects related to the extraction and food and feed formulation processes will be addressed in the respective Work Packages (WP2 and WP4).

However, the intended downstream use is considered from the sourcing stage because the classification and handling history of the starting biomass influence the regulatory feasibility of subsequent food or feed applications.

The regulatory review therefore identifies early compliance checkpoints to be communicated to WP2 and WP4, particularly where the initial status of a crustacean residue, its origin or its handling conditions could constrain the future use of extracted building blocks.

The MARMADE Project explicitly links WP1 biomass sourcing with downstream cascade extraction in WP2 and the assessment of quality, allergenicity, safety and future Novel Food information in WP4.

Accordingly, D1.2 provides the upstream regulatory foundation required to ensure that biomass selected for technical valorisation is compatible, as far as can be determined at the sourcing stage, with the intended food and feed development pathways.

2.2. Methodology for VC2: Seaweed (Macroalgae biomass)

For VC2, regulatory relevance is assessed according to the availability and origin of macroalgae biomass by species across the EU, rather than according to trade volumes alone. D1.1 characterises the macroalgae value chain in terms of wild-harvested and cultivated (aquaculture) sources, landing and production sites, and the actors involved in supply. This distinction is maintained in D1.2 because the applicable regulatory obligations, and the practical availability of biomass, differ substantially according to species, production system and country of origin.

The regulatory assessment for VC2 follows the biomass-availability mapping established in D1.1 and is structured around two sequential phases: biomass mapping and species identification, and regulatory and practice-based verification through direct stakeholder interviews.

In the first phase, publicly available biomass data were extracted from the EU platform EMODnet to identify macroalgae species present and quantifiable at EU level, and this was complemented with market and production data from Phyconomy and Rubisko to cross-check species availability, commercial relevance and production trends. This combined dataset provided the basis for identifying which species are realistically accessible as feedstock within the EU, as opposed to species that are only documented in the literature without an associated supply base.

From this initial mapping, the species pool was narrowed to six species considered most relevant to MARMADE, comprising two brown, two green and two red

macroalgae, selected on the basis that they are currently understudied relative to their availability and valorisation potential. This set of six is not final: a further selection will be made for WP2 (MS1.2, M15), based on circularity, sustainability, legal aspects and biochemical composition criteria. The regulatory deep-dive carried out in the following subsections, covering legal status, geographic and country-level variation, species-specific rules and cross-border/third-country sourcing, is one of the inputs feeding that legal-aspects criterion.

Unlike a desk-based regulatory review alone, the VC2 methodology combines this biomass and species screening with a direct stakeholder-interview approach. Based on the species and countries identified in the mapping phase, more than 20 seaweed suppliers and project owners were contacted and interviewed to understand, in detail, the regulations applicable to their activity and their current operational practice. This is necessary because published national legislation does not always reflect how macroalgae harvesting, cultivation and first processing are regulated and enforced in practice, and because permitting regimes, licensing authorities and species-specific restrictions are frequently fragmented across national, regional and local levels.

The results of the interviews are reported against an introduced categorisation framework and summarised per country in the national regulatory analysis, allowing the regulatory findings to be read consistently across species and jurisdictions.

The VC2-Seaweed chain assessment is structured around the following questions:

Assessment step	Methodological question	Regulatory purpose
1. Biomass availability and species identification	Which macroalgae species are available at EU level, in what quantities, and from which production system (wild harvest or cultivation)?	Establish the EU biomass base using EMODnet, Phyconomy and Rubisko data, and identify the six target species (2 brown, 2 green, 2 red) taken forward for detailed regulatory analysis
2. Origin and production system	Is the biomass wild-harvested, cultivated, or both, and in which country/region?	Identify the applicable harvesting, licensing and aquaculture regulatory regime for each of the six target species
3. Regulatory and practice verification	What regulations apply to harvesting, cultivation and first handling, and how are they applied in practice by	Validate desk-based findings through interviews with 20+ suppliers and project owners

	suppliers and project owners?	
4. National categorisation and reporting	How is the regulatory status and practice reported per country and per species?	Summarise findings under a consistent introduced category, enabling cross-country comparison
5. MARMADE downstream interface	Is the biomass intended for food, feed or another valorisation pathway?	Identify regulatory constraints to be considered before WP2 processing and subsequent WP4 safety/regulatory assessment

Legal status screening, geographic and country-level selection, species-specific screening and cross-border/third-country sourcing are addressed in the subsections below, structured in parallel with the VC1 subsections above. These sections will be finalised once the interview results and national categorisation have been completed with Algae Scope and CTAQUA.

Interface with downstream MARMADE activities

As with VC1, the purpose of the VC2 methodology is to determine under which legal status and conditions macroalgae biomass can be sourced, handled and transferred for MARMADE purposes. It does not affect the technical optimisation of extraction processes in WP2 or the detailed safety and regulatory assessment of resulting food and feed ingredients in WP4; these are addressed in the respective Work Packages. The intended downstream use is nonetheless considered from the sourcing stage, since the species, origin and harvesting/cultivation history of the biomass influence the regulatory feasibility of subsequent food or feed applications, and D1.2 identifies early compliance checkpoints to be communicated to WP2 and WP4 accordingly.

3. Overview of EU-Level Regulatory Frameworks

3.1. Consolidated Regulatory Summary: VC1 and VC2

The table below consolidates the regulations addressed in this section and sets out their applicability to each value chain side by side.

Regulation	Core requirement	Applies to VC1 (Crustaceans)	Applies to VC2 (Seaweed)
Reg. (EC) No 178/2002 – General Food Law	General principles of EU food law: operator responsibility, traceability (Art. 18), withdrawal/recall obligations	Yes. Traceability must preserve species, origin, supplier, processing establishment, stage and batch history for any fraction intended for a food pathway	Yes. FBO registration and one-step-back/one-step-forward traceability required throughout the supply chain
Reg. (EC) No 852/2004 – Hygiene of Foodstuffs	Hygiene requirements from primary production through processing and distribution, including HACCP	Yes. Separation, collection, cooling/freezing, storage and transport of residue fractions must sit inside HACCP procedures if food-destined	Yes. Wild harvesters fall under Annex I; processors need full HACCP systems
Reg. (EC) No 853/2004 – Specific Hygiene Rules for Food of Animal Origin	Specific hygiene rules for products of animal origin, including fishery products (Annex III, Section VIII)	Yes. Applies directly to crustaceans as fishery products	No direct equivalent. Seaweed is not a product of animal origin

Reg. (EC) No 1069/2009 – Animal By-Products	Governs material of animal origin not intended for human consumption; the operator's diversion decision is irreversible (Art. 2)	Yes. Central to VC1: determines whether a shell/head fraction becomes an ABP (typically Category 3) once diverted from food use	Not applicable. Seaweed cannot be an animal by-product
Reg. (EU) No 142/2011 – ABP Implementation	Detailed handling, processing, identification, storage, transport and traceability rules for ABPs	Yes. Applies once a crustacean fraction enters the Category 3 route; establishments must be registered/ approved	Not applicable
Directive 2008/98/EC – Waste Framework Directive (Art. 3, 5, 6)	Defines waste; sets the four-condition test for by-product status (Art. 5) and the end-of-waste test (Art. 6)	Yes. Determines whether a residue is waste, a by-product, or has achieved end-of-waste status; normally sits behind the ABP regime rather than alongside it	Only if seaweed residues are classified as waste; not otherwise addressed in this range

3.1.1 VC1 - Crustaceans

Crustacean residues sit at the intersection of three regimes: food law, animal by-products law, and waste law. Which one applies depends on a decision the operator makes at the point the fraction is generated, not on the species or the country of origin. Once a fraction is diverted from human food use, that decision is irreversible under Regulation (EC) No 1069/2009, so the regulatory pathway (food-grade, ABP Category 3, non-waste by-product, or waste) has to be designed into the supply chain from the sourcing stage, before the material reaches WP2 extraction.

3.1.2 VC2 - Seaweed

Seaweed's regulatory picture is structurally simpler at this stage, because Regulation (EC) No 853/2004, Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011 do not apply at all: there is no animal by-product question to resolve. The live issue

for VC2 is not which legal regime the biomass falls under, but whether the biomass qualifies as food in the first place, which is a Novel Food question addressed in Section 3.3 rather than a food-law/ABP/waste question

3.2. Food Safety & Hygiene

Regulation (EC) No 178/2002, Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004

Food safety and hygiene form the foundational regulatory layer applicable to any marine biomass intended for human consumption or use as a feed ingredient, regardless of species or value chain (see Section 3.1 for the applicable regulations). In practice, the compliance burden differs by value chain: crustacean residue streams typically enter the regulatory framework at the processing stage as a by-product of existing fisheries and aquaculture supply chains already subject to food safety oversight, whereas macroalgae biomass is more frequently sourced via primary wild harvest or dedicated cultivation, placing greater emphasis on Annex I primary production requirements and traceability from point of harvest. The following subsections set out the specific relevance of each regulation to MARMADE's target biomass streams.

3.2.1. VC1 – Crustaceans

Food safety and hygiene constitute the first regulatory layer to be considered where marine biomass, or fractions generated during its processing, are intended to remain within the food chain. For VC1 (Crustacean), this distinction is particularly important because crustacean processing can generate shells, heads, tails, legs and other fractions at different stages of heading, peeling, cooking, freezing, brining and further processing. Depending on their handling and intended destination, these materials may either remain within the food regulatory framework or leave the human food chain and become subject to a different legal regime, as discussed in Section 3.

For this reason, the VC1 assessment does not classify crustacean processing residues solely according to their physical nature. Their intended use, processing history, hygienic status and point at which they are separated from the edible product are considered together, against the food-chain pathway set out in Regulations (EC) No 178/2002, 852/2004 and 853/2004 below. Their applicability is determined primarily by the intended destination of the material at the moment it is generated and collected.

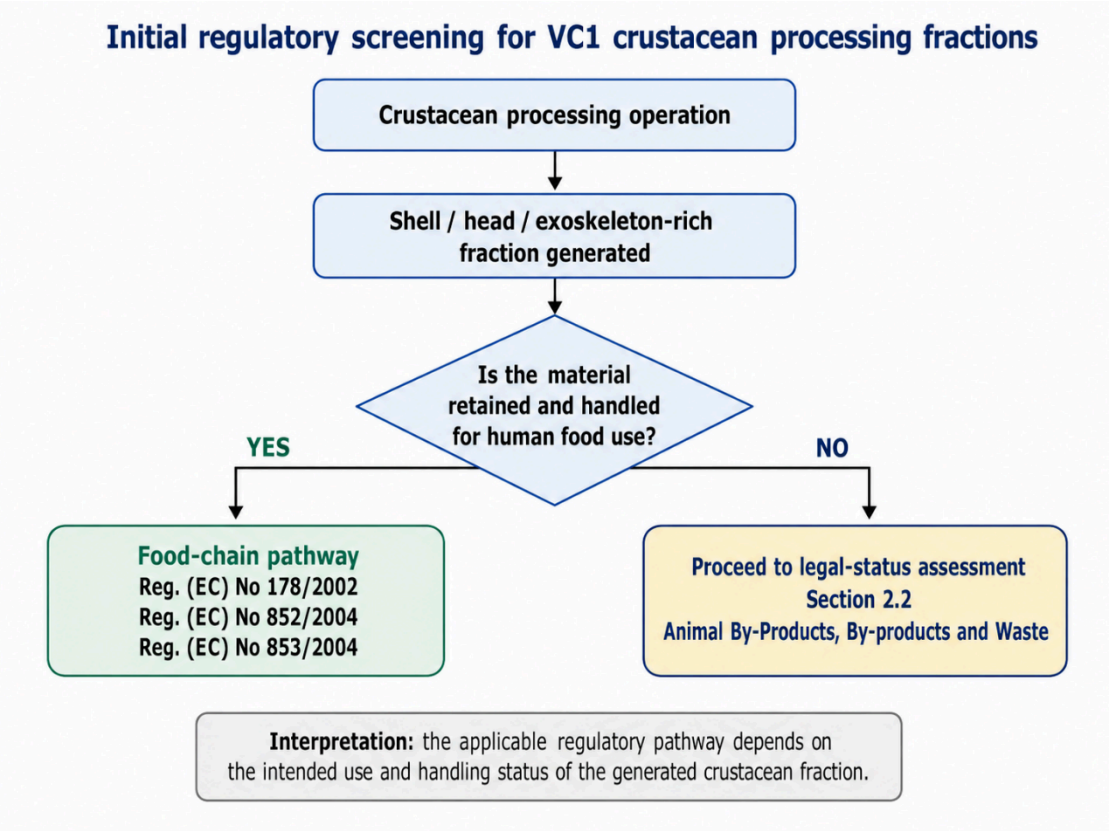


Figure 1: Initial regulatory screening for VC1 crustacean processing fractions

This distinction is essential because the aims to recover high-value building blocks for food and feed applications from crustacean biomass. The project activities explicitly foresees extraction of chitin/chitosan, peptides, lipids, astaxanthin and mineral fractions from shrimp shells and blue-crab residues, with subsequent safety and regulatory assessment in WP4.

Maintaining information on the original regulatory and hygienic status of the starting biomass is therefore an important upstream prerequisite for evaluating the feasibility of the intended downstream applications foreseen in WP2 and WP4.

Regulation (EC) No 178/2002: General Food Law

Type	**Eu Regulation**
Scope	Food and feed placed on the EU market and food/feed business operators throughout production, processing and distribution

Summary	Establishes the general principles of EU food law, including operator responsibility, food safety requirements, traceability, withdrawal and recall obligations. Article 18 requires traceability throughout production, processing and distribution and requires operators to identify both their suppliers and the businesses to which products have been supplied.
Relevance for VC1	Applies where crustaceans or crustacean derived fractions remain intended for human consumption or are used as starting materials for food ingredients. For MARMADE, traceability should therefore preserve information on species, origin, supplier, processing establishment, processing stage and batch history where the biomass is intended to support a future food pathway. If a processing fraction is deliberately removed from the human food chain, its subsequent status must instead be assessed under the regulatory framework described in Section 3.

(European Parliament, Council of the European Union, 2026)

This Regulation is particularly relevant to MARMADE because the same crustacean species may be used through different supply-chain configurations of potential biorefinery. D1.1 identifies locally landed Mediterranean crustaceans, imported whole or head-on-shell-on shrimp, outsourced peeling chains and invasive or underused crab streams. Consequently, traceability should link the biomass not only to the species and country of origin, but also to the processing node at which the relevant fraction is generated.

Regulation (EC) No 852/2004: Hygiene of Foodstuffs

Type	**Eu Regulation**
Scope	Food business operators throughout production, processing and distribution
Summary	Establishes general hygiene requirements for food businesses. Article 5 requires food business operators carrying out activities after primary production to implement and maintain procedures based on HACCP principles. Article 6 requires establishments to be notified to the competent authority for registration and, where required by EU or national legislation, to be approved.
Relevance for VC1	Relevant to seafood-processing establishments generating crustacean fractions that are retained within a food-grade supply chain. Separation, collection, handling, cooling or freezing, storage and transport of these materials must be incorporated into appropriate hygiene and HACCP procedures where they are intended for food use. A key MARMADE

	consideration is therefore whether the supplier can demonstrate that the biomass has been collected under conditions compatible with its intended downstream food application rather than through a waste-management stream.

(European Parliament, Council of the European Union, 2021)

For VC1, this requirement has a direct operational implication. Two apparently identical batches of shrimp shells may have a different regulatory suitability for downstream food valorisation depending on how they were segregated, handled and stored at the processing establishment.

Consequently, food-grade sourcing cannot be inferred solely from species or chemical composition, the hygienic and documentary history of the biomass is also relevant.

Regulation (EC) No 853/2004: Specific Hygiene Rules for Food of Animal Origin

Type	**Eu Regulation**
Scope	Food business operators handling products of animal origin; specific provisions apply to fishery products
Summary	Supplements Regulation (EC) No 852/2004 with specific hygiene rules for products of animal origin. Its definition of “fishery products” encompasses wild or farmed seawater and freshwater animals, including their edible forms, parts and products, and therefore covers crustaceans intended for human consumption. Annex III, Section VIII establishes specific requirements applicable to fishery products, including handling, storage and temperature-related conditions.
Relevance for VC1	Particularly relevant where shrimp, Norway lobster, crab or their edible fractions are processed within an approved food establishment and material is retained for food use. The sourcing should therefore record whether the residue-generating operation takes place within a food establishment operating under the applicable hygiene framework and whether the collected fraction remains part of the food chain at the point of collection.

(European Parliament, Council of the European Union, 2026)

Regulation (EC) No 853/2004 is particularly important for VC1 because it introduces requirements that do not have a direct equivalent for seaweed (VC2) .

Crustaceans fall within the hygiene framework for foods of animal origin, and their processing may therefore be linked to establishments subject to specific approval and control requirements in addition to the general obligations of Regulation (EC) No 852/2004.

Legal Status of Crustacean Processing Residues: Animal By-Products and Waste

The legal classification of crustacean processing residues is a critical regulatory issue for VC1 because apparently similar materials, such as shells, heads or exoskeleton-rich fractions, may fall under different legal regimes depending on their intended use, residual soft tissue content, handling history and the decision taken by the operator at the point of generation.

It is therefore important to distinguish four different regulatory situations: material that remains within the human food chain; animal by-products not intended for human consumption; production residues that may qualify as non-waste by-products under waste legislation; and materials that have become waste.

This distinction is particularly important because Regulation (EC) No 1069/2009, (European Parliament, Council of the European Union, 2019) provides that, where an operator decides that a product of animal origin or a raw material for the production of products of animal origin is destined for purposes other than human consumption, “that decision is irreversible”.

Consequently, the regulatory status assigned to a crustacean fraction at the processing stage may directly influence its suitability for subsequent food and feed pathways.

Regulation (EC) No 1069/2009: Animal By-Products

Type	**Eu Regulation**
Scope	Animal by-products (ABPs) and derived products not intended for human consumption
Summary	Establishes public and animal-health rules for materials of animal origin that are excluded from, or irreversibly diverted away from, human consumption. Animal by-products are classified into Categories 1, 2 and 3 according to risk.

Relevance for VC1	Crustacean residues generated in seafood-processing establishments may fall within "*Category 3*" where the requirements of "*Article 10"* are fulfilled. The Regulation is particularly relevant to shells, heads, exoskeleton fractions and other aquatic-animal processing residues that are no longer intended for human consumption.

(European Parliament, Council of the European Union, 2019).

For VC1, several provisions of Article 10 are directly relevant to how crustacean residues are categorised, as set out in the table below.

This means that a shell-rich fraction originating from shrimp, Nephrops, blue crab or another crustacean cannot automatically be described merely as "*processing waste*" in the MARMADE Project. Where it has been intentionally removed from the human food chain and falls within *Article 10*, it is first governed as an "*animal by-product"*, generally Category 3, subject to the specific conditions of Regulation (EC) No 1069/2009.

Within the context of the MARMADE Project, the distinction is particularly relevant to the processing hotspots identified in D1.1. In fact, Spain and Italy combine local crustacean landings and seafood processing, while the *Crangon crangon* chain includes outsourced peeling in Morocco and the *Pandalus borealis* chain involves processing and redistribution through northern European hubs.

The regulatory classification must therefore be established at the actual point at which the shell-rich fraction is generated, rather than inferred from the country of capture or import.

Category 3: material and permitted downstream routes

Regulation (EC) No 1069/2009 provides several permitted routes for Category 3 materials, subject to the applicable processing and health conditions.

These include processing for:

- feed,
- pet food,
- organic fertilisers
- soil improvers,
- biogas and composting,

 as well as the manufacture of certain derived products.

Specific provisions also exist for shells and carapaces containing residual soft tissue or flesh.

VC1 Biomass	Indicative Regulatory status under Reg. 1069/2009	Main regulatory implication
Aquatic-animal processing residues from food establishments	Potential Category 3, Art. 10 (j).	ABP rules apply once material is no longer intended for human consumption
Crustacean shells/carapaces with soft tissue or flesh	Category 3, Art. 10 (k) (i), where conditions are met	Handling and using subject to ABP requirements
Aquatic animals or parts without signs of communicable disease	Potential Category 3, Art. 10 (i)	Relevant particularly to whole or partial crab biomass diverted from human consumption
Shells/carapaces with soft tissue and flesh completely removed	Outside the scope of Reg. 1069/2009 under Art. 2 (2)(f)	Waste/by-product or product status must be assessed separately
Material maintained for human-food use	Not treated as ABP merely because it is a processing fraction	Food-law pathway described in Section 3 remains applicable

(European Parliament, Council of the European Union, 2019).

The last distinction is particularly important. Regulation (EC) No 1069/2009 expressly excludes "**shells and carapaces of crustaceans and molluscs from which soft tissues and flesh have been removed from its scope**".

However, this exclusion does not automatically mean that the resulting shell fraction is a "*non-waste by-product*". Once the ABP Regulation no longer applies, the material must be assessed according to its actual intended use and, where relevant, under the Waste Framework Directive.

Regulation (EU) No 142/2011: Implementation of ABPs Framework

Regulation (EU) No 142/2011 implements Regulation (EC) No 1069/2009 and provides more detailed requirements concerning the handling, processing, identification, storage, transport and use of animal by-products and derived products, (European Commission, 2025).

These requirements are relevant where crustacean residues enter the Category 3 route. Regulation (EC) No 1069/2009 already requires animal by-products to be collected, identified and transported without undue delay under conditions preventing risks to public and animal health. Operators must maintain traceability systems

identifying both suppliers and recipients, and relevant establishments must be registered or, depending on the activity, approved by the competent authority.

This has a practical consequence for supply: biomass intended for subsequent valorisation cannot be evaluated only on the basis of chemical composition or extraction yield. Its regulatory chain of custody, establishment status, category, separation from other materials and traceability documentation are also relevant to determining whether that biomass can enter the intended downstream route.

Interface with Directive 2008/98/EC: Waste Framework Directive

Directive 2008/98/EC defines waste as any substance or object which the holder discards, intends to discard or is required to discard. It also establishes an important exclusion for animal by-products covered by the specific EU ABP regime, except for defined waste-management routes such as incineration, landfill, biogas or composting. Furthermore, The Directive still refers textually to the predecessor Regulation (EC) No 1774/2002.

Nevertheless, the Regulation (EC) No 1069/2009 subsequently repealed that Regulation and provides that references to it are to be construed as references to Regulation 1069/2009.

Accordingly, the Waste Framework Directive and the Animal By-Products Regulation should not be applied as “interchangeable classifications”.

Where the crustacean material is an animal by-product governed by Regulation (EC) No 1069/2009, that specific regime normally takes precedence.

Waste law classification becomes particularly relevant where the material falls outside the ABP regime or where the specific destination brings it within the waste-management interface.

Article 5 of Directive 2008/98/EC: By-product rather than waste

Article 5 of the *Waste Framework Directive* establishes the conditions under which a substance or object resulting from a production process may be regarded as a by-product and not as waste.

This status is not automatic, and all four conditions must be satisfied:

Art 5 Condition	Relevance for crustacean residues

Further use is certain	A defined and documented recipient or valorisation route should exist
The material can be used directly without processing other than normal industrial practice	Stabilisation, washing, drying or other operations must be assessed according to whether they constitute normal industrial practice
The material is produced as an integral part of the production process	Shells and heads generated during organised peeling or processing may potentially fulfil this criterion
Further use is lawful and does not lead to adverse environmental or health impacts	The intended food, feed or technical application must comply with all applicable product, health and environmental legislation

Where no EU-wide detailed criteria exist for a particular material, Member States may establish national criteria for determining by-product status, (European Parliament, Council of the European Union, 2024).

This point is particularly relevant to the country level analysis later in this deliverable. While the four core criteria arise from EU law, their practical demonstration and administrative implementation may differ between Member States. This is the reason why countries, such as Italy, must subsequently be analysed separately, including their national rules on demonstrating that a production residue qualifies as a by-product rather than waste.

Status of end-of-waste and by-product

A further distinction is necessary between "**by-product"** and "**end of waste"** status.

A by-product under *Article 5* has never become waste because the conditions for by-product classification are fulfilled from the point of generation.

By contrast, *Article 6* concerns a material that has already become waste and subsequently ceases to be waste after recycling or another recovery operation and once the relevant conditions are fulfilled. Those conditions include the following conditions:

- defined use;
- existence of a market or demand;
- compliance with technical and product requirements;
- absence of overall adverse environmental or human-health impacts.

For a concrete circular bioeconomy and real implementation of biorefinery, this distinction is strategically important. If a crustacean processing fraction is collected from the outset through a controlled, documented valorisation chain and satisfies the applicable legal conditions, a by-product route may be more appropriate than allowing the material to become waste and subsequently attempting to establish end-of-waste status, (Table 1).

Table 1. - Legislative routes as ABP or Waste applied to the crustacean residues (VC1), (Biochica, 2026).

Regulatory Concept	Has the material become a waste	Regulatory basis	MARMADE Implication
Animal by-product (ABP)	Not necessarily; it is a separate animal-health legal category	Reg. 1069/2009	Applies to animal-origin material not intended for human consumption
By-product under waste law	No	Directive 2008/98/EC, Art. 5	Potential route for eligible production residues outside the ABP regime
Waste	yes	Directive 2008/98/EC, Art. 3	Waste management obligations apply
End-of-waste material	Was waste previously	Directive 2008/98/EC, Art. 6	Requires recovery plus fulfilment of end-of-waste conditions

At last, the term "*food waste*" should be used cautiously in relation to VC1.

Therefore, under Directive 2008/98/EC, food waste means food, as defined under Regulation (EC) No 178/2002, that has become waste, (i.e. food waste from restaurant, households, and canteens).

Consequently, the term should not be used as a generic description for all shrimp shells, crab shells, heads or seafood-processing residues.

Depending on their legal and operational history, those materials may instead remain food raw materials, become animal by-products, qualify as non-waste production by-products, or become waste.

For consistency throughout D1.2, the terms "*crustacean processing residues*" and *"exoskeleton-rich fractions*" are therefore preferred as neutral technical descriptions until the applicable legal status has been established.

Regulatory interpretation for crustacean residues (VC1)

For the MARMADE project the destination of the residues is clear, therefore the regulatory assessment should follow the material from the moment at which the fraction is generated and remains under the food legislative route. Otherwise, further valorisations can be considered in relation to the regulatory interpretation, (Fig. 2).

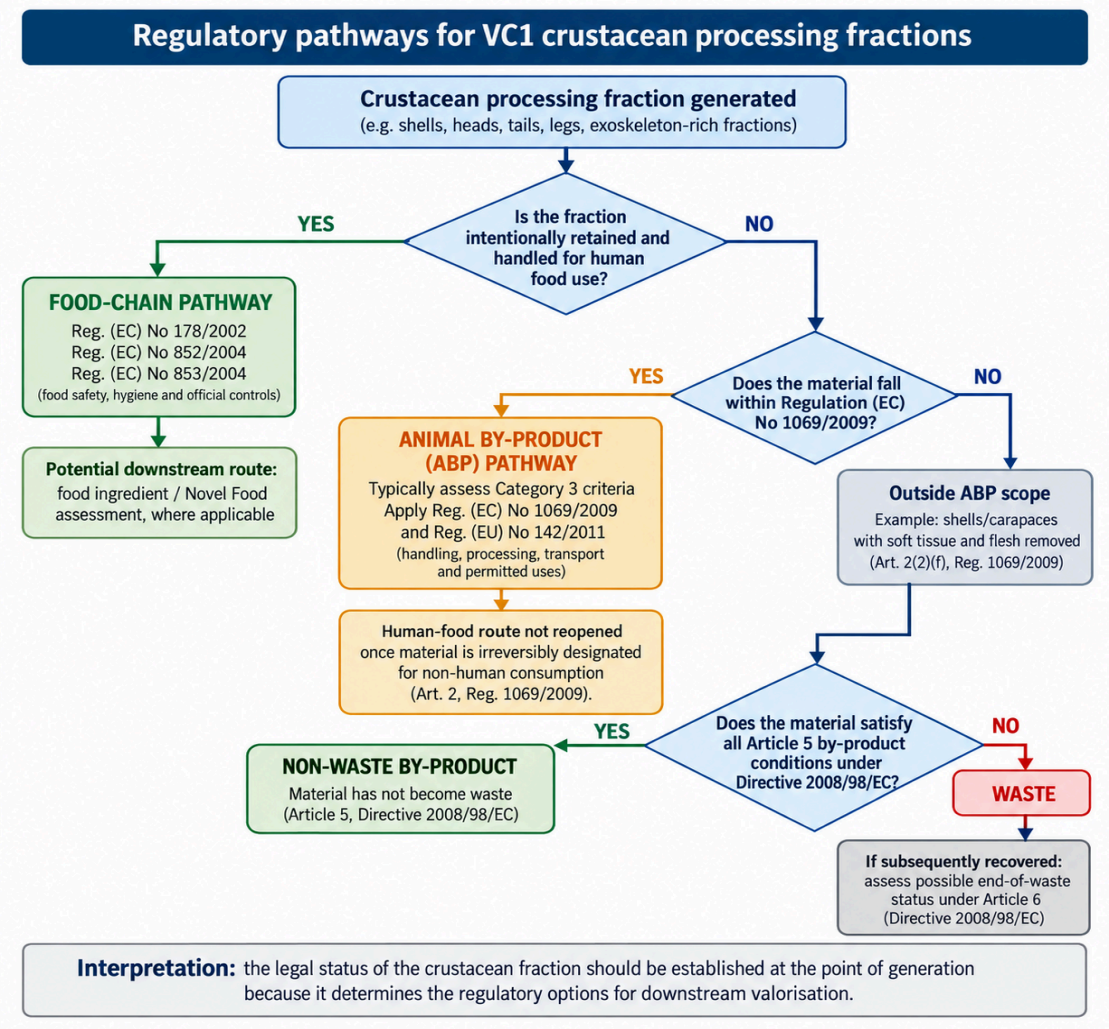


Figure 2. – Regulatory decision pathway for crustacean residues (VC1), (Biochica, 2026).

The most important MARMADE implication is that regulatory status should be defined before biomass collection and before transfer to the *CBBs* extraction processes (i.e. WP2 of MARMADE Project).

In fact, the *article 2 of Regulation 1069/2009* makes the operator's decision to divert an animal origin material away from human consumption irreversible.

Therefore, where a certain *CBBs - Chemical Building Blocks* are ultimately intended for human food use, the upstream supply chain should be designed from the beginning to preserve an appropriate "*food law pathway*", rather than assuming that an ABP or waste stream can later be converted back into a food raw material solely through purification processes.

This issue is to subsequently be linked to WP2 activities design and WP4 safety and regulatory validation. Nevertheless, the present deliverable already establishes the regulatory checkpoint at the sourcing stage.

3.2.2. VC2 – Seaweed

As set out in Section 3.1, the animal by-product/waste classification analysis in Section 3.2.1 has no equivalent for macroalgae biomass. This section therefore covers the two horizontal food-law regulations that do apply to seaweed, before the analysis moves to the Novel Food status question addressed in Section 3.3.

Regulation (EC) No 178/2002: General Food Law

Type	EU Regulation
Scope	All food and feed businesses operating within the EU
Summary	Establishes the general principles and requirements of EU food law. Defines food business operator (FBO) responsibilities, traceability obligations, and the precautionary principle. All seaweed intended for food or feed must comply with general food safety requirements: it must not be injurious to health or unfit for human/animal consumption.
Relevance	Mandatory for all seaweed suppliers providing food-grade biomass. Requires FBOs to register with national competent authorities. Traceability one-step-back / one-step-forward must

	be maintained throughout the supply chain. Cited by 4 of 10 survey respondents as a compliance framework they operate under.

Regulation (EC) No 852/2004: Hygiene of Foodstuffs

Type	EU Regulation
Scope	All food business operators; primary production of seaweed included
Summary	Establishes hygiene requirements for food business operators from primary production (harvesting) through processing and distribution. Requires implementation of HACCP (Hazard Analysis and Critical Control Points) procedures at processing stage. Primary production (wild harvest, cultivation) covered by Annex I basic hygiene rules.
Relevance	All food-grade seaweed suppliers must comply. Wild harvesters are subject to Annex I; processors require full HACCP systems. Several operators identified during the mapping exercise reported operating in compliance with Regulation (EC) No 852/2004 and being registered with the relevant competent authorities. Suppliers of food-grade biomass must operate in compliance with the applicable hygiene requirements and establishment registration/approval provisions.

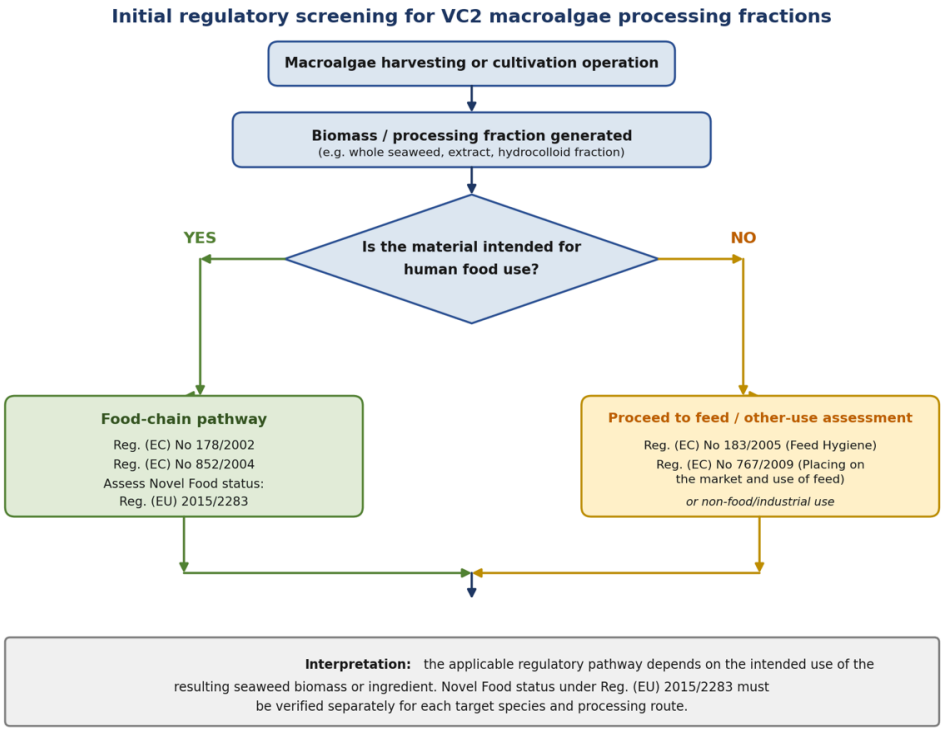


Figure 3. Initial regulatory screening — VC2

3.3. Novel Food Regulation

Regulation (EU) 2015/2283: General framework

Regulation (EU) 2015/2283 establishes the EU framework for foods and food ingredients that were not consumed to a significant degree within the Union before 15 May 1997. Novel Food status must be assessed not only in relation to the biological source, but also with regard to the specific ingredient, production process, composition, specifications and intended use, (European Parliament, Council of the European Union, 2021).

For MARMADE Project, this distinction is particularly relevant because the project is not limited to the direct use of crustaceans residues or seaweeds but aims to obtain purified or concentrated chemical building blocks and functional ingredients through innovative biorefinery processes (i.e.,WP2, WP4). The regulatory assessment must therefore consider the final ingredient and its production route rather than the source species alone.

Type	EU Regulation
Scope	Foods and food ingredients not consumed to a significant degree in the EU before 15 May 1997
Summary	Establishes the authorisation framework for novel foods, including new species of seaweed, extracts, and seaweed-derived ingredients not previously in regular human consumption in the EU. Applicants must submit a safety dossier to EFSA for scientific assessment before market placement. A Union authorisation is required per species/product. The regulation includes a simplified notification procedure for traditional foods from third countries.
Relevance	Critical for several MARMADE target species. Alaria esculenta has established food use history in Ireland (pre-1997); however, several Ulva, Codium, and Gracilaria species may require Novel Food authorisation depending on end use and jurisdiction. Rugulopteryx okamurae has no established EU food use and would require full authorisation before any food application. Several suppliers identified during the mapping exercise operate under Novel Food compliance frameworks. Operators must check the EU Novel Food Catalogue per species (https://food.ec.europa.eu/food-safety/novel-food/novel-food-status-catalogue_en). Novel Food status should be verified for the precise species, plant/algal part, preparation, production process and intended use.

<u>Determination of Novel Food status: Authorisation and Union List</u>

The first step is to determine whether the specific food or ingredient has a documented history of significant consumption in the EU before 15 May 1997. Where this cannot be demonstrated, the food business operator must assess its Novel Food status in accordance with Article 4 of Regulation (EU) 2015/2283 and, where necessary, consult the competent authority, (European Parliament, Council of the European Union, 2021).

The EU Novel Food Status Catalogue may support this preliminary assessment, but it should be considered a screening tool rather than a legal authorisation in itself.

Where a product is considered novel, an authorisation procedure is required before placement on the EU market. The assessment considers the identity of the novel food, production process, composition, specifications, proposed uses and use levels, nutritional information, toxicological and allergenicity data, and other relevant safety information. EFSA may be requested to perform the scientific safety assessment.

Authorised novel foods are included in the Union List established by Commission Implementing Regulation (EU) 2017/2470, which defines the specifications and conditions under which each authorised novel food may be marketed, (European Commission, 2020).

A simplified notification procedure exists for traditional foods from third countries where a documented history of safe food use can be demonstrated. However, this pathway applies to the specific traditional food and cannot automatically be extended to purified extracts or new ingredients produced from that source.

Relevance for MARMADE Value Chains

VC1 - Crustacean residues

For VC1, the regulatory question is not whether shrimp, crab or Norway lobster are themselves conventional foods, but "*whether the specific extracted ingredient obtained from crustacean biomass falls within the scope of the Novel Food Regulation*".

MARMADE may recover several chemical building blocks from crustacean residues, including chitin, chitosan, chito-oligosaccharides, astaxanthin fractions, lipids, proteins, peptides and mineral fractions.

The use of innovative extraction technologies may also be relevant where the production process results in significant changes in composition, structure, nutritional value, metabolism or levels of undesirable substances.

VC2 - Seaweed

For VC2, the same principle applies. Novel Food status should be verified for the specific seaweed species and the specific form in which it is intended to be marketed, including whole biomass, dried material, extracts, purified polysaccharides or other derived fractions.

The existing assessment of *Alaria esculenta*, *Ulva* spp., *Codium* spp., *Gracilaria* spp., *Palmaria palmata* and *Rugulopteryx okamurae* should therefore be retained, but the regulatory analysis should distinguish between documented traditional use of a

species and the status of a concentrated or purified ingredient derived from that species.

In both VC1 and VC2, a documented history of consumption of the original biomass does not automatically establish the non-novel status of every extract or purified fraction obtained from it.

For each resulting ingredient, Novel Food status should therefore be assessed in relation to the several conditions, as follows (Fig. 4).

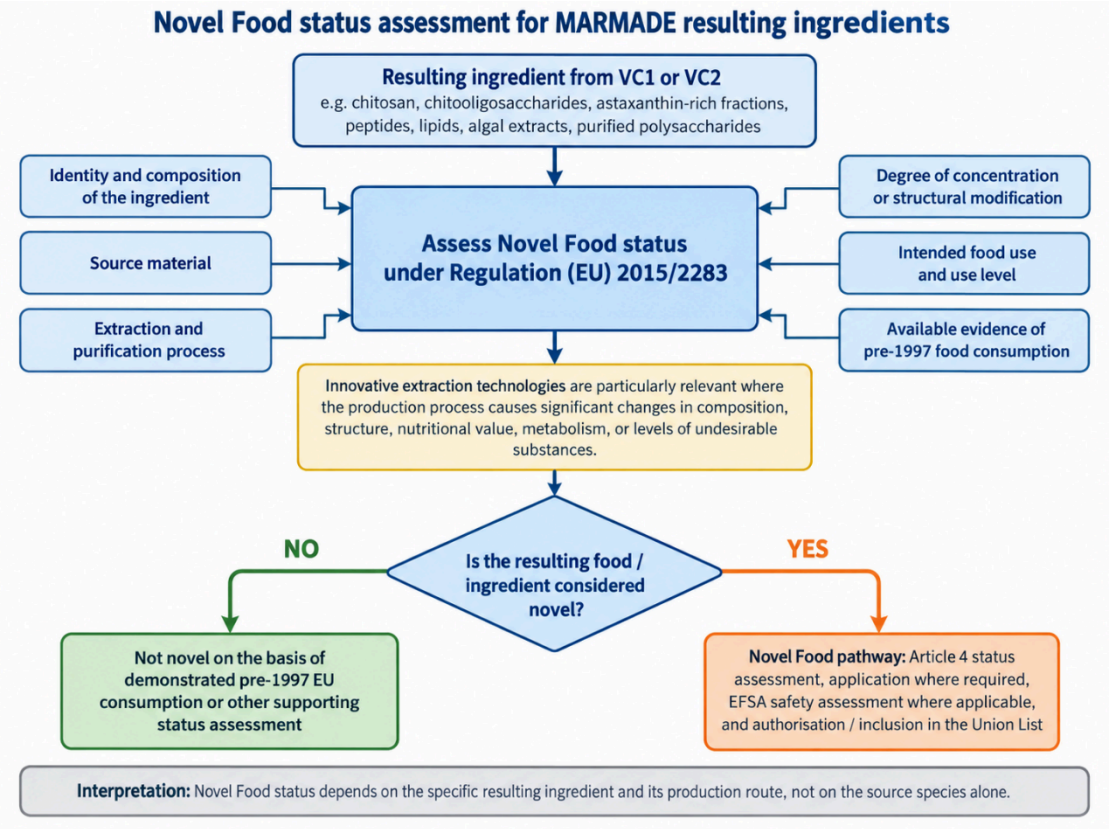


Figure 4. – Novel Food status assessment for biomass considered in MARMADE Project, (Biochica 2026).

Interface with other WPs of MARMADE Projects

The Novel Food assessment identified in D1.2 provides an early regulatory framework for subsequent MARMADE activities but does not replace the detailed regulatory assessment to be undertaken during ingredient development.

In WP2 the choice of extraction, purification and fractionation technologies may influence the regulatory feasibility of the resulting food ingredients, particularly where novel solvents (i.e. DESs), processing aids or highly selective extraction techniques are used.

While in WP4, the resulting ingredients will require detailed assessment of composition, specifications, safety, allergenicity, contaminants and other parameters relevant to possible future food or Novel Food applications.

D1.2 therefore identifies these regulatory checkpoints at an early stage, while the detailed assessment of specific ingredients and production processes will be further developed within the relevant WP2 and WP4 activities, respectively.

3.4. Animal Feed Regulations

Feed applications represent one of the principal downstream valorisation routes considered in the MARMADE Project. The applicable regulatory pathway depends not only on the marine biomass source (VC1, and VC2), but also on whether the resulting product is marketed as a feed material, compound-feed ingredient or feed additive, and in addition to VC1, on the regulatory status of the animal-derived starting material.

The main horizontal requirements for feed hygiene and marketing are established by Regulation (EC) No 183/2005 and Regulation (EC) No 767/2009.

For crustacean-derived materials (VC1), these provisions must be considered together with the *Animal By-Products framework* where the starting material has been diverted from human consumption.

Regulation (EC) No 183/2005: Feed Hygiene

Type	EU Regulation
Scope	Feed business operators throughout the feed chain, from primary production to placing feed on the market, including imports and exports
Summary	Establishes general feed-hygiene requirements, traceability provisions and conditions for registration or approval of feed establishments. Feed business operators carrying out activities beyond primary production are generally required to implement procedures based on HACCP principles.

Relevance	Applies to MARMADE derived materials intended to enter the feed chain. Operators supplying or manufacturing feed ingredients must comply with the applicable hygiene, registration/approval and traceability requirements and source feed from appropriately registered or approved establishments.

Regulation (EC) No 183/2005 aims to ensure feed safety throughout the feed chain and explicitly covers imports and exports of feed. It also establishes registration and approval systems for feed establishments and requires operators to obtain feed only from appropriately registered or approved establishments, (European Parliament, Council of the European Union, 2022).

VC1 – Crustacean-derived feed ingredients

For crustacean derived materials, compliance with Regulation (EC) No 183/2005 is only one part of the regulatory pathway, (European Parliament, Council of the European Union, 2022). Where shells, heads or other fractions have become animal by-products, their eligibility for feed use must first be established under Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, including the applicable Category 3 classification, processing, handling and permitted-use requirements. Feed-hygiene obligations subsequently apply to the resulting material entering the feed chain. Regulation (EC) No 1069/2009 specifically provides permitted utilisation routes for Category 3 materials, subject to the applicable requirements.

VC2 – Macroalgae-derived feed materials

Macroalgae intended for feed applications must similarly comply with Regulation (EC) No 183/2005. For cultivated or harvested seaweed, the relevant feed operators must ensure hygienic production, traceability and appropriate establishment registration where required.

Regulation (EC) No 767/2009: Placing on the Market and Use of Feed

Regulation (EC) No 767/2009 states that the catalogue is non exhaustive and its use by feed business operators is voluntary. If a feed material is placed on the market for the first time and is not included in the catalogue, the operator must notify its use so that it can be entered in the "*Feed Materials Register*"; this is not, by itself, an EU authorisation procedure comparable to "Novel Food authorisation", (European Parliament, Council of the European Union, 2018).

Type	EU Regulation
Scope	Feed materials and compound feed placed on the EU market
Summary	Establishes requirements for the safety, marketing, use and labelling of feed materials and compound feed. It also establishes the EU Catalogue of Feed Materials and the mechanism for notification of feed materials not included in the Catalogue.
Relevance	Relevant to MARMADE ingredients intended to be marketed as feed materials or incorporated into compound feed. The legal status, identity, manufacturing process and labelling of the resulting ingredient must be established before market placement.

VC1 – Crustacean-derived feed ingredients

For crustacean derived proteins, peptides, mineral fractions, chitin/chitosan related products or other recovered components intended as feed materials should therefore be assessed according to their specific identity, manufacturing process and intended feed use.

Where the starting material falls under the ABP framework, compliance with Regulation (EC) No 767/2009 does not replace the preceding requirements of Regulations (EC) No 1069/2009 and (EU) No 142/2011.

VC2 – Macroalgae-derived feed materials

Seaweed biomass and derived fractions should be checked against the current Catalogue of Feed Materials. Where a material is not listed, this does not automatically prohibit its use; the notification requirements established by Article 24(6) of Regulation (EC) No 767/2009 and the applicable safety and labelling requirements must instead be considered, (European Parliament, Council of the European Union, 2009)

<u>Relevance for MARMADE value chains: Feed materials versus feed additives</u>

A final distinction is particularly relevant, where marine-derived CBBs may be regulated as "*feed material*" when primarily supplying nutritional or material value,

whereas a substance deliberately added to perform a specific technological, nutritional, sensory or zootechnical function may fall within the scope on "*feed additives*".

This distinction should be assessed case by case during downstream ingredient development. Regulation (EC) No 1831/2003 specifically includes categories such as technological, nutritional and zootechnical additives, with *digestibility enhancers* expressly recognised as a functional group of zootechnical additives, (European Parliament, Council of the European Union, 2021).

In other words, this means that the regulatory pathway should be defined not solely according to the marine origin, but according to the function and intended use of the resulting ingredient.

3.5. Environmental & Harvest Permits

CFP, Technical Measures, Habitats and Birds Directives, EIA and Aquaculture Permitting

Environmental and harvesting requirements depend strongly on the origin of the marine biomass.

For VC1, the main regulatory issue concerns the lawful and sustainable capture or production of crustaceans before processing residues are generated.

For VC2, the focus is primarily on wild harvesting, cultivation permits and environmental protection of collection or farming areas. National and regional authorisations therefore complement the common EU environmental and fisheries framework.

Regulation (EU) No 1380/2013: EU Common Fisheries Policy (CFP)

Type	EU Regulation
Scope	Conservation of marine biological resources and management of fisheries and fleets exploiting them; also relevant to aquaculture, macroalgae, and the processing and marketing of fisheries and aquaculture products within the CFP framework.
Summary	Establishes the EU framework for environmentally sustainable fisheries and conservation of marine biological resources. It is

	complemented by technical conservation and fisheries-control legislation and by national or regional management measures. Seaweed wild harvesting may fall under national implementations of CFP measures. Member states are responsible for issuing harvest licensees and setting sustainable yield limits.
Relevance	Provides the principal EU framework for the lawful and sustainable origin of wild-caught crustacean biomass used in VC1. For VC2, wild seaweed harvesting is primarily governed through national/regional authorisation systems within the broader EU marine-resource and environmental framework. Wild harvesting of target species (particularly Alaria, Palmaria, Laminaria) requires national harvest licences issued under CFP provisions. In Ireland, France, and Spain, regional/national aquaculture or marine spatial planning permits are typically required. Suppliers cited national aquaculture permits as the primary enabling licence.

The CFP requires fishing activities to be environmentally sustainable in the long term and establishes conservation and management measures for marine biological resources, (European Parliament, Council of the European Union, 2023).

VC1 – Crustaceans

The CFP is particularly relevant to wild-caught Mediterranean shrimps, Nephrops norvegicus and conventional crab fisheries.

Italy, Spain and Greece as important landing and processing areas for these streams and distinguishes them from imported aquaculture-derived shrimp and from emerging invasive/bycatch crab biomass.

The CFP is complemented by Regulation (EU) 2019/1241 on technical measures, which establishes species- and area-specific conservation requirements, including minimum conservation reference sizes and fishing-gear provisions. Relevant species for the project covered by these measures include Parapenaeus longirostris and Nephrops norvegicus.

Traceability of legally sourced fisheries products is further supported by Regulation (EC) No 1224/2009, which requires fisheries and aquaculture products to remain traceable through production, processing and distribution.

VC2 – Seaweed

The existing VC2 analysis should be retained, while clarifying that wild seaweed harvesting permits are primarily issued under national or regional regulatory systems rather than through a specific EU CFP harvesting licence. These systems may establish harvest areas, seasons, quantities and environmental conditions.

Habitats Directive (92/43/EEC) & Birds Directive (2009/147/EC) - Natura 2000

Type	EU Directives and national/regional permitting frameworks
Scope	Activities potentially affecting Natura 2000 sites and projects requiring environmental assessment
Summary	Directive 92/43/EEC requires assessment of plans or projects likely to have significant effects on Natura 2000 sites. Directive 2011/92/EU establishes EIA requirements for specified projects, including potential screening of intensive fish-farming developments. Many European seaweed cultivation and harvest areas are located in or adjacent to Natura 2000 marine protected areas. EIAs may be required under Directive2011/92/EU for new cultivation installations above specified thresholds.
Relevance	Particularly relevant to new seaweed cultivation/harvesting activities and, for VC1, to fishing, removal or aquaculture activities occurring within or potentially affecting protected marine areas. For VC2, cultivation or harvest sites in Natura 2000 areas require formal Appropriate Assessment/EIA. A supplier consulted during the mapping exercise underscored the importance of this for any new Spanish cultivation sites. Irish, Scottish, and French operators cited these requirements as part of their permitting process.

Under Article 6(3) of the Habitats Directive, plans or projects likely to significantly affect a Natura 2000 site must undergo an appropriate assessment in relation to the site's conservation objectives, (European Commission, 2025).

VC1 - Crustaceans

For VC1, Natura 2000 requirements may become relevant where crustacean fishing, aquaculture or targeted removal takes place within or may significantly affect protected marine sites. This is particularly relevant to emerging biomass streams such as Callinectes sapidus and Liocarcinus depurator, whose availability is local, seasonal and dependent on fishing authorisations, control measures and regional management strategies.

Importantly, the subsequent valorisation of residues obtained from an already lawful fishery does not in itself create a new harvesting permit requirement. Environmental permitting applies primarily to the upstream capture, removal, aquaculture or infrastructure activity.

VC2 - Seaweed

For macroalgae, new cultivation installations may additionally require environmental screening or assessment according to Directive 2011/92/EU and the relevant national implementation. Intensive fish farming is expressly included in Annex II of the EIA Directive, (European Parliament, Council of the European Union, 2014).

Aquaculture permitting remains largely implemented through national and regional systems and not only through a single EU-wide licensing regulation. EU policy is supported by the Strategic Guidelines for sustainable and competitive aquaculture 2021–2030, while Member States maintain their own licensing and spatial-planning procedures, (European Commission, 2021).

3.6. Invasive Alien Species

Invasive alien species are relevant to both MARMADE value chains, although their regulatory status differs between species. Regulation (EU) No 1143/2014 establishes the EU framework for preventing and managing invasive alien species of Union concern, while Member States may adopt additional national or regional measures

for invasive species that are not included in the Union List[1], (European Parliament, Council of the European Union, 2019), (European Commission, 2026).

3.6.1. Regulation (EU) No 1143/2014: Invasive Alien Species

Type	EU Regulation
Scope	Invasive alien species included in the Union List of Invasive Alien Species of Union Concern
Summary	Establishes restrictions on the introduction, keeping, breeding, transport, placing on the market, use and release of species of Union concern, and use of invasive alien species listed on the Union List. Member States must implement prevention, early detection, eradication or management measures according to the establishment status of the species. Species on the Union List cannot be commercially traded, released into the environment, or distributed across borders without explicit authorisation under a management plan.
Relevance	Directly relevant to *Rugulopteryx okamurae* (VC2), which is included in the Union List; and *Callinectes sapidus* (VC1) is currently not included in the Union List for commercialisation and exploitation reasons; its capture, control and valorisation therefore depend primarily on applicable fisheries and national/regional invasive-species measures. Rugulopteryx okamurae is listed on the **EU Union List of Invasive Alien Species of Union Concern** (added by Commission Implementing Regulation (EU) 2022/1203, in force since 12 July 2022, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02016R1141-20250807), and is also listed in Spain's national Invasive Species Catalogue under Ley 42/2007 and RD 630/2013. Because it sits on both the EU and Spanish national lists, the stricter EU-level restrictions under Regulation (EU) No 1143/2014 apply directly, alongside Spain's national management and authorisation requirements. Any commercialisation of Rugulopteryx requires both national management-plan authorisation and compliance with EU restrictions on the movement, keeping, breeding and release of

[1] Invasive Alien species: Union List

	listed species. Operators must check both the EU Union List and national invasive species catalogues for each target country, since national lists may include additional species beyond the EU list.

Article 7 of Regulation (EU) No 1143/2014 establishes general restrictions for species of Union concern, including intentional transport, placing on the market and use. However, for invasive species already widely established, Article 19 allows Member States to implement management measures aimed at eradication, population control or containment. Temporary commercial use may be authorised as part of such management measures, where strictly justified and subject to controls preventing further spread, (European Parliament, Council of the European Union, 2019).

VC1 - Crustaceans

The Atlantic blue crab, *Callinectes sapidus*, is identified in D1.1 as an emerging VC1 biomass stream, particularly in Northern Adriatic lagoons and coastal areas, where biomass availability is driven by population outbreaks, targeted fishing, control measures and local management strategies rather than by a conventional stable supply chain.

As *C. sapidus* is not currently included in the EU Union List, the specific restrictions of Regulation (EU) No 1143/2014 applicable to species of Union concern do not apply to it solely on the basis of its invasive status. Its capture, handling and potential valorisation must instead be assessed against the applicable fisheries legislation and national or regional management measures in each sourcing country. This means that the legal possibility of sourcing blue-crab biomass should be assessed at the local capture and management level, before applying the food, animal by-product or waste classification pathways described in the preceding sections.

VC2 – Seaweed

Rugulopteryx okamurae was added to the Union List of invasive alien species of Union concern by Commission Implementing Regulation (EU) 2022/1203 and therefore falls directly within Regulation (EU) No 1143/2014, (European Parliament, Council of the European Union, 2019).

Its collection, transport, use and potential valorisation must therefore be assessed in accordance with the restrictions and management provisions established at EU level. Where the species is already widely established, any valorisation pathway should remain compatible with the applicable management measures for eradication, population control or containment.

Specific national and regional requirements applicable to *R. okamurae* should be assessed separately in the relevant country-specific sections of this report.

3.7. Emerging Contaminant Limits (Heavy Metals & Iodine)

Targeted Stakeholder Consultation - Maximum Levels for Cadmium, Inorganic Arsenic, Iodine and Lead in Seaweed

Marine biomass may accumulate environmental contaminants, and their occurrence can vary substantially according to species, geographical origin and environmental conditions. Contaminant control is therefore relevant to both MARMADE value chains, both VC1 and VC2, although the main hazards differ: metals and iodine are particularly relevant for macroalgae, while heavy metals and other environmental contaminants require attention in crustacean-derived biomass and resulting fractions (i.e. heads). In addition, processing and fractionation may additionally concentrate or redistribute contaminants, making assessment of the final ingredient particularly important.

Type	European Commission targeted stakeholder consultation
Status	Draft maximum levels proposed for consultation; not currently legally binding Published 4 December 2025. No maximum levels for these substances currently exist for seaweed at EU level, apart from the cadmium maximum level already set for seaweed-based food supplements under Regulation (EU) 2023/915.
Scope	Cadmium, inorganic arsenic, iodine and lead in seaweed intended for food
Summary	Following monitoring and exposure assessments, the Commission services proposed possible harmonised maximum levels for selected metals and iodine in seaweed. These values remain subject to the EU regulatory process and should therefore be treated as emerging requirements rather than current legal limits. Following EFSA's 2023 scientific report on dietary exposure to heavy metals and iodine from seaweed consumption, which found that seaweed can significantly increase consumer exposure to metals and iodine beyond existing health-based guidance values, the Commission has proposed new maximum levels, differentiated by seaweed colour and type: lead at 0.50 mg/kg for laver/nori, 1.5 mg/kg for brown seaweed and 2.0 mg/kg for red (other than nori) and green seaweed; cadmium at 3.0 mg/kg for brown seaweed and 4.0 mg/kg for red and green seaweed; inorganic arsenic at 1.0 mg/kg for brown and green

	seaweed and 0.50 mg/kg for red seaweed; and iodine at 1.0 g/kg across all seaweed types (FRUCOM, 2025).
Relevance	Particularly relevant to VC2. A monitoring of regulatory developments is needed because future harmonised limits could directly influence biomass sourcing, processing conditions and specifications of seaweed-derived ingredients. If adopted, this would be the first harmonised EU-wide numerical limit for iodine in seaweed. Currently there is none; the EU instead relies on monitoring under Commission Recommendation (EU) 2018/464, while individual member states have set their own interim iodine limits, for example France at approximately 2,000 mg/kg dry weight for edible seaweed, with a higher allowance for brown seaweed used as seasoning, and Germany at 20 mg/kg for dried products (PHAROS Project, 2026). This is directly relevant to MARMADE's target species, particularly Ascophyllum and other brown or Laminarian species, which characteristically show the highest iodine concentrations. Operators should monitor the outcome of this consultation closely, as adopted limits would apply EU-wide regardless of country of harvest.
Broader contaminant framework already in force.	Commission Regulation (EU) 2023/915, which repeals Regulation (EC) No 1881/2006, already sets maximum levels of 3.0 mg/kg each for cadmium and lead, and 0.1 mg/kg for mercury, in seaweed-based food supplements specifically. New nickel limits entered into force on 1 July 2025: 30 mg/kg for seaweed generally and 40 mg/kg for wakame; the regulation gives no scientific name for 'wakame,' so whether this extends to Alaria esculenta remains to be confirmed. Inorganic arsenic in seaweed is currently governed by the As Low As Reasonably Achievable principle rather than a fixed numerical threshold, pending the outcome of the current consultation (PHAROS Project, 2026).

Commission Recommendation (EU) 2018/464 already established monitoring of arsenic, cadmium, iodine, lead and mercury in seaweed and seaweed-based products, including MARMADE-relevant genera such as Ulva, Codium, Palmaria and Alaria, (European Commission, Directorate-General for Health and Food Safety, 2018).

Broader contaminant framework already in force

VC1 – Crustaceans

Commission Regulation (EU) 2025/1891 establishes maximum levels for several contaminants in crustaceans intended for food, including lead, cadmium and mercury. In addition, Commission Regulation (EU) 2025/1891 introduced maximum levels for inorganic arsenic in fish and other seafood, including crustaceans. For

prawns, shrimps and crabs the inorganic arsenic maximum level is 0.10 mg/kg, while for Nephrops norvegicus it is 1.5 mg/kg.

However, these maximum levels generally apply to edible muscle tissue, explicitly excluding the cephalothorax and, for crabs, applying to muscle from the appendages. They therefore cannot be directly transferred to the shell-rich residues targeted by the MARMADE Project, (European Commission, Directorate-General for Health and Food Safety, 2025).

For VC1 chain, contaminant monitoring should consequently address both the incoming crustacean residue and the resulting extracted ingredient, particularly where concentration or fractionation processes may alter contaminant levels.

VC2 – Seaweed

For seaweed, Regulation (EU) 2023/915 already establishes certain contaminant limits for specific product categories, while Regulation (EU) 2024/1987 introduced maximum levels for nickel of 30 mg/kg for seaweed generally and 40 mg/kg for wakame, applicable from 1 July 2025, (European Commission, Directorate-General for Health and Food Safety, 2024).

The proposed harmonised limits for cadmium, inorganic arsenic, iodine and lead should therefore be monitored as an evolving regulatory issue and incorporated into MARMADE specifications if and when formally adopted.

For both value chains, contaminant compliance should therefore be assessed not only for the original biomass but also after extraction and purification, since MARMADE processing technologies may reduce, redistribute or concentrate on specific contaminants in the resulting chemical building blocks.

4. National Regulatory Frameworks

4.1. VC1 – Crustacean residues

The national regulatory review for VC1 follows the residue-generation and hotspot approach as indicated in Deliverable 1.1. Priority is given to countries where crustaceans are physically processed and exoskeleton-rich fractions can realistically be generated or intercepted, together with selected fishing, import and outsourced-processing nodes that materially affect the MARMADE supply chain.

The biomass mapping results of D1.1 points out Spain and Italy as the principal EU processing hotspots, while Morocco represents the clearest extra-EU outsourced peeling and residue-generation node for *Crangon crangon*. Denmark, the Netherlands/Germany, and then France and Greece have different but relevant functions as processing, landing, trade or redistribution nodes. Other countries are retained only where specific operator-level processing or regulatory relevance has been identified, (Table 2).

Table 2. - Priority tiers of VC1 sourcing countries and processing nodes, by residue-generation potential, (Biochica, 2026).

Priority	Countries / nodes	VC1 relevance
Primary	Italy, Spain, (extra EU Countries) Morocco	High-potential residue-generation and processing hotspots
Secondary	France, Denmark, Netherlands/Germany, Greece	Major supply-chain nodes: landing-import-export
Contextual / niche	Poland, Estonia, Sweden, Norway, United Kingdom	Specific and additional processing streams.
Origin / import interface	Greenland, Canada, Faroe Islands, Ecuador, India, Vietnam, etc.	Considered mainly through product form and EU-entry requirements rather than detailed domestic regulatory review.

This prioritisation avoids equating trade volumes with residue availability and focuses the national analysis on jurisdictions where regulatory decisions can materially affect biomass residues sourcing for MARMADE.

4.1.1. Italy

Italy is a high-priority VC1 country because several relevant crustacean streams converge within the same national processing system: Mediterranean wild shrimps and *Nephrops norvegicus*, imported warm-water shrimp, and emerging crab biomass, particularly *Callinectes sapidus* and *Liocarcinus depurator*. D1.1 identifies Italy as one of the strongest EU opportunities for locally generated crustacean residues, with particular relevance to Adriatic and local processing chains.

The Italian regulatory framework therefore needs to be considered at several interconnected levels, (Table 3):

Table 3. - Italian regulatory framework applicable to VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Regulatory area	Main Italian framework / authority	Relevance for MARMADE VC1
Food-chain processing	Ministry of Health, Regions and local competent health authorities; national implementation of EU official-control requirements	Seafood-processing establishments retaining crustacean fractions for food use must operate within the applicable food-hygiene and approval framework
Animal By-Products (SOA – Sottoprodotti di origine Animale)	Reg. 1069/2009 and 142/2011; national registration/approval system and Legislative Decree No 186/2012	Relevant where shell/head fractions are diverted from human consumption and enter the Category 3 pathway
By-product / waste status	Legislative Decree No 152/2006, Art. 184-bis; Ministerial Decree No 264/2016	Relevant to production residues outside the ABP regime where non-waste by-product status is claimed
Fishing and crustacean capture	Legislative Decree No 4/2012, EU CFP and national/regional fisheries measures	Relevant to Mediterranean wild crustaceans and local landing streams
Blue crab management	National Extraordinary Commissioner and specific national/regional measures	Particularly relevant to sourcing Blue Crab - *Callinectes sapidus* from the Northern Adriatic

Food and Animal By-Product controls

Italian establishments producing food of animal origin are registered or approved through the national and regional control system, and the Ministry of Health maintains the official lists of establishments recognised under Regulation (EC) No 853/2004. Italy also maintains official lists of operators and establishments registered or approved under Regulation (EC) No 1069/2009 for Animal By-Products, (SANCO, 2026).

The practical implication is that a potential supplier should be assessed not only according to the species and quantity of residues available, but also according to the regulatory status of the establishment and the status assigned to the crustacean fraction at the point of generation. Where the ABP route applies, Italian operators are subject to registration or approval requirements and to the national sanctioning framework established by Legislative Decree No 186/2012, (SANCO, 2026).

By-product versus waste

Where crustacean fractions fall outside the ABP framework and waste legislation becomes applicable, Italy implements the EU by-product concept through Article 184-bis of Legislative Decree No 152/2006. Ministerial Decree No 264/2016 provides indicative criteria intended to facilitate demonstration that a production residue satisfies the conditions for classification as a by-product rather than waste.

This affects that shell-rich material cannot be considered a non-waste by-product merely because a future valorisation route exists: the applicable conditions must be demonstrated and documented at the production stage, (MoA, 2016).

Fisheries and blue crab

Italian fisheries are additionally governed by Legislative Decree No 4/2012, which reorganises the national framework for professional fishing and aquaculture, together with the directly applicable EU fisheries legislation, (MoA, 2012).

The blue crab constitutes a specific Italian regulatory case. A Special Government Commissioner for Callinectes sapidus was appointed in 2024 under Decree-Law No 63/2024, converted by Law No 101/2024, with responsibility for implementing a national intervention plan to contain and manage the species; the mandate currently runs until 31 December 2026. Regional measures remain particularly relevant in the Northern Adriatic. For example, Emilia-Romagna has extended specific authorisation for capture, landing and commercialisation of blue crab within the Sacca di Goro aquaculture area until July 2027 (RE-R, 2026).

MARMADE Implication

Italy should therefore be treated as both a conventional crustacean-processing hotspot and a specific regulatory case for emerging invasive-crab biomass. For each sourcing stream, it should be verified the legal origin of the biomass, the regulatory status of the generating establishment, the classification assigned to the resulting residue and its compatibility with the intended food or feed pathway before collection and transfer to downstream processing.

4.1.2. Spain

Spain is a high-priority VC1 country because it combines an established seafood-processing industry with Mediterranean crustacean landings and substantial imports of warm-water shrimp. In fact D1.1 identifies Spain as one of the principal EU hotspots where shell-bearing products may undergo cooking, peeling, packing or preparation, thereby generating locally recoverable exoskeleton-rich fractions.

The national regulatory framework is particularly relevant to the status of seafood-processing establishments, the management of animal by-products and production residues, and the legal origin of wild-caught crustaceans, (Table 4):

Table 4. – Spanish regulatory framework applicable to VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Regulatory area	Main Spanish framework / authority	Relevance for MARMADE VC1
Food-chain processing	Real Decreto 191/2011; RGSEAA; AESAN and competent authorities of the Autonomous Communities	Registration/approval and traceability of establishments generating crustacean fractions retained for food use
Animal By-Products	Real Decreto 1528/2012 implementing Regulations 1069/2009 and 142/2011	Relevant where shells, heads or other animal-origin fractions leave the human-food chain
By-product / waste status	Ley 7/2022, Art. 4	Relevant to eligible production residues outside the ABP regime where non-waste by-product status is claimed
Fisheries	Ley 5/2023 on Sustainable Fisheries and Fisheries Research, together with EU CFP and technical measures	Relevant to Mediterranean wild shrimps and other locally landed crustaceans

Food-processing and Animal By-Product controls

Spanish food establishments are registered through the Registro General Sanitario de Empresas Alimentarias y Alimentos (RGSEAA) under Real Decreto 191/2011. Establishments handling products of animal origin that require approval under Regulation (EC) No 853/2004 must obtain authorisation from the competent authority of the relevant Autonomous Community. AESAN maintains access to the corresponding national and EU-approved establishment registers, (Ministerio de Sanidad, Política Social e Igualdad, 2011).

Where crustacean fractions are no longer intended for human consumption, Real Decreto 1528/2012 establishes the Spanish implementation framework for Regulations (EC) No 1069/2009 and (EU) No 142/2011. Competent authorities are primarily the Autonomous Communities, while the General State Administration retains relevant responsibilities for exchanges with third countries, (Ministerio de la Presidencia, 2012).

Therefore, the classification and documentary status of shell and head fractions should therefore be verified at the Spanish processing establishment where the residues are physically generated.

By-product and waste status

Where the material falls outside the ABP regime and waste legislation becomes applicable, Article 4 of Ley 7/2022 on waste and contaminated soils for a circular economy implements the EU by-product conditions. All four conditions must be fulfilled for a production residue to be considered a by-product rather than waste. The law also assigns an important role to the competent authorities of the Autonomous Communities in evaluating and authorising specific by-product uses, (Jefatura del Estado, 2022).

This is relevant to the project, particularly for clean shell-rich fractions for which ABP applicability has first been excluded and a documented non-waste valorisation route is envisaged.

Fisheries

For wild-caught crustaceans, Ley 5/2023 on Sustainable Fisheries and Fisheries Research provides the current national framework for marine fisheries management, conservation and access to resources, particularly in Spanish external waters, in coordination with the EU Common Fisheries Policy and the Autonomous Communities. The Law expressly includes crustaceans within the definition of fishing activity, (Jefatura del Estado, 2023).

The law is relevant to the Mediterranean shrimp streams identified in D1.1. Spain, together with Italy and Greece, accounts for the large majority of EU landings of Parapenaeus longirostris, while Spain and Italy are also major landing countries for other Mediterranean shrimp species.

MARMADE Implication

Spain represents a priority VC1 sourcing jurisdiction where imported shell-bearing shrimp and locally landed Mediterranean crustaceans may converge in the same processing system.

It should therefore verify the approval status of the processing establishment, the legal classification assigned to the resulting shell-rich fraction and its traceability, while distinguishing locally generated residues from biomass already processed before entering Spain.

4.1.3. Morocco

Morocco represents a specific high-priority VC1 processing node rather than a conventional EU sourcing country. D1.1 identifies Morocco as the clearest outsourced peeling hotspot for *Crangon crangon*: North Sea shrimp caught and traded through EU countries, particularly the Netherlands and Germany, may be transported to Morocco for hand peeling before the processed product re-enters the European market, (Table 5).

Approximately 14,000 tonnes of cold-water shrimp products were exported to Morocco in 2024, corresponding to an estimated 3,000 tonnes/year of potential shell-rich residues generated outside the EU.

This case illustrates a central methodological principle: *"the place of capture or trade is not necessarily the place where the residue is generated".*

Table 5. – Moroccan regulatory framework applicable to VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Regulatory area	Main Moroccan framework / authority	Relevance for MARMADE VC1
Food-processing establishments	Law No 28-07 on food safety; ONSSA and competent fisheries-product authorities	Relevant to establishments carrying out peeling and processing of crustaceans
Sanitary approval and controls	Decree No 2-10-473 and implementing measures	Processing establishments must operate under the applicable sanitary approval/authorisation system
Waste/residue management	Law No 28-00 on waste management and disposal	Relevant where shell fractions are classified and managed as waste under Moroccan law
EU-entry interface	EU third-country import and establishment-listing requirements	Critical where processed shrimp, shell material or derived products are subsequently intended to enter the EU

Processing and sanitary controls

Moroccan Law No 28-07 on the sanitary safety of food products requires food products to be produced, handled, processed, transported and stored under sanitary conditions and provides for sanitary authorisation or approval of establishments before operation. Decree No 2-10-473 specifies the corresponding approval framework, including provisions for establishments working with maritime fishery products, (MoH, 2010).

ONSSA publishes national information and lists concerning approved establishments involved in the treatment and transformation of fishery and aquaculture products, (ONSSA, 2026).

The relevant aspects is the regulatory point is therefore the peeling establishment at which the shell fraction is physically separated, including the sanitary status of that establishment and the classification and handling assigned to the resulting residues.

Residue and waste status

Where shell fractions are managed as waste, the principal Moroccan framework is Law No 28-00 on waste management and disposal, currently available in a consolidated version updated to July 2025, (SECRÉTARIAT GÉNÉRAL DU GOUVERNEMENT ROYAUME DU MAROC, 2025).

However, the legal status of a Moroccan shrimp-shell fraction should not be automatically translated into the EU concepts of Animal By-Product, by-product or waste. If the material is subsequently intended to enter the EU, its EU legal classification and import requirements must be assessed separately according to its intended use and processing history.

Interface with the EU market and MARMADE implication

Morocco is authorised for entry of fishery products into the EU under the applicable third-country framework, while eligible establishments must be included in the relevant Commission/TRACES lists.

Within the project, a distinction must be however maintained between processed shrimp returning to the EU as food and the possible movement of the shell-rich residue itself. The latter may be subject to different EU-entry requirements depending on whether it is classified as food raw material, animal by-product/derived product, feed material or waste, (European Commission, 2026).

At last, Morocco should therefore be considered primarily as an outsourced residue-generation hotspot rather than automatically as a feedstock sourcing location. Any potential use of Moroccan-generated shell biomass requires verification of the processing establishment, the legal status assigned to the residue at generation and the corresponding conditions for its subsequent entry into the EU.

4.1.4. France

France is considered a secondary but relevant VC1 processing and market node. The Deliverable (D1.1) identifies the country as a mixed seafood-processing and distribution area for warm-water shrimp, crabs and other crustaceans, although the actual availability of locally generated shell residues is less certain than in Spain or Italy, (Table 6).

Table 6. – French regulatory framework applicable to VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Regulatory area	Main French framework / authority	Relevance for MARMADE VC1
Food-processing establishments	Ministry of Agriculture and competent departmental services; Regulation (EC) No 853/2004 sanitary approval	Relevant where crustacean fractions are generated in approved seafood-processing establishments
Animal By-Products	Regulation (EC) No 1069/2009; French Rural and Maritime Fishing Code	Relevant where shell/head fractions leave the human-food chain
By-product / waste status	French Environmental Code, Art. L541-4-2	Relevant where a production residue outside the ABP regime is claimed as a non-waste by-product
Fisheries	French Rural and Maritime Fishing Code	Relevant to wild-caught crustaceans and fishing authorisations

French establishments preparing, processing, handling or storing products of animal origin for supply to other establishments are subject to sanitary approval under Regulation (EC) No 853/2004. The French Ministry explicitly includes crustacean cooking vessels and other establishments handling animal-origin food within this approval framework, (MAASA, 2026).

Where crustacean fractions are no longer intended for human consumption, the French ABP system applies together with Regulation (EC) No 1069/2009. Operators handling animal by-products must at least be registered, while certain activities require specific approval by the competent departmental authority, (MAASA, 2025).

For residues outside the ABP regime, Article L541-4-2 of the Code de l'environnement transposes the EU by-product concept and requires the relevant conditions to be fulfilled before a production residue can be considered a by-product rather than waste, (MAASA, 2021) . French maritime fisheries are governed through the Code rural et de la pêche maritime, which provides for fishing authorisations according to species, areas, periods, gears and volumes (MAASA, 2015).

MARMADE Relevance

France should be retained as a relevant but secondary VC1 sourcing and processing jurisdiction. Potential suppliers should be assessed primarily according to the actual processing stage performed in France, the regulatory status of the generating establishment and the classification assigned to the resulting crustacean fraction.

4.1.5. Denmark

Denmark is a high-relevance trade and redistribution node for cold-water shrimp, particularly Pandalus borealis, but the Deliverable D1.1 does not identify it as a proportional shell-residue hotspot.

Much of the biomass entering Denmark is already cooked-frozen or partially processed, so local residue generation depends strongly on the processing stage performed domestically.

Denmark maintains official lists of establishments approved for handling food of animal origin under Regulation (EC) No 853/2004, including fishery-product plants and cold stores, (Danish Veterinary and Food Authority, 2026). Operators handling animal by-products or derived products must similarly be registered or approved by the competent Danish authority according to the activity performed, (Foedevarestyrelsen, 2026).

The main regulatory issue is therefore not Danish trade volume itself, but whether shell-bearing crustaceans undergo a residue-generating processing step in Denmark. Where products are merely stored, redistributed or re-exported, Denmark should remain a supply-chain and traceability node rather than being treated as a major biomass-sourcing hotspot, (Table 7).

Table 7. - Danish regulatory framework applicable to VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Regulatory area	Danish framework / authority	Relevance for MARMADE VC1
Food-processing establishments	Danish Veterinary and Food Administration; approval under Regulation (EC) No 853/2004	Relevant where crustacean products are actually processed in Denmark
Animal By-Products	Danish Veterinary and Food Administration; Regulations 1069/2009 and 142/2011	Relevant where crustacean fractions leave the food chain
Fisheries and first sale	Danish fisheries authority under the Ministry of Food, Agriculture and Fisheries	Relevant to locally landed crustaceans and traceability
Trade/redistribution	EU food, fisheries and traceability rules	Particularly important because Denmark functions mainly as an entry, storage and redistribution hub

MARMADE Implication

Denmark should primarily be considered a cold-water shrimp flow and traceability node. Detailed sourcing assessment is required only where operator-level evidence confirms that peeling or other shell-generating processing actually takes place within Denmark.

4.1.6. Netherlands and Germany – North Sea *Crangon crangon* Chain

The Netherlands and Germany are important production, landing and trade nodes for North Sea common shrimp (Crangon crangon), but they should not automatically be considered major shell-residue hotspots. The Deliverable D1.1 shows that a substantial part of the peeling activity is outsourced to Morocco; consequently, shell generation may occur outside the countries in which the shrimp are caught, traded or initially handled, (Table 8).

Table 8. - Dutch and German regulatory framework applicable to the North Sea Crangon crangon chain, by regulatory area, (Biochica, 2026).

Regulatory area	Netherlands	Germany	Relevance for MARMADE
Food-processing establishments	Netherlands Food and Consumer Product Safety Authority (NVWA)	Competent authorities of the Länder; establishments listed through BVL	Relevant where Crangon is processed or peeled domestically under Reg. 853/2004
Animal By-Products	NVWA registration/approval under Regs. 1069/2009 and 142/2011	Regs. 1069/2009 and 142/2011, complemented by TierNebG and TierNebV	Relevant where shell fractions leave the human-food chain
By-product / waste status	National implementation of EU waste-law requirements	Kreislaufwirtschaftsgesetz (KrWG), particularly §4 on by-products	Relevant only where the material falls outside the ABP regime
Fisheries / traceability	EU CFP and national fisheries-control implementation	EU CFP and national fisheries-control implementation	Relevant to legal catch, landing and traceability of North Sea shrimp

In the Netherlands, operators carrying out activities with animal by-products or derived products may require registration, approval or authorisation by the **NVWA**, depending on the activity. The authority also applies the requirements of Regulations (EC) No 1069/2009 and (EU) No 142/2011 concerning identification, transport and documentation, (MoAFFSN, 2026).

In Germany, establishments producing or marketing foods of animal origin requiring approval under Regulation (EC) No 853/2004 are authorised by the competent authorities of the Länder and included in the national BVL database, (BVL, 2026). The EU Animal By-Products framework is complemented nationally by the Tierische Nebenprodukte-Beseitigungsgesetz (TierNebG) and Tierische Nebenprodukte-Beseitigungsverordnung (TierNebV), (BLEH, 2026). Where waste law applies instead, §4 of the German Kreislaufwirtschaftsgesetz (KrWG) establishes the conditions for classification as a by-product rather than waste, (BfJ, 2026).

MARMADE Implication

The Netherlands and Germany should primarily be treated as North Sea shrimp production and trade nodes. MARMADE sourcing should therefore verify whether peeling or other residue-generating processing actually occurs locally; where peeling is outsourced to Morocco, the regulatory status of the shell biomass must instead be assessed at the Moroccan generation point.

4.1.7. Greece

Greece is a secondary but relevant VC1 sourcing country, particularly for Mediterranean wild shrimps. The Deliverable D1.1 identifies Greece, together with Italy and Spain, as one of the principal landing areas for Parapenaeus longirostris and related Mediterranean crustaceans, with residues more likely to remain close to ports, auctions and local processing activities.

EFET maintains the national lists of approved establishments handling fishery products under Regulation (EC) No 853/2004, (EFET, 2026). Greece also maintains official lists of establishments registered or approved for handling animal by-products under Regulation (EC) No 1069/2009.

For residues falling outside the ABP regime, Law 4819/2021 implements the by-product concept and provides a national procedure for assessing whether a substance generated during a production process can be regarded as a by-product rather than waste, (MoEE, 2026).

Greek fisheries are additionally subject to species-specific national measures. For example, dedicated fishing authorisation provisions exist for deep-water red shrimp species such as Aristaeomorpha foliacea and Aristeus antennatus, (General Directorate of Fisheries, 2019).

MARMADE Implication

Greece should be retained as a relevant Mediterranean crustacean sourcing node, particularly for wild shrimp streams. Regulatory assessment should focus on the legal origin of the catch, the status of the processing establishment and whether shell-rich fractions are actually generated and separately collected at local processing points.

4.1.8. Secondary and contextual processing nodes

The Deliverable D.1.1 also identifies a limited number of secondary or contextual EU northern processing nodes that may be relevant to VC1 chain, but for which the available evidence does not justify a detailed national regulatory review. These countries are retained to reflect specific processing niches or potential sourcing opportunities that may become more relevant if operator-level evidence is confirmed, (Table 9).

Table 9. – Secondary and contextual EU processing nodes for VC1 crustacean residues, by regulatory area, (Biochica, 2026).

Country / node	Role identified in D1.1	MARMADE relevance
Poland	Niche cold-water shrimp processing and hand-peeling.	Potential local generation of shell-rich residues, but limited scale.
Estonia/Bulgaria	Specialised Pandalus borealis hand-peeling and packaging.	Direct but niche residue-generation node.
Sweden	Nordic seafood-processing and cold-water shrimp market.	Secondary node requiring operator-level validation.
Norway	Contextual northern node for cold-water shrimp, Norway lobster and crab products.	Relevance depends on whether residues are generated locally.
United Kingdom	Contextual northern node, particularly for Nephrops norvegicus and crab flows.	Potentially relevant, but current evidence is insufficient to confirm recoverable residue availability.

Notably, Poland, Estonia and Bulgaria as specific hand-peeling or specialised processing contexts of crustacean coming from northern EU countries; while for example, Sweden represents bigger Nordic producer but smaller processing node. At the same time, Norway and the United Kingdom are treated as contextual northern nodes because the available information does not yet allow robust quantification of locally generated shell residues.

MARMADE implication

These countries should therefore remain under consideration as secondary sourcing or processing nodes, but detailed regulatory assessment should be undertaken only where specific MARMADE suppliers or residue-generating operators are subsequently identified.

4.2. VC2 – Seaweed

In addition to EU-level legislation, seaweed operators must comply with national and regional permitting requirements. This section covers the primary supply countries identified in the D1.1 desk study. While licensing procedures vary by country, the EU4Algae Licensing Toolkit notes for farmers (European Commission, 2023) that the application process for a seaweed farming licence generally follows three phases common across Europe: preparation (farm concept design, stakeholder pre-engagement and documentation), public consultation (engagement with local stakeholders and evaluation by the licensing authority), and pre-installation/installation (including any additional permits for equipment, seabed use, or food safety). An interactive country-by-country overview of these licensing processes is also available on the same site through the EU4Algae Licensing Toolkit's country-specific licensing map, which readers may find a useful visual complement to the national summaries below.

4.2.1. Ireland

Ireland has the most mature regulatory framework for seaweed harvesting in Europe, developed in parallel with the Aquaculture Act 1997 and Sea-Fisheries and Maritime Jurisdiction Act 2006. The Department of Agriculture, Food and the Marine (DAFM) oversees both aquaculture licensing and wild seaweed harvesting authorisation.

- Wild harvesting requires a foreshore licence under the Foreshore Act 1933 (as amended). The Marine Institute advises on environmental sustainability of harvest levels.

- Aquaculture (including seaweed cultivation at sea) requires a licence under the Fisheries (Amendment) Act 1997. Licences are granted per site and may be subject to EIA for larger operations.

- Food safety compliance falls under the Food Safety Authority of Ireland (FSAI), which enforces EU Regulations 178/2002 and 852/2004.

- Several operators hold both food safety and aquaculture licences, enabling commercial supply to EU food businesses.

- No specific Novel Food authorisation issues for Alaria esculenta and Palmaria palmata in Ireland, as both have documented pre-1997 consumption history.

4.2.2. France

France has a well-developed regulatory framework for professional seaweed harvesting, managed under the Comités Régionaux des Pêches Maritimes et des Élevages Marins (CRPMEM). Commercial harvest requires:

- A professional harvester card (carte de pêcheur professionnel) or conchyliculture licence for commercial seaweed harvest.
- An arrêté préfectoral (prefectoral order) establishing species-specific quotas, harvest seasons, and geographic restrictions per region (Brittany, Normandy, etc.).
- Environmental assessment under French environmental law (Code de l'Environnement) for new cultivation or large-scale harvest operations.
- Food-grade supply must comply with EU 178/2002 and 852/2004, enforced by the Direction Générale de l'Alimentation (DGAL) and Direction Départementale de la Cohésion Sociale et de la Protection des Populations (DDCSPP).
- France has a high density of commercial-scale operators (31 companies) and an established institutional framework supporting the seaweed sector.

4.2.3. Spain

Spain's seaweed regulatory framework operates at both the national level (Ministerio de Agricultura, Pesca y Alimentación) and autonomous community (Comunidad Autónoma) level. The Galician sector is the most developed, operating under Decreto 9/2009 and Orden do 30 de decembro de 2009 for seaweed harvest in Galicia.

- Galicia: Operators require a marisqueo or alga collection licence issued by the Xunta de Galicia. Commercial certification (Biocertificate Galicia) is available for sustainably harvested biomass.

- Andalusia: Wild harvest and beach collection are governed by BOJA Decreto 93/2023 for species of ecological interest. Rugulopteryx okamurae collection requires an explicit research licence from the Junta de Andalucía.

- National invasive species framework: Ley 42/2007 (Ley de Patrimonio Natural y de la Biodiversidad) and Real Decreto 630/2013 (Catálogo Español de Especies Exóticas Invasoras) apply to invasive species including Rugulopteryx okamurae, prohibiting commercial collection and trade.

- Food safety: AESAN (Agencia Española de Seguridad Alimentaria y Nutrición) enforces EU food law. Novel Food Regulation compliance for Ulva, Codium, and Gracilaria was confirmed by several suppliers consulted during the mapping exercise..

4.2.4. Portugal

The seaweed sector in Portugal is regulated primarily through the Direcção-Geral de Recursos Naturais, Segurança e Serviços Marítimos (DGRM). Operators require:

- An aquaculture licence (licença de aquicultura) for cultivation operations, issued by DGRM.

- For wild harvesting in coastal and marine protected areas, additional licenses from the Instituto da Conservação da Natureza e das Florestas (ICNF) may be required.

- Azores and Madeira operate under autonomous regional regulations; operators in these regions must comply with regional marine resource management legislation.

- National aquaculture permits and GDPR-compliant supply chain data sharing practices were confirmed by one accessible Portuguese supplier for MARMADE purposes.

4.2.5. United Kingdom

Following the UK's departure from the EU, seaweed operators based in England, Scotland, Wales, and Northern Ireland are no longer subject to EU regulations as a matter of law. However, most UK food-grade operators have maintained alignment with equivalent UK standards to preserve export access to the EU market.

- Scotland: Marine Scotland issues aquaculture licences and Crown Estate Scotland leases. Long-term Crown Estate leases (typically up to 15 years) are considered best practice for tenure security among operators in the sector.

- England/Wales: The Marine Management Organisation (MMO) issues marine licences for seaweed cultivation and wild harvest. DEFRA's guidance for new and expanding marine seaweed aquaculture businesses in England sets out a three-stage pathway, including: 1) scoping (determining target species, site, and cultivation method); 2) pre-application (checking compatibility with marine plans and protected areas, and engaging relevant bodies (for example, the Crown Estate and local planning authorities); and 3) formal application (for the marine licence itself, plus other leases/permission as appropriate and relevant). Several of these steps carry direct cost to the applicant

- UK Food Safety: The Food Standards Agency (FSA) enforces equivalent requirements to EU Reg. 178/2002 under the Food Safety Act 1990 (as amended). UK HACCP guidance mirrors EU 852/2004.

- Import to EU: UK-origin seaweed entering the EU market must comply with EU import conditions, including phyto-sanitary requirements. Health certificates may be required.

- Novel Foods: UK has its own Novel Food authorisation system under the UK Novel Food Regulations 2021, administered by the Food Standards Agency (FSA). Species authorised in the EU are not automatically authorised in the UK and vice versa.

4.2.6. Norway

Norway sits outside the EU but, as an EEA member, aligns closely with EU food and feed law while operating its own distinct licensing regime for aquaculture and wild harvesting.

Wild harvesting of Laminaria hyperborea and Ascophyllum nodosum has taken place at industrial scale since the 1970s, with Norway operating one of the most established and longest-running seaweed harvest management systems in Europe. Annual wild harvest volumes are substantial, with Laminaria hyperborea harvested at approximately 120,000 to 180,000 tonnes per year and Ascophyllum nodosum at around 15,000 to 20,000 tonnes per year, placing Norway among the largest wild seaweed harvesting nations in Europe.

Wild harvesting is regulated by the Directorate of Fisheries (Fiskeridirektoratet), under the Ministry of Trade, Industry and Fisheries, based on the Marine Resources Act (Havressurslova). Harvest licences are issued by the Directorate of Fisheries, with management delegated regionally to the counties of Rogaland, Vestland, Møre og Romsdal, and Trøndelag, informed by research from the Institute of Marine Research. Norway's harvest model uses designated zones on a five-year rotational cycle, with harvesting permitted only between five and twenty metres depth, allowing regrowth between cycles. This rotational zone-based approach is widely regarded as one of the more sustainable wild harvest management systems globally and could serve as a useful reference model for MARMADE when assessing supply security and environmental permitting timelines for other supply countries.

Seaweed cultivation is a more recent development in Norway relative to wild harvesting, with the first cultivation licences granted in 2014. The sector has since expanded significantly, and cultivation licensing is administered through the same Directorate of Fisheries framework as other Norwegian aquaculture.

Food safety compliance falls under the Norwegian Food Safety Authority (Mattilsynet), which enforces food law aligned with EU requirements through Norway's EEA obligations, including provisions equivalent to Regulation (EC) No 178/2002 and Regulation (EC) No 852/2004.

Novel Food status follows the EU framework by virtue of the EEA Agreement, meaning species requiring Novel Food authorisation in the EU generally require equivalent authorisation for the Norwegian market, administered by Mattilsynet.

Given Norway's status outside the EU customs union, seaweed biomass sourced from Norway for supply into the EU is subject to the same import conditions applicable to other EEA-member sourcing, as noted in Section 5.3 below, and does not require the additional import checks applied to non-EEA third countries.

5. Species-Specific Regulatory Considerations

5.1. VC1 – Crustacean residues

5.1.1. Cold-water shrimps: *Crangon crangon* and *Pandalus borealis*

Cold-water shrimp represents a specific VC1 pathway because the place of capture, trade and residue generation may occur in different jurisdictions. The D1.1 identifies two principal sub-chains: North Sea common shrimp (Crangon crangon) and northern prawn (Pandalus borealis).

For Crangon crangon, the biomass is predominantly wild-caught in North Sea waters, with the Netherlands and Germany acting as important production and trade nodes. However, a substantial share of peeling is outsourced to Morocco, where the shell-rich fraction is physically generated before the peeled product returns to the European market. Consequently, the regulatory status of the residue must be established at the Moroccan processing stage, rather than inferred from the EU origin of the shrimp.

For Pandalus borealis, the main origin areas include Greenland, Canada, the Faroe Islands and northern European waters. The product frequently enters the EU through Denmark already cooked-frozen or partially processed. Denmark is therefore primarily a trade and redistribution hub, while the actual generation of shell residues may have occurred upstream.

Table 10. - Regulatory specificity and MARMADE implication for cold-water shrimp species (Crangon crangon and Pandalus borealis), (Biochica, 2026).

Species	Main regulatory specificity	MARMADE implication
Crangon crangon	Wild-caught EU resource with significant outsourced peeling in Morocco	Verify legal status and handling of shells at the actual Moroccan residue-generation point and, if sourced, the applicable EU-entry pathway
Pandalus borealis	Transnational northern supply chain; products may enter the EU already processed	Verify product form and processing history before considering Denmark or another EU trade node as a residue source

For both species, the general food, Animal by-product, waste and feed frameworks remain applicable according to the status and intended use of the material. The species itself does not determine whether the shell fraction is food-grade, an animal by-product or another type of production residue; the decisive factors are the processing stage, handling history, intended destination and jurisdiction in which the fraction is generated.

Cold-water shrimp sourcing should therefore be assessed on a supply chain basis rather than by country of capture or trade volume. For MARMADE Project is relevant to identify the actual "residue generation point" and verify the legal and hygienic status of the shell fraction before considering it eligible for downstream valorisation.

5.1.2. Warm-water shrimps: *Litopenaeus vannamei* and *Penaeus* spp.

Concerning the water shrimp species, they represent a distinct VC1 regulatory case, because the EU supply chain is dominated by aquaculture derived imports from third countries, and not by EU fisheries, if not only for niche cases. The principal species are whiteleg shrimp (*Litopenaeus vannamei*), while Asian supply also includes giant tiger shrimp (*Penaeus monodon*).

The decisive factor is the product form at the point of entry into the EU. Ecuadorian shrimp frequently enters Southern Europe as whole, raw or head-on-shell-on (HOSO) product, increasing the likelihood that shells and heads are generated during processing in countries such as Spain, France or Italy. By contrast, a significant share of shrimp from India and Vietnam reaches the EU already peeled or otherwise prepared, meaning that the main exoskeleton-rich residue may have been generated upstream in the producing country.

Table 11. - Regulatory implication by supply configuration for warm-water shrimp species (Litopenaeus vannamei and Penaeus spp.), (Biochica, 2026).

Supply configuration	Main regulatory implication	MARMADE relevance
Whole / HOSO shrimp imported into the EU	Residue is generated at the EU processing establishment; its food, ABP or other legal status must be established there	Higher potential for controlled EU-side sourcing
Peeled / prepared shrimp imported into the EU	Shell and head residues have generally been generated upstream in the third country	EU trade volume does not correspond to local residue availability

Residues sourced directly from a third country	EU-entry requirements depend on the legal status and intended use of the material	Requires separate import and traceability assessment

Warm-water shrimp residues should be assessed according to product form and actual processing location. Therefore, the most relevant EU sourcing opportunities are therefore associated with whole, or HOSO imports processed within approved EU establishments, while residues generated upstream in third countries require a separate import and regulatory assessment.

In particular, D1.1 identified Spain, France and Italy as the principal EU destinations where warm-water shrimp may generate recoverable residues when shell-bearing biomass is physically processed, while the Netherlands and Belgium are more frequently associated with logistics and redistribution.

5.1.3. Mediterranean wild shrimps and related crustaceans.

Mediterranean wild shrimps represent a more regional and locally integrated VC1 stream, because capture, landing, first sale and primary processing generally occur within the same Southern European macro-region. The *Parapenaeus longirostris* is considered as the principal species, together with other commercially relevant Mediterranean shrimps.

In particular, Italy, Spain and Greece are the principal EU countries for these fisheries. In 2023, these three countries represented more than 90% of EU landings of Parapenaeus longirostris, while Italy and Spain also accounted for most landings of the broader miscellaneous-shrimp group, (Table 12).

Unlike imported tropical shrimp chains, the main species-specific regulatory issue is therefore the lawful origin of the wild catch. These fisheries fall within the Common Fisheries Policy and the EU technical-measures framework, including Regulation (EU) 2019/1241, complemented by national or regional fishing authorisations, seasonal restrictions, gear requirements and other conservation measures. The current D1.2 already identifies *Parapenaeus longirostris* among the species directly relevant to this framework.

Table 12. – Regulatory framework applicable to Mediterranean wild shrimps and related crustaceans, by regulatory area, (Biochica, 2026).

Regulatory specificity	MARMADE implication
Wild-caught origin	Legal capture and landing must be demonstrated before the biomass enters the sourcing chain

Strong regional concentration	Residues are more likely to be generated close to ports, auctions, wholesalers and local processors in Italy, Spain and Greece
Fisheries-management measures	Species-, area-, season- and gear-specific requirements may affect availability and seasonality
Local processing	Legal status of shells and heads must be established at the processing establishment where they are generated

Related Mediterranean crustaceans, (i.e.: *Squilla mantis)*, may also enter similar local handling chains, although D1.1 considers their residue potential more secondary because they are often marketed without an intensive peeling step.

For MARMADE concerns, the Mediterranean wild crustacean residues should therefore be sourced through legally authorised fisheries and with "traceable local processing chains". The main opportunity lies in linking lawful capture and landing with processing points where exoskeleton-rich fractions can be separately collected and assigned an appropriate regulatory status.

5.1.4. Norway lobster: *Nephrops norvegicus*

The current D1.2 already identifies Nephrops norvegicus among the MARMADE-relevant species covered by this fisheries framework. It represents a conventional wild-caught crustacean stream with relevant shell-rich biomass potential for VC1. The species is commercially important across Atlantic and European waters, with significant fisheries in the Irish and North Seas, the Bay of Biscay and the Atlantic-Iberian area.

Its main regulatory specificity is linked to fisheries management and seasonality rather than to a distinct downstream residue regime. Capture is governed by the Common Fisheries Policy and by Regulation (EU) 2019/1241 on technical measures, complemented by national measures applicable to fishing areas, gears, seasons and landing conditions, (Table 13).

Table 13. – Regulatory framework applicable to Norway lobster (Nephrops norvegicus), by regulatory area, (Biochica, 2026).

Regulatory specificity	MARMADE implication
Wild-caught fishery	Legal capture, landing and traceability must be demonstrated
Fisheries technical measures	Area-, gear- and season-specific rules may affect biomass availability

Seasonal supply	Residue collection should be aligned with fisheries and processing calendars
Local processing	Shell-rich fractions must be classified at the establishment where they are generated

D1.1 also highlights marked seasonal variability in first-sales volumes, with peaks differing among Denmark, France and Sweden. Consequently, potential residue availability may vary substantially through the year and should be assessed at operator and processing level rather than inferred from annual catch statistics alone.

As for other conventional VC1 streams, the resulting shells and processing fractions of the mentioned species remain subject to the food, Animal By-Product, by-product/waste and feed pathways described in Section 2 according to their handling and intended destination.

Also for this species, MARMADE will prioritise traceable processing chains linked to legally authorised fisheries and verify residue availability at the actual processing point, taking seasonal fluctuations into account.

5.1.5. Emerging crab biomass: *Callinectes sapidus* and *Liocarcinus depurator*

Emerging crab biomass requires a separate VC1 assessment because its availability is driven less by established processing chains and more by local abundance, fishing or control measures, bycatch interception and regional management strategies. D1.1 identifies Callinectes sapidus and Liocarcinus depurator as distinct emerging crustacean streams, particularly in the Adriatic and Mediterranean areas.

Concerning *Callinectes sapidus*, the principal regulatory specificity is its status as an alien and invasive species in European waters. However, the current D1.2 correctly distinguishes this ecological classification from legal inclusion in the EU Union List: C. sapidus is not currently included in the Union List of invasive alien species of Union concern. Consequently, the specific restrictions of Regulation (EU) No 1143/2014 applicable to Union-listed species do not automatically apply; sourcing instead depends primarily on applicable fisheries rules and national or regional management measures. Italy represents the most relevant case per MARMADE Project. D1.2 already identifies specific national and regional management measures, including the appointment of a Special Government Commissioner and regional authorisations concerning capture, landing and commercialisation in the Northern Adriatic.

While the *Liocarcinus depurator* follows a different regulatory logic and it represents an interesting case that could be considered for other similar crab species in other EU countries. D1.1 treats it as an underutilised or bycatch associated biomass stream, particularly in the Central Adriatic. Local project evidence indicates that the species can be intercepted through bottom-trawl activities and may show seasonal peaks, but its exploitation remains less structured than that of conventional crustaceans, (Table 14).

Table 14. - Regulatory framework applicable to emerging crab biomass (Callinectes sapidus and Liocarcinus depurator), by regulatory area, (Biochica, 2026).

Species	Main regulatory specificity	MARMADE implication
Callinectes sapidus	Alien/invasive species; sourcing linked to local fisheries and management/control measures	Verify local capture authorisation and management conditions before assessing downstream residue status
Liocarcinus depurator	Underutilised/bycatch-associated stream	Verify lawful capture/bycatch handling and actual availability before considering organised residue sourcing

For both species, once the biomass has been lawfully captured or collected, the subsequent legal status of shells, whole animals or other fractions must still be determined under the food, Animal By-Product, by-product/waste and feed pathways.

In other words, the legality of capture does not by itself determine the legality of the downstream valorisation route.

Therefore, emerging crab biomass should therefore be assessed through a two-step regulatory approach: first, verify that capture or removal is lawful under the applicable local fisheries or management regime; second, determine the legal status of the resulting biomass or processing fraction according to its handling and intended food, feed or other valorisation pathway.

5.2. VC2 – Seaweed

5.2.1. Ulva spp. (Green Algae)

Ulva lactuca and related Ulva species have a long history of human consumption in Europe (Ireland, France, Japan). Most European species are considered traditional foods and do not require Novel Food authorisation. However, certain farmed or novel strains may require case-by-case assessment. Operators should verify the specific

species and intended use against the EU Novel Food Catalogue before supply. Key certifications held by principal suppliers include EU food safety hygiene (852/2004) and national aquaculture permits.

5.2.2. Codium spp. (Green Algae)

Codium species have limited documented EU consumption history prior to 1997. Some preparations (particularly Codium tomentosum in Portugal and Spain) may have localised traditional use. Operators supplying Codium for food applications should conduct a Novel Food assessment per species. For feed use, the EU Catalogue of Feed Materials should be checked. Commercially, several principal EU suppliers operate under the Novel Food Regulation (EU 2015/2283) and Biocertificate Galicia.

5.2.3. Alaria esculenta (Brown Algae Atlantic Wakame)

Alaria esculenta benefits from established consumption history in Ireland (pre-1997), meaning it is generally not classified as a Novel Food in Irish regulatory contexts. However, at EU level, operators in other member states should confirm Novel Food status for their jurisdiction. Certified food-grade supply has been confirmed by an Irish research company identified in the mapping exercise, in line with EU Reg. 852/2004. Bantry Marine Research Station is certified accordingly. For feed use, Alaria esculenta should be verified against the EU Catalogue of Feed Materials. At-sea cultivation requires national marine/aquaculture licences.

5.2.4. Rugulopteryx okamurae (Invasive Species Mediterranean)

Commercial collection currently prohibited

Rugulopteryx okamurae is listed in Spain's Catálogo Español de Especies Exóticas Invasoras under Ley 42/2007 and Real Decreto 630/2013. Commercial collection, transport, and commercialisation are prohibited without an approved administrative management plan. Only dead beach wash-ups (recogida de arribazones) may be collected, exclusively under a research licence.

Examples of key regulatory instruments are:

- Catálogo Español de Especies Exóticas Invasoras: Lists the species and imposes general prohibitions. Administered by Ministerio de Transición Ecológica.

- Ley 42/2007 de Patrimonio Natural y de la Biodiversidad: Provides the national legal basis for prohibitions and requires autonomous communities to establish management plans before any collection or commercialisation can proceed.

- Real Decreto 139/2011: Develops the national lists of protected and threatened species. Note: Rugulopteryx is not 'protected' under this decree; it is an invasive species in the separate catalogue.

- BOJA Decreto 93/2023 (Junta de Andalucía): Specifically grants a research licence for beach wash-up collection in Andalusia. Currently the only legal pathway for obtaining Rugulopteryx biomass in Spain.

- EU Regulation 1143/2014 (IAS Regulation): Rugulopteryx is not yet on the EU Union List of Concern, but Spain's national measures apply equivalent restrictions. Future listing at EU level cannot be excluded.

Pathway to commercialisation: Any commercial supply pathway for R. okamurae would require: (1) an approved management/eradication plan at regional or national level; (2) an explicit authorisation for commercial collection under Ley 42/2007; (3) potentially a Novel Food authorisation (EFSA) if intended for human consumption; (4) verification of EU IAS Regulation status. This is a medium-term opportunity, not immediately actionable for commercial supply.

5.2.5. Palmaria palmata (Red Algae- Dulse)

Palmaria palmata (Dulse) has established consumption history in Ireland, the UK, and Iceland and is generally not classified as Novel Food in these countries. For EU member states without documented pre-1997 consumption, a Novel Food assessment may be required. Multiple Irish and UK suppliers are food-grade certified. For feed use, Palmaria is listed in the EU Catalogue of Feed Materials. Wild harvest requires national marine licences; cultivation at sea requires aquaculture permits.

5.2.6. Gracilaria spp. (Red Algae)

Gracilaria species are primarily used for agar production and are well-established in food and feed globally. In Europe, Gracilaria gracilis is cultivated in Portugal and Spain. Food-grade supply requires EU Reg. 852/2004 compliance. Novel Food status varies by species and member state — Gracilaria spp. used in agar production are generally considered established, but specific species or preparations for new

applications may require authorisation. Feed use should be verified against the EU Catalogue of Feed Materials.

6. Transportation and Supply Chain Regulations

The transportation of seaweed biomass across EU borders is subject to the following regulatory frameworks:

- Agreement on the International Carriage of Perishable Foodstuffs (ATP): Applies to refrigerated or temperature-controlled transport of perishable food products across EU borders. Fresh and refrigerated seaweed transported by road must comply with ATP requirements (certified refrigerated vehicles and containers).
- EU Regulation (EC) No 853/2004 - Specific hygiene rules for food of animal origin: Note that seaweed (algae) are not of animal origin, so this regulation does not apply to macroalgae supply chains. However, blended products or co-processed biomass with animal-origin components must comply.
- EU Regulation (EU) No 142/2011 (Animal By-Products): Not directly applicable to seaweed, unless seaweed is co-cultivated or contaminated with animal by-products. Relevant for feed-grade biomass produced in aquaculture facilities with fish/shellfish co-culture.

The following compliance matrices consolidate the principal regulatory checkpoints identified for the two MARMADE value chains. Due to the different regulatory characteristics of crustacean processing residues and macroalgae biomass, VC1 and VC2 are presented separately. For VC1, compliance is primarily driven by the legal status and handling history of the biomass, whereas VC2 is more strongly influenced by species status, harvesting or cultivation permits and intended use.

The following matrix summarises which regulatory frameworks apply to each target species, by intended end use.

6.1. Cross-Border Supply within the EU

VC1 – Crustacean residues

For intra-EU movement of VC1 biomass, documentation depends on the legal status of the consignment. Food-chain materials remain subject to food traceability and hygiene requirements. Animal by-products and derived products must comply with the movement and documentation requirements of Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011; the TRACES system includes the DOCOM

commercial document used for movements of animal by-products between Member States, (European Commission, 2024).

Where a crustacean fraction has legally become waste and is not governed by the ABP movement regime, cross-border shipment must instead be assessed under Regulation (EU) 2024/1157 on shipments of waste, applicable from 21 May 2026, (European Commission, 2026) , (European Commission, Directorate-general for Environment, 2026).

Table 15. - Regulatory compliance matrix by target species, status generation and end-uses, (Biochica, 2026).

Regulatory checkpoint	Main regulatory framework	When relevant to VC1	MARMADE action
Species and legal origin	CFP Reg. 1380/2013; Reg. 2019/1241; national fisheries measures	Wild-caught shrimp, *Nephrops*, crabs	Verify lawful capture, landing and traceability
Generating establishment	Reg. 852/2004; Reg. 853/2004	Residues generated in seafood-processing establishments	Verify registration/approval and processing history
Status at point of generation	Reg. 178/2002; Reg. 1069/2009; Directive 2008/98/EC	All shell/head/ exoskeleton-rich fractions	Establish whether material remains food, becomes ABP, qualifies as non-waste by-product or becomes waste
Human-food pathway	Reg. 178/2002; 852/2004; 853/2004	Where future food ingredients are envisaged	Preserve an appropriate food-chain pathway from sourcing onward
Animal By-Product pathway	Reg. 1069/2009; Reg. 142/2011	Material no longer intended for human consumption	Verify Category 3 eligibility, permitted use, identification and traceability
Feed pathway	Reg. 183/2005; Reg. 767/2009; Reg. 1831/2003 where applicable	CBBs intended for feed applications	Determine feed material vs feed additive status and verify ABP eligibility where relevant
Novel Food assessment	Reg. 2015/2283	Extracted CBBs intended for food	Assess the specific ingredient, process, composition and intended use; not the crustacean species alone

Invasive / bycatch biomass	National/regional fisheries and management measures; Reg. 1143/2014 where applicable	Particularly *Callinectes sapidus* and *Liocarcinus depurator*	Verify lawful capture/removal before downstream classification
Cross-border movement	Food/ABP/feed rules; Reg. 2024/1157 where waste	Intra-EU or third-country sourcing	Determine legal status before shipment and apply the corresponding documentation/import route
Safety and contaminants	Reg. 2023/915 and subsequent amendments; food/feed safety framework	Biomass and resulting CBBs	Assess contaminants and other safety parameters at biomass and ingredient level; detailed assessment in WP4

The matrix confirms that, for VC1, regulatory compliance cannot be assigned solely on the basis of species. The decisive checkpoint is the legal status of the biomass at the point of generation and its compatibility with the intended downstream food or feed pathway. This status should therefore be documented before collection, transport and transfer to WP2 processing activities.

VC2 – Seaweed

Intra-EU trade in seaweed biomass for food or feed does not require phytosanitary certificates (seaweed is not a regulated plant in the EU plant health framework under Regulation (EU) 2016/2031). However, operators should note:

- Traceability documentation (EU Reg. 178/2002, one-step-back / one-step-forward): All commercial shipments must be accompanied by documentation identifying origin, species, harvest date, and batch number.
- Food business operator registration: The receiving country's food safety authority must have the supplier registered as an FBO if the seaweed is for human consumption.
- Country-of-origin labelling: EU Regulation (EU) No 1169/2011 (Food Information to Consumers) requires origin information on packaged food products. 'Seaweed from the Atlantic Ocean' or equivalent geographic designation is typically required.

Feed consignments: Must be accompanied by a commercial document referencing the feed material, species, quantity, producer registration number, and compliance with Reg. 767/2009

Table 16. - Regulatory compliance matrix by target species and intended end use, (Algae Scope, CTAQUA, 2026)

Species	Reg. 178/2002	Reg. 852/2004	Novel Food 2015/2283	Feed 183/2005	IAS 1143/2014	National Permit
Ulva spp.	Required	Required	Check per spp.	If feed use	Not applicable	Required
Codium spp.	Required	Required	Likely required	If feed use	Not applicable	Required
Alaria esculenta	Required	Required	IRE: likely exempt	Check catalogue	Not applicable	Required
Ruguloptery x okamurae	N/A (not food)	N/A	Full auth. needed	Check catalogue	Spain: prohibited	Research licence only
Palmaria palmata	Required	Required	IRE/UK: exempt	Check catalogue	Not applicable	Required
Gracilaria spp.	Required	Required	Check per spp.	If feed use	Not applicable	Required

6.2. Non-EU Imports

VC1 - Crustacean biomass

For VC1, third-country movements are particularly relevant to the outsourced and upstream processing nodes (as previously identified in D1.1), including Morocco and the principal warm- and cold-water shrimp origin countries (i.e. Vietnam, Greenland, Ecuador). Before entry into the EU, the legal status of the material must be established. Food products of animal origin and animal by-products/derived products are subject to different EU entry conditions, including, where applicable, authorised countries and establishments, official certification, border controls and *TRACES documentation,* (European Commission, 2024).

This distinction is particularly important for Moroccan-generated shrimp shells: authorisation of processed shrimp for entry into the EU as food does not

automatically establish eligibility of the resulting shell fraction for import as a MARMADE feedstock.

VC2 - Seaweed biomass

For seaweed biomass originating in the UK (post-Brexit) or third countries (e.g., Iceland, Norway), the following applies:

- UK: Seaweed entering the EU from Great Britain is subject to EU import controls. As of 2024–2025, the UK–EU Trade and Cooperation Agreement (TCA) includes provisions for sanitary and phytosanitary measures. Food-grade UK seaweed must comply with EU food safety standards and may require official certificates issued by UK competent authorities.
- Norway and Iceland: As EEA members, Norway and Iceland operate under EU internal market rules for food and feed. Seaweed from EEA members may enter the EU without additional import checks, subject to food safety compliance documentation.

Frozen biomass storage and transport: Frozen seaweed (at -20°C or below) must be transported in certified freezer vehicles with temperature logging. Cold chain documentation should accompany each consignment

6.3. Shelf Life and Storage Considerations

VC1 - Crustacean biomass

For VC1, storage conditions depend on both the physical condition and the regulatory status of the crustacean biomass. Where shell-rich fractions are retained within the food chain, fresh, chilled or frozen materials must be stored under appropriate hygiene and temperature-controlled conditions in accordance with the applicable food legislation. Where the material is classified as an Animal By-Product, appropriate segregation, identification and storage conditions must instead be maintained in accordance with Regulations (EC) No 1069/2009 and (EU) No 142/2011, in order to prevent risks to public and animal health and preserve traceability.

The relevant storage conditions should therefore be defined at the sourcing stage according to the intended downstream pathway and the legal status assigned to the biomass. Detailed technical protocols concerning stabilisation, storage duration, freezing, drying and shipment conditions are addressed separately within Deliverable D1.3.

VC2 - Seaweed biomass

Survey data from Algae Scope's supplier mapping reveals the following storage and shelf life profiles for MARMADE target species suppliers:

Table 17. - Storage and shelf-life profiles for MARMADE target species suppliers, (Algae Scope, 2026).

Storage Method	**Shelf Life Range**	**Typical Use**	**Compliance Req.**	**Example Suppliers**
Fresh / refrigerated	< 1 week to 3 weeks	Research samples, local supply	ATP transport; HACCP; cold chain docs	Research-oriented suppliers
Air-dried / mechanically dried	1–2 years	Commercial supply, bulk	Food-grade packaging; batch traceability	Commercial-scale suppliers
Frozen (−20°C or below)	6 months to 2+ years	Food, feed, research	Certified freezer transport; temp logging	Confirmed suppliers
Salted / brined	6 months to 2 years	Food preservation	Labelling; food additives reg. compliance	Confirmed suppliers
Ensiled / fermented	Variable	Feed applications	Feed hygiene (183/2005); HACCP	Limited — not widely reported

7. Key Compliance Recommendations for MARMADE

The regulatory review carried out in D1.2 therefore, identifies a number of requirements that should be transferred to the downstream technical activities of MARMADE (WP2, WP3 and WP4). These requirements concern not only the legal status and traceability of the starting biomass, but also the identity, purity, composition, analytical characterisation, processing history and intended function of the chemical building blocks (CBBs) obtained during the project.

This interface is particularly relevant because WP2 is responsible for the extraction, fractionation, purification and chemical characterisation of the marine-derived building blocks, WP3 for their incorporation and validation in food and feed formulations, and WP4 for their nutritional, technological, safety, allergenicity and regulatory assessment

7.1. Technical specifications and analytical standardisation

A key challenge is that the level of regulatory and analytical standardisation differs substantially between the targeted building blocks. In fact, some compounds already have legally defined EU specifications when used within a particular regulatory category, whereas other marine-derived fractions do not yet benefit from harmonised commodity-specific EN/ISO specifications.

For example, alginic acid and alginates, agar and carrageenan are established food additives, and Regulation (EU) No 231/2012 provides identity and purity specifications for these substances, (European Commission, 2026). For sodium alginate (E401), these include assay, moisture, insoluble matter, heavy metals and microbiological criteria; carrageenan (E407) is similarly subject to compositional, purity and microbiological specifications. Their conditions of use in foods are governed by Regulation (EC) No 1333/2008.

The situation is different for fucoidan. The EU Union List of Novel Foods contains authorised fucoidan extracts from *Fucus vesiculosus* and *Undaria pinnatifida* with detailed product-specific specifications covering fucoidan content, associated components, heavy metals and microbiological criteria. These specifications are, however, linked to those authorised products and production routes and should not be interpreted as a general specification applicable to every fucoidan obtained from any macroalgal species or extraction process, (European Commission, 2015).

A similar distinction applies to astaxanthin. EU specifications exist for the authorised novel food “astaxanthin-rich oleoresin from *Haematococcus pluvialis*”, most recently amended by Commission Implementing Regulation (EU) 2024/1026. These specifications are source- and product-specific and therefore cannot automatically be transferred to astaxanthin-rich fractions extracted from crustacean residues within the MARMADE project, (European Commission, 2026).

European standardisation for algae and algae-derived products is also still evolving. CEN/TC 454 has already produced standards such as EN 17908:2023 for determination of total lipids in algae, while work has continued on methods for proteins, amino acids, polysaccharides, fatty acids, inorganic arsenic, carotenoids and other algal constituents. This confirms that a complete harmonised analytical framework for all CBBs within MARMADE Project, is not yet available, (CEN/CENELEC, 2024).

For this reason, WP2 should establish a technical specification sheet for every priority building block, defining identity, source, production process, purity and the analytical parameters necessary to demonstrate batch-to-batch consistency.

Table 18. – CBBs, Regulatory overview and Key characterisation challenge for MARMADE Project, (Biochica, 2026).

CBBs	Regulatory: standardisation situation	Key characterisation: challenge for WP2/WP4
Lipid fractions	Several horizontal analytical methods available	Fatty-acid profile, oxidation stability, contaminants and residual extraction agents
Astaxanthin-rich fractions	Specific EU specifications exist for *H. pluvialis* oleoresin, but not automatically for crustacean-derived fractions	Total astaxanthin, ester/isomer profile, carotenoid composition, oxidation stability, residual solvents and contaminants
Proteins / peptides	Horizontal analytical methods exist, but product-specific specifications depend on intended use	Protein and amino-acid profile, peptide MW distribution, digestibility and residual allergenic proteins
Chitin / chitosan / COS	No equivalent EU food-additive purity monograph covering crustacean-derived chitosan	DD/DA, molecular weight, DP for COS, residual protein, ash/carbonates, moisture, residual solvents, contaminants and microbiology

Alginate	EU additive specifications available where used as E400–E405	Compliance with legal purity criteria plus MW, M/G ratio, viscosity and functional properties relevant to WP3
Fucoidan	Product-specific Novel Food specifications exist for selected sources	Fucoidan content, sulphation, monosaccharide profile, MW distribution, co-extracted alginate/polyphenols, contaminants
Carrageenan / agar	EU additive specifications available	Identity/type, sulphation, molecular-weight profile, purity and functionality
Mineral-rich fractions	Existing elemental analytical methods available	Mineral composition, bioavailability, heavy metals and purity

7.2. Regulatory checkpoints for WP2: extraction and purification

WP2 should integrate regulatory considerations into process development from an early stage. The proposal foresees DES/NADES, supercritical CO_2, ultrasound, hydrodynamic cavitation, precipitation, membrane separation and other extraction and purification technologies, including the use of hydrophobic and acidic DES systems for carotenoids, proteins and chitin/chitosan recovery.

For food applications, the selection of extraction solvents and processing aids cannot be based exclusively on extraction efficiency, sustainability or low toxicity. Directive 2009/32/EC establishes specific requirements for extraction solvents used in food and food-ingredient production, including authorised substances, conditions of use and, where applicable, maximum residue levels. Consequently, novel DES/NADES systems and their individual components should be assessed for regulatory acceptability and residual presence in the resulting ingredient before the relevant processes are selected for scale-up, (Commission, 2023).

Recommendation for WP2**:** extraction optimisation should therefore include a regulatory screening step covering the identity and regulatory status of solvents and processing aids, residual levels, impact of the process on *Novel Food status*, and compatibility of the resulting ingredient with its intended food or feed use.

7.3. Regulatory checkpoints for WP3: function and formulation

The WP3 introduces another important regulatory decision point because the regulatory category of a CBBs (*Chemical building Blocks)* may depend on the function it performs in the final formulation, and not only on its chemical identity.

For example, an alginate used as a thickener, stabiliser or gelling agent must be assessed against the conditions applicable to authorised food additives. Similarly, a marine-derived compound intentionally added to feed to perform a technological, sensory, nutritional or zootechnical function may fall within the *feed-additive framework* rather than being treated simply as a feed material.

WP3 should therefore document for each CBBs its intended technological or nutritional function, proposed use level, target food/feed category and expected consumer or animal exposure. This information should be transferred to WP4 before the final regulatory pathway is assigned.

7.4. Regulatory and safety checkpoints for WP4

In the Project context, the WP4 should use the analytical specifications considered within the WP2 with exploitation of evidence packages suitable for evaluating the intended food or feed pathway.

In addition, particular attention should be given to contaminants, microbiological safety, processing residues and allergens. In fact, the Regulation (EU) 2023/915 provides the current EU framework for maximum levels of contaminants in foods, while Regulation (EC) No 2073/2005 establishes microbiological criteria for relevant food categories, (Commission, European, 2026).

Coherently to that, indeed the proposal already foresees nutritional and biochemical characterisation, heavy-metal analysis, technological properties, toxicity, allergenicity, digestibility and a dedicated regulatory gap analysis within the same WP4.

For VC1, allergenicity deserves specific consideration. Regulation (EU) No 1169/2011 lists "*crustaceans and products thereof*" among substances or products causing allergies or intolerances. The relevance of this requirement for purified chitin, chitosan, astaxanthin, lipid or other crustacean-derived fractions should therefore be assessed on the basis of their residual protein profile and the characteristics of the final ingredient rather than assumed solely from extraction efficiency, (European Parliament , 2025).

Where a MARMADE ingredient may ultimately require Novel Food authorisation, WP2 and WP4 should generate compositional, production-process, stability,

toxicological, allergenicity and exposure data in a form compatible, as far as practicable, with the latest EFSA Novel Food scientific guidance. This should be considered before initiating key regulatory studies, since studies intended to support a future application may be subject to EFSA pre-submission and study-notification requirements.

Where a MARMADE ingredient may ultimately potential require Novel Food authorisation, WP2 and WP4 should generate compositional, production-process, stability, toxicological, allergenicity and exposure data in a form compatible, as far as practicable, with the latest EFSA Novel Food scientific guidance.

This should be considered before initiating key regulatory studies, since studies intended to support a future application may be subject to EFSA pre-submission and study-notification requirements.

This will be very useful for further activities that can be implemented as "*legacy*" beyond the end of the project.

7.5. Cross-cutting operational compliance: Recommendations

In addition to the WP-specific regulatory checkpoints identified above, a number of horizontal compliance actions should be maintained throughout the MARMADE value chains:

- **Novel Food screening.** Novel Food status should be verified at an early stage for each target biomass-derived ingredient and intended use before commercial exploitation pathways are defined. The EU Novel Food Status Catalogue should be used as an initial screening tool, while recognising that it is non-binding and that the assessment must consider the precise species or biological source, ingredient, production process, composition and intended use, (Directorate-General for Health and Food Safety, 2023).
- **Supplier regulatory status.** For biomass intended to remain within a food pathway, MARMADE should verify that prospective suppliers operate under the applicable food-hygiene framework, including registration or approval where required under Regulations (EC) No 852/2004 and 853/2004. Where relevant, the regulatory status of the specific biomass or ingredient should also be checked before long-term commercial supply arrangements are established.
- **Traceability and documentation.** Establish a traceability and documentation protocol compliant with EU Reg. 178/2002 for all biomass received: origin, species, harvest date, batch ID, handling chain.

- **Temperature-controlled logistics.** Fresh, chilled and frozen biomass should be transported under conditions appropriate to its legal status and physical condition. Temperature-controlled transport and monitoring should be implemented where required, with ATP requirements considered for relevant international carriage of perishable foodstuffs. Detailed operational conditions should remain aligned with the shipping and storage protocols developed in D1.3.
- **Invasive alien species.** *Rugulopteryx okamurae* is already included in the Union List of invasive alien species of Union concern pursuant to Commission Implementing Regulation (EU) 2022/1203. Its collection, transport, use and potential valorisation must therefore be assessed under Regulation (EU) No 1143/2014 together with applicable Spanish and regional management measures. MARMADE partners working with this biomass should maintain dialogue with the competent Spanish authorities, and monitor amendments to applicable management and authorisation conditions, (European Commission, 2022).

- **Cross-country licensing fragmentation.** National licensing and permitting frameworks across the priority sourcing countries remain highly fragmented, with different competent authorities, application procedures and documentation requirements applying even where the underlying EU food-law obligations are the same. The invasive alien species example above illustrates this pattern: EU-level designation under Regulation (EU) No 1143/2014 is applied through country- and region-specific management measures that vary in scope and administration. A harmonised, cross-country reference for licensing and species-specific management requirements would reduce this fragmentation and support more consistent compliance decisions across the sector.

These horizontal actions will be monitored and implemented together with the further WP2-WP4 recommendations above, so that biomass sourcing, extraction-process development, ingredient specification, formulation and safety/regulatory validation remain aligned throughout the project.

Conclusion

Deliverable 1.2 sought to achieve three objectives: to map the EU-level and national regulatory frameworks applicable to each value chain and priority sourcing country identified in D1.1; to identify species-specific and cross-border compliance requirements; and to translate these findings into operational compliance recommendations for WP2 and WP4. This review has addressed each in turn.

The regulatory landscape confirmed by this analysis is fragmented rather than harmonised. For VC1, requirements diverge significantly across the priority sourcing countries, with by-product and waste status frequently determined at the point of processing rather than at the point of capture, and further complicated by invasive species such as the Atlantic blue crab, which fall outside conventional fisheries management. For VC2, the principal constraint is Novel Food status: several MARMADE-relevant species lack an established EU food use history, and clarifying their authorisation pathway will remain necessary before large-scale valorisation can proceed. Across both value chains, the main regulatory challenge is not simply demonstrating that valuable compounds can be extracted from currently underexploited marine biomass within a zero-waste approach, but ensuring that each resulting building block is produced, characterised and validated according to specifications compatible with its intended regulatory pathway.

These findings are translated into the key compliance recommendations set out in Section 7, which are intended to guide sourcing, licensing and documentation decisions across the consortium. D1.2 should therefore be considered the upstream regulatory starting point for an iterative process across the relevant project activities, from WP1 to WP4, in which biomass status, extraction technologies, ingredient specifications, intended functions and safety evidence are progressively aligned with future market applications.

This integrated approach is expected to support the long-term exploitation of MARMADE results and contribute to the project's legacy beyond its duration.

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