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# Risk Assessment Strategies for Contaminants in Seafood (RASCS)

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# Abstract

Risk Assessment Strategies for Contaminants in Seafood (RASCS) is an EFSA Partnering Grant focusing on KEamong seven European Institutions. The project lasted from June 2021 to June 2023. The proposal was built to establish links among seven major research and regulatory institutions in the EU dealing with seafood safety: IPMA (Portugal), Istituto Superiore di Sanità (Italy), Ghent University (Belgium), BfR (Germany), ANSES (France), CREDA and IRTA (Spain). The purpose was to increase KEto foster harmonization and improve strategies for RA of contaminants in seafood products and the related risk communication to the population. RASCS included 6 work-packages (WPs) focused on Hazard Identification, Dietary Exposure Assessment, RA: present and future strategies in a changing world and balance with nutritional benefits, Risk/Benefit Perception and Communication, Dissemination and outreach, and Management of the project. The project started during the COVID pandemic, and interaction during the first year was exclusively online. Although this circumstance partially limited interactions, the execution of the project was not significantly impacted. Exchange among partners was ensured through monthly meetings and additional exchanges by mail or web meetings, while during the second year also physical meetings were organised: the first meeting in Paris in June 2022, was followed by an additional interim meeting focused on specific webinars in Barcelona in November 2022. Four sessions of ToS were held in 2023 in Rome, Lisbon, Barcelona and Paris, and a final meeting in Parma at EFSA's premises in June 2023. The RASCS Partnering Grant has allowed to reach three main goals: i) Significantly improve the participant's knowledge within the subject of RA of contaminants in seafood, ii) Increase awareness on EFSA's goals and tools regarding RA, and iii) Strengthen links and network among multidisciplinary institutions and experts also for future consortia.




**Key words:** Contaminants, seafood, food safety, risk assessment, strategies

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## Summary

Risk Assessment Strategies for Contaminants in Seafood (RASCS) was built to establish links among seven major research and regulatory institutions in the EU dealing with seafood safety: IPMA (Portugal), Istituto Superiore di Sanità (Italy), Ghent University (Belgium), BfR (Germany), ANSES (France), CREDA and IRTA (Spain). The purpose was to increase KEto foster harmonization and improve strategies for RA and risk communication of contaminants in seafood products. This exchange was ensured by different strategies including online meetings, physical meetings, webinars and trainings on spot at different institutions. A communication strategy within the consortium and with external stakeholders and social media was established.

Within the RASCS consortium converged a quite wide spectrum of professional profiles dedicated to contaminants in seafood. To cite a few examples, professional profiles included very technical backgrounds close to complex analytical techniques, environmentalists dedicated to the presence and trends of contaminants in the environment, toxicologists, risk assessors, consumer analysts and communication professionals. Hence, the wholistic RA approaches were described, explained and learned along the execution of the project, and particularly, the novel challenges imposed by social and climate changes. This definitively fulfilled the purpose of EFSA's partnering grants focusing on KE.

With the objective to improve the identification of contaminants present in seafood (hazards), their analysis was conducted at a consortium level, gathering information from the different partners, relative to the physico-chemical characteristics, potential effects, chemical and other methods of analysis and presence of these contaminants in seafood, with major focus on emerging contaminants. Regulations in the EU on specific contaminants were evaluated and recent changes were remarked. Also, particular attention was given to non-regulated compounds such as CTXs, TTX or MCs, due to the major existing gaps at several levels such as metabolization, toxicological profile, validated analytical methods or availability of standards, making difficult their reliable quantification in seafood. Lists of the EU Reference Laboratories on contaminants was set and shared. Regarding monitoring programs in the environment (harvesting and production areas) and in the market (points of sale and distribution) and associated methods, a specific questionnaire on the experimental design and analytical conditions was distributed within the consortium and transferred to competent authorities. The results of this questionnaire are synthetically provided within this report. This was a contribution within Workpackage 2 on the dietary exposure assessment. These results contributed to analyze different monitoring programs responding to current regulations. A second questionnaire was implemented within RASCS, to identify the existing dietary surveys related to seafood products and contaminants. A list of these surveys and most significant data are presented in this report. Particular attention was given to the critical parameters for the design of efficient dietary surveys and the existing strategies for dietary exposure assessment.

With a look into the future, RASCS approached the RA strategies in a changing world considering the evolution of society, particularly on seafood related choices, and also climate change. First, the strategies for RA across the EU considering hazard identification and exposure assessment were studied. Within the frame of this KEproject, partners shared their experience regarding the way the RA procedures are usually carried out in the field of seafood potential contamination and safety. Despite the methodologies are similar, during the exchanges and especially during the various trainings on spot, it clearly appeared that among the EU countries participating to

the Project, the food safety issue is dealt in each country with the intervention of different types and networks of institutions, each with specific roles. The trends of hazards identification and consumer exposure in a changing world according to social changes and climate change were considered. Specific attention was given to combined exposure to contaminants, and the inherent difficulties to study interaction between contaminants. Climate change can affect seafood contamination and the risk of human exposure to toxins and chemical contaminants through the food chain, by either changing the occurrence of toxins/chemical contaminants in the environment or changing the organisms' physiology and response to the presence of toxins/chemical contaminants. The different drivers of climate change having an impact on different aspects of contamination were assessed. Particular attention was given to toxin producing microalgae whose physiology and distribution may be determined by future climate scenarios. Within the social changes that may affect consumers, a crucial aspect approached by RASCS was the balancing of the risk with the nutritional benefit deriving from fish and seafood intake by means of case studies and predictive tools. Among the many issues approached in this matter, the required holistic perspective that balances risks and nutritional benefits for any food consumption scenario was strengthened.

RASCS also approached more closely the current societal drifts that may have an impact on food safety. The risk/benefit perception by consumers and its impact on seafood consumption and related decision-making was considered. A review on previous projects aiming at the study of consumer attitudes and behaviors were studied. This analysis helps risk assessors and scientists understand the key factors that drive consumer behaviors, enabling future RA to effectively set priorities and address the actual needs and concerns of consumers. A consumer survey, specifically oriented to contaminants in seafood was conducted within RASCS with consumers involving more than 1,800 consumers in Belgium, Poland and Spain. The survey included different information for each specific group on the hazards and benefits of consuming seafood, as well as regulation and the impact of three different messages was evaluated. To mitigate the hypothetical bias which may occur in stated preference valuation (assessment) studies (the case of our hypothetical survey), the survey was complemented with a more modest exercise involving student real food choices according to the different received messages. Also related to consumer choices, RASCS approached the strategies for long-term promotion of seafood consumption with the identification and assessment of current strategies and development of new strategies. The particular focus on communication during food safety crisis was assessed.

It is important to state that the conclusions and recommendations found within this report need to be well framed within the RASCS consortium and its particular composition of professional profiles and expertise. The conclusions and recommendations herein do not intend to cover all contaminants and are not based on an exhaustive and universal vision of contaminants in seafood. This was not the purpose of RASCS. On the contrary, our focus on contaminants has been linked to our present challenges, doubts and interests that derive from our day-to-day work, and hence the conclusions and recommendations are oriented to a short-list of compounds that we consider of present and future interest from our own perspective. Some other interesting contaminants are under-represented, and this is not for negligence, nor for lack of interest, nor for considering them not relevant, but only due to the present orientations of the small group of professionals within RASCS.

Overall, RASCS has demonstrated to be an extremely valuable opportunity to improve our skills within the RA of contaminants in seafood. The activities within RASCS have stressed how important it is for experts to improve our awareness on RA associated knowledge, by listening to other experts, and how important are the synergic efforts of experts from different fields that converge in the same room to discuss on emerging issues on food safety, for which important gaps require action.

RASCS has definitively improved the connections among individual partners, strengthening a multidisciplinary network of professionals dedicated to RA of contaminants in seafood. Although some participants in the RASCS consortium had already established collaborations in several international projects and activities, RASCS has allowed to create a "new" network of professionals, increasing a shared vision on the benefits that a multidisciplinary approach can provide to RA. This network has allowed to identify, within institutions that were already known, new experts that have enlarged our vision on RA with their particular expertise and vision of RA. This is leading, beyond RASCS, to favor new experimental work, the writing of new research proposals and scientific publications. It has overall increased the knowledge and expertise on contaminants in seafood across European institutions.

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# 1. Introduction

Seafood constitutes a major source of key nutritional factors required in our diet. In the EU, seafood consumption in many countries does not satisfy the current recommendations to include seafood in 2-3 meals per week. The gastronomy surrounding seafood is also a major cultural tradition, being developed over the centuries and still evolving. It represents a source of individual and community wellbeing and also a very powerful economic driver for food industry. Several chemicals present in marine ecosystems, whether natural or anthropogenic, are of concern regarding seafood safety. Some chemicals are covered by EU regulations and are under surveillance in monitoring programs, whereas other (emerging) contaminants are not included in the monitoring programs and their impact on human health is still unknown or under evaluation: both the toxicological profile and the actual exposure are still poorly investigated. Nonetheless, the adaptation of EU regulations to the design of monitoring programs taking into consideration the specific regional context in relation to seafood product availability, chemical hazards and consumer habits, has not always received consensus. Therefore, dietary exposure assessment generally relies on available consumer surveys. Finally, the definition of an effective communication strategy, whether in the long-term or during specific crises, is a crucial factor to influence consumer response, hence exposure. This needs to be considered when depicting strategies to modulate market responses, taking care of balancing risks and benefits, when promoting/limiting seafood consumption. RA and risk communication are closely linked, as the latter has definitively an impact on consumer habits and hence exposure.

RASCS was built to establish links among seven major research and regulatory institutions from different countries in the EU dealing with seafood safety in order to foster harmonization and improve strategies for RA and risk communication of contaminants in seafood products.

## 1.1. Background and terms of reference

This grant was awarded by EFSA to:

Beneficiary – project coordinator: Institut de Recerca i Tecnologia Agroalimentàries (Institute of Agriculture and Food Research and Technology) (IRTA)

Grant title: RISK ASSESSMENT STRATEGIES FOR CONTAMINANTS IN SEAFOOD (RASCS)

Grant number: GP/EFSA/ENCO/2020/03

RISK ASSESSMENT STRATEGIES for CONTAMINANTS in SEAFOOD (RASCS) is a project that responded to the EFSA Call on Partnering grants (GP/EFSA/ENCO/2020/03) and that has been executed for two years, between June 2021 and June 2023.

The seven partners institutions are:

- Institute of Agriculture and Food Research and Technology (IRTA, Spain, Coordinator)

- Center for Agro-Food Economics and Development (CREDA, Spain)
- Portuguese Institute for the Sea and Atmosphere (IPMA, Portugal)
- Istituto Superiore di Sanità (ISS, Italy)
- Universiteit Gent – Ghent University (UGENT, Belgium)
- German Federal Institute for Risk Assessment (BfR, Germany)
- Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety) (ANSES, France)

## 1.2. Interpretation of the Terms of Reference

RASCS focused on KEbetween "knowledge sharing" organisations, within the field of contaminants in seafood. RASCS has contributed to capacity building at the EU level by strengthening and harmonizing the RA capacities of the consortium members through KEand sharing of skills and competences regarding contaminants in seafood among seven partners representing six EU countries. RASCS intended to strengthen the interaction between Risk Assessors and Risk Communicators from different countries and institutions in the EU. RASCS not only intended to ensure information exchange but has been a proactive proposal that includes analysis of current methodologies and strategies linked to RA and Risk Communication of contaminants in seafood in the present and some possible future scenarios.

The work plan in RASCS consisted in six work packages (WP):

WP1: Hazard Identification
- O-1: Establishing a list of chemical hazards in seafood with particular emphasis on emerging contaminants.
- O-2: Directory of analytical methods for contaminants in seafood and laboratories in Europe.

WP2: Dietary Exposure Assessment
- O-3: Strategies for the design of monitoring programs for contaminants in seafood complying with EU regulations.
- O-4: Identification of datasets on food consumption in the EU.
- O-5: Strategies for exposure assessment of consumers adapted to the present list of contaminants and seafood on the market.

WP3: Risk Assessment: present and future strategies in a changing world and balance with nutritional benefits
- O-6: Description of current Risk Assessment procedures and the impact of potential risks associated to contaminated seafood consumption associated to changes in both climate and social habits.
- O-7: Balancing the risk with the nutritional benefit deriving from fish and seafood intake by means of case studies and predictive tools.

WP4: Risk/Benefit Perception and Communication

- O-8: Insight into seafood consumers risk/benefit perception and its impact on seafood consumption and related decision-making.
- O-9: Recommendations for the development of strategies for risk/benefit communication regarding seafood consumption.

WP5: Dissemination and outreach
- O-10: Ensuring effective communication inside the Project partnership (management and other WPs) to foster synergies and capitalization of activities (internal communication).
- O-11: Engaging stakeholders and advocating activities of dissemination and outreach (external communication).

WP6 - Management

# 2. METHODOLOGIES, RESULTS, CONCLUSIONS AND RECOMMENDATIONS

## 2.1 WP1: HAZARD IDENTIFICATION

### 2.1.1 O-1: Establishing a list of chemical hazards in seafood with particular emphasis on emerging contaminants.

Task 1.1 Overview of and critical view on EU regulations

Within WP1, the activities related with potential chemical hazards in seafood for Task 1.1 (Overview of and critical view on EU regulations) and Task 1.2 (Non-regulated compounds. Trends and emerging contaminants) were gathered. A single Excel file for internal use only was created where several information was included to enable the selection of a shortlist of contaminants and to identify gaps and research needs within this project. The information for each compound was composed by: associated regulations and recommendations, existing expertise among the partners, compound's persistence, accumulative potential, hydrophobicity, speciation, and potential sea-based sources, EU MSwith threshold exceedances, EU MS finding/detecting emerging contaminants, status of compound use (i.e. banned or used), need for toxicological or other data, monitoring strategies, scale of concern, and existence of recall and species involved. A total of 43 groups of compounds (regulated and emerging/non-regulated) were identified, and the information was incorporated for each compound by partners based on their knowledge/expertise on the specific compound (without performing any exhaustive specific literature review). Based on the information, ten groups of compounds were selected for further work in other WPs, namely: toxic metals (organic and inorganic arsenic, cadmium, mercury), mycotoxins (ochratoxin A, zearalenone), polychlorinated biphenyls (PCBs), per- and polyfluorinated compounds (PFAS), marine biotoxins (TTX, CTXs), and cyanotoxins (MCs). For these compounds, relevant scientific and regulatory literature was collected and made available to other project partners for use whenever needed.

Among regulated compounds, Regulations (EU) 2023/915, (EC) No 852/2004, (EC) No 853/2004, and (EC) 2017/625 specify the requirements for compliance with criteria of seafood safety, including maximum levels for organic and inorganic arsenic, cadmium, mercury, PCBs, PFASs in, e.g. fish and seafood, as well as marine biotoxins in live bivalve mollusks, echinoderms, tunicates and marine gastropods. Part of these EU regulations dealing with marine biotoxins have been published almost 20 years ago. In the meantime, the reference detection methods have moved away from animal testing to chemical methods based on liquid chromatography (some coupled with mass spectrometry), and the regulatory limits of certain toxins have been raised (e.g. yessotoxin) or eliminated (e.g. pectenotoxins), respectively. On the other hand, more recent data on the re-evaluation of the toxic potential of marine biotoxins, or findings regarding the effect of industrial food processing (e.g. steaming that may increase toxicity of seafood products) have raised discussions about the need to update the regulatory limits, presumably to more conservative levels, and/or to introduce maximum levels for seafood considering the change in toxin content due to processing. The aspect of processing was also discussed within the consortium during the Webinar session in Barcelona, Spain. Generally, this debate does not reach a consensus among scientists, researchers, regulators, and stakeholders, since reports of acute cases of poisoning within the population are scarce and it is therefore assumed that the current maximum levels protect seafood consumers from acute intoxications. However, little is known about chronic effects which might occur from regular intake of contaminants via seafood consumption, e.g. marine biotoxins such as neurotoxins of the group of cyclic imines which are not regulated.

In case of heavy metals, current legislation does not provide maximum levels for all seafood groups. While mercury is regulated for all mollusks species, maximum levels for cadmium and lead refer to bivalve mollusks only. Maximum levels for arsenic in bivalve species were not considered in the latest Commission Regulation (EU) 2023/465.

## Task 1.2 Non-regulated compounds. Trends and emerging contaminants.

PFASs were non-regulated compounds until the end of 2022. Since 1st January 2023 four PFAS, namely perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS) have been regulated in the EU with maximum levels for both the individual and the sum of the four compounds in food of animal origin including, e.g. fish meat and fishery products, bivalve mollusks and crustaceans. Seafood and fish are among the main dietary sources of human intake of these compounds (EFSA, 2020 a). Maximum levels are listed in Commission Regulation (EC) No 2023/915 repealing Commission Regulation (EC) No 1881/2006.

Among the non-regulated contaminants, the marine biotoxins TTX and CTXs, as well as MCs (cyanotoxins), and mycotoxins were initially considered to be of particular importance for seafood safety.

After oral ingestion, CTXs can cause ciguatera poising (CP). Worldwide, 10,000 to 50,000 cases are reported annually, but a high rate of underreporting is assumed with only 10-20% of the

cases being officially recorded. CTX producing organisms (dinoflagellates of the genera *Gambierdiscus* and *Fukuyoa*) are found in tropical and subtropical waters, making CP endemic in these regions. Due to (increasing) international fish trade, CP cases are also reported in non-tropical countries. In addition, rising seawater temperatures may favor the growth of CTX-producers in other regions previously considered as CP-free, resulting in endemic CP cases, e.g. on the Canary Islands (EFSA CONTAM Panel, 2010; Diogène et al., 2021; EUROCIGUA PROJECT, https://www.efsa.europa.eu/en/topics/ciguatoxins-and-other-marine-biotoxins#eurocigua-project-i). According to Regulation (EC) No 853/2004 fishery products must not be placed on the market if they contain CTXs. MPLs and analytical methods are not defined and not harmonized between laboratories in the EU or worldwide. Concerns about the need for method harmonization were also discussed within the KE Issue on Ciguatera. Participants agreed that the challenges associated with the analysis of CTXs (limited availability of standards and of contaminated, characterized material; limited method validation due to limitations in sample material and standards) hinder understanding of CTXs dynamics in the marine food web. Partners in the RASCS consortium as well as institutes outside the consortium (contacted by partners as relevant stakeholders) discussed the potential of some methods and initiated a small-scale method intercomparison study outside the RASCS project to address the analysis of CTXs using different analytical approaches.

The presence of the neurotoxin TTX is considered problematic worldwide. As highlighted during the Webinar session in Barcelona, the pufferfish *Lagocephalus sceleratus*, a tropical species known to potentially contain high levels of TTXs, occurs as an invasive species in the Mediterranean Sea. Recently, bivalve mollusks and gastropods from European waters have been reported to contain TTX. Shellfish and gastropod species are not currently covered by EU legislation and there are no maximum levels for TTX. Fish species of certain families (e.g. *Tetraodontidae*) are prohibited from being placed on the market according to Regulation (EC) No 853/2004 (EFSA CONTAM Panel, 2017; Katikou, 2019).

Microcystins (MCs) are produced by cyanobacteria such as *Microcystis aeruginosa*. Producers and toxins are mainly found in freshwater ecosystems and can therefore potentially cause contamination of drinking water (WHO, 2021 a). Another route of exposure for humans is the consumption of contaminated aquatic food (Testai et al., 2016; World Health Organization, 2020), but data are still limited, also considering the lack of harmonized detection methodologies in the complex food matrix, with a different recovery and efficiency for MC variants (endowed with different toxicity potential (TCiW, 2021). Recent data from the EMERGTOX scheme (Scheme for monitoring the emergence of marine biotoxins in shellfish in France; Amzil et al, 2021) indicate that the occurrence of MCs is not limited to freshwater systems. MCs are occasionally monitored and quantified at some coastal sampling points in France.

The production volume of aquaculture contributes almost the same share to global fish production as fisheries (FAO, 2022). By the use of plant-based fish feed, fish could be exposed to mycotoxins, if feed is contaminated. In addition, mycotoxins might be transferred into the fish product (Pietsch, 2019; Gonçalves et al., 2020). Furthermore, it has been shown that mycotoxins may occur in dried fish upon storage conditions (Adebayo-Tayo et al., 2008;

Akinyemi et al., 2012). Currently, only Fumonisin B1+B2 guidance level is mentioned in Commission Recommendation 2006/576/EC in relation to fish feed.

#### 2.1.2 O-2: Directory of analytical methods for contaminants in seafood and laboratories in Europe

Task 1.3 Critical view on experimental methods.

As part of task 2.1, ANSES elaborated a questionnaire jointly with IRTA and BfR, to collect information on the monitoring programs for contaminants in seafood in the Member States (MS) represented in the consortium, namely Belgium, France, Germany, Italy, Portugal and Spain. This questionnaire included questions about the analytical methods used for monitoring purposes. As part of task 1.3, the answers to these questions were compiled and the outcome is presented here. The statements in the following sections refer exclusively to the answers received as part of the questionnaires and do not claim to be exhaustive.

The MPLs for the regulated contaminants and the official methods used in the MS as part of the monitoring programs are presented in Table 1. All the regulated contaminants, whatever their nature (toxins, toxic metals, organic compounds), are associated to an MPL and an official method, except for CTXs. Indeed, Regulation (EC) No 853/2004 stipulates that these toxins should not be present in fish products placed on the market. There is no reference to any regulatory threshold or official method. The scientific Opinion of the EFSA CONTAM Panel of EFSA (2010) reported that a level of 0.01 µg P-CTX-1 eq/kg fish should not exert effects in sensitive individuals when consuming a single meal. Yet, due to the sparse toxicological data available, EFSA did not establish an oral acute reference dose. Hossen et al. (2015) estimated the lowest adverse effect level of P-CTX-1 (CTX1B) derived from eight ciguatera fish poisoning events in Guadeloupe, thus contributing to the RA of CTXs. From the analytical point of view, CTXs can be analyzed using notably chemical methods (LC-MS/MS) or *in vitro* (cytotoxicity, immunochemical and receptor binding) assays. Yet, the sensitivity of the methods can be an issue, considering the provisional level of 0.01 µg CTX1B equivalents (eq.)/kg fish. These are some data obtained within RASCS regarding the implementation of methods in different laboratories. In the Canary Islands (IUSA-ULPGC), CTXs are analyzed in fish products using a neuroblastoma cell-based assay (Neuro2a assay) with a LOD and a LOQ of 0.015 and 0.043 µg CTX1B eq./kg, respectively. The LOQ reported for the Neuro2a assay in Catalonia (IRTA) is 0.005 µg CTX1B eq./kg and for the LC-MS/MS it used to be 0.112 µg CTX1B eq./kg and now is 0.014 µg CTX1B eq./kg close to the provisional level of 0.01 µg CTX1B eq/kg fish, showing how difficult it can be to have a method with the required level of sensitivity.

**Table 1:** MPLs in different matrices* and official methods used for the monitoring of the regulated contaminants in Europe. (*See the regulation for specificities)

| | Contaminants | Maximum permitted level | Official method | Reference |
|---|---|---|---|---|
| **Natural toxins** | Azaspiracids (AZAs) | 160 µg AZA eq./kg | LC-MS/MS | Regulation (EC) 853/2004 |
| | Ciguatoxins (CTXs) | Absence | None | Regulation (EC) 853/2004 |
| | Domoic acid (DA) and its isomers | 20 mg DA/kg | LC-UV<br>LC-MS/MS‡ | Regulation (EC) 853/2004 |
| | Saxitoxins (STXs) | 800 µg STX eq. diHCl/kg | LC-FLD | Regulation (EC) 853/2004<br>Regulation (EC) 2021/1374 |
| | Okadaic acid (OA) and dinophysistoxins (DTXs) | 160 µg OA eq./kg | LC-MS/MS | Regulation (EC) 853/2004<br>Regulation (EC) 2021/1374 |
| | Yessotoxins (YTXs) | 3.75 mg YTX eq./kg | LC-MS/MS | Regulation (EC) 853/2004<br>Regulation (EC) 786/2013 |
| **Toxic metals** | Cadmium (Cd) | 0.05–1.00 mg/kg wet weight | ICP-MS | Regulation (EU) 2023/915 |
| | Lead (Pb) | 0.3–1.5 mg/kg wet weight* | ICP-MS | Regulation (EU) 2023/915 |
| | Mercury (Hg) | 0.3–1.0 mg/kg wet weight* | ICP-MS; AAS | Regulation (EU) 2023/915 |
| | Dioxins and dioxin-like polychlorinated biphenyls (PCBs) | 6.5–20.0 pg/g wet weight*,** | GC-MS/MS | Regulation (EU) 2023/915 |
| **Organic compounds** | Polyaromatic hydrocarbons (PAHs) | Benzo(a)pyrene: 2.0–6.0 µg/kg*<br>Sum: 12.0–35.0 µg/kg* | GC-MS | Regulation (EU) 2023/915 |
| | Perfluoroalkyl substances (PFASs) | 2.0–45.0 µg/kg*** | LC-MS/MS | Regulation (EU) 2023/915 |

LC-MS/MS: liquid chromatography coupled to tandem mass spectrometry; HILIC-MS/MS: hydrophilic liquid chromatography coupled to tandem mass spectrometry; LC-UV: liquid chromatography coupled to UV detection; LC-FLD: liquid chromatography coupled to fluorescence detection (*) MPL different according to the food product; (**) Sum of dioxins and PCBs, expressed as toxic equivalents (TEQ); (***) Sum of Perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS); (‡) Official method used in Schleswig-Holstein (DE) for the analysis of domoic acid and its isomers.

Taking into consideration the MPL of the regulated contaminants (Table 1) and the performances of the official methods (Table 2), the latter are sensitive enough to ensure a good level of safety according to the MPL. Furthermore, the methods are generally validated in-house or as part of an interlaboratory trial and if not, they should be to be fully characterized in terms of sensitivity, accuracy, precision, linearity, and specificity. The participation to proficiency testing programs is also a way to confirm competent performance of the official methods.

Besides the regulated compounds, it is important to be able to monitor emerging compounds as well, as they may represent a health hazard. Thus, Commission Regulation (EU) 2022/2388 amended Regulation (EC) No 1881/2006 by implementing maximum levels of PFASs in certain foodstuffs. The PFASs that were monitored as unregulated contaminants should now be integrated in the official control.

**Table 2:** Limits of determination (LODs, LOQs) reported in the questionnaires for the different regulated contaminants monitored in Germany (DE), Spain (ES), France (FR), Italy (IT) and Portugal (PT).

| Limits of determination (LOD / LOQ) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Contaminant** | **DE – Lower Saxony** | **DE - Schleswig Holstein** | **DE - Bavaria** | **ES - Catalonia** | **ES - Canary Islands** | **FR - Anses** | **FR - Ifremer** | **IT** | **PT** |
| **Natural toxins** | AZAs (µg/kg) | 1.0 / 3.0 | 2.5 / 5.0 | 5.0 / 15.0 | NA / 140* | | 0.8-1.4* / 2.0 | | 2.5 / < 8.0 | |
| | CTXs (µg/kg) | | | | NA/0.005 | 0.015 / 0.043** | | | | |
| | DA and its isomers (mg/kg) | 0.5 / 1.5 | 0.1 / 0.2 | 0.2 / 2.0 | NA / 2 | | 0.3 / 1.0 | | 0.4 / <2.0 | |
| | STXs (µg/kg) | 5.0-15.0 / 15.0–45.0*** | 2.0-65.0 / 5.0-193.0*** | | NA / ≥ 20 to ≥ 150*** | | 330 / NA | | | |
| | OA and DTXs (µg/kg) | 4.0-6.0 / 12.0-18.0*** | 10.0 / 20.0 | 5.0 / 15.0 | NA / 204* | | 1.8-3.9* / 10 | | 6.0 / <20.0 | |
| | YTXs (µg/kg) | 6.0 / 18.0 | 50.0 / 100.0 | 10.0 / 30.0 | NA / 350 | | 1.8-1.9* / 5.0 | 15.0 / 50.0 | | |
| **Toxic metals** | Cd (µg/kg) | 0.6-3.2 / 1.8-9.5**** | 1.3 / 4.0 | | NA / 50.0 | | 5.0 / 17.0 | NA / 10.0 | | 2.0 / 6.0 |
| | Pb (µg/kg) | 5.4-7.4 / 16.1-22.2**** | 2.7 / 8.0 | | NA / 300 | | 1.5 / 5.0 | NA / 8.0 | | 20.0 / 60.0 |
| | Hg (µg/kg) | 1.0 / 3.1 | 0.7 / 2.0 | | NA / 10.0 | | 2.5 / 8.3 | NA / 15.0 | | 5.0 / 11.0 |
| **Organic compounds** | Dioxins and PCBs (µg/kg) | | 0.5 / 1.0 | | NA / 0.6* | | | NA / 0.001 | | 0.002-1.2*** / NA |
| | PAHs (µg/kg) | | | | NA / 2.0* | | | NA / 0.05 | 0.30 / 0.90 | 0.009-0.068 / 0.027-0.210‡ |
| | PFAS | | | | | | | | | |

NA: not available; for other abbreviations the reader is referred to Table 1; (*) sum of the regulated contaminants; (**) refers to CTX1B equivalents, determined by Neuro2a assay; (***) depending on the analogue considered; (****) depending on the analytical method used (AAS or ICP-MS); (‡) LODs/LOQs expressed in ng/L.

Task 1.4 Directory of EU laboratories and expert institutes for contaminants in seafood.

Several European Reference Laboratories (EURL) cover the development, harmonization and transfer of analytical methods and monitoring strategies for contaminants, some of them found in seafood. A list of the EURLs is available under https://food.ec.europa.eu/horizontal-topics/european-union-reference-laboratories_en. The EURLs often provide a list of laboratories within the EU countries (mainly national reference laboratories, NRLs) that could be contacted on a national scale. Few examples are provided below:

- EURL for Monitoring of Marine Biotoxins https://www.aesan.gob.es/en/CRLMB/web/red_eu_nrls/seccion/marine_biotoxin.htm
- EURL for Halogenated Persistent Organic Pollutants in Feed and Food (EURL POPs) (https://eurl-pops.eu/about-us)
- EURL for the Analysis of Mycotoxins and Plant Toxins in Food and Feed, https://www.wur.nl/en/research-results/research-institutes/food-safety-research/reference-laboratory/european-union-reference-laboratory/eurl-mycotoxins-plant-toxins/nrls-mycotoxins.htm)
- EURL for heavy metals in Feed and Food https://www.feedsafety.org/activities/eurl/eurl-heavy-metals/

The administrative structures involving specific institutes/agencies in food and feed safety can vary considerably for different countries. An overview of the structures in most European countries is provided in the BfR World Food Safety Almanac. It is online available at https://worldfoodsafetyalmanac.bfr.berlin/

Based on this revision of contaminants, regulations, and methods, some take-away messages can be highlighted:

- Toxic metals, PCBs, PCDD/Fs and PFASs as well as marine biotoxins, cyanotoxins and mycotoxins must be closely monitored in seafood.
- EU legislation in this area has been in permanent evolution, being important to revise it, regardless of beings older (EC 2004/852; EC 2004/853) or more recent (EU 2017/625; EU 2022/2388; and EU 2023/915).
- In the case of toxic metals, current legislation does not provide maximum levels for all seafood matrices.
- PFASs were non-regulated substances until January 2023, when four PFASs were regulated, thereby setting maximum levels for both the individual substances and the sum of the four compounds in food of animal origin.
- Among the non-regulated compounds, the marine biotoxins TTX, CTXs, MCs, and mycotoxins are considered to be of particular importance for seafood safety.
- Mycotoxins have gained more relevance and interest goes beyond their occurrence in dried fish, since other feeds are used in farmed fish such as plant-based meal.
- Through the past years, several reference methods for marine biotoxins have moved away from animal testing to chemical methods.

- Taking into consideration the maximum permissible levels of the regulated contaminants and the performance indicators of the official methods, it can be concluded that methodologically a good level of safety can be ensured to comply with current regulations.
- For the non-regulated compounds, it is important to monitor emerging compounds, since they may present a hazard.
- As a consequence of the RASCS discussion forum, partners in the RASCS consortium together with institutions outside RASCS have initiated a small-scale method comparison study for CTXs.

## 2.2 WP2: DIETARY EXPOSURE ASSESSMENT

### 2.2.1 O-3: Strategies for the design of monitoring programs for contaminants in seafood complying with EU regulations.

Task 2.1 Description and comparison of selected monitoring programs for contaminants in seafood in the EU (Member States in the consortium).

**METHODOLOGY**

In this task, Anses elaborated a questionnaire jointly with IRTA and BfR, to collect information on the monitoring programs for contaminants in seafood in the MS represented in the consortium, namely Belgium, France, Germany, Italy, Portugal and Spain. Anses started working on the questionnaire in July 2021 and consolidated the final version in June 2022 ("RASCS APPENDIX A Monitoring program questionnaire", see Appendix A). The questionnaire was officially sent to all partners in the consortium on 13 June 2022.

The questionnaire was in Excel format with five separate sheets including questions dedicated to:

- Bivalve mollusks – Marine biotoxins – Environmental monitoring (for toxins and phytoplankton)
- Bivalve mollusks – Chemical contaminants – Environmental monitoring
- Bivalve mollusks – Official market monitoring – Biotoxins and chemical contaminants
- Fish and fishery products – Official market monitoring – Biotoxins and chemical contaminants
- Other seafood products – Official market monitoring – Biotoxins and chemical contaminants (e.g. edible macroalgae).

For each topic, the questionnaire had five areas of questions:

- General questions related to the objectives of the program, the institutions involved in the strategy, the frequency of update, and the funding;

- Questions on the sampling strategy related to the number of sampling points, number of samples, frequency of sampling, species sampled (Latin name);
- Questions on analytical methods related to the type of laboratories involved (public/private), name of the contaminants analyzed (regulated and non-regulated), LOD/LOQ;
- Questions on data management related to the nature of information recorded and how the data are accessible (FAIR data);
- Questions on the potential impact of the COVID19 pandemic situation on the monitoring program in terms of sampling and analysis.

To facilitate the answer and gain time in completing the questionnaire, most of the questions were built as YES/NO answers with an automatic list. An open cell was offered to enter information to justify the YES or NO answer.

In France, the questionnaire was sent to six contacts to cover all the scope of the questions: the General Directorate for food (as risk manager for fish and shellfish), the General Directorate for competition policy, consumer affairs and fraud control (for other seafood products such as algae, food supplements), the National Reference Laboratories on Marine Biotoxins (Anses) and on Trace elements (Anses), the coordination of the environmental monitoring programs on marine biotoxins/phytoplankton (Ifremer) and on chemical contaminants in seafood (Ifremer). This situation illustrates how difficult it is to gather information on monitoring programs for seafood (and for food in general). Answers from the above-mentioned French institutes to the questionnaire were received between 30 September and 9 December 2022.

In Spain, questionnaires were sent to five institutions, and replies from two of them only were obtained (Universidad de Las Palmas de Gran Canarias, ULPGC and IRTA).

The questionnaire was sent to one institution in Greece and one in Belgium without receiving a reply.

Answers from Germany, Italy, Portugal and Spain (Catalonia and Canary Islands) were received respectively in October 2022, in January 2023 (updated in March 2023), January 2023, and March 2023.

First, in occasions, the institutions in the consortium had difficulties to identify the institutions in their country to which the questionnaire should be sent. Second, it was difficult to get answers from these institutions.

## RESULTS

The statements in the following sections refer exclusively to the answers received as part of the questionnaires and do not claim to be exhaustive.

2.2.1.1. Bivalve mollusks – Marine biotoxins – Environmental monitoring (for toxins and phytoplankton)

**General aspects**

Depending on the countries and their administrative/political organization, the environmental monitoring for live bivalve mollusks can be done at the national (France-FR) or the regional level (Portugal-PT, Spain-ES, Italy-IT, Germany-DE). If this monitoring targets primarily the regulated toxins, it generally includes some unregulated toxins or unregulated analogues of regulated toxins, as well. The Schleswig Holstein federal state (DE) is the only one monitoring solely the regulated toxins. In France and in Portugal, the unregulated toxins are monitored via specific programs (e.g. EmergTox in France). In the Canaries (ES) and Bavaria (DE), there is no environmental monitoring for marine biotoxins in bivalve mollusks. In Bavaria, this is due to its terrestrial location in the south of Germany. In the Canaries, no shellfish harvesting areas are declared.

When in place, the environmental monitoring is dedicated to the toxins but also to the phytoplankton, the latter being used to trigger or increase the monitoring of toxins in bivalve mollusks in the five countries (FR, PT, ES, IT, DE), except in the Schleswig-Holstein federal state (DE). There is no harmonization about the taxa and the thresholds or warning limits considered as a trigger. This is related to the specificity and contamination history of each environment. Both the toxic and non-toxic flora are monitored in France and in Catalonia (ES), while the toxic flora is the only one being monitored in Portugal, Italy and Germany (Lower Saxony and Schleswig-Holstein). The monitoring programs implemented in the five countries should enable the detection of emerging species. Although the environmental monitoring focuses on the planktonic cells, the benthic species can be detected via the programs in place in Italy and in Catalonia (ES), provided that the cells are present in the water column as there is no specific sampling.

Since the environmental monitoring of bivalve mollusks and phytoplankton is risk-based, the frequency of sampling, the number of sampling points and/or the species are likely to change. The changes in strategy are generally reviewed annually (FR, PT, ES-Catalonia, DE-Lower Saxony) or at another frequency (every 3-5 years: IT; when necessary: DE-Schleswig-Holstein). The monitoring is publicly funded except for Schleswig-Holstein (DE), where the funding comes from public and private sources. France, Portugal and Spain (Catalonia) reported the annual cost for the phytoplankton and toxin monitoring. The total costs, including the staff, are comprised between 500 k€ (Catalonia) and 1,150 k€ (FR).

**Sampling of the environmental monitoring program for live bivalve mollusks**

Despite the heterogeneity in terms of shellfish production (tonnage, area, number of sampling points, number of bivalve mollusks sampled, etc.), the sampling strategy applied in the different countries has many common features. Regarding the frequency of sampling of bivalve mollusks, as the sampling is risk based, it can be modulated according to the environmental conditions and empirical knowledge. Thus, in classified areas the sampling is done weekly in agreement with the commission implementing regulation (EU) 2019/627, notably during at-risk periods characterized by a high risk of occurrence of a contamination event of shellfish. On a regular basis that is outside at-risk periods, the sampling frequency can be reduced to every two weeks (DE-Lower Saxony) or to once a month (FR, PT, DE-Schleswig-Holstein). On the request of food

business operators (FBO), additional points can be included in the monitoring (FR, ES), but in such circumstances they would have to cover the additional costs (FR).

In the case of shellfish sampled offshore (e.g. scallops), the sampling takes place weekly or every two weeks during the harvesting period, but at a lower frequency otherwise. In France for instance, the sampling takes place one month and two weeks before the harvesting period starts. The frequency of sampling is then every two weeks during the harvesting period and increased further to once a week during at-risk periods.

Except in Germany where the monitoring of bivalve mollusks solely concerns mussels, other bivalves and types of shellfish, including gastropods and equinoderms can be sampled annually. In case of contamination of shellfish above the regulatory threshold, the production area is closed and can only re-open after two consecutive negative results. The time between two consecutive analyses may not be less than 48 hours.

Regarding the monitoring of the phytoplankton, the water is generally sampled on a regular basis every two weeks and weekly in Catalonia, except in some areas. The bimonthly frequency can be increased to once a week in certain circumstances: during an at-risk period or if the cell counts are above the threshold defined for the toxic species. The sampling is performed using a bottle/bucket or a hose. With the use of a hose, the sample is considered as being integrative of the water column.

**Analytical methods of the environmental monitoring program for live bivalve mollusks**
The regulated toxins are monitored in live bivalve mollusks. This can be completed by the analysis of unregulated toxins and/or unregulated analogues of regulated toxins. In Germany (Lower Saxony), TTXs are the only unregulated toxins analysed and the most extensive monitoring of the unregulated toxins is performed in France, as part of the EmergTox program, which targets both marine and freshwater toxins (cyanotoxins). The frequency of analysis of the unregulated toxins varies among countries; it can be weekly (ES: gymnodimines, spirolides, pinnatoxins), monthly (FR: EmergTox program) or even annually (ES: TTX).

The CTXs are not monitored in bivalve mollusks but can be searched for in the case of food poisoning events.

The official methods for the analysis of the regulated toxins and the methods used for the analysis of the unregulated toxins are presented in Table 3.

**Data management**
The way the results of the monitoring are handled and reported in the different countries can vary. There are different communication channels available; this includes databases (not necessarily publicly available), websites, annual reports, emails sent to the stakeholders. The information tends to be easily accessible but is not always available in English.

**Table 3: Official methods for the analysis of the regulated toxins and methods used for the analysis of the unregulated toxins**

| | Official methods | Methods for unregulated toxins |
|---|---|---|
| **Toxins of the group of okadaic acid** | LC-MS/MS | |
| **Domoic acid and its isomers** | LC-UV; LC-MS/MS* | |
| **Azaspiracids** | LC-MS/MS | |
| **Yessotoxins** | LC-MS/MS | |
| **Saxitoxins** | LC-FLD | |
| **Gymnodimines** | | LC-MS/MS |
| **Spirolides** | | LC-MS/MS |
| **Pinnatoxins** | | LC-MS/MS |
| **Pteriatoxins** | | LC-MS/MS |
| **Brevetoxins** | | LC-MS/MS |
| **Palytoxin and ovatoxins** | | LC-MS/MS |
| **Microcystins** | | LC-MS/MS |
| **Nodularins** | | LC-MS/MS |
| **Tetrodotoxins** | | HILIC-MS/MS |
| **β-N-Methylamino-L-alanine** | | HILIC-MS/MS |
| **Anatoxins** | | HILIC-MS/MS |
| **Cylindrospermopsins** | | HILIC-MS/MS |

LC-MS/MS: liquid chromatography coupled to tandem mass spectrometry; HILIC-MS/MS: hydrophilic liquid chromatography coupled to tandem mass spectrometry; LC-UV: liquid chromatography coupled to UV detection; LC-FLD: liquid chromatography coupled to fluorescence detection.
(*) Official method used in Schleswig-Holstein (DE) for the analysis of domoic acid and its isomers.

**Impact of the Covid19**

Despite the activity disruption related to the Covid19 pandemic, this barely affected the implementation of the national monitoring programs in 2020 for marine biotoxins in bivalves. Portugal and Germany (Lower Saxony) reported a "negative" impact although it was ranked as "a little".

### 2.2.1.2. Bivalve mollusks – Chemical contaminants – Environmental monitoring

**General aspects**

Similarly to the monitoring of toxins, the environmental monitoring of chemical contaminants in live bivalve mollusks can be done at different levels: national (FR), regional (PT, ES, DE) or local (IT). The Canaries (ES) and Bavaria (DE) have not implemented an environmental monitoring for chemical contaminants in bivalve mollusks. In Bavaria, again this is due to its terrestrial location in the south of Germany and in the Canary Islands since no harvesting zones for shellfish are established.

The monitoring programs relate to regulated compounds only (PT, IT, ES-Catalonia), but can also include unregulated compounds (FR, DE). The strategy implemented by the government itself (DE-Lower Saxony) or in association with other entities (research institutes, RA agencies, local authorities, FBO…) is reviewed periodically (generally on an annual basis). Changes can be included in the monitoring concerning the frequency of sampling, the number of sampling points or even the species sampled.

Apart from the federal state of Schleswig-Holstein (DE) where the funding of the environmental monitoring is both public and private, in all other countries/regions (FR, PT, IT, ES, DE-Lower Saxony), the funding is only public. The reported annual costs are comprised between 80 k€ (ES-Catalonia) and 175 k€ (PT). This is much less than the annual costs reported for the monitoring of marine biotoxins in bivalve mollusks.

**Sampling of the environmental monitoring program for live bivalve mollusks**

The bivalve mollusks are generally sampled once a year (FR, IT, ES, DE) but the frequency can be increased to twice a year (PT, ES) and can even be on a monthly basis (PT). The representativeness of the sampling is based on specific studies and/or on empirical knowledge. Except in Germany where the monitoring of bivalve mollusks solely concerns mussels, other bivalves and types of shellfish, including gastropods and equinoderms, can be sampled annually.

**Analytical methods of the environmental monitoring program for live bivalve mollusks**

The EU regulated contaminants analysed in bivalve mollusks include metals (cadmium-Cd, lead-Ld, mercury-Hg), polycyclic aromatic hydrocarbons (PAHs), dioxins and PCBs. In addition to these compounds, other unregulated chemical contaminants can be monitored, including other trace elements and organic compounds.

The analytical methods used for the monitoring of the regulated and unregulated contaminants are presented in Table 4.

**Table 4: Official methods for the analysis of the regulated contaminants and methods used for the analysis of the unregulated contaminants.**

| | Official methods | Methods for unregulated contaminants |
|---|---|---|
| **Toxic metals** | | |
| **Cadmium** | ICP-MS | |
| **Lead** | ICP-MS | |
| **Mercury** | ICP-MS; AAS | |
| **Methylmercury** | AAS | |
| **Arsenic** | | ICP-OES |
| **Chromium** | | AAS, ICP-OES |
| **Copper** | | AAS, ICP-OES |
| **Manganese** | | ICP-OES |
| **Nickel** | | AAS, ICP-OES |
| **Zinc** | | AAS, ICP-OES |
| | | |
| **Organic compounds** | | |
| **PAHs** | GC-MS | |
| **Dioxins and PCBs** | GC-MS/MS | |
| **Pesticides** | | GC-MS/MS |
| **Polybrominated diphenyl ethers** | | GC-HRMS |
| **Organo tin** | | GC-MS/MS |
| **Phtalates** | | GC-MS/MS |

ICP-MS: inductively coupled plasma mass spectrometry; ICP-OES: inductively coupled plasma optical emission spectroscopy; AAS: atomic absorption spectroscopy; GC-MS/MS: gas chromatography coupled to

tandem mass spectrometry; GC-HRMS: gas chromatography coupled to high-resolution mass spectrometry.

**Data management**

The way the results of the monitoring are handled and reported in the different countries can vary. There are different communication channels available; this includes databases (not necessarily publicly available), websites, annual reports, emails sent to the stakeholders. The information tends to be easily accessible but is not always available in English.

**Impact of the Covid19**

Despite the activity disruption related to the Covid19 pandemic, this barely affected the implementation of the national monitoring programs in 2020 for contaminants in bivalves. Germany (Lower Saxony) reported a "negative" impact although it was ranked as "a little".

2.2.1.3. Bivalve mollusks – Official market monitoring – Biotoxins and chemical contaminants

**General aspects**

Marine biotoxins

Toxins are monitored in bivalve mollusks placed on the market. In France and Germany, this monitoring is performed at the national (FR) or regional level (DE) and relates to regulated toxins only (FR, DE-Bavaria, DE-Schleswig-Holstein) or also includes unregulated toxins (DE-Lower Saxony). The monitoring strategy is defined by the government itself (FR; DE-Schleswig-Holstein), or in association with RA agencies (DE-Bavaria, Lower Saxony) and is reviewed annually.

Chemical contaminants

The contaminants monitored at the national level in France and the regional level in Germany (Schleswig-Holstein) are regulated. The monitoring strategy defined by the government is reviewed annually.

**Sampling of the official market program for live bivalve mollusks**

Marine biotoxins

The sampling put in place relates to live and frozen/canned/processed bivalve mollusks. No gastropods or echinoderms are being monitored, just bivalves (mussels only in Bavaria, six bivalve species in Schleswig-Holstein and 17 in France).

Chemical contaminants

Live and frozen/canned/processed bivalve mollusks are monitored for the presence of contaminants in France and Germany (Schleswig-Holstein). In France, the occurrence of chemical contaminants is completed by data obtained from specific studies not related to the official control. In France, TDS are conducted on a regular basis (but not annually). The latest TDS called EAT2 conducted in 2006-2010, looked at the occurrence of chemical contaminants in bivalve mollusks (scallops, oysters, mussels). As part of another study, 24 mussel samples were analysed for the presence of 11 toxic metals to assess the sanitary impact of a local pollution

generated by the Alteo company that discharged some 20 million tons of bauxite residue (called red mud) into the Cassidaigne Canyon (northwest French Mediterranean) from 1996 to 2015.

**Analytical methods of the official market program for live bivalve mollusks**

Marine biotoxins

In France and Germany, the regulated toxins are analysed according to the official methods presented in Table 3. In Lower Saxony (DE), TTX are also monitored and analysed by HILIC-MS/MS.

Chemical contaminants

The regulated trace elements (cadmium, lead and mercury) are analysed using the official methods presented in Table 4 (ICP-MS; AAS). In Germany (Schleswig-Holstein), unregulated toxic metals are also monitored: aluminium, arsenic, total chromium, nickel and silver.

**Data management**

The results of the monitoring performed in Schleswig-Holstein are sent to the stakeholders and stored in a database.

2.2.1.4. Fish – Official market monitoring – Biotoxins and chemical contaminants

General aspects

Marine biotoxins

France and Spain (Catalonia and the Canaries) answered to this questionnaire. There is an official monitoring program for marine toxins in fish placed on the market in Spain (Catalonia, Canaries), but not in France. Yet, in the latter country the fish/fish products are analysed for the presence of marine biotoxins in case of human food poisoning.

Chemical contaminants

The monitoring of chemical contaminants in Spain is dedicated to the regulated ones only, while in France both regulated and unregulated contaminants are monitored. The monitoring strategy involving the government together with laboratories (FR) or with research institutes (ES), is reviewed annually whatever the country. This risk-based and publicly funded environmental monitoring can lead to an increase/change in either the species sampled (FR) or the number of sampling points & species sampled (ES-Canaries).

**Sampling of the official monitoring program for fish and fishery products on the market (excluding importation)**

In France, the number of samples analysed in 2019 varied between none (marine biotoxins) and 310 (toxic metals). These samples included (wild and farmed) fish, crustaceans and cephalopods. Regarding Spain, in 2020 a total of 1,909 samples were analysed for CTXs in the Canaries and five samples were dedicated to the analysis of dioxins and PCBs in Catalonia in 2022.

The strategy aimed to ensure the representativeness of the sampling points varies between countries and even at a regional level (ES). Yet, there are some common features, notably between FR and Catalonia, where the sampling establishments are randomly chosen, they are

representative of the different regions and focus on the most consumed species. In Spain, the identification of the sampling points is based on specific studies (Catalonia, Canaries). In France and in the Canaries, the sampling is planned all over the year.

The samples monitored are of different natures, yet in France and Spain this concerns raw fish fillet or piece of flesh, as well as eviscerated fish. In France and in the Canaries, the fish are peeled unless there is a traditional consumption habit with the skin. In France, smoked fish are also monitored for the presence of PAHs.

In Spain, the monitoring only involves marine fish, in France marine and freshwater fish are monitored along with crustaceans and cephalopods.
The official monitoring is publicly funded in France and Spain, yet in the Canaries, private funding is also involved.

In France, the official monitoring can be completed by specific studies such as the TDS EAT2 and the ALTEO project (cf paragraph 2.1.3).

**Analytical methods of the official monitoring program for fish and fishery products on the market**
Marine biotoxins
In the Canaries, the presence of CTXs in fish is monitored by a neuroblastoma cell-based assay (Neuro2a assay).
Chemical contaminants
The official methods used in France involve ICP-MS and AAS for toxic metals and GC-MS(/MS) or GC-HRMS for the organic compounds (PAHs, dioxins and PCBs).

**Data management**
The way the results of the monitoring are handled and reported in the different countries can vary. Yet, the date and the monitored species are traced both in France and Spain. In the Canaries, the location is indicated at the sub-regional and FAO level.
In both countries an annual report is produced. In Spain, the results are sent to stakeholders and in the Canaries they can also be available from a public database and on a website. In France the results are compiled in a national database that is not publicly available.

**Impact of the Covid19**
In the Canaries, the impact of the Covid19 was considered as being light (ranked as "A little"), while no impact was reported from Catalonia.

2.2.1.5. Other seafood – Official market monitoring – Biotoxins and chemical contaminants

France is the only country that replied to this questionnaire.

**General aspects**

Macroalgae used as seaweed or as food supplements are monitored for the presence of toxic metals (Pb, Cd, Hg, As, Ni). This program is implemented under the aegis of the directorate for competition policy, consumer affairs and fraud control, and is publicly funded.

**Sampling of the monitoring program on the market (excluding importation)**
Between 2013 and 2015, six to nine samples were analysed annually.

The other parts of the questionnaire related to the analytical methods, the data management and the impact of the Covid19 were not answered.

Task 2.2 Analysis and methodological recommendations for monitoring programs taking into account statistical approach, risk assessment and budget availability.

In this task, we had the objective to conduct a critical analysis of information collected in task 2.1, taking into account the context, the regulatory requirements, and limitations of the selected monitoring programs in the light of the global objective of RA. However, the information gathered in response to the questionnaire was too limited to allow a refined analysis and giving any methodological recommendations.

### 2.2.2 O-4: Identification of datasets on food consumption in the EU

Task 2.3 Identification of dietary surveys that can be used for exposure assessment related to seafood.

Food consumption data is essential for dietary RA supporting risk managers in their decision-making on food safety. The task 2.3 aimed at identifying the dietary surveys that can be used for exposure assessment related to seafood. From the partners in RASCS we tried to identify in-house dietary surveys concerning seafood consumption, in a second step the EFSA comprehensive database was investigated, and in a third step other sources of data were investigated.

**Method**

The different partners in RASCS were asked to identify in-house dietary surveys on seafood. National dietary surveys on the general population, including but not specifically dedicated to seafood, were targeted, as well as specific studies on seafood consumers. A questionnaire was prepared to make this inventory and to collect information on the surveys, from a methodological point of view. Critical methodological points were identified to be present in specific questions, such as the product description, the food codification used, the various ways to precisely quantify the quantity consumed, etc. A first draft of questionnaire was prepared by Anses, then reviewed by BfR. It was presented at the June 2022 meeting to the partners with filling examples from French studies. Finally, the questionnaire was reviewed by EFSA, before sending to all partners in September 2022.

The questionnaire ("RASCS APPENDIX B Questionnaire_consumption_surveys", Appendix B) was divided into eight parts: study identification, objectives and target populations of the study, sampling strategy, recruitment of participants, information collection (e.g. FFQ or recall), questionnaire and data collection, study funding, publication/use of results. Apart from the title

and country, the first part on study identification allows to get information on the type of study, its periodicity and geographical coverage. The second part records the main objectives of the study and the targeted populations. The sampling strategy part allows to identify the data basis and method used for the individual sampling, whereas the recruitment of participants part deals with the practical recruitment of participants. The part on information collection describes the method and tools used to collect data. The questionnaire and data collection part allows to describe all data types recorded regarding consumption (quantities, frequencies, portion sizes etc. as well as food coding systems), data on individuals, perception, and other data. The last parts concern the study funding and the use of results, including publication and open access conditions.

It was planned to analyze the answers to the questionnaire to identify critical points in consumption data for exposure assessments associated with seafood, to underline gaps and strengths and to propose recommendations.

**Results of data coming from RASCS partnership (closed return questionnaire 22 February 2023)**

Unfortunately, only six questionnaires were collected during the project: 1 from Germany, 1 from Portugal, 1 from the RASCS project and 3 from France. The survey for the RASCS project was not yet conducted at the time of the analysis, consequently, information is difficult to use in a prospective analysis. The surveys are summarized in the following table:

**Table 5: Summary of the surveys**

| Study name | Country | Study type | Study years | Population | Reference |
|---|---|---|---|---|---|
| **Consumer perception of seafood risk and benefit and the effect of that perception on seafood consumption** | Spain, Belgium and Poland | Cross-sectional | On-going | Adults, seafood consumers | No reference available at the time of publication of this report |
| **KiESEL (Kinder-Ernährungsstudie zur Erfassung des Lebensmittelverzehrs), Children´s Nutrition Survey to Record Food Consumption** | Germany | Cross-sectional | 2014-2017 | Children aged from 6 month up to inclusive 5 years | https://doi.org/10.1186/s40795-022-00527-6 https://edoc.rki.de/handle/176904/2813 https://www.bfr.bund.de/en/kiesel__the_childrens_nutrition_survey_to_record_food_consumption-260123.html |
| **Projeto Fileira do Pescado - Determinação do Índice Ómega** | Portugal | Cross-sectional | Not provided | All adults (≥18 year old) that do a regular blood analysis | No reference available at the time of publication of this report |
| **INCA3 (Individuelle Nationale de Consommation Alimentaire)** | France | Cross-sectional | 2014-2015 | Adults (18-79 y) and children (0-17 y) | https://pubmed.ncbi.nlm.nih.gov/30394264/ |
| **Consomer** | France | Cross-sectional | 2016-2017 | Adults, coastal areas | No reference available at the time of publication of this report |
| **Calipso (Fish and seafood consumption study and biomarker of exposure to trace elements, pollutants and omega 3)** | France | Cross-sectional | 2004 | Adults (≥18 y), high seafood consumers | https://www.anses.fr/en/system/files/PASER-Ra-CalipsoEN.pdf |

### 2.3.2 Investigating food consumption data coming from EFSA Comprehensive European Food Consumption

Some national consumption studies are reported in the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) (EFSA 2011, https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6223#efs26223-bib-0158). The Comprehensive Database developed since 2011 is the most complete compilation of national consumption data in Europe. It contains (in February 2023) detailed information on 83 surveys from 29 EU and pre-accession countries as well as UK, with a last recent update in 2022 and other data expected for 2023. The less recent surveys started in 1997 (n=3) and the most recent ones in 2019 (n=5). The number of surveys varies between countries, from 1 for Bosnia and Herzegovina, Czechia, Montenegro, Poland, Republic of North Macedonia, and Slovakia, until 7 for Finland. Among the RASCS partners, Belgium provided 3 datasets, France: 2, Germany: 4, Italy: 3, Portugal: 2, and Spain: 6.

Data are mainly recorded with the latest version of FoodEx2, the EFSA comprehensive food classification system that allows to precisely describe food (including beverages) data across different food safety domains, and that is used by EFSA to combine consumption and

concentration data for RA. FoodEx2 is based on a hierarchical parent-child relationship. For example, Cod can be classified in the general food group "Fish, seafood, amphibians, reptiles and invertebrates", then in a subgroup "Fish (meat)", then "Marine fish", then "Cods, hakes, haddocks", then "Cod". A facet/descriptor system allows to provide additional information for a particular aspect of a food, such as the source, the ingredient, the process, the packaging format and material, etc.

Consumption statistic's levels are available at different FoodEx2 levels for 76 surveys from 27 countries. They are listed in Annex F of this report. Consumption data for the food group "Fish, seafood, amphibians, reptiles and invertebrates" are available for different subpopulations (see Table below). All those surveys present data for fish consumption, 74 for processed seafood, 68 for crustaceans, 47 for fish offal, and only 1 for sea urchins and other echinoderms.

**Table 6: Number of surveys with consumption data in the EFSA Comprehensive European Food Consumption Database depending on the type of seafood**

| Type of seafood | Nb of surveys with consumption data in the EFSA Comprehensive European Food Consumption Database |
|---|---|
| Crustaceans | 68 |
| Fish (meat) | 76 |
| Fish and seafood processed | 74 |
| Fish offal | 47 |
| Fish, seafood, amphibians, reptiles and invertebrates | 1 |
| Mollusks | 62 |
| Sea urchins and other echinoderms | 1 |

Common statistics can easily be found regarding seafood consumption. As an example, chronic consumption (g/day) for the whole group "Fish, seafood, amphibians, reptiles and invertebrates" is presented below for adults in the last French National dietary survey (INCA3, 2014-2015) (table 7).

**Table 7: Chronic consumption (g/day) of the whole group "Fish, seafood, amphibians, reptiles and invertebrates" for adults from the last French National dietary survey (INCA3, 2014-2015)**

| Population | Nb subjects | % consumers | Mean | SD | P5 | P10 | P50 | P95 | P97.5 | P99 |
|---|---|---|---|---|---|---|---|---|---|---|
| **All subjects** | 1,773 | 60.0% | 36.96 | 46.67 | 0.00 | 0.00 | 15.69 | 132.71 | 157.60 | 189.67 |
| **Consumers only** | 1,063 | - | 59.98 | 46.82 | 6.67 | 10.81 | 49.80 | 149.72 | 175.36 | 207.86 |

Data can be produced at the different FoodEx2 levels. For example, the chronic food consumption data for mussel (Exposure hierarchy L5) is presented for adults in the last French National dietary survey (INCA3, 2014-2015) in the table below (in g/kg bw per day) (Table 8)

**Table 8: Chronic consumption (g/kg bw/day) of mussels for adults from the last French National dietary survey (INCA3, 2014-2015)**

| Population | Nb of subjects | Nb of consumers | Mean | SD | P5 | P10 | P50 | P95 | P97.5 | P99 |
|---|---|---|---|---|---|---|---|---|---|---|
| **All subjects** | 1,773 | 40 | 0,01 | 0,07 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,39 |
| **Consumers only** | 40 | - | 0,40 | 0,30 | 0,06 | 0,09 | 0,36 | 0,91 | 0,94 | 1,23 |

Acute consumption is also available. As an example, the acute food consumption data for mussel (Exposure hierarchy L5) is presented for adults in the last French National dietary survey (INCA3, 2014-2015) in the table below (in g/kg bw) (Table 9).

**Table 9: Acute consumption (g/kg bw) of mussels for adults from the last French National dietary survey (INCA3, 2014-2015)**

| | Number of consuming days | % consuming days | Mean | SD | P5 | P10 | P50 | P95 | P97.5 | P99 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Consuming days only** | 43 | 0,8% | 1,19 | 0,93 | 0,20 | 0,24 | 1,07 | 2,77 | 2,91 | 3,70 |

Regarding populations, most of the surveys include different age classes among which infants (< 12 months old), toddlers (≥ 12 months to < 36 months old), other children (≥ 36 months to < 10 years old), adolescents (≥ 10 years to < 18 years old), adults (≥ 18 years to < 65 years old), elderly (≥ 65 years to < 75 years old), and very elderly (≥ 75 years old). Some surveys include also specific populations such as pregnant women (≥ 15 to ≤ 45 years old for Latvia; 17–46 years for Portugal) or lactating women (≥ 28 to ≤ 39 years old for Greece; 18–45 years for Estonia). The following table summarizes, for each subpopulation, the number of surveys in which data on seafood consumption is available (Table 10).

**Table 10: Number of surveys with consumption data on "Fish, seafood, amphibians, reptiles and invertebrates" per subpopulation in the EFSA Comprehensive European Food Consumption Database**

| Population groups | Nb surveys with consumption data on "Fish, seafood, amphibians, reptiles and invertebrates" in the EFSA Comprehensive European Food Consumption Database |
|---|---|
| **Adolescents** | 37 |
| **Adults** | 43 |
| **Elderly** | 31 |
| **Infants** | 14 |
| **Lactating women** | 2 |
| **Other children** | 34 |
| **Pregnant women** | 9 |
| **Toddlers** | 24 |

| | |
|---|---|
| **Vegetarians** | 2 |
| **Very elderly** | 17 |

EFSA is conducting a two-phase survey to collect data on consumption of certain fish species and other seafood and on consumer awareness of national advice related to consumption of these foods. The data generated by the survey will be used to respond to a European Commission request for a 'Scientific Report on frequency of consumption of different fish species, crustaceans and molluscs and on effectiveness of MSs' advice on consumption of these species for their contamination with mercury'. The survey includes two main parts: a food propensity questionnaire covering all 27 EU Member States, Iceland and Norway; and an 'awareness' questionnaire. The survey will generate data on consumption of fish (some 40 species linked to higher occurrence of methylmercury or to higher exposure to methylmercury in the diet) and other seafood (molluscs, crustaceans). It will also generate data on consumer awareness of national dietary advice on fish/other seafood consumption, of the potential risks and benefits of fish/other seafood consumption, and of the presence of contaminants in fish/other seafood. The first wave will collect data from 500 respondents in the 29 countries, with oversampling of pregnant women and children (the most vulnerable populations with respect to methylmercury in food). In a second wave (2024) EFSA will focus on a smaller group of countries who have indicated that they will update their advice to consumers, plus a small control group of countries that will not update their advice. The final report is scheduled for finalisation in 2025.

Task 2.4 Critical parameters for the design of efficient dietary surveys.

Unfortunately, the low participation rate to the questionnaire part did not allow to perform a relevant analysis of the methodologies between countries regarding seafood consumption surveys. However, some discussion points are identified below from the other data sources.

- Subpopulations

Regarding populations, it appears that data on specific population are sparse. In particular, few data are available for pregnant woman and lactating women that are particularly sensitive populations regarding seafood contaminants. Some studies however tried to include pregnant women (for example ENALIA2 in Spain, or INCA3 in France), or women of childbearing age (Calipso survey registered through the questionnaires). Specific populations should certainly be more considered in the consumption survey designs. Seafood consumption is heterogeneous in space (higher in coastal areas) and time (winter for oysters for example), so to detect high consumers or high consumption specific surveys have to be conducted (e.g. the French Calipso survey that focused on adults consuming at least seafood twice a week, and the French Consomer study focusing on adults in French coastal population).

- 24h-recalls vs food propensity questionnaire

The surveys included in the EU comprehensive database follow the recommendations of the 2011 "What's on the Menu in Europe? - EU Menu" project and different guidance reports, implemented by EFSA in order to harmonize the methodology of data collection and provide accurate and standardized data (Food consumption data | EFSA (europa.eu)). The revision of the general guidelines is currently ongoing. Among the main recommendations, consumption should be collected on two non-consecutive days with a 24-hour dietary recall method (apart from infants

and young children). A short food propensity questionnaire (FPQ) should be used to collect information on the consumption of some less frequently eaten foods and the consumption frequencies of food supplements. However, FPQ is neither always conducted, nor used for RA. In the Comprehensive Database, 56% of the surveys used 24-hours dietary recalls, sometimes combined with food records and/or FPQ, in accordance with the recommendations. One of the limitations of 24-hours dietary recalls, even repeated, is to underestimate the consumption of foods that are not consumed on a regular basis. Consequently, seafood consumption may be underestimated. As an example, in the last French National dietary survey (INCA3, 2014-2015), the adult fish consumer rate is 42.5% on the basis of the 24-hours dietary recalls, whereas, on the basis of the FPQ, 97.8% of adults declared having consumed fish in the last 12 months. For mollusks and crustaceans, the bias is higher, as 13.8% of adults ate mollusks and/or crustaceans during the 2 or 3 days of recording, whereas they were respectively 77.2% and 75.8% of consumers during the previous year. However, this bias is certainly dependent on the geographical situation of the country. As an example, the Spain surveys of the EU comprehensive database, with 2 or 3-repetead 24-hours dietary recalls (in 2009 and 2013) present a consumer rate for fish, seafood, amphibians, reptiles and invertebrates higher than 75%, that can be easily explained by the sea proximity. But consumer rates higher than 75% are relatively sparse. Consequently, 24-hours dietary recalls only clearly appear to be insufficient to assess seafood consumption in a RA perspective. That is why FPQ should be used to collect information on the consumption of seafood that is generally less frequently consumed, in order to estimate usual intakes. In a FPQ, seasonality of consumption can be considered by asking the consumption frequency by season or period of time (e.g. oysters at Christmas time).

- Protocol for estimation of edible portion

For food consumption surveys, the estimation of edible part is critical for all "exoskeleton animals": when, for example, one individual is estimating eating one crab, how is the edible part estimated? In some studies, the food is directly weighted (e.g. KiESEL study); sometimes the consumer directly gives its portion size in grams (e.g., Fileira do Pescado study). In other cases, studies use unit (number of eaten oysters, crabs, shrimps…) or photos with conversion factors to assess the edible weight (e.g. Calipso andConsomer surveys). Photos can be generic (with 3 or 4 photos representing all species), or very specific as in the Fishchoice project tool (https://www.fishchoice.eu/calculator/). All those methods can be biased, and data are clearly missing regarding the way shell/carapace are taken into account.

- Seafood list and classification

Only three surveys, recorded through the questionnaires, appeared to focus on seafood consumption: the survey developed in the RASCS project (on-going), the French Calipso survey that focused on adults consuming at least seafood twice a week, and the French Consomer study focusing on adults in French coastal population. The data on specific food products can be poorly estimated if seafood is not consumed frequently. This is the reason why specific seafood consumer surveys are needed (i.e. Consomer or CALIPSO in France) using FPQ on specific seafood. However, the list of seafood studied has to be complete, not to forget algae consumption for example. The list of seafood that can be used for seafood consumption survey is not trivial: in FoodEx2 (the food classification system that should be used for the reported foods in the EU comprehensive database), the number of classified "common species" and products is around 424 items, the number of monitored seafood products can be high (e.g., in

EUFOMA, 1,325 species; 104 common names). A good compromise is hard to find to reduce those lists to common names that citizens know and recognize to buy or eat. Considering groups, the FoodEx2 classification is also missing meaningful intermediate levels of food classification related to the contaminant investigated such as marine bivalves/gastropods for phycotoxins.

#### 2.2.3 O-5: Strategies for exposure assessment of consumers adapted to the present list of contaminants and seafood on the market.

Task 2.5 Analysis of existing strategies for dietary exposure assessment

Some existing strategies for acute and chronic dietary exposure assessment have been discussed during the ToS at Anses (11-12 May 2023), where the partners could share their methodologies, for the general population and for specific population (high consumers of seafood products, sea coastline area). Strengths and weaknesses have been discussed. In particular the following cases were presented for the French dietary exposure assessment as carried out by Anses.

**Chronic exposure**

Different cases were presented. Regarding the general population, consumption data from the national surveys can be combined with specific concentration data obtained from the analysis of specific samples representative of the French diet (TDS) to assess chronic exposure to a large set of chemicals. For high seafood consumers, consumption data come from specific surveys (e.g. Calipso, Consomer, see task 2.3). In the case of ubiquitous contaminants, all the diet is taken into account for the RA, whereas when seafood is the main contributor to the exposure (e.g. methylmercury), only seafood consumption is taken into account.

**Acute exposure**

For acute exposure, variability of contamination is important as well as variability of consumption. Extreme events, with extreme contamination and/or high consumption, leading to acute risk of severe cases, fortunately, are rare and are linked to a particular event concerning only one or several seafood products: data from specific surveys of consumption and contamination are usually employed. A sea-to-fork scenario of phycotoxin contamination in oysters was presented. Using portion size of specific survey (Consomer study) and contamination variability, we estimated by quantitative RA the relationship between exposure and probability of illness using different scenarios. The importance of precise measurement of contamination, precise measurement of consumption of specific seafood, adapted monitoring (frequency of control), adapted sanitary threshold and rapid management to avoid harmful situations were stressed.

#### 2.2.4: Conclusions and Recommendations

In WP2, focused on monitoring programs for contaminants in seafood and on consumption dietary surveys, the partners in charge of leading the tasks (Anses, BfR, IRTA) - and more broadly all the partners of the consortium - shared information and their experience. The questionnaire by itself is already an outcome of this project because the institutions shared their

views during the building steps and exchanged during monthly meetings on the difficulties to identify the relevant institutions in their country to which this questionnaire should be sent and then to collect information to answer the questions. This questionnaire was very ambitious in terms of quantitative data and it illustrates how difficult it is to find information in each country on the strategy and the costs of the monitoring programs for contaminants in food, both at environmental and market level. In the area of FAIR data (Findable, Accessible, Interoperable, Reusable), this outcome shows that there is room for improvement.

## 2.3 WP3: Risk Assessment: present and future strategies in a changing world and balance with nutritional benefits

### 2.3.1 O-6: Description of current Risk Assessment procedures and the impact of potential risks associated to contaminated seafood consumption associated to changes in both climate and social habits.

Task 3.1 Strategies for Risk Assessment across the EU considering hazard identification and exposure assessment

Within the frame of this KEproject, partners have shared their experience regarding the way the RA procedures are usually carried out in the field of seafood potential contamination and safety. It has been quite clear during the different exchanges, especially during the different ToS, that the RA approaches and methodologies underpinning regulatory decisions with regard to individual chemicals in general and specifically for seafood contaminants are the same in the different countries participating to the consortium. They are essentially based on the internationally accepted approaches, as used in EFSA and well described in the WHO Human Health RA Toolkit (WHO, 2021 b) (2nd edition, updated in 2021), for which the RA is defined as "*a process intended to estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system"*.

The processes consist on the identification and characterization (dose-response relationship) of chemical hazards (hazard being dealt with in WP1), exposures assessment for the chemicals under evaluation (focus of WP2), which is the result of the integration of occurrence data with consumption data, with the aim to determine whether these exposures pose a risk for public health, and can be depicted in the scheme and the road map taken from the WHO publication.

As discussed among the participants especially in the ToS in Lisbon, depending on the available data set, both the exposure (occurrence + consumption) and the hazard can be determined by applying a tiered approach spanning from semi-quantitative to deterministic up to probabilistic estimate, in an increasing level of complexity, the latter being possible only for data rich compounds (as illustrated during the ToS for Hg in fish and seafood). The most frequently used approach by the partners foresees that the intake of contaminants are compared with established health-based guidance values (HBGVs) with a deterministic approach. The output of this risk characterization may be also expressed in terms of the probability of exceeding the threshold(s). In a fully integrated probabilistic approach, exposure and HBGV are defined by distributions that describe their variability and/or uncertainty. Although considered by the consortium as more refined approach, this is a challenging strategy that requires adequately ample and detailed sets of data, which are rarely available and may only be possible to be assembled in the future.

The similarity of the methodologies used by the different partners can be attributable to the regulatory rules for chemical safety (e.g. REACh Regulation) and food safety in particular (e.g. as applied by EFSA), which were aimed to provide a high level of protection for human health, and so far, these approaches have been serving their purpose reasonably well. Indeed, to be protective of public health, RA are typically performed in a manner that is unlikely to underestimate the actual risk.

During the discussions, the possibility of using population-health metrics such as Disability-Adjusted Life Years (DALYs) and Quality-Adjusted Life Years (QALYs), where one DALY is equal to one healthy year of life lost and one QALY corresponds to one year of life lived in perfect health, has been also explored. These health metrics may also be addressed as a distribution. Although DALYs and QALYs have been successfully used for decision-making in public healthcare with a focus on disease prevention, the Consortium concluded that the application of this approach is very limited in the area of food safety among RASCS partners. This is due to the fact that it can be used only with very data-rich chemicals, due to their modeling-intensive nature and to the need to obtain results in a very short time, e.g. in the event of an alert.

However, despite the methodologies being similar, during the exchanges and especially during the various ToS, it clearly appeared that among the EU countries participating to the Project, the food safety issue is dealt in each country with the intervention of different types and networks of Institutions, each with specific roles. To describe the situation better, in the framework of WP3, a survey was carried out among the RASCS partners, to identify the institutions dealing with RA in seafood products. Several institutions with an official mandate have been identified, some only devoted to RA for human health, while others deal with RA, management and communication, or in charge to do also research and/or environmental monitoring. In addition, Institutions in different countries may report to different Ministries not necessarily the Ministry of Health (as in Italy) but also the Ministry of Food and Agriculture (as in Germany) or the Ministry of Economy (as in Portugal), just to give a few examples. The results of the survey are summarized in an excel file ("RASCS APPENDIX C Risk Assessment Institutions", Appendix C) where relevant information, such as details on competences, type of activities and contact information, are reported.

Although the general organization may be different, very similar problems have to be faced in different countries in the area of RA and the approach taken is similar as well. Among these issues, one of them is certainly the lack of sufficient data, in some cases for the toxicological profile of the chemical, but in most cases for the scant availability of robust exposure data. For consumption information, the EFSA Food Comprehensive database (Food consumption data | EFSA (europa.eu)) can be used, although especially for seafood products, tailored data taking into account local habits is crucial for reducing uncertainties. In addition, regarding the consumption data set that may not clearly differentiate among species, it is worth to note that the fish species behave differently with respect to their ability to accumulate contaminants, thus influencing the exposure to contaminants. Therefore, each main species should be considered and treated as individual food.

Task 3.2 Trends of hazards identification and consumer exposure in a changing world according to social changes and climate change

Within the RASCS consortium, as described before, a quite wide spectrum of professional profiles dedicated to contaminants in seafood has converged. To cite a few examples, professional profiles included very technical backgrounds close to complex analytical techniques,

environmentalists dedicated to the presence and trends of contaminants in the environment, risk assessors, consumer analysts and communication professionals. Hence, the holistic RA approaches needed to be described during the execution of the project, and particularly, the novel challenges imposed by social and climate changes. To consolidate this background, we describe herein in detail some of the major issues of concern that have been exchanged throughout the project.

There is an increasing demand from both the general public and the scientific community for a progressive reduction of animal testing and this is challenging the RA procedure as generally applied nowadays. Following this societal demand, the EU legislator in these last decades has tried to balance the need for information on properties of chemicals avoiding unnecessary animal testing: new animal testing must only be done as a last resort and registrants have the possibility to make use of alternatives to fulfil information requirements (ECHA, 2021).

The regulatory acceptance of many non-animal approaches has been achieved for some of the so-called lower-tier information requirements of local toxicity and short-term effects, but not for effects that generally become evident over long-term exposure. In the context of 21st century toxicology, a number of new approaches and methods have been developed to support RA which are generally referred to as NAMs or New Approach Methodologies, based on a collection of computational or *in silico*, *in chemico*, *in vitro*, kinetics modelling and omics approaches (EFSA, 2014). It should be noted that no validated replacement alternatives are currently available for repeated-dose toxicity (subacute and sub-chronic toxicity), carcinogenicity, developmental toxicity, and the major part of toxicokinetics.

To overcome the lack of alternatives and favor the implementation of NAMs in RA (the so-called NGRA: New Generation Risk Assessment) the need of combining evidence to characterize hazards in an Integrated Approach to Testing and Assessment (IATA), a pragmatic, science-based approach, consisting of modules or components that are each based on types of evidence (i.e. by type of information or at the mechanistic level), is clear now. An IATA necessarily includes a degree of expert judgement in weighing the available information for which again harmonization among the risk assessors is crucial.

Beside IATA, the Adverse Outcome Pathway (AOP) concept significantly increases the possibilities for constructing non-animal approaches, where an AOP is defined according to the OECD as an analytical construct that describes a sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health effect (OECD, 2017). AOPs do not include aspects related to the toxicokinetics of a substance and indeed are considered chemical agnostic. On the other hand, it is generally assumed that the threshold for adversity has to be exceeded to provoke the molecular initiating event and each of the following events leading to the adverse outcome. The MoA, which is substance-specific, includes elements such as toxicokinetics and metabolism. These approaches are promising but the knowledge of various potential MoAs and AOPs is still limited to data rich chemicals, thus restricting the development of AOP-based methods. Approaches and their acceptance at regulatory levels has not been implemented so far.

EFSA has recently published a road map for the implementation of NAMs in NGRA (EFSA, 2022) and launched projects to this aim. At the same time the EU financed together with MS the Partnership PARC, to address the various challenges associated with innovating chemical RA, including strengthening the scientific basis of NGRA approaches to drive true innovation in chemical RA by incorporating scientific progress and innovative approaches into hazard and

exposure assessments in a manner that is workable as well as feasible from a legislative perspective (Marx-Stoelting et al., 2023).

In addition, already in 2013, the non-food EU Scientific Committees opinion 'Addressing the New Challenges for Risk Assessment' (SCHER/SCENIHR/SCCS, 2013) proposed a paradigm shift from a hazard-driven process to one that is exposure-driven, leading to a progressive reduction of tests using laboratory animals and at the same time an increasing importance of mechanistic and kinetics data. Indeed exposure-based waiving of testing for Hazard can be expected, for example making use of the so-called non-testing approaches, such as TTC, grouping and read-across (supported by *in silico* analysis), while toxicokinetics can inform on the need for further testing based on bioavailability considerations.

All these possibilities have been discussed among the partners, concluding that for data poor compounds these methodologies can be very useful, although for the time being we are still not ready to conduct a full risk without animal data. In addition, the Consortium highlighted that assessors need to be trained and prepared in conducting RA by means of data sets obtained in an animal-free environment. Harmonization of criteria is therefore important in this area.

***From RA for individual chemicals to RA for combined exposure***

There is a general societal concern related to the effects associated to combined exposure, often referring in the layman language to 'mixtures' or 'cocktail' effects. The human population is continuously exposed to a multitude of substances, and this is obviously true also for combined exposure via the consumption of seafood, which can be contaminated by multiple chemicals present in the environment. Indeed, this specific topic has been treated in a dedicated webinar, held with a mixed formula, both held in presence for the consortium and online for other colleagues not directly involved in the Project, but expressing their interest in participating, in order to enlarge the audience. It is possible that an individual is exposed to the same chemical contaminating the seafood (e.g. mercury) via other sources, e.g. other dietary constituents or from other media (e.g. dental amalgam). In this case the exposure is defined as aggregate, when the individual can be exposed to the single chemical through multiple sources (food, drinking water, air), which therefore activate or interact with multiple pathways (oral, cutaneous, inhalation).

At regulatory level, the RA for combined exposure is actively being developed by European and international organizations, such as EFSA, WHO, the International Programme on Chemical Safety (IPCS) and OECD (Kienzler et al., 2016, Rotter et al., 2018).

For example, in Europe, the Classification, Labelling and Packaging (CLP) Regulation (EC, 2008a) establishes clear criteria for hazard classification of intentional mixtures (e.g. formulated plant protection products or biocidal products) and proposes four classification methods, depending on the available data and on the properties of the components of the mixture (ECHA, 2017). General principles and requirements for food safety are regulated by the European Food Law (EC 2002), requiring that unsafe food shall not be placed on the market, which includes, amongst others, the determination of whether potential cumulative exposure might be injurious to health (Article 14). Also the Regulation defining the setting of limit values for residues in food and feed products (EC, 2005), known as MRLs, requires the development of methodologies for RA of combined exposures to chemicals from multiple products, i.e. incidental mixtures as defined above. Regulation on feed additives (EC, 2008c) requires a separate assessment of each component and the consideration of the cumulative effect for consumer safety or the assessment

of the mixture (EFSA, 2020 b). So, the legislative requirements are present, but for the time being they have been taken into account for pesticide residues in food by EFSA (EFSA 2013; EFSA 2020), but very rarely for any other products.

EFSA has been very active in the area of RA for combined exposure. In its Guidance document adopted in 2019, EFSA describes a harmonized framework based on the RA steps, for both WMA (when the mixture is poorly defined and is treated as a single entity, similar to single chemicals) and Component-Based Approaches (CBA) (when a mixture is judged to be fully chemically defined, the risk is assessed based on exposure and effect data of the individual components) (EFSA, 2019). The harmonized approach foresees the same steps as for the individual chemicals: problem formulation, exposure assessment, hazard identification and characterization, and risk characterization. A special focus has been devoted during the discussion to the application of tiering principles which allow for simple and conservative approaches/assumptions at lower tiers, avoiding unnecessary expenditure of resources. Indeed, an assessment can be concluded as soon as there is clarity on sufficient protection for the exposed population on the basis of simple assumptions on exposure and hazard estimates, resulting in risk metrics that do not flag potential risk (e.g. sufficient margins of exposure). If clarity on sufficient protection is lacking, one progresses to risk management (e.g. introduction of risk mitigation measures) or to a higher tier. At increasing tier levels, more data should be available, allowing assessments to become more accurate, with a better characterization of uncertainties: the lower the uncertainty for RA, the higher the tier.

In the problem formulation step, the first issue to be addressed (known also as the 'gatekeeper' step) is to determine if a combined exposure assessment is warranted and if so, which chemicals should be considered together. This step can be based on the likelihood that chemicals co-occur in the scenario under assessment, in this case exposure through fish and seafood. If co-occurrence/co-exposure within a relevant time frame is unlikely, a combined exposure assessment can be considered redundant. For acute exposure, the relevant timescale required for two or more chemical substances to elicit combined toxicity may be as narrow as a single eating occasion. Under these circumstances, detailed information on co-occurrence of the individual chemicals in the seafood product is required.

For fish and seafood contamination the WMA is not frequently applied, unless the contamination is with emerging contaminants for which no robust analytical chemistry is available. Since the availability of dose–response information for the mixture of concern is necessary, the application of the WMA for the time being implies testing of huge number of samples, due to all the possible combinations and the variability of mixtures composition over time: this requires an intensive animal testing not having available NAMs implemented in the NGRA, and is rarely feasible.

If the components of the mixture and their exposure levels are chemically defined, and this seems to be the case for most seafood contaminants, the CBA can be applied using exposure and hazard data of the individual components, often using the dose addition model as a default, unless it is known they act independently (dissimilar action). Dose addition, for which substances are assumed to behave as simple dilutions of each other, and assuming that individual components exert their effects without diminishing or enhancing each other's toxicity, has been shown to be applicable to a wide range of endpoints and provides sound approximations of observed combination effects. Components are often organized in assessment groups: setting up assessment groups can be based on the pragmatic aspects from the regulatory domain, from co-occurrence data or from common properties (from physico-chemical to hazard features). The specific approach to be used for grouping will be determined by the context of the assessment and the problem formulation. The approach taken can also be a combination of the different

approaches, for example grouping based on a MoA combined with kinetic considerations (grouping chemicals that affect a common target and that have similar kinetics). The topic of grouping which is crucial for combined effects RA has been extensively dealt with by a dedicated EFSA document (EFSA, 2021).

Among the partners it has been discussed how to save time and resources by applying a tiering approach to grouping. At a lower tier, the analysis may begin with all components being grouped together, i.e. an exposure-driven grouping which neglects the modes of action, e.g. by considering all the contaminants detected in seafood, such as microcystin, cadmium, lead and mercury, in the same assessment group. This approach is simple and conservative, as it assumes all components have a 'common adverse outcome', which is unlikely. If the outcome of the RA shows sufficient protection for the exposed population including also vulnerable groups, the simplified and conservative approach yields sufficient information to stop the assessment. If not, refinement is needed (e.g. creating subgroups of chemicals based on hazard criteria, for example based on a common adverse outcome). Using the previous example specific attention should be given whenever children are the exposed population through consumption of fish since they constitute a most vulnerable population for mercury and lead. The assessment group should include MCs, lead and mercury, since all show neurotoxic effects excluding cadmium which is not neurotoxic. Then dose-addition can be applied. It is important to underline that the critical effect for lead and mercury is well known to be neurotoxicity in children, while for the natural toxin the critical effect is on the liver, but so far neurotoxic effects have been also reported for some MC variants, and therefore it should be included in the group as well. If a risk is identified, it can be possible to further refine the grouping looking at the specific target and MoA or AOP, to see if the three components actually belong to the same assessment group: the obtained results can be the basis for appropriate measure(s) to mitigate the risk. In case the major contribution to the risk is given by mercury, it is possible to prevent the risk by avoiding/ limiting the consumption in children of those species known to accumulate high level of mercury.

In the risk characterization of combined exposure to multiple chemicals, the WMA foresees that the mixture is treated as a single chemical substance. If a reference value has been derived, the aim is to identify whether the estimated exposure exceeds that reference value or results in an (in)adequate Margin of Exposure (MoE) or Hazard Quotient (HQ). For the CBA, methodologies and associated calculations for risk characterization of combined exposure to multiple chemicals using dose addition are described in the EFSA guidance document. It is important also during this step to apply the tiering: at lower tiers it is common to use the HI as the sum of the HQ of the individual components calculated as the ratio between exposure to a chemical and the respective reference values (i.e. ADI, TDI). At higher tiers other methods such as RPF (Relative Potency Factor) or TEF (Toxic Equivalent Factor) are used (EFSA 2019).

***RA in a climate change scenario***

Climate change can affect seafood contamination and the risk of human exposure to natural toxins and chemical contaminants through the food chain, by either changing the occurrence of toxins/chemical contaminants in the environment or by changing the organisms' physiology and response to the presence of toxins/chemical contaminants (e.g. capacity of bioaccumulating or transforming). Therefore, the major impact will be on the exposure estimates both quantitatively (e.g. increasing the contamination of fish and seafood with known contaminants), but also qualitatively, since new emerging contaminants might occur.

According to the last report of IPCC (2022), climate change will further impact the risks to health by increasing contamination of crops with mycotoxins, and contamination of seafood from harmful algal blooms, mycotoxins, and chemical contaminants (high confidence according to IPCC). This has been previously highlighted also by the EFSA project CLEFSA (2020).

Different drivers of climate change will have an impact on different aspect of food contamination: increase in seawater temperature can affect the occurrence of toxins/chemicals by expanding toxic organisms niches, by accelerating their growth rate, by accelerating toxins production or by melting polar ice releasing trapped mercury (Paerl and Huisman, 2008; Davis et al., 2009; IPCC, 2022). While floods, via discharge of nutrients, can increase coastal eutrophication, favoring the increase of opportunistic organisms potentially toxic, or they could transport freshwater organisms/toxins into coastal water and increase the risk of the exposure to freshwater toxins in seawater (Lehman et al., 2010) or to mixtures of contaminants (Peacock et al., 2018). However, the relationships between physical variables like temperature, growth rate, and toxin production, are highly strain- and species-specific. Temperature increase can promote the growth of *Dynophisis* spp. and the production of diarrhetic shellfish toxins, while for other organisms, inverse relationships have been described (Griffith and Gobler 2020). In toxic cyanobacteria, the positive impact of temperature on growth is well established (i.e. Burford et al., 2020, while the impact on toxin production is more complex and can have both positive, in *Microcystis aeruginosa*, *Planktothrix agardhii* and *Dolichospermum* spp., and negative impact, in other strains of *M. aeruginosa* (Griffith and Gobler, 2020).

During the webinars held in Barcelona the complex and sometime inconsistent relationships between climate change stressors, algae growth and toxin production were approached using several examples. Spanning from *Ostreopsis ovata* in the Mediterranean Sea (where it produces ovatoxins) to *Gambierdiscus* spp. from Virgin Islands (where it produces CTXs, the causative toxin of ciguatera poisoning). Higher temperature (28°C vs 24°C) has been shown to positively affect the production of ovatoxin in two *O. ovata* strains (Carnicer et al., 2016), althlugh other authors reported conflicting results. A three-year study on *Gambierdiscus* spp. showed that the highest density occurred in summer, while the ciguatoxin cell quota peaked in winter times (Liefer et al., 2021). Very complex interactions between periods of floods and droughts, causing extremely high concentration of soluble reactive phosphorus, and increasing temperature, could explain significant variability in density and toxicity of *Microcystis* in San Francisco estuary and the extreme long, intense, and toxic bloom produced in 2014 (Lehman et al., 2017). This indicates that for the moment, our knowledge is not robust enough to develop modelling based on known changes of specific climate-related parameters, since each species reacts in a different way, also depending on the specific localization.

In the framework of this RASCS project, some case studies on combined RA relevant to the climate change-related increased exposure were presented and discussed. Among these, the application of the CBA approach when seafood is contaminated by a number of microcystin (MC) variants was discussed. Their presence linked to climate change was also considered (e.g. increased temperature, draughts increasing the nutrient concentrations, floods causing the transport of nutrient from agricultural soils into water). The presence of different variants has a high likelihood to occur, considering that a single MC-producing cyanobacteria species can contain and/or release in water a pattern of different variants, and more than one species can co-occur in water. By adopting a conservative approach, acute toxicity may be referred to MC-LR equivalents (considering all the variants having exactly the same toxicity of MC-LR). Since this congener is the most acutely toxic, the toxicity of the mixture is likely to be overestimated by this approach. However, in case this tier 0 approach gives rise to exposures not exceeding the HBGV, there is no need to proceed. Otherwise, there is the need to go for a refinement as

explained above. For example, we can estimate the composite toxicity of a mixture of toxin analogues by applying the Toxicity Equivalent Factor for each specific analogue. The RA for these compounds representing emerging contaminants for seafood associated to climate change as well as many other natural toxins, presents a number of weak aspects, related to both the definition of the toxicological profile (in this case few data available for repeated toxicity) and even more to scant data on exposure (also due to the lack of robust analytical methods available). Differences among partners were evidenced in considering some studies to derive the HBGV: ANSES in its opinion included some reproductive toxicity studies, which in Italy were not considered robust enough by ISS, in line with the RA conducted by WHO in 2021 (WHO, 2021 b).

The example of STXs was also presented and discussed together with some open points that need to be addressed in order to conduct a RA for mixture of contaminants in sea food such as information on the co-occurrence of mixtures of toxins, mixtures of toxins and other contaminants to define exposure and information on the toxicological properties of toxins able to support a combined RA and on which are the other chemicals we need to prioritize. This is particularly important in a climate change scenario as we are experiencing nowadays with increasing temperature and extreme events like draught and floods.

#### 2.3.2 O-7: Balancing the risk with the nutritional benefit deriving from fish and seafood intake by means of case studies and predictive tools.

| Task 3.3 Balancing risks with nutritional benefits: integrated approach among institutions. |
|---|

Within the RASCS consortium, partners dealing with analytical work and focusing on the evaluation of the hazards and risks were dominant in relation to partners leading with the risk/benefit approach. The latter was the case for some members of IPMA, and therefore, there was a need within the consortium to require IPMA's transfer of concepts in this matter. For this reason, the ToS in Lisbon was devoted to the presentation of the experience in the Risk/Benefit (R/B) analysis IPMA has achieved, which was discussed among partners.

RA *per sé* is insufficient for the formulation of dietary recommendations to consumers and a pondered and well-reasoned decision-making process by public authorities. It should be noted that lowering specific risks by decreasing consumption of a particular food or food group entails an increase of other risks associated to alternative foods. For this reason, it is critically important to have a so-called holistic perspective that balances risks and nutritional benefits for any food consumption scenario. Just as for RA, the Risk-Benefit Assessment can be done using equivalent methodologies and identical strategies. This encompasses direct comparison with concentration and/or intake thresholds, specific ratios and indices, and other deterministic solutions as well as semi-probabilistic (using fixed consumption scenarios and nutrient and contaminant concentration distributions in seafood) and full probabilistic approaches (fitting distributions to large datasets of constituents' contents and consumption frequencies).

It should be noted that the assessment of the risk as well as the benefit associated to the intake of a component present in any given seafood or in a whole diet has witnessed remarkable progress and the simultaneous evaluation of risks and benefits in seafood has been the subject of various studies. Every approach/strategy has advantages and drawbacks, but an integration of all meaningful risks and benefits in a unified approach must be achieved. There are always

several problems that range from the absence of an adequate calibration to the assumptions of the statistical models to the definitions and related uncertainty of the used threshold values and dose-response functions.

There are important issues that relate to the assessment of food-related risk on the basis of chronic exposure versus the acute intake situation. Bioavailability *in vivo* studies have shown the importance of continuous nutrient or contaminant intake versus the episodic overdosage. On the other hand, *in vitro* studies lack the host factor for an adequate assessment of the complex interactions that lead to a chronic situation. The *in vitro* studies, usually limited to the intestinal absorption availability, so-called bioaccessibility assays, are useful for understanding the digestive processes. The comparison of results from *in vitro* and *in vivo* approaches using acute intakes conveys invaluable information and shows the importance of the host factor even for a single intake. Hence, whenever a health risk is to be associated to a chronic exposure, *in vivo* studies or *in vitro* results solidly backed by an *in vivo* validation are fundamental.

The coupling of bioaccessibility and bioavailability information with the Risk Benefit Assessment tools can be advantageous and shed a light into important public health issues. The overall approach/strategy advocated by IPMA is to combine the bioaccessible/bioavailable contents of the various substances found in foods with a probabilistic (assuming variability in the contents and the food consumption frequencies) or, at least, semi-probabilistic analysis of the risk-benefit binomial. Future advances in this field will be very relevant for the formulation of public health policies. The sector stakeholders should also do their part in fostering bioaccessibility/bioavailability studies and the progressive inclusion of data concerning bioaccessible/bioavailable content of seafood in the product labeling. Consumers should try to meet the seafood consumption guidelines based on probabilistic and integrated models. Finally, whenever possible through the existence of adequate information (including data-response functions for all meaningful health endpoints related to each identified risk and benefit), a net health benefit or loss should be calculated and associated to specific seafood consumption scenarios. Such DALY/QALY-based approach would enable to better calibrate any consumer advice concerning specific seafood products and seafood as a whole.

Some conclusions coming from the discussion related to WP3 activities:

- The RA approaches/methodologies underpinning regulatory decisions regarding seafood contaminants are the same in the consortium (the same as used in EFSA).
- The most frequently used approach by the partners foresees that the intakes/exposure estimates of contaminants are compared with established health-based guidance values (HBGVs) with a deterministic approach.
- The probabilistic approach is recognised as a more refined approach, although it is challenging since it requires ample and detailed sets of data, which are rarely available so far.
- About the possibility to use DALYs and QALYs as population-health metrics, the Consortium concluded that the application of this approach is very limited in the area of food safety.
- Food safety is dealt with in each country participating in the Consortium by different types and networks of Institutions, each with specific roles (see the survey in the excel file).
- A common and major problem in RA is the lack of sufficient data, in some cases for the toxicological profile of the chemical, but in most cases for the scant availability of robust exposure data (levels of contamination or food consumption): in case of seafood there is the need to differentiate among species, since seafood cannot be treated as a food item with a few categories.

- Regarding the change towards a RA in an animal-free environment, by introducing NAMs, the Consortium concluded that for data poor compounds, some non-testing methods (e.g. TTC, read across, QSAR) could be implemented, mechanistic and kinetic data are useful to refine RA, but for the time being we are still not ready to conduct a full RA without any animal data.
- The Consortium highlighted that assessors need to be trained and prepared to conduct RA using data sets obtained by animal-free assays. Harmonization of criteria is therefore important in this area.
- The consideration of several contaminants concurrently present in seafood is possible (using the Component based approach) in order to carry out a cumulative RA, especially applying a tiering strategy. It is noted that for many emerging marine and freshwater natural toxins the available data are still too scant to allow a robust evaluation, especially for long term effects.
- Regarding the impact of climate change on seafood contamination affecting the human dietary exposure to toxins and chemical contaminants, it was concluded that this can happen by either changing the occurrence of toxins/chemical contaminants in the environment or changing the organisms' physiology and response to the presence of toxins/chemical contaminants (e.g. capacity of bioaccumulating or transforming).
- The complex and sometime inconsistent relationships between climate change stressors, algae growth and toxin production have not allowed the Consortium to draw any clear-cut conclusions. Data are still limited and can result in different conclusions depending on the species and sometimes strain of producers.
- A holistic perspective that balances risks and nutritional benefits for any food consumption scenario is needed, considering that lowering specific risks by lowering consumption of a particular food or food group entails an increase of other risks associated to alternative foods or to lack of beneficial component of the 'limited' food item.
- The Risk-Benefit Assessment can be done using equivalent methodologies and identical strategies used for RA either as deterministic evaluation as well as semi-probabilistic (using fixed consumption scenarios and nutrient and contaminant concentration distributions in seafood) and full probabilistic approaches (fitting distributions to large datasets of constituents' contents and consumption frequencies).
- Including bioaccessibility and bioavailability information in the Risk Benefit Assessment tools can be advantageous, especially when using a probabilistic (assuming variability in the contents and the food consumption frequencies) or, at least, semi-probabilistic analysis of the risk-benefit binomial.

## 2.4 WP4: Risk/Benefit Perception and Communication

### 2.4.1 O-8: Insight into seafood consumers risk/benefit perception and its impact on seafood consumption and related decision-making

Task 4.1 STATUS ANALYSIS ON EUROPEAN CONSUMERS' RISK/BENEFIT PERCEPTION REGARDING SEAFOOD CONSUMPTION: LITERATURE REVIEW, RE-ANALYSES, AND CHOICE EXPERIMENT.

#### 2.4.1.1 Literature review

Consumer perception of fish consumption is influenced by various factors, as demonstrated by several studies. One key finding is the limited public knowledge about specific risks and benefits associated with consuming fish, specifically regarding contaminants like mercury and PCBs (Burger and Gochfeld, 2009). There is a disconnect between general awareness and accurate information (Pieniak et al., 2013; Boase et al., 2019), and respondents tend to express a desire for more information to make better decisions (Burger and Gochfeld, 2009). This highlights the need for effective communication campaigns to bridge the gap between knowledge and awareness.

Country-related traditions, regional preferences and habits also play a significant role in shaping consumer attitudes (Anacleto et al., 2014). Cultural differences among consumer segments necessitate targeted national-level information campaigns suggesting that a one-size-fits-all approach may not be effective and that tailored communication strategies may be required (Jacobs et al., 2015).

Findings also indicate that information about home preparation, purchase decisions and consumption practices can effectively inform communication strategies used by authorities (Crovato et al., 2019). Moreover, while regulation values can increase safety perception (Murakami et al., 2017), they should be carefully considered to avoid promoting excessive intake or excessive avoidance behavior. The internet is viewed as a valuable source to address knowledge gaps, underscoring the importance of utilizing digital platforms for effective communication (Tediosi et al., 2015).

In addition, in a specific study, it was found that demographic groups respond differently to seafood risk information with only white males showing consistent patterns. Initial information intended to ease concerns affects perceived risk and consumption estimates differently among other groups. This highlights the need for targeted messaging and communication strategies that consider demographic variations (Haab et al., 2010).

Barriers to fish consumption identified in the studies include sensory disliking of fish, lack of convenience, lack of self-efficacy in selecting and preparing fish, health risk concerns, lack of availability, and perceived high prices (Grieger et al., 2012; Govzman et al., 2021). Price

variability and heterogeneity of fish products were seen as adjacent complex issues that require further investigation (Carlucci et al., 2015).

On the other hand, motivational factors such as positive attitudes towards eating fish, perception of fish as a healthy food (Pieniak et al., 2008; Wongprawmas et al., 2021), general health involvement, and personal involvement in seafood (Carlucci et al., 2015) are identified as drivers of fish consumption (Pieniak et al., 2010b).

Consumer segments based on health-related attitudes are identified in some studies. These segments show differences in fish consumption patterns and socio-demographics, pointing towards challenges in reaching the low interest segments. Communication strategies should be tailored to address the unique characteristics of each segment (Pieniak et al., 2010a).

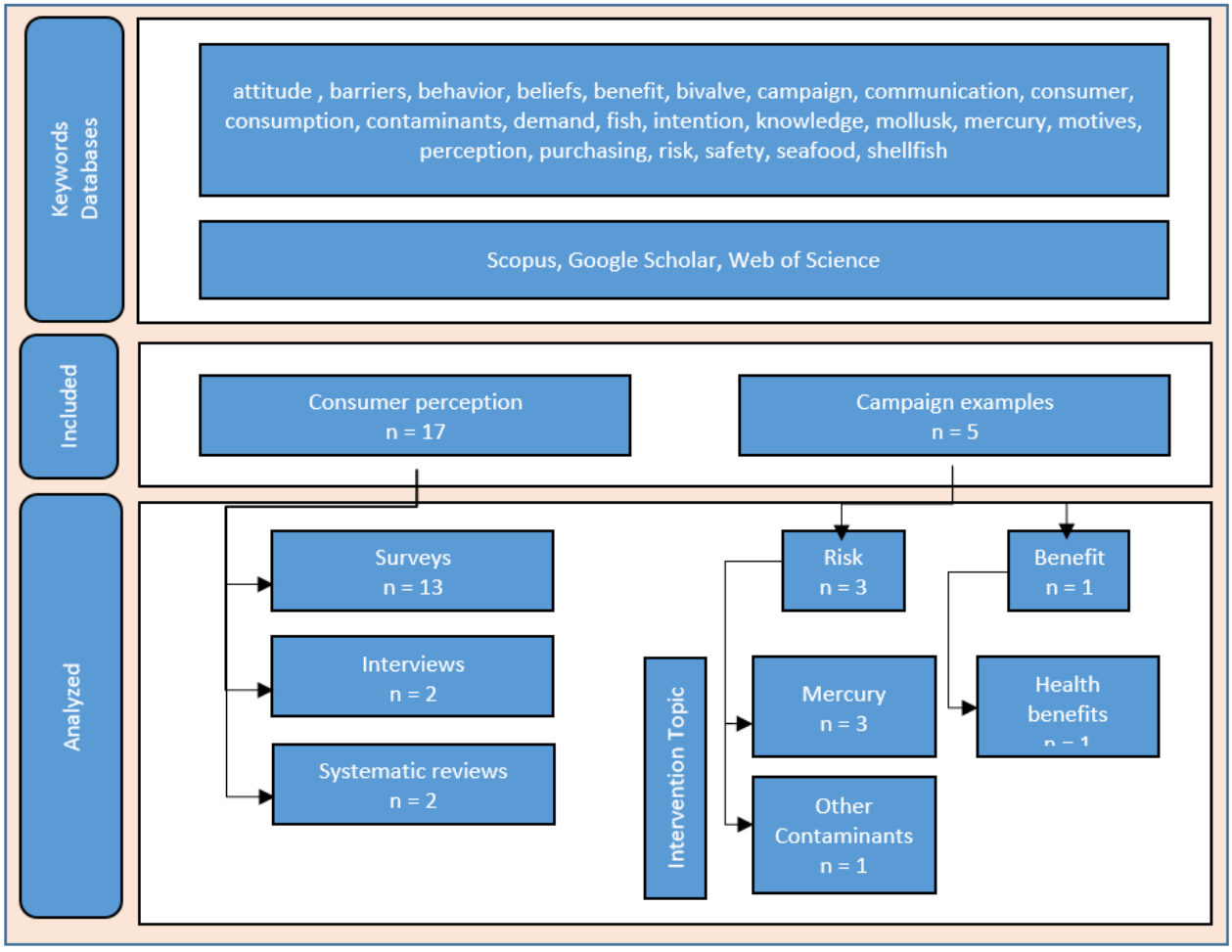


**Figure 1: Selection of relevant studies regarding the risk perception of seafood. The flow diagram shows the number of studies and campaign examples which have been selected from the provided databases. The diagram also displays the categories into which the studies and campaigns have been divided into; namely, the type of study and content of the campaigns.**

In terms of personal factors, convenience, weight control, living arrangements, age, income, and family size were found to predict seafood consumption. Living alone, large families, and economic reasons were associated with lower seafood consumption, while elderly and high-income individuals were more likely to consume fish (Thong and Solgaard, 2017) (Table 11).

**Table 11. General literature review regarding the perception of fish and seafood consumption and its health benefits and risks**

| Reference | Study type (sample size) | Key findings |
|---|---|---|
| (Burger and Gochfeld, 2009) | Field survey with pedestrians (N = 329) in the USA | Public knowledge about specific risks and benefits of fish consumption is limited, particularly regarding contaminants. |
| (Jacobs et al., 2015) | Online survey (N = 2824) from Belgium (n = 540), Ireland (n = 575), Italy (n = 560), Spain (n = 561), Portugal (n = 588) | Country-related traditions influence perception, and attitudes towards seafood consumption and the marine environment. |
| (Tediosi et al., 2015) | Survey with stakeholders (N = 531) in 30 countries | Results highlight communication gaps in seafood safety. |
| (Haab et al., 2010) | Telephone survey with seafood eaters (N= 1087) in the USA. | Demographic groups respond differently to seafood risk information, with white males showing consistent patterns. |
| (Grieger et al., 2012) | Online and computer assisted telephone interviews (CATI) of Australians (N = 854) | Factors such as information exposure, correct knowledge of recommendations, and belief in health benefits are associated with increased consumption of fish. |
| (Pieniak et al., 2013) | Online survey (N = 3213) in the Czech Republic (n = 400), Germany (n = 401), Greece (n = 400), Italy (n = 403), Portugal (n = 403), Romania (n = 403), Sweden (n = 401) the UK (n = 402) | Consumers lack knowledge, prioritize quality and food safety, and rely on the internet for information. |
| (Pieniak et al., 2008) | Mail, online and face-to-face surveys (N = 4,786) from Belgium, The Netherlands, Denmark, Spain, Poland (n = 800-1,100 per country) | Interest in healthy eating positively influences fish consumption and subjective health. Increased risk perception negatively affects subjective health and fish consumption. |
| (Anacleto et al., 2014) | Online survey of (N = 1778) with Portuguese consumers | Consumers prefer national bivalves, consider smell, size, and cleaned shells when choosing, buy from supermarkets, and show good knowledge about risks. |
| (Boase et al., 2019) | Stakeholder and public interviews (N = 1,433) in the UK. | Misunderstandings and knowledge gaps about shellfish affect consumption intentions. |
| (Carlucci et al., 2015) | Systematic review with studies (N = 49) | Perception of fish as a healthy food is the main driver of consumption. |
| (Crovato et al., 2019) | Focus group interviews (N = 42) in Italy. | Home preparation, purchase decisions, consumption practices, and production chain control, can inform risk communication strategies around fish consumption. |
| (Murakami et al., 2017) | Online survey in Japan (N = 1148). | Tuna consumption linked to dread risk perception of mercury. Perception does not drive tuna consumption. Regulation values increase safety perception. |

| Reference | Study type (sample size) | Key findings |
|---|---|---|
| (Govzman et al., 2021) | Systematic review with publications (N = 121) from Europe, USA, Canada, Australia, New Zealand | Seafood consumers tend to be older, more affluent, and physically active. |
| (Pieniak et al., 2010a) | Survey with samples (N = 2400) in France (n = 800), Poland (n = 800) and Spain (n = 800). | Four consumer segments are identified with respect to fish consumption: low interest in healthy eating, positive health enthusiasts, health strivers and health uninvolved. |
| (Pieniak et al., 2010b) | Survey (N = 4786) from Belgium, the Netherlands, Denmark, Poland, Spain | Consumers' belief that fish is healthy only weakly influences fish consumption frequency. |
| (Thong and Solgaard, 2017) | Online survey with French adults (N = 996). | Convenience and weight control were the most significant motives affecting seafood consumption. |
| (Wongprawmas et al., 2021) | Online survey with Italian consumers (N = 804). | Wild fish is perceived as tastier and more nutritious and farmed fish as cheaper, safer, and more ethical. |

In conclusion, consumer perception of fish and seafood consumption is influenced by a multitude of factors, including limited knowledge about risks and benefits, traditions and habits, communication gaps, barriers, motivational factors, health-related attitudes, and personal factors. Overall, the literature suggests that, to promote fish consumption, communication efforts should focus on health-related benefits. Lastly, strategies need to be developed to address the challenge of reaching the different segments, populations and cultures while considering the above factors.

#### 2.4.1.2 Existing consumer data

The existing consumer data from multiple national and EU-funded research projects over the past decades, including SEAFOODplus (FP6), FOODRISC (FP7), ECsafeSEAFOOD (FP7), and SEAFOODTomorrow (H2020) have been identified and re-analysed in consultation with the consortium partners. Large-scale European consumer studies were performed within each of these projects, assessing consumer attitudes and behaviours related to seafood from various perspectives while covering risk and benefit perceptions. The relevant Eurobarometer studies, such as 'EU consumer habits regarding fishery and aquaculture products' were also incorporated. Table 12 shows an overview of large-scale European consumer studies identified in this subtask with the earliest one dating back to 2004 and the latest in 2021.

**Table 12. Large-scale European studies on consumer attitudes and behaviours towards seafood consumption covering aspects related to risk and benefit perceptions.**

| Year | Dataset | Responsible institution | Sample size | Country |
|---|---|---|---|---|
| 2004 | SEAFOODplus 1 | UGent | 4 786 | BE, DK, ES, NL, PL |
| 2005 | PODO Fish | UGent | 381 | BE (Flanders) |
| 2008 | CONSENSUS | UGent | 1 319 | BE, ES, NO |
| 2008 | EUROFISH | UGent | 3 213 | CZ, DE, GR, IT, PT, RO, SE, UK |
| 2008 | SEAFOODplus 2 | UGent | 2 400 | ES, FR, PL |
| 2013 | ECsafeSEAFOOD 1 | UGent | 2 880 | BE, ES, IR, IT, NL, PT |
| 2015 | ECsafeSEAFOOD 2 | UGent | 986 | BE, PT |
| 2016 | Special Eurobarometer 427 | EC | 27 818 | EU-28 |
| 2017 | French Consumer Survey | ANSES | 2 479 | FR |
| 2018 | Special Eurobarometer 427 | EC | 27 732 | EU-28 |
| 2019 | SEAFOOD$^{TOMORROW}$ 2* | UGent | 1 203 | BE, HU, IT |
| 2020 | SEAFOOD$^{TOMORROW}$ 3 | UGent | 971 | BE, HU, IT |
| 2021 | Special Eurobarometer 515 | EC | 26 669 | EU-27 |

* SEAFOOD$^{TOMORROW}$ 1 was a qualitative exploratory focus groups (n=45) and thus is excluded.

The studies were conducted in different countries over different time periods. Hence, they offer a comprehensive overview and potentially insights into the evolution of consumer perceptions over time. A number of relevant overlapping constructs that could be found from multiple datasets are listed in the following:

- Consumption frequency (of different products / consumption occasions)
- Perceptions about different seafood products
- Place of purchase
- Objective and subjective knowledge
- Importance of the product attributes (credence-related such as healthiness, environmental impacts; or experience-related such as taste, price)
- Involvement with fish / seafood
- Attitudes (related to the products or consumption behaviour, healthy eating, environmental welfare)
- Use and trust of information sources

Although all the constructs were built on validated behavioural science methodologies and are scientifically sound, they were not identical nor measured in a consistent manner that allow meaningful matching and direct comparison. Thus, it is not recommended to merge the datasets, as they were designed to address the specific research questions or problems faced during the project periods. Only the three waves of Special Eurobarometer studies could be effectively merged and matched (e.g. per country) to shed light on the evolutions.

With regard to risk and benefit perceptions, all datasets tend to offer a more balanced or in-depth view than the Special Eurobarometer studies. While benefit perceptions of seafood were addressed in almost all surveys, risk perceptions were not investigated in the Special Eurobarometer studies, the only related variable was 'health concerns' as the reason for never eating seafood or aquaculture products. In all other surveys, 'safety' was explicitly evaluated,

'contaminants' was mentioned in most surveys and 'mercury' was specifically addressed in the CONSENSUS dataset.

The RASCS project presented opportunities to connect RA with consumers' risk and benefit perceptions. The KE from this subtask helps risk assessors and scientists understand the key factors that drive consumer behaviours, enables future RA to effectively set priorities and address the actual needs and concerns of consumers. National food safety institutes can also use these datasets and the associated questionnaires in their future consumption surveys. This multi-disciplinary collaboration fosters more comprehensive RA and more relevant consumer and consumption studies in the future considering the diverse aspects of seafood risk and benefit perception.

2.4.1.3 Consumer survey and test:

2.4.1.3.1 Methodology

**2.4.1.3.1.1 Consumer survey conducted within RASCS**

The study attempts to establish an effective communication strategy for food safety authorities that combines and balances information on risks, benefits, recommendations and regulations. An online survey was conducted in three different European countries: Spain, Belgium, and Poland. The choice of these countries was based on the considerable differences in fish consumption habits and traditions. This made it possible to reveal the impact of different information upon attitudes and behavioral intentions. Specifically, it allowed to examine how people react to communication in different segments with heterogeneous population in terms of cconsumption frequency, attitudes, and knowledge.

In each country, the survey was conducted among 600 regular consumers of seafood who were divided into three sub-groups of 200 participants each with similar sociodemographic characteristics. Each participant was randomly provided with one of the following three messages:

- 1st group (n=200): Participants of this group received information on health benefits and seafood intake recommendations.
- 2nd group (n=200): Participants within this group received the same information as group 1 (health benefits, seafood intake recommendations) plus information on hazards.
- 3rd group (n=200): Participants within this group received the same information as group 2 (health benefits, seafood intake recommendations and hazards plus information on regulation.

Measurements prior to the provision of the information (messages) were conducted and used as a baseline measure to assess seafood consumption and current related consumption frequency. Post measurements were also conducted, and ex-post comparisons were undertaken to determine the impact of the three below different communication strategies on attitudes and

behavioural intentions. The provided messages are formulated based on existing literature, European authorities' communication, and the information of expert panels.

The text introducing the messages is the following: "*Please read the following message relating to seafood consumption which has appeared recently on the official website of the national food safety authority [ES: Spanish Agency for Food and Nutrition Safety; BE: Federal Public Service Health, Food Chain Safety and Environment; PL: Polish National Institute of Public Health].* And the detailed messages are:

- 1st Message

Seafood (fish and shellfish) are the most important natural sources of omega-3 fatty acids and vitamin D in the human diet. Omega-3 fatty acids and vitamin D have a beneficial impact on human health. Omega-3 fatty acids have several positive effects with respect to brain development during pregnancy and childhood, and the prevention of heart and coronary disease and depression in adults, while a sufficient intake of vitamin D contributes to the prevention of bone weakening and osteoporosis. Consumption of X portions of seafood per week [ES: 3; BE: 2, PL:2] possibly varying the species, and limiting the consumption of fatty/big fish (e.g. tuna, swordfish, cod and pike), is the best benefit-risk balance for a sufficient intake of the beneficial omega-3 fatty acids and vitamin D and the tolerable intake of the undesirable dioxins and mercury.

- 2nd Message

Seafood (fish and shellfish) are the most important natural sources of omega-3 fatty acids and vitamin D in the human diet. Omega-3 fatty acids and vitamin D have a beneficial impact on human health. Omega-3 fatty acids have several positive effects with respect to brain development during pregnancy and childhood, and the prevention of heart and coronary disease and depression in adults, while a sufficient intake of vitamin D contributes to the prevention of bone weakening and osteoporosis. Seafood (fish and shellfish) is also the main sources of some environmental contaminants such as dioxins and mercury in the human diet. After repeated exposure for a long period of time, dioxins and mercury have an undesirable impact on human health. Dioxins can have effects toward the immune and reproduction system, skin disorders, and cancer development, while mercury has effects on the development of the nervous system and the brain. Consumption of X portions of seafood per week [ES: 3; BE: 2, PL:2] possibly varying the species, and limiting the consumption of fatty/big fish (e.g. tuna, swordfish, cod and pike), is the best benefit-risk balance for a sufficient intake of the beneficial omega-3 fatty acids and vitamin D and the tolerable intake of the undesirable dioxins and mercury.

- 3rd Message

Seafood (fish and shellfish) are the most important natural sources of omega-3 fatty acids and vitamin D in the human diet. Omega-3 fatty acids and vitamin D have a beneficial impact on human health. Omega-3 fatty acids have several positive effects with respect to brain development during pregnancy and childhood, and the prevention of heart and coronary disease and depression in adults, while a sufficient intake of vitamin D contributes to the prevention of

bone weakening and osteoporosis. Seafood (fish and shellfish) is also the main sources of some environmental contaminants such as dioxins and mercury in the human diet. After repeated exposure for a long period of time, dioxins and mercury have an undesirable impact on human health. Dioxins can have effects toward the immune and reproduction system, skin disorders, and cancer development, while mercury has effects on the development of the nervous system and the brain. Consumption of X portions of seafood per week [ES: 3; BE: 2, PL:2] possibly varying the species, and limiting the consumption of fatty/big fish (e.g. tuna, swordfish, cod and pike), is the best benefit-risk balance for a sufficient intake of the beneficial omega-3 fatty acids and vitamin D and the tolerable intake of the undesirable dioxins and mercury. European and NATIONAL [ES: Spanish, BE: Belgian, PL: Polish] authorities have regulations for most contaminants and monitoring programmes are implemented to protect consumers. Local fish, imported fish and feed are checked by authorities.

The research's assumptions and hypotheses can be summarized as follows:

- H1: Balanced messages regarding health benefit and risks do not cause a drop in general seafood consumption for consumers that do not exceed the recommended intake.
- H2: Consumers trust balanced messages from food safety authorities.
- H3: Consumers from different countries perceive messages differently and react differently to messages.

Data collection was conducted in late April and early May 2023 in the three countries.

#### 2.4.1.3.1.2. Real-world experiment with students

Because online surveys are subject to hypothetical bias, we also conduct a real-world experiment with students in a university restaurant (Spain) context to assess the impact of the same communication strategies (already used in the online survey). For this end, 30 students who are regular consumers of seafood were recruited and divided into three groups of 10. The steps of the experiment are as follows:

- Step 1: The students were recruited.
- Step 2: The students were invited to lunch at the university restaurant (purchase). The purchase tickets were collected (on March 29).
- Step 3: Students received the messages (communication). Each group received one of the three messages (communication strategies) that we have already used in the survey (information interventions) (April 12).
- Step 4: On the same day that they receive the messages, they were invited to lunch at the university restaurant (re-purchase). The purchase tickets were collected (on April 12).

A comparison of students' food choices before and after receiving the messages was conducted to evaluate the impact of the different communication strategies about the risk benefits of eating seafood. Days of purchase and repurchase were set so that food offerings are similar. The

university restaurant offers fish and meat every day. Students were compensated for the cost of the dishes they bought during the two days of the experiment.

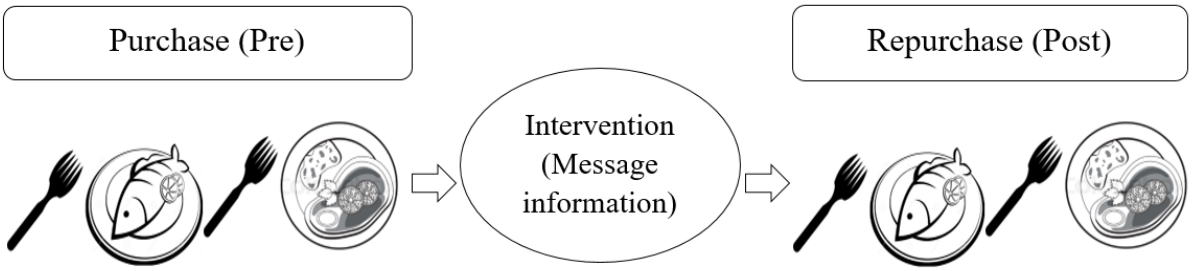


**Figure 2. Steps of the real-world experiment**

#### 2.4.1.3.2 Results

##### 2.4.1.3.2.1. Results of the online survey

Table 13 shows some sociodemographic characteristics of the sample surveyed in the three countries. Three samples of 634, 628, and 623 consumers participated in the study in Spain, Poland, and Belgium, respectively. Each sample is representative of the corresponding country in terms of gender and age. All participants are mainly responsible for food purchases in their household and regularly consume seafood (fish and shellfish), either frozen or canned.

**Table 13: Some sociodemographic characteristics of the samples**

| | | Spain | Poland | Belgium |
|---|---|---|---|---|
| **Sample** | N | 634 | 628 | 623 |
| **Gender** | Feminine | 53.00% | 47.13% | 49.92% |
| | Masculine | 47.00% | 52.87% | 49.92% |
| | Prefer not to say | - | - | 0.16 |
| **Age** | Average | 43.06 *(13.59)* | 41.49 *(12.71)* | 42.56 *(13.03)* |
| **Level of education** | Uncompleted primary studies | 0.32% | 0.32% | 1.77% |
| | Primary studies | 2.84% | 1.27% | 5.14% |
| | Secondary studies | 35.49% | 50.00% | 38.68% |
| | University studies | 61.36% | 48.41% | 54.41% |

*(): Standard deviation.*

Table 14 shows consumers impressions about the provided messages. The three messages are perceived as 'highly credible', 'trustworthy', 'clear' and 'in line with what they believe'.

**Table 14 Consumers impressions about the provided messages**

| Average score | Group 1 | Group 2 | Group 3 | Sample |
|---|---|---|---|---|
| **Spain** | | | | |
| **1 not credible…….7 credible** | 6.05 | 5.89 | 5.79 | 5.91 |
| **1 untrustworthy……..7 trustworthy** | 5.95 | 5.75 | 5.58 | 5.76 |
| **1 confusing …….. 7 clear** | 5.94 | 5.77 | 5.65 | 5.79 |
| **1 contrary to what I believed……7 in line with what I believed** | 5.89 | 5.57 | 5.35 | 5.60 |
| **Poland** | | | | |
| **1 not credible…….7 credible** | 5.91 | 5.77 | 5.73 | 5.81 |
| **1 untrustworthy……..7 trustworthy** | 5.87 | 5.77 | 5.68 | 5.77 |
| **1 confusing …….. 7 clear** | 6.09 | 5.95 | 5.88 | 5.97 |
| **1 contrary to what I believed……7 in line with what I believed** | 5.79 | 5.59 | 5.52 | 5.64 |
| **Belgium** | | | | |
| **1 not credible…….7 credible** | 5.80 | 5.63 | 5.70 | 5.71 |
| **1 untrustworthy……..7 trustworthy** | 5.73 | 5.55 | 5.67 | 5.65 |
| **1 confusing …….. 7 clear** | 5.82 | 5.60 | 5.59 | 5.66 |
| **1 contrary to what I believed……7 in line with what I believed** | 5.52 | 5.27 | 5.33 | 5.37 |

*One-way ANOVA results showed no significant differences between the three countries.*

Table 15 shows consumers' perceptions of seafood consumption before and after receiving the messages per group and per country. The results show that seafood consumption is perceived as healthy, safe, nutritious, ethical, expensive, and sustainable, with average scores above 5 or 6 in all three countries. After the information was provided, the average scores decreased significantly in the three countries, especially in groups 2 and 3, suggesting that providing information about risks significantly changes consumer perceptions and that providing additional information about regulation does not halt the decline in positive perceptions. The perceptions of group 1 members are more stable and less influenced by the messages. It is important to note that even though most of the averages have decreased after receiving the messages, the new values are still high.

**Table 15: Eating seafood (fish and shellfish) is…**

| Average scores | GROUP 1 | | | GROUP 2 | | | GROUP 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | PRE | POST | df | PRE | POST | df | PRE | POST | df |
| **Spain** | | | | | | | | | |
| 1 unhealthy to 7 healthy | 6,34 | 6,29 | | 6,22 | 6,02 | *** | 6,32 | 5,97 | *** |
| 1 unsafe to 7 safe | 5,92 | 5,81 | * | 5,74 | 5,57 | ** | 5,86 | 5,55 | *** |
| 1 not nutritious to 7 nutritious | 6,30 | 6,27 | | 6,15 | 6,08 | | 6,21 | 6,09 | ** |
| 1 unethical to 7 ethical | 5,58 | 5,60 | | 5,82 | 5,48 | *** | 5,73 | 5,53 | *** |
| 1 expensive to 7 cheap | 3,49 | 3,52 | | 3,70 | 3,55 | * | 3,69 | 3,65 | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 not sustainable to 7 sustainable | 5,30 | 5,28 | | 5,28 | 5,21 | | 5,38 | 5,16 | *** |
| **Poland** | | | | | | | | | |
| 1 unhealthy to 7 healthy | 6.21 | 6.27 | | 6.39 | 6.13 | *** | 6.34 | 6.09 | *** |
| 1 unsafe to 7 safe | 5.78 | 5.80 | | 5.90 | 5.67 | *** | 5.89 | 5.57 | *** |
| 1 not nutritious to 7 nutritious | 6.12 | 6.26 | *** | 6.34 | 6.16 | *** | 6.25 | 6.16 | |
| 1 unethical to 7 ethical | 5.62 | 5.71 | | 5.74 | 5.54 | *** | 5.73 | 5.53 | ** |
| 1 expensive to 7 cheap | 3.31 | 3.23 | | 3.23 | 3.14 | | 3.38 | 3.29 | |
| 1 not sustainable to 7 sustainable | 5.34 | 5.33 | | 5.38 | 5.13 | *** | 5.35 | 5.27 | |
| Belgium | | | | | | | | | |
| 1 unhealthy to 7 healthy | 6.18 | 6.06 | ** | 6.12 | 5.74 | *** | 6.15 | 5.86 | *** |
| 1 unsafe to 7 safe | 5.74 | 5.69 | | 5.66 | 5.39 | *** | 5.67 | 5.55 | * |
| 1 not nutritious to 7 nutritious | 6.10 | 6.03 | | 5.96 | 5.83 | * | 6.20 | 5.91 | *** |
| 1 unethical to 7 ethical | 5.45 | 5.38 | | 5.35 | 5.22 | * | 5.40 | 5.27 | ** |
| 1 expensive to 7 cheap | 3.67 | 3.66 | | 3.46 | 3.40 | | 3.54 | 3.58 | |
| 1 not sustainable to 7 sustainable | 5.00 | 5.07 | | 5.03 | 5.00 | | 5.00 | 5.05 | |

****, **, * ==> Significance at 1%, 5%, 10% level of the difference (df) between PRE & POST average scores.*

Table 16 shows the consumer knowledge level with regards to the European regulations for pollutants and monitoring programs aimed to protect consumers. On a seven-point scale from 1 "Not knowledgeable at all" to 7 "Very knowledgeable", consumers showed an intermediate level of knowledge of European regulations on contaminants and monitoring programmes to protect consumers. This level of knowledge was influenced positively by the messages provided, especially message 1 and message 3 in both Poland and Belgium.

**Table 16: Please indicate how knowledgeable you feel with regards to the European regulations for contaminants and monitoring programmes aimed to protect consumers?**

| Average score | GROUP 1 | | | GROUP 2 | | | GROUP 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | PRE | POST | df | PRE | POST | df | PRE | POST | df |
| **Spain** | | | | | | | | | |
| European regulations | 4.23 | 4.22 | | 4.17 | 4.40 | *** | 4.27 | 4.33 | |
| **Poland** | | | | | | | | | |
| European regulations | 3.88 | 4.15 | *** | 3.97 | 4.09 | * | 4.06 | 4.30 | *** |
| **Belgium** | | | | | | | | | |
| European regulations | 3.81 | 4.10 | *** | 4.08 | 4.13 | | 3.79 | 4.08 | *** |

****, **, * ==> Significance at 1%, 5%, 10% level of the difference (df) between PRE & POST average scores.*

Table 17 shows the level of consumer confidence in government seafood regulations. On a seven-point scale from 1 "Completely distrust" to 7 "Completely trust", consumers showed a medium level of trust in European and national regulations on contaminants and monitoring programmes to protect consumers. This level of trust increased significantly after providing the message 1 (Spain and Belgium), message 2 and 3 (Spain).

**Table 17: To what extent do you trust seafood related public regulations?**

| Average score | GROUP 1 | | | GROUP 2 | | | GROUP 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | PRE | POST | df | PRE | POST | df | PRE | POST | df |
| **Spain** | | | | | | | | | |
| European regulations | 4.72 | 5.16 | *** | 4.57 | 4.77 | ** | 4.53 | 4.77 | ** |
| National regulations | 4.85 | 5.04 | * | 4.72 | 4.79 | | 4.74 | 4.73 | |
| **Poland** | | | | | | | | | |
| European regulations | 4.45 | 4.42 | | 4.51 | 4.51 | | 4.55 | 4.61 | |
| National regulations | 4.40 | 4.27 | * | 4.50 | 4.42 | | 4.51 | 4.57 | |
| **Belgium** | | | | | | | | | |
| European regulations | 4.65 | 4.80 | * | 4.66 | 4.73 | | 4.73 | 4.76 | |
| National regulations | 4.79 | 4.89 | * | 4.87 | 4.91 | | 4.95 | 4.79 | * |

****, **, * ==> Significance at 1%, 5%, 10% level of the difference (df) between PRE & POST average scores.*

Table 18 shows how consumers are likely to follow seafood intake recommendations. On a five-points scale from 1 "Extremely Unlikely" to 5 "Extremely Likely", consumers showed a high level of disposition to follow seafood intake recommendations and in general this high level was not influenced by the provided messages in the three countries.

**Table 18: How likely are you to follow seafood intake recommendations?**

| Average score | GROUP 1 | | | GROUP 2 | | | GROUP 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | PRE | POST | df | PRE | POST | df | PRE | POST | df |
| **Spain** | | | | | | | | | |
| Seafood intake recommendations | 4.24 | 4.21 | | 4.15 | 4.12 | | 4.12 | 4.04 | |
| **Poland** | | | | | | | | | |
| Seafood intake recommendations | 4.10 | 4.06 | | 4.19 | 4.13 | | 4.15 | 4.09 | |
| **Belgium** | | | | | | | | | |
| Seafood intake recommendations | 3.74 | 3.83 | | 3.89 | 3.95 | | 3.97 | 3.99 | |

****, **, * ==> Significance at 1%, 5%, 10% level of the difference (df) between PRE & POST average scores.*

Table 19 shows the frequency of current seafood consumption (PRE) and the intention to consume seafood in the next few weeks (POST). The results show that most (89.92%) of Spanish consumers consume seafood at least once a week, followed by Belgium (72.43%) and Poland (54.12%). The most common frequency of current seafood consumption is "2 times per week" in Spain and "once per week" in Poland and Belgium. In the three countries, the information

(messages) provided increased the percentage of consumers with a high frequency of seafood consumption (specifically "3-4 times per week" and "2 times per week"), while decreasing the percentage of consumers with a low frequency of seafood consumption. Data in green indicate increase after receiving information, while red indicates a decrease.

**Table 19: current intake frequency vs intake intention of seafood (fish and shellfish) per country**

| Percentage % | PRE | POST |
|---|---|---|
| **Spain** | | |
| Daily | 0.95 | 1.58 |
| 5-6 times a week | 3.79 | 4.42 |
| 3-4 times a week | 19.56 | 35.65 |
| 2 times a week | 41.80 | 42.74 |
| Once a week | 23.82 | 11.83 |
| 2-3 times a month | 7.10 | 3.00 |
| Once a month | 3.00 | 0.63 |
| Less than once a month | | |
| Never | | 0.16 |
| **Poland** | | |
| Daily | 1.32 | 2.14 |
| 5-6 times a week | 2.80 | 4.11 |
| 3-4 times a week | 5.26 | 12.83 |
| 2 times a week | 15.63 | 40.30 |
| Once a week | 29.11 | 26.32 |
| 2-3 times a month | 23.36 | 10.20 |
| Once a month | 13.32 | 2.80 |
| Less than once a month | 9.21 | 1.15 |
| Never | - | 0.16 |
| **Belgium** | | |
| Daily | 1.96 | 1.14 |
| 5-6 times a week | 4.89 | 3.43 |
| 3-4 times a week | 6.85 | 11.42 |
| 2 times a week | 14.68 | 32.79 |
| Once a week | 44.05 | 36.70 |
| 2-3 times a month | 16.97 | 10.44 |
| Once a month | 7.50 | 3.10 |
| Less than once a month | 3.10 | 0.65 |
| Never | | 0.33 |

Table 20 shows the current frequency of consumption (PRE) and intention to consume (POST) seafood (fish and shellfish), either fresh, frozen, or canned, on average for main meal (fish consumed at home and away from home) in the coming weeks. The results of the Pearson chi2 test show that there is a statistically significant relationship between frequency and groups in the three countries. In Spain, there is a significant increase in the frequency of "3-4 times per week" within the three groups and a significant decrease in the frequency of "once per week" within the three groups. In Poland, there is a significant increase in the frequency of "3-4 times per week" and "2 times per week" and a significant decrease in the frequency of "2-3 times per month" and "once per month". In Belgium, there is a significant increase in the frequency of "3-4 times per week" and "2 times per week" and a significant decrease in the frequency of "once per week", "2-3 times per month" and "once per month". In Spain the frequency with the highest increase due to the messages is "3-4 times a week" and this increase is higher in group 1 than groups 2 & 3. In both Poland and Belgium, the frequency with the highest increase due to the messages is "2 times a week" and this increase is also higher in group 1 than groups 2 & 3.

**Table 20: current intake frequency vs intake intention of seafood (fish and shellfish) per country and group**

| Percentage % | GROUP 1 | | GROUP 2 | | GROUP 3 | |
|---|---|---|---|---|---|---|
| | PRE | POST | PRE | POST | PRE | POST |
| **Spain** | | | | | | |
| Daily | 0.48 | 1.43 | 1.42 | 1.42 | 0.94 | 1.89 |
| 5-6 times a week | 3.81 | 5.71 | 4.72 | 4.25 | 2.83 | 3.30 |
| 3-4 times a week | 18.57 | 41.43 | 18.87 | 33.02 | 21.33 | 32.55 |
| 2 times a week | 39.05 | 39.05 | 41.51 | 45.75 | 44.81 | 43.40 |
| Once a week | 25.71 | 8.57 | 25.47 | 12.74 | 20.28 | 14.15 |
| 2-3 times a month | 9.52 | 3.33 | 4.72 | 1.89 | 7.08 | 3.77 |
| Once a month | 2.86 | 0.48 | 3.30 | 0.94 | 2.83 | 0.47 |
| Less than once a month | | | | | | |
| Never | | | | | | 0.47 |
| **Poland** | | | | | | |
| Daily | 2.31 | 2.78 | 1.52 | 2.53 | - | 1.03 |
| 5-6 times a week | 2.78 | 4.17 | 3.54 | 3.54 | 2.06 | 4.64 |
| 3-4 times a week | 4.63 | 15.28 | 6.06 | 12.12 | 5.15 | 10.82 |
| 2 times a week | 13.43 | 41.20 | 18.18 | 39.39 | 15.46 | 40.21 |
| Once a week | 31.02 | 20.83 | 25.76 | 30.81 | 30.41 | 27.84 |
| 2-3 times a month | 24.54 | 10.65 | 21.21 | 8.08 | 24.23 | 11.86 |
| Once a month | 12.04 | 2.31 | 16.67 | 3.03 | 11.34 | 3.09 |
| Less than once a month | 9.26 | 2.31 | 7.07 | 0.51 | 11.34 | 0.52 |
| Never | - | 0.46 | | - | | |
| **Belgium** | | | | | | |
| Daily | 1.03 | 1.03 | 3.41 | 0.98 | 1.41 | 1.41 |
| 5-6 times a week | 4.62 | 3.08 | 5.85 | 4.39 | 4.23 | 2.82 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 3-4 times a week | 7.69 | 9.23 | 8.78 | 12.68 | 4.23 | 12.21 |
| 2 times a week | 16.41 | 35.90 | 13.17 | 31.22 | 14.55 | 31.46 |
| Once a week | 40.51 | 35.90 | 41.46 | 36.59 | 49.77 | 37.56 |
| 2-3 times a month | 19.49 | 8.72 | 16.59 | 10.24 | 15.02 | 12.21 |
| Once a month | 7.18 | 4.62 | 9.27 | 2.93 | 6.10 | 1.88 |
| Less than once a month | 3.08 | 1.03 | 1.46 | 0.49 | 4.69 | 0.47 |
| Never | - | 0.51 | - | 0.49 | - | |

*Results of Pearson chi2 test indicate that there is statistically significant relationship between the frequency and the groups in the three countries.*

Following the variable "consumption frequency" as well as the continuous variable "number of times per week" are analysed.

Figure 3 shows a comparison of the mean consumption of the whole sample before and after receiving the information (messages). Results show a clear and significant increase of mean consumption after receiving the information.

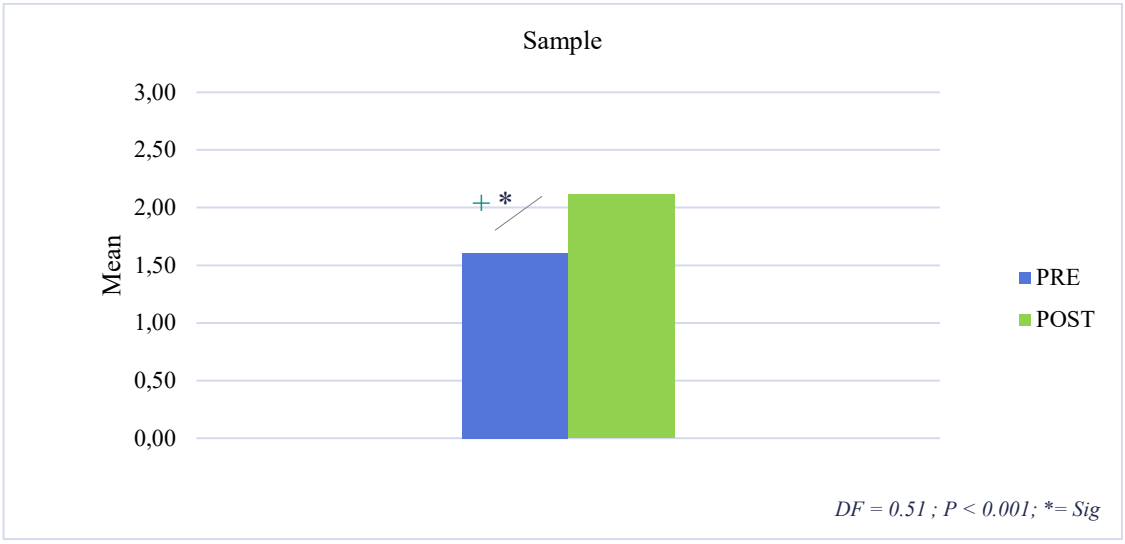


**Figure 3: Mean consumption before and after receiving the information (messages)**

Figure 4 shows a comparison of the mean consumption before and after receiving the information per group. Results show a significant increase of mean consumption after receiving the information in the three different treatment groups.

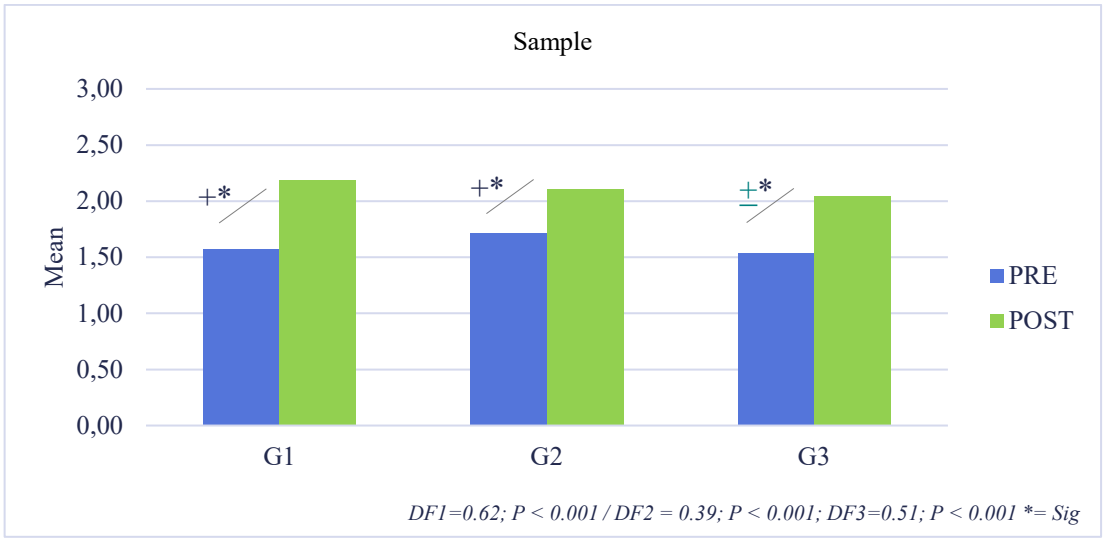


**Figure 4: Mean consumption before and after receiving the information (messages) per group**

Figure 5 shows a comparison of the mean consumption before and after receiving the information per country. Results show a significant increase of mean consumption after receiving the information in the three countries.

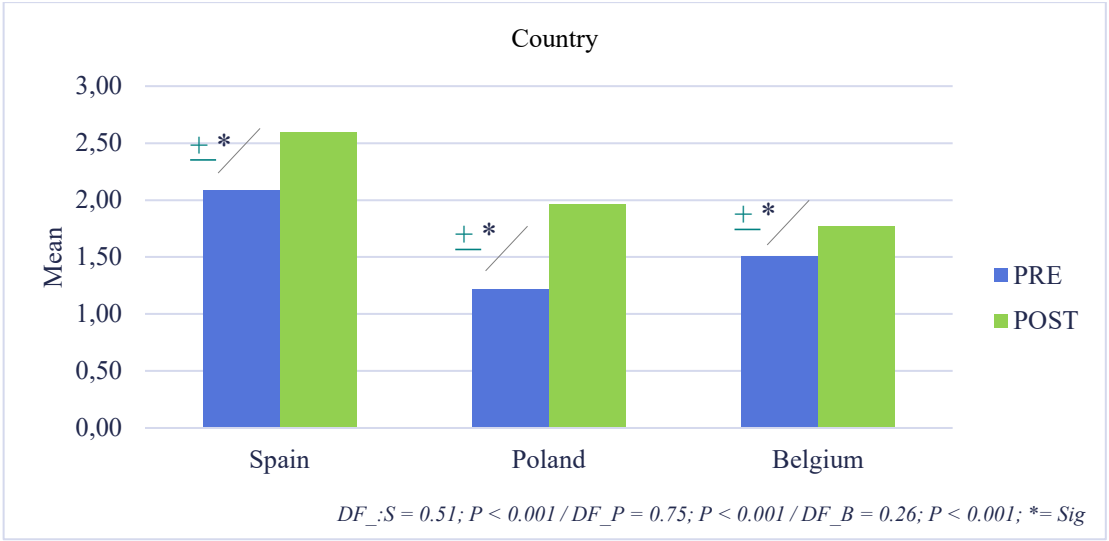


**Figure 5: Mean consumption before and after receiving the information (messages) per country**

Figure 6 shows a comparison of the mean consumption before and after receiving the information per group in Spain. Results show a significant increase of mean consumption after receiving the information in the three different groups.

Results of an ANOVA test showed no significant difference (p = 0.463) between the three groups before receiving the information, while significant difference (p = 0.074) are found between the three groups after the provision of the information.

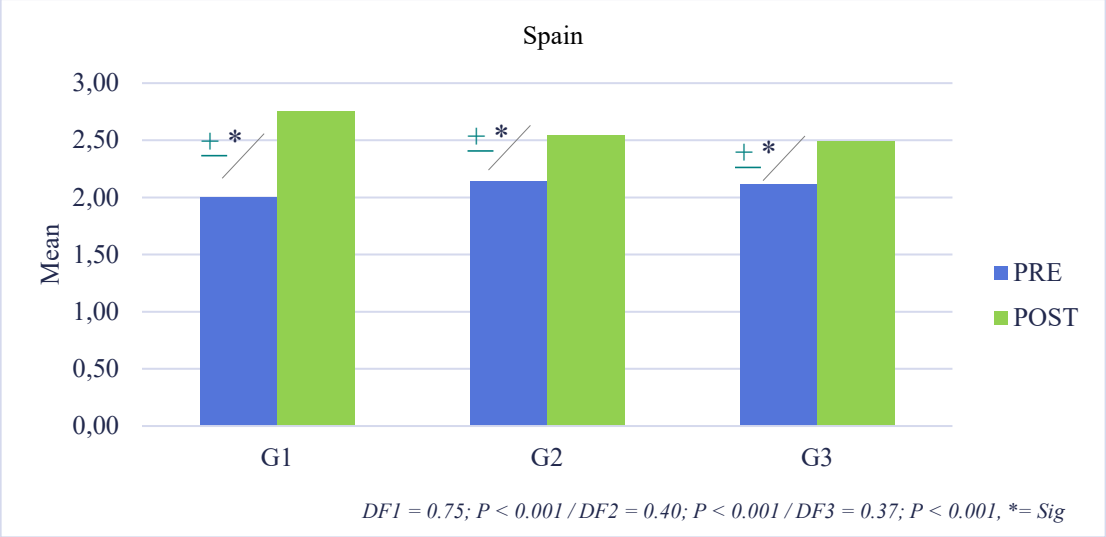


**Figure 6: Mean consumption before and after receiving the information (messages) per group – Spain**

Figure 7 shows a comparison of the mean consumption before and after receiving the information per group in Poland. Results show a significant increase of mean consumption after receiving the information in the three different groups.

Results of an ANOVA test showed no significant differences between the three groups before (p = 0.225) and after (p = 0.367) receiving the information.

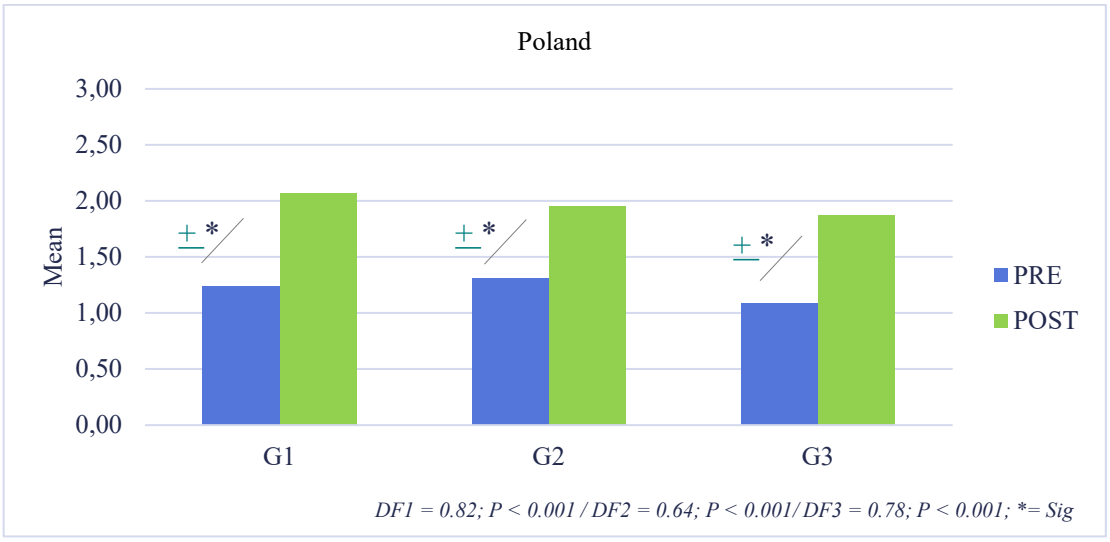


**Figure 7: Mean consumption before and after receiving the information (messages) per group - Poland**

Figure 8 shows a comparison of the mean consumption before and after receiving the information per group in Belgium. Results show a significant increase of mean consumption after receiving the information in the groups G1 and G3, while there is no significant difference (at 5% level) in G2 who received information about risks.

Results of an ANOVA test showed no significant differences between the three groups before (p = 0.104) and after (p = 0.694) receiving the information.

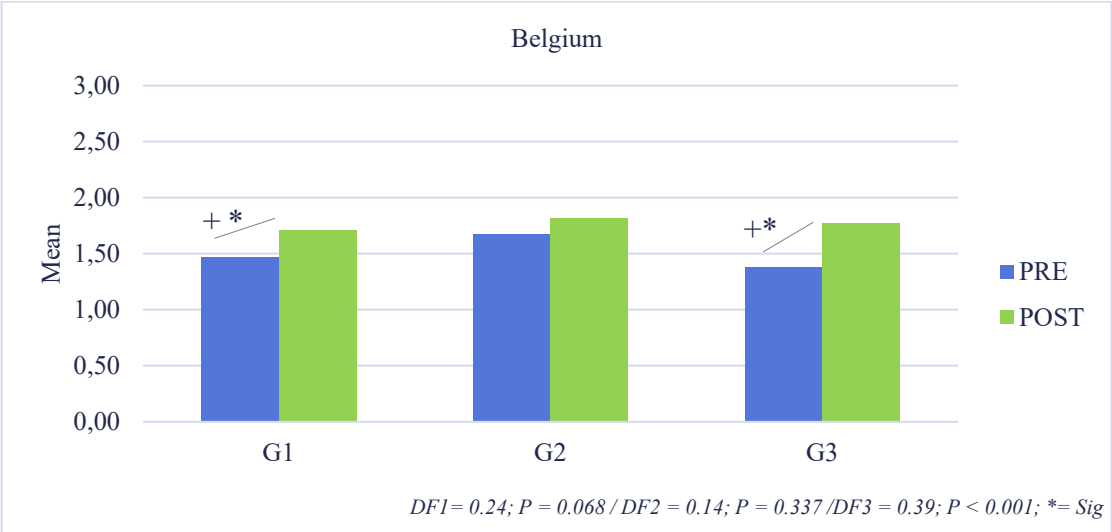


**Figure 8: Mean consumption before and after receiving the information (messages) per group - Belgium**

Figure 9 shows a comparison of the mean consumption before receiving the information per country. Results of an ANOVA test show a significant difference of mean consumption across the three countries, being Spain the country with the highest mean (2.09 times per week), followed by Belgium (1.51 times per week) and Poland (1.21 times per week).

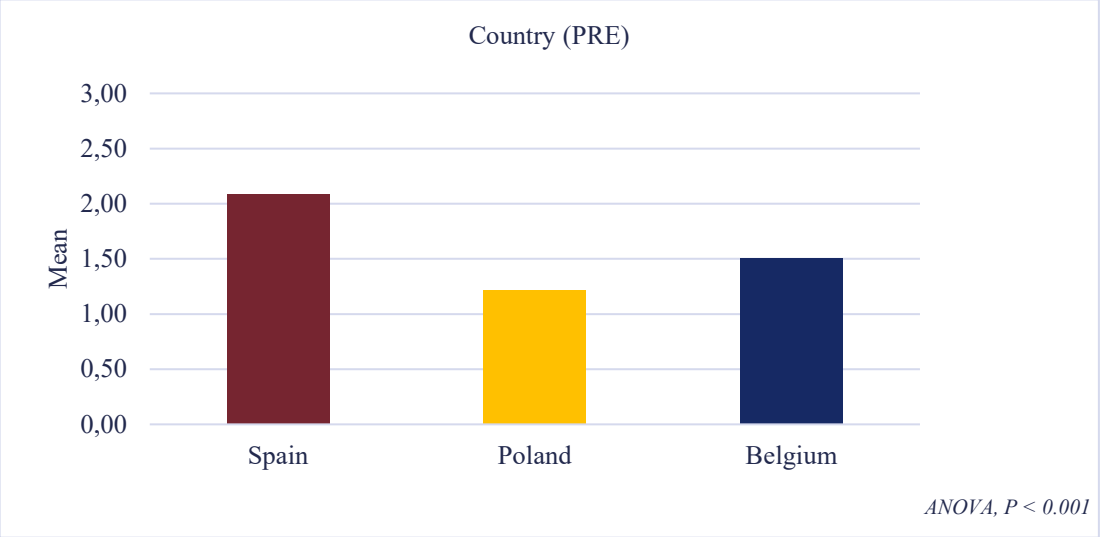


**Figure 9: Mean consumption before receiving the information (messages) per country**

Figure 10 shows a comparison of the mean consumption after receiving the information per country. Results of an ANOVA test show a significant difference of mean consumption across the three countries.

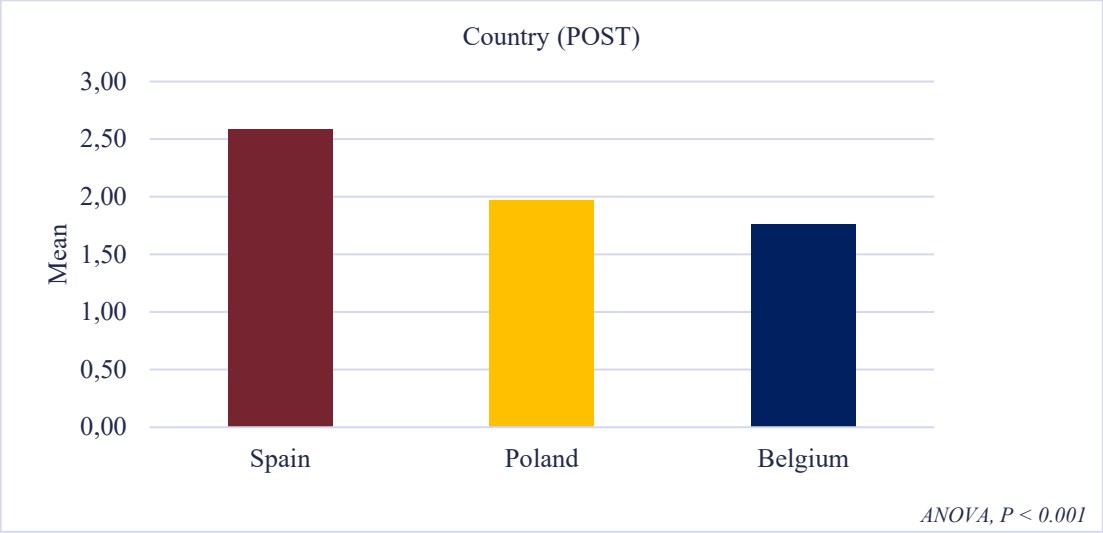


**Figure 10: Mean consumption after receiving the information (messages) per country**

Figure 11 shows a comparison of the whole sample mean consumption before receiving the information per group. Results of an ANOVA test show a significant difference (at 10% level) of mean consumption across the three groups.

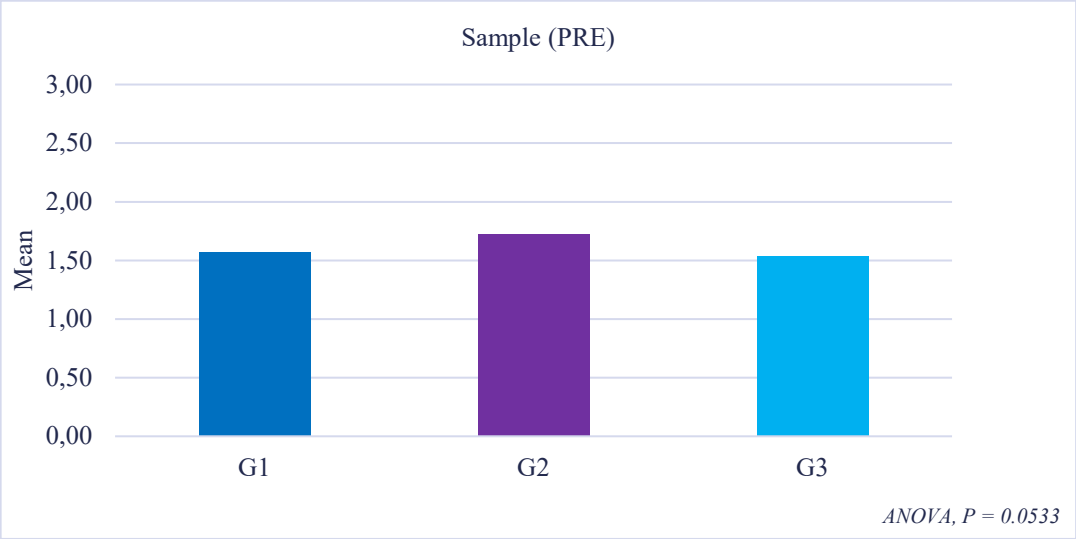


**Figure 11: Mean consumption before receiving the information (messages) per group**

Figure 12 shows a comparison of the whole sample mean consumption after receiving the information per group. Results of an ANOVA test show no significant difference of mean consumption across the three groups.

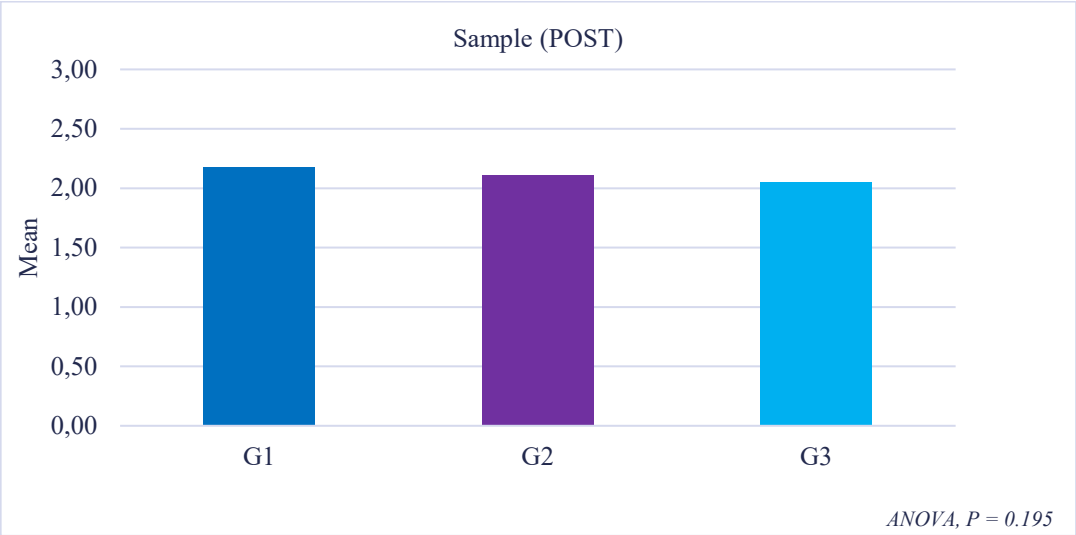


**Figure 12: Mean consumption after receiving the information (messages) per group**

From the preliminary results of the RASCS survey, the following conclusions can be made:

- Seafood is perceived as healthy, safe, nutritious, ethical, expensive, and sustainable by consumers of the three surveyed countries.
- The three messages were perceived as highly credible, trustworthy, clear and in line with what consumers from the three countries believe.
- Consumers showed an intermediate level of knowledge of European regulations on contaminants and monitoring programmes to protect consumers.
- Consumers showed a medium level of trust in European and national regulations on contaminants and monitoring programmes to protect consumers.
- The results show that most (89.92%) of Spanish consumers consume seafood at least once a week, followed by Belgium (72.43 %) and Poland (54.12 %).
- The most common frequency of current seafood consumption is "2 times per week" in Spain and "once per week" in Poland and Belgium. The majority are not reaching the recommendation even after the information.
- Most reported that they are (very) likely to follow seafood intake recommendations (81.8%), yet, among them, 33% intend to consume seafood less than 2 times per week after receiving the information.
- The information (messages) provided increased the frequency of seafood consumption, especially message 1.
- The information provided increased significantly:
    - The whole sample mean consumption.
    - The mean consumption in the three different treatment groups.
    - The mean consumption in the three countries.
    - The mean consumption in the three different treatment groups in Spain.
    - The mean consumption in the three different treatment groups in Poland.
    - The mean consumption in the groups G1 and G3 in Belgium.
- There is significant difference in mean consumption across the three countries, being Spain the country with the highest mean consumption (2.09 times per week), followed by Belgium (1.51 times per week) and Poland (1.21 times per week).

#### 2.4.1.3.2.2. Results of the real wild experiment

Table 21 displays the recorded results of the students' choice in both interventions before receiving the information message (pre) and after reading the information message (post). On average, results show that:

- Most of the participants (72.41%) chose meat before and after they receive the information ("Meat-Meat", no shift), which means that they are not affected at all by the information, and they have clear preferences for meat over seafood.
- 17.24% of the participants shifted from meat to seafood ("Meat-Seafood", positive shift) after receiving the information, which means that they are positively influenced by the information they received.
- All the participants who chose seafood in the first occasion (10.35%) they also chose seafood in the second purchase occasion ("Seafood-Seafood", no shift), which means that

they are not affected at all by the information, and they have clear preferences for seafood.

Within each group we observed the following changes:

- Group 1: Results show that 33.33% of this group members shift from meat to seafood after receiving the information on health benefits and seafood intake recommendations. It was the group with the highest rate of positive change. We can conclude that the message with information on health benefits and seafood intake recommendations was the most efficient communication strategy to shift consumer preferences in favour of seafood.
- Group 2: A 100% of the group members did not make any change in their food choices after receiving the information regarding risk, benefit and seafood intake recommendations. This means that the second communication strategy does not affect negatively food choices of consumers who already prefer seafood over meat (H1). However, this strategy was not able to shift the preferences of consumers who already prefer meat over seafood. We can conclude that including information on risks neutralise the positive effect of the message on health benefits.
- Group 3: Results show that 20% of members of this group shift from meat to seafood after receiving the information on health benefits, risks, seafood intake recommendations and regulation. We can conclude that including information on regulation moderate the effect of the message on risk (H2).

**Table 21. Recorded results of students' choices.**

| Interventions | Groups | | | Total (%) |
|---|---|---|---|---|
| **Pre- information - Post information** | **G 1 (%)** | **G 2 (%)** | **G 3 (%)** | |
| **Meat - Meat** | 55.55 | 90 | 70 | 72.41 |
| **Meat – Seafood** | 33.33 | 0 | 20 | 17.24 |
| **Seafood – Seafood** | 11.12 | 10 | 10 | 10.35 |
| **Total (%)** | 100 | 100 | 100 | 100 |

Meat-Meat and Seafood-Seafood: No shift in behaviour; Meat-Seafood: positive shift in behaviour.

From the results of this real world experiment we can conclude that communication focused on health benefits and seafood intake recommendation is the best strategy to promote seafood consumption. However, the efficiency of this strategy is neutralised when additional information on risks is provided. Moreover, this effect of the information on risks maybe moderated by providing information on regulation. However, we should keep in mind that this experiment has a limitation of using too small samples. So, its findings may or may not be confirmed in studies with large samples. The experiment allowed us to explore student reactions to the messages but we cannot extrapolated the findings. This is just an alternative to the hypothetical surveys to assess the impact of communication. For future studies, we recommend conducting the

experiment on large samples to examine the statistical differences between the groups. For the use of this method, we recommend:

- To use a representative sample of the population to be able to extrapolate the findings.
- To consider the minimum size of the groups to be able to conduct statistical analysis.
- To recruit groups with similar profiles to control for other variables.
- To use a control group, especially if the period between pre and post measurements is long. The control group helps to control for changes which are not related to the interventions.
- To ensure that food availability (offer) is similar during the two assessments (PRE & POST).

To use other targets rather than students (general consumers).

### 2.4.2 O-9: Recommendations for the development of strategies for risk/benefit communication regarding seafood consumption.

| |
|---|
| Task 4.2 Strategies for long-term promotion of seafood consumption: identification and assessment of current strategies and development of new strategies. |

#### 2.4.2.1 Seafood promotion programs

Several issues related with promotion of seafood were discussed with practical examples of promotion programs.

*1. Examining the Impact of a Public Health Message on Fish Consumption in Bermuda (McLean Pirkle et al., 2015)*

A study was conducted in Bermuda to assess changes in fish consumption among pregnant women after exposure to public health messages about mercury contamination. The study found that mean cord blood mercury concentrations in pregnant women decreased five-fold after the public health messages were implemented. However, while 71 % of women reported reducing consumption of larger fish species with higher mercury levels, 60 % also reported reduced consumption of smaller fish species which have low mercury concentration, indicating that the nutritional value message of small fish species was overwritten. The study suggests that adjustments are needed to better balance the risk and benefit communication. The main sources of information during pregnancy were health care providers and the internet. The frequency of exposure to public health messages was associated with lower reported consumption of fish. Overall, the study highlights the need for careful communication strategies and better balancing of risk and nutritional value messages in public health campaigns.

*2. Can fish consumption advisories do better? Providing benefit and risk information to increase knowledge (Engelberth et al., 2013)*

An evaluation was conducted regarding the effectiveness of Maine's fish consumption advisory. The study tested the improvement of knowledge among women regarding the risks and benefits of consuming fish during pregnancy. The study found that the advisory successfully increased women's knowledge of both the benefits and risks of consuming fish during pregnancy, as well as their ability to differentiate fish based on their mercury content. The study suggested that the advisory had the potential to reduce mercury-related health risks while avoiding a drop in fish consumption, which has been observed in other studies. The increased ability of readers to minimize risk while maintaining the benefits of fish consumption indicates the potential effectiveness of the advisory in promoting informed decision-making among consumers.

*3. What's the Catch? Reducing Consumption of Contaminated Fish among Anglers (Jonick et al., 2010)*

A social marketing campaign was developed by the U.S. EPA to reduce the quantity of contaminated white croaker fish caught in Southern California. The campaign targeted anglers and aimed to change their behavior regarding bringing back white croaker to the community. Results showed that the intervention was highly successful, with a 93% reduction in the number of white croaker entering the community after the intervention.

*4. Promoting seafood consumption: an evaluation of the Danish campaign for fresh fish (Scholderer and Grunert, 2003)*

A study was conducted in Denmark to evaluate the effects of a 3-year generic advertising campaign for fresh fish on consumer behavior. Before and after the campaign, consumers were surveyed. Availability in shops, meal preparation skills, and intentions to buy fresh fish were significant determinants of consumption. The campaign was designed to address these barriers by providing recipes for fresh fish and making packaged fresh fish available in supermarkets. The campaign integrated a family-oriented motive to utilize the influence of family expectations. After the campaign, availability in shops and meal preparation skills lost their influence on consumption frequency, and family norms became the only direct and indirect (mediated by intention to buy) influences. Mean levels of intention to buy and consumption frequency were significantly higher after the campaign (Table 22).

**Table 22. Example campaigns showing the success and failures of communicating health risks and benefits of fish and seafood consumption**

| Reference | Methods (interventions) | Key Findings |
|---|---|---|
| **(McLean Pirkle et al., 2015)** | Survey with pregnant women asking about whether they encountered information | Mercury risk messages lowered cord blood mercury levels in pregnant women, but also reduced consumption of less contaminated fish, indicating a need for balanced messaging. |
| **(Engelberth et al., 2013)** | Two booklets developed using focus groups | Fish consumption advisory educated about fish consumption during pregnancy, reducing mercury-related health risks without negative impacts on consumption. |

| | | |
|---|---|---|
| **(Roosen et al., 2007)** | Intervention using flyer distributed to anglers | EPA campaign reduced contaminated fish catch by 93 % and improved angler behavior and consumption habits. |
| **(Scholderer and Grunert, 2003)** | TV spots and supplementary materials distributed through retailers | Study found that a 3-year advertising campaign for fresh fish increased consumption frequency, with family norms being the main influencing factor. |

### 2.4.2.2 Consumer tools for informed seafood choices

A review of the potential of existing tools that have been available to consumers to match their seafood choices with their preferences while taking risk and benefit into account. Owing to the continuous increase in internet literacy in the EU, most of the existing tools or related information channels are online. Based on the third waves of Special Eurobarometer data (listed in 4.1.2), the number of European consumers who had no internet access at all was 5.7% in 2016, 2.2% in 2018 and 1.1% in 2021. European consumers have free access to the following tools to assist them in making more informed seafood choices.

**Seafood-specific tools**

- FishChoice (www.fishchoice.eu): An interactive tool developed and optimised within the ECsafeSEAFOOD and SEAFOOD$^{TOMORROW}$ projects funded by the EU. It informs consumers the health benefits and risks linked to their seafood consumption pattern. The recommendations are computed based on the users' inputs about consumption frequency and species. The tool was built on data that include a wide variety of emerging contaminants present in fish and shellfish samples collected over the EU, integrated with the nutrient information from various EU food composition databases.
- Seafood Watch (www.seafoodwatch.org and mobile app): An information tool developed by the Monterey Bay Aquarium, Canada. It provides recommendations indicating which seafood (species, harvest method, regions, body of water) are "Best Choices,", "Certified", "Good Alternatives," or ones to "Avoid," based on sustainability and environmental impact.
- Seafood Selector (seafood.edf.org): An information tool developed by the Environmental Defense Fund (EDF), indicating whether the seafood are "Certified", "Eco-Best Choices", "Eco-OK Choices" or "Eco-Worst Choices", including contaminant risks related to mercury and nutrients related to omega-3s.
- Front-of-pack labelling such as MSC that indicates sustainably caught seafood, Aquaculture Stewardship Council (ASC) that indicates responsibly farmed seafood.
- Websites by international or national food safety authorities where recommendations for seafood consumption are elaborated such as EFSA (https://www.efsa.europa.eu/en/efsajournal/pub/3982) and ISSalute (https://www.issalute.it/) from Italy

**General tools non-specific to seafood**

- Mobile apps such as Etiquettable (https://etiquettable.eco2initiative.com) which supports collaborative sustainable cooking by indicating the endangered species of seafood and the related nutrition information; Yuka (https://yuka.io) allows users to scan and assess

food products in relation to nutritional quality, presence of additives and production method (organic or not).

- Front-of-pack labelling such as the Nutri-Score that provides information about the nutritional quality of a food product, Eco-Score that provides information about the environmental impact.

Seafood-specific tools developed for end-consumers that provide information related to potential contaminants such as FishChoice are rare. The level of consumer acceptance of the FishChoice tool was assessed by an online survey in Belgium, Norway, Spain, Portugal, and Ireland (n=703). Two-thirds of consumers expressed willingness to use the FishChoice tool for making informed decisions, including the selection of seafood species, portion size, and consumption frequency. FishChoice was evaluated as user-friendly and useful, consumers who consumed seafood more frequently showed a greater propensity to reuse the tool in the future (Minnens et al., 2020).

Information used to develop and train the tools are often based on the recommendations from the international or national food safety authorities. EFSA recommends that each Member State should consider its own pattern of seafood consumption, species, and carefully assess the risks and benefits. The Knowledge4Policy (K4P) initiative by the European Commission offers an overview of Food-Based Dietary Guidelines for fish in different MS (https://knowledge4policy.ec.europa.eu/).

Recommendations can be derived for the development of long-term strategies for the promotion of seafood consumption while accounting for the risks and benefits of seafood consumption:

- Consumer education using balanced messages: currently most tools available inform consumers about the health benefits and environmental impacts of different seafood species, information about potential risks associated with overconsumption of certain species (like mercury content in large predatory fish) should be made available. Consumers in general perceive a positive image about seafood consumption. Consumer studies enable the identification of market segments based on seafood consumption frequency, messages related to potential risks should be targeted at consumers with a high level of consumption to enable mindful consumption, while targeting consumers with a low consumption with benefits of seafood to encourage consumption. Consumers could be encouraged to consume a larger variety of seafood to reduce the risk associated with consuming large amounts of a single species, especially in EU countries with a lower level of and less diverse seafood consumption such as Belgium and Poland (in comparison to Spain). This might also distribute the demand across different types of seafood, supporting more local or seasonal productions.
- Strengthening partnerships with different actors: actors who disseminate risk/benefit information should collaborate with national or local public health organizations and food safety authorities to ensure accuracy of information tailored to the local population, as well as timely and appropriate responses to potential crises related to seafood risks, such as contamination scares or recalls. A national crisis management plan should be developed and revised, the communication strategies in the event of crisis should remain transparent and offer clear information about the risks, how the situation is being

handled, and what concrete actions consumers can take for protection with frequent updates.

For actors who are not involved in risk communication on seafood, this work yields several key lessons. Online tools like FishChoice and Seafood Watch could be used as a platform to provide balanced, comprehensive information about both the benefits and risks of seafood consumption. Consumers appreciate user-friendly, accessible tools for making informed seafood choices, highlighting the need for such tools in other risk-prone sectors. Consumers value information tailored to their specific needs or consumption patterns, pointing to the need for region-specific RA and the translation of results into feasible guidelines. This local focus should extend to collaborations between communication experts, information providers and local health and food safety authorities for accurate, timely and easily accessible information.

#### 2.4.2.3 Development of strategies for communication

Task 4.3 Development of strategies for communication about seafood consumption during food safety crisis: identification and assessment of current strategies and development of new strategies.

Effective risk communication is crucial in mitigating the impact of food-borne diseases, which pose a constant threat to human health, the environment, and the economy (Frewer et al., 2015). The risk analysis process typically involves three steps: RA, risk management, and risk communication. However, during a crisis, urgency to respond may override the protocol.

Although there is a vast body of literature on risk communication, there is a dearth of research on actual cases of risk communication during a crisis that evaluates the impact of the communication, especially in the case of seafood. To address this gap, the analysis includes data retrieved from news reports and grey literature. The text is structured based on the principles of risk communication summarized from the literature (Covello and Allen's, 1988; FAO/WHO, 2016; and Frewer et al., 2015). These principles include timely response; clear messages, honesty and transparency; communication of uncertainty and involvement of the public, tailored messages, and collaboration with stakeholders.

**Timely response**

Responding promptly to a risk notification is crucial for minimizing the reach and impact of an incident. It is also essential to take charge of the situation and not let other interest parties, such as the media, dictate the narrative, as this can cause panic among consumers on an unscientific basis.

The Alar controversy of 1989 in the United States is a clear example of how inaction by responsible agencies can cause widespread panic and significant economic losses. The Environmental Protection Agency (EPA) had initiated a process as early as 1985 to ban Alar, a growth regulator with cancer risks (Denchak, 2016). However, the ban was overturned by its Scientific Advisory Panel, citing a lack of scientific evidence. Meanwhile, the NRDC, a non-profit

environmental group, published a report titled "Intolerable Risk" on the dangers of pesticide residues in children's food.

The issue gained momentum in February 1989, when the television broadcast CBS 60 Minutes labelled Alar as "the most potent cancer-causing agent in the American food supply" (Jacques, 2011), emphasizing its health risks to children based on the NRDC's report. The news anchor appeared in front of a graphic showing a skull and crossbones superimposed over an apple. Although the EPA later explained that "there is no imminent health hazard posed to children," the panic had already taken root, with consumers confusing the long-term cumulative threat with imminent danger, boycotting apples and demanding for pesticide-free and organic varieties. Apple growers reported losses of $100 million due to the incident (Jacques, 2011).

**Clear messages, honesty and transparency**

Effective communication during a crisis is crucial, not just in terms of providing timely responses, but also in delivering clear messages to the public and being transparent about the risk management process. This is exemplified by two dioxin contamination crises in Europe - one in Belgium in 1999 and the other in Ireland in 2008.

In the Belgian crisis, a delayed response, accusations of a cover-up by the media, and inadequate information provided to the public led to bans on Belgian agricultural products and a loss of public trust (Jacob, Lok, Morley, and Powell, 2010). In contrast, in the Irish crisis, the Food Safety Authority of Ireland quickly confirmed the contamination and publicly announced the discovery of dioxins in animal feed. The agency provided relevant information to the public, leading citizens to trust that the government would resolve the problem quickly (Jacob, Lok, Morley, and Powell, 2010). However, successful risk communication may not always result in uniform behaviour or consensus on controversial issues, as seen in the confusion of Irish consumers who didn't understand why the pork was recalled despite the low risk.

Effective risk communication should provide the public with as complete an understanding of the information as possible and follow a clear RA and risk management protocol to avoid confusion and bigger economic losses.

**Communication of uncertainty**

However, following a predefined risk communication protocol is not always possible due to the urgency of the incident. In 2017, when the Fipronil incident occurred in the Netherlands, risk management did not follow a RA and information was updated as it became available (European Commission, n.d). Instead of communicating the uncertainties, authorities wanted to increase confidence, to reassure consumers and government information went from stating that there was no immediate danger, to issuing a precautionary warning against eggs with certain batch numbers that could be hazardous to young children to a massive recall of products. This process confused consumers even more and caused economic losses of about 65-75 million euros, 1.9 million chickens were slaughtered, and 77.4 million eggs were affected (Mcdougal, 2018)

Even when uncertainties are communicated, some economic losses are inevitable. In the case of the fenugreek contamination in Germany in 2011, the responsible authorities reacted swiftly

and shared updates as new information became available. Although the risk management process did not adhere to the RA process, unlike the previous case, the German authorities did not blindly reassure consumers but shared the uncertainties publicly (Focker, 2021). They provided daily updates and disseminated information related to the outbreak case: definitions, sample reporting forms, diagnostic procedures, and hygienic measures, among other things. The authorities also issued joint press releases with relevant departments and implemented precautionary measures to protect consumers. However, the late discovery of the outbreak's cause led to a significant drop in cucumber sales, specially from Spain, which were wrongly believed to be the source of the outbreak. Even if Spain denied from the beginning, this led to substantial economic losses, with EU farmers reporting losses of up to $417 million per week (CTVNews, 2012).

The discrepancies in messaging between the German (Spain is the source) and Spanish governments (Spain is not the source) resulted in a loss of trust in the competent authorities. This highlights the importance of collaboration among stakeholders to ensure consistent messaging.

**Involvement of the public, tailored messages, collaboration with relevant stakeholders**

The 2021 listeria outbreak in Spain involving smoked salmon saw prompt action taken by Andalusian regional authorities. Following the detection of *Listeria monocytegenes* levels above the permitted limits, the relevant national agencies were informed, and the affected product was promptly removed from the market (AESAN, 2021). No cases were reported, and consumers were kept informed through clear communication regarding the product, the symptoms of the infection caused by the bacteria, specific risks to pregnant women, as they were the most vulnerable in this case, and provided guidance on the steps to take in case the product has already been consumed, as Mrs. Raquel Arpa Cuadrado from the Catalan Food Safety Agency emphasized during the ToS in Barcelona. This quick response and transparent communication helped to prevent any negative impacts on consumers.

**Conclusions and recommendations**

It is difficult and unrealistic to classify the effect of communications by successes and failures as the criteria for measurement is still a gap in the literature. Successfully protecting the consumer so that it does not consume the product anymore or takes adequate measures if the food has already been consumed, can on the other hand lead to huge economic losses from food recalled and not consumed or from a decrease in demand, which can in turn lead to environmental impact from food stocked gone bad.

Following the previous analysis, and the conclusions arrived during the ToS in Barcelona, some recommendations can be provided:

- When notified of an incident, start conducting a RA immediately and notify the corresponding authorities.
- Based on the assessment, provide risk management options while acknowledging uncertainties if exist.

- Clearly communicate information about the incident, including its risks, vulnerable populations, prevention, and mitigation strategies.
- Personalize messages to ensure they reach everyone and target the most vulnerable.
- Be open, honest and transparent to gain public trust and credibility.
- Work with other credible sources and address media needs through press conferences to provide them with the right information.
- Train communicators to understand both technical RA and societal responses to risk.
- Harmonize messages about risk uncertainty from various sources and address consumer concerns.

In this regard, Raquel Arpa Cuadrado, Head of Interadministrative Coordination of the Risk Planning, Audit and Assessment Service of the Catalan Food Safety Agency, explained during the training organized in Barcelona on the implementation of risk communication that: *"Our objective in communication is to maintain a high level of knowledge and confidence in food safety regulations and to achieve a balanced, coherent perception of food risk based on scientific information and our values: Transparency, Independence, Scientific Excellence and Participation. We are continuously working on food safety and related risks through the following tools: our website, meetings with representatives of the food chain, with consumers, workshops, conferences, etc. It is necessary to explain to society our control programs, the results and the actual risks, etc. It is a continuous work aimed at positioning ourselves as a reference and recognized organization. Thus, in times of crisis, we have already been recognized as a reference organization. The information we provide to society is truthful, adapted to the target groups and based on scientific rigor, and should not give more information than we have. This pre-crisis contact is very important to identify the needs of citizens and work with them to improve their perception of risk. Transparency always. In summary, prior and continuous communication with the public and stakeholders, scientific rigor, transparency and adaptation to the target audience are key factors to be considered for successful communication in times of crisis. And knowing how to identify and involve all the potential actors who can help us communicate and who are very close to the public (our prescribers): the general practitioner, schools, pharmacies, the grocer or supermarket, is also a determinant factor for success.".*

Mrs. Garazi Rodriguez, head of production and marketing plans at the Spanish Aquaculture Farmer's Association (APROMAR) recommended during her presentation in the meeting on Risk Communication implementation organized in Barcelona the following actions for developing long-term strategies to promote the consumption of fish and shellfish:

- Prior analysis of the current situation (market, trends, consumers, etc.).
- Focus on the target audience selected after the analysis.
- Annual communication and promotion campaigns. The duration of the campaigns should be adapted to the objective of the advertising. For a new brand, for example, it may take more than 10 years; to reinforce the messages of something already known, it may be less, the duration varies greatly, but in general they are long and expensive.
- Involve as many stakeholders and the entire value chain as possible if it is something general. Reach agreements, look for commonalities and synergies among all producers, marketers, etc., to carry out a broader campaign.

- Annual measurement of results and strategy rethinking based on these.

## 2.5 WP5: Dissemination and outreach

### 2.5.1 O-10: Ensuring effective communication inside the Project partnership (management and other WPs) to foster synergies and capitalization of activities (internal communication).

> Task 5.1 Designing a guide that will include recommendations to ensure an effective internal communication and provide an overview of main communication templates and rules in line with the project provisions, including the visual identity.

We began our project by developing the visual identity, including the Twitter and LinkedIn profiles and logo. These social media were selected through a participatory process. Specifically, an online survey was conducted among the partners to determine their preferences for the various social media. A similar process was used to select the project logo. Specifically, several logos were developed, and an online survey was conducted among partners to select the preferred logo. The logo was developed in different sizes so that it could be used on different platforms and documents. After developing the project logo and social media, we created a communication protocol.

To improve internal communication, direct and continuous contact was maintained with the various partners through the TEAMS platform. A project folder was created and shared with all partners so that all participants could access the documents created by others and make changes or suggestions as necessary. In addition, monthly meetings were organised via video call to share and discuss progress on each work package and to resolve issues. Several additional meetings were organised to solve problems that arose in the different tasks. Another channel that helped us to promote this constant contact was the update emails through which we shared information with the different partners.

In addition, several face-to-face trainings were organised by the partners in different organisations to share knowledge and experiences. Several local stakeholders and experts (local food safety and nutrition authorities, private companies, etc.) participated in these trainings. The trainings served as a meeting point for the participating partners and fostered communication between participants and non-participants, as a summary of the topics covered was published after the training was conducted and was accessible to all. These trainings encouraged interaction between the different parties and led to a series of debates on the progress of our tasks. In this way, we were able to rely on feedback from participants, which served as an incentive to refocus our research and achieve better results.

A training session on communication was organised in Barcelona, inviting professionals from different companies in the sector to show how they manage internal communication in high-level organisations that are also responsible for the rest of the population.

To improve internal communication, we guided the different partners to share their own content with the rest of the project participants, because the basis of good communication is that we all know what moves everyone forward.

### 2.5.2 O-11: Engaging stakeholders and advocating activities of dissemination and outreach (external communication).

> Task 5.2 Identifying target groups and coordinating network communication to engage stakeholders, namely regional (subnational) policy makers, to lead advocacy actions at different governance levels.

Regarding social networks and the volume generated by them, as a new project we had to create Twitter and LinkedIn profiles, which is a big effort since we started from scratch.

For this reason, we created a guide on how to use these platforms, highlighting especially the use of Twitter and its advantages: Hashtags, Photos and Tags. We shared this document with all project participants to collect their profiles in the social networks and promoted the content created through their institutions.

Once the profiles were created, we updated the relevant information about the trainings that took place during the development of the project and present to the external community the topics that were covered during those days. We have also created flyers with information relevant to the project that highlight some of the benefits of eating seafood.

In addition, we have shared our content with relevant associations and organisations within our sector but outside the project, such as Mercabarna or the Gremi de Peixeters de Catalunya (Spain), Autoridade de Segurança Alimentar e Económica (Portugal), Italian Ministry of Health (Italy), etc. Thanks to the reach of social networks, we have also shared content with government agencies from different countries, such as the Catalan Food Security Agency of the Generalitat de Catalunya.

In addition, an extensive database of audiences and stakeholders at the national, regional, and European levels was created. Once EFSA has validated the content of the final report, a summary of each task will be prepared and shared with all these organisations and stakeholders, as well as the published report.

> Task 5.3 Designing a communication protocol for the thematic web seminars and meetings to reach the largest audience.

A common protocol was established for the seminars and meetings, and with the aim of sharing as much information as possible with all the partners involved in the project, a summary of each training and the feedback from the participants were collected and shared with all the partners. Thus, after the trainings were conducted, we had a lot of material to share with the other partners:

- A general summary from the conference organizers explaining the most important information about each contribution and debate.

- A summary and individual evaluation of each participant on the topics covered and the information learned during the day (feedback).
- Presentations and scripts of the participants to make them accessible to each partner.

Thanks to the collection of this information, we were able to keep all participants informed. In addition, once the documents had been shared, we have created templates for social networks in which the most relevant aspects of each of the trainings are summarized in 10 headlines.

### 2.6 WP6 – Management

#### Meetings

We briefly present herein a summary of the meetings held within RASCS over the 2 years of execution. The agenda and all meeting notes were uploaded in the TEAMS platform.

Monthly meetings were held within the consortium for the exchange and for the management of the project. In addition, four meetings with higher relevance were held.

KICK-OFF meeting (Web) (June 21 and 22, 2021).

The kick-off and first consortium presential meetings could not be held in Parma due to the COVID situation and were organized online. The interaction between EFSA and the RASCS consortium was followed by 1.5 day meeting within the consortium.

INTERIM meeting (Paris, ANSES's headquarters, physical and online), (June 8 and 9, 2022).

This interim meeting favored the interaction among partners, since it was the first physical meeting held within the consortium.

INTERIM meeting WEBINARS (Barcelona, ACSA's headquarters, physical and online), (November 23-25, 2022).

This meeting, which is further described in section 3.4, was not initially planned in the project agreement. It was proposed considering that all the budget necessary for the kick-off meeting in Parma had not been used due to COVID, and instead, was used to this interim meeting. The Webinars session in Barcelona, represented an extremely important occasion to deeply analyze and exchange, the topics dealt with within the webinars. This meeting was open to additional professionals beyond the consortium upon invitation. In addition to 22 persons attending the webinars physically, 35 people attended online.

FINAL WORKSHOP at PARMA (EFSA's headquarters, physical and online), (June 7-9, 2023).

Final meeting of the RASCS consortium, included 2-day meeting within the consortium and a half day meeting between EFSA and RASCS to evaluate the final report and address questions regarding the execution of the project.

**Partner structure**

Several changes in the staff participating to the consortium occurred and these were managed following EFSA's requirements. No major incidence was observed in the execution of the project.

**Budget**

Budgetary change proposals were communicated to EFSA on a regular basis. The major budgetary change related to COVID19, involved the use of budget originally dedicated to the kick-off meeting to participate instead to the Interim Webinar meeting in Barcelona. Regular update of the budget was communicated to EFSA and approval was requested for all changes proposed.

**KE Platform in TEAMS**

IRTA hosted a TEAMS platform accessible to RASCS partners and EFSA staff, where all the information about the project and exchanges performed were included. This TEAMS platform allowed to facilitate access to the information, work jointly on common documents and be used by all partners and EFSA staff to follow the advancement of the project.

**Communication with EFSA**

Regular communication with EFSA was maintained by mail and TEAMS meetings. Communication was fluent, easy, and all issues raised by EFSA or by the RASCS consortium were conveniently addressed.

# 3. Description of exchanges performed

**3.1 SIMPLE DUAL EXCHANGE:** Throughout the project exchange among partners could proceed at an individual basis, to dealt with relatively simple topics. Exchange consisted on the transfer of information by providing documents, clarifications, questions and answers. These were addressed by mail and video conferences. This was the scenario in which one partner has the precise knowledge requested by a second partner, and the transfer was unidirectional. Eventually, additional information was provided by other partners to complement the exchange and to close the issue.

**3.2 DISCUSSION AND ANALYSIS:** Some topics required a deeper approach and included some analysis and debate by different partners. Open discussion forums among partners were set to evaluate during the meetings, the topic and gather different points of views, to address the issue, identify gaps, and provide the required information and conclusions before closing the topics.

**3.3 RASCS FAQs (Frequently Asked Questions):** Originally planned in the proposal, the FAQs list was finally not considered since many issues described above could not be synthesized in a

simple FAQs format. In addition, the term "Frequently" could not be objectively defined according to our professional expertise, certainly different from questions raised by consumers. Hence the consortium preferred not to raise such list, but instead, provide a much deeper explanation of the several issues in the report, in a more extended text that could better describe some conclusions and answers about the different topics.

### 3.4 SPECIFIC WEBINARS (Barcelona, November 23 to 25 2022, physical):

A series of WEBINARS were held within the interim meeting in Barcelona (November 23 to 25, 2022). The titles of the webinars were as follows (Complete agenda and abstracts in ANNEX X). Each topic was followed by a very fruitful discussion among participants (in person as well as on line), sharing their experiences, which was the major aim of the webinars.

WP-1- Processing of Seafood - Impact on contaminant concentration and compliance with maximum levels (BfR).

WP-1 - Alternative screening methods for marine toxins (IRTA).

WP-2 - Scientific approaches for the definition of optimal sampling in monitoring programmes (IRTA).

WP-3 - The risk assessment of multiple chemicals contaminating seafood (ISS).

WP-3 - The impact of climate change on seafood contamination (ISS-IPMA).

WP-3 - Balancing risks and benefits: approaches applied to seafood consumption (IPMA).

WP-4 - The assessment of risk and benefit perception (UGENT and CREDA).

WP-4 - The role of risk and benefit perception on consumer purchase decisions (UGENT and CREDA).

WP-4 - Seafood promotion and crisis communication strategies (UGENT)

### 3.5 WEBINAR on Prioritization (March 13, 2023, online)

ANSES specifically addressed the issue on prioritization of contaminants, and a webinar was proposed that allowed ANSES researchers to explain a long-term project held in France, to develop methodologies for hazard prioritization. (See Annex C)

Title: Multi-Criteria Decision Analysis methodology for prioritization of biological and chemical hazards in food (by Anses, speakers: Laurent Guillier and Nawel Bemrah).

### 3.6 INDIVIDUAL TRAININGS ON SPOT:

- Four physical Trainings on Spot (ToS) hosted by four partners, allowed to tackle specific issues. These are clearly described in the Annex section. As foreseen by the protocol described in task 5.3, after any ToS a general summary of the days was prepared by the organizers, describing both the scientific aspects and the social activities. Each

participants added his/her individual evaluation and the take home message. The presentations as well as the report were uploaded on the TEAMS platform, available for each Consortium members. and for EFSA as well. They are included as an Annexes to this Report (Annexes D to G)

- Rome "Institutional approach to Risk Assessment, RA" (February 16 and 17, 2023)
- Lisbon (IPMA): "Risk-benefit analysis" (February 28 and March 1, 2023)
- Barcelona (CREDA): "Dissemination and outreach" (April 11 and 12, 2023)
- Paris (ANSES): "Anses experience: From laboratory to risk assessment and beyond" (May 11 and 12, 2023)

# 4. Overall Conclusions and Recommendations

It is important to state that the conclusions and recommendations found within this report, including this section, need to be well framed within the RASCS consortium, its composition of multidisciplinary professional profiles and expertise, and especially the major aim/focus of the Project, that is the KEamong the partners. This means that the conclusions and recommendations herein do not intend to cover all contaminants and are not based on an exhaustive and universal vision of contaminants in seafood. This was not the purpose of RASCS. On the contrary, our focus on contaminants has been linked to our present challenges, doubts, interests that derive from our day-to-day work, and hence the conclusions and recommendations are oriented to a short-list of compounds that we consider of interest from our own perspective. Some other interesting contaminants are under-represented, and this is not for negligence, nor for lack of interest, nor for considering them not relevant, but only due to the present orientations of the small group of professionals within RASCS.

The RA of contaminants in seafood is of major concern due to the implications in human health, animal health and environmental health: it is therefore a relevant issue from a One-Health perspective.

While some regulated compounds are regularly monitored and large data series, which allow robust evaluations, are available, the RA of non-regulated or emerging contaminants is eventually limited due to the limited amount of data for both the toxicological profile and the extent of contamination often due to lack of enough reliable data coming from good quality determinations. A very recent example is that of PFASs, for which some data exist, but not on a wide spatial and temporal scale. Since January 2023, a new regulation is requiring to monitor PFASs in shellfish and crustaceans, and this will certainly increase our awareness on the occurrence of these contaminants. In addition, for several contaminants such as marine toxins (e.g. CTXs), there is a lack of certified standards and validated methods that can provide reliable data. The activities in RASCS have allowed to better exchange monitoring practices and data sources among participants. In that sense, one recommendation is to facilitate existing data exchange between relevant actors in the food system and favor data acquisition for those contaminants under-represented in scientific publications and data bases.

Improving inter-collaboration among laboratories to have access to valuable samples and exchange of methodological approaches to emerging contaminants can help through inter-comparative exercises to harmonize methods and eventually facilitate their validation at an international level. This is especially true for those alternative screening methods such as biosensors, that may complement more traditional laboratory methods, generally more costly or time consuming. Another issue regarding analytical methods implemented in monitoring programs is that of processed food, for which the quantitative approach to some contaminants may require a more detailed analysis to correctly estimate actual exposure and then risks. As an example, when considering the contamination of processed food analyzed for marine toxins it is necessary to take into account water losses, to avoid an impact on the decisions taken regarding affected stocks. RASCS discussed the issue on regulations and processing of food, since levels of toxins in fresh samples could change through processing of food, and hence that might generate discrepancies between analysis conducted in shellfish harvesting areas and marketed products from those same areas.

The approach to existing regulations, or also to scientific challenges on contaminants, is not equally addressed within the different monitoring programs that have been evaluated. Certainly, regional differences according to the contaminants may partially explain these differences. Nonetheless, KE, such as the one in RASCS, can definitively expose key actors that participate in the design of monitoring programs to other visions and approaches in other regions or countries. This will ultimately improve how these monitoring programs are implemented.

The combined effects of different contaminants to which consumers may be exposed is a field of study that would also require further work. Again, networks of experts such as RASCS, in which knowledge on different types of contaminants is shared, may also improve our approach to a wholistic vision on RA for major contaminants to which consumers may be concurrently exposed through seafood consumption and better tackle gaps of information. Beside the aspects concerning co-exposures, approaches for deciding when is necessary to go for a combined RA as well as the identification of combined risks still need some harmonization.

Harmonization on the use and acceptability of NAMs in RA has been also discussed: the major issue has been identified in the need for training for risk assessors.

Climate change is certainly a new driver that may have an impact on the future exposure of consumers to contaminants. The RASCS consortium has exchanged intensively information on toxin-producing marine microalgae, some of which, coming from tropical and sub-tropical areas may now be better adapted to temperate areas, where toxin exposure through seafood consumption, among other circumstances, may increase in the future under climate change scenarios, increasing the risk for the exposed population. The Mediterranean is an example. It is therefore important to increase studies and regular monitoring of these specific contaminants and try to understand how climate change may affect their impact on food safety in order to increase preparedness of the different responsible Institutions.

Focus on contaminants in seafood cannot disregard the beneficial aspects of seafood consumption. The risk-benefit approach is a key issue needed by managers that have to define protective measures to reduce risks. Within RASCS, several approaches to risk-benefit studies

were discussed, showing that this is also a field that requires important attention and development of tools to better quantify hazards and implement measures to improve the formulations of products and diet of consumers.

The analysis of consumer perception and behavior towards contaminant hazards in seafood is a key element to improve public health. RASCS has tackled several issues regarding consumers, including their perception on risks and benefits. Studies to better understand how consumers confront their daily food purchases is crucial to ensure that their decision-making process does not negatively affect them. Improving strategies to better seize these patterns and identify non-beneficial dietary drifts are needed for public health authorities to better define communication campaigns and implement other measures within the food systems to improve food choices among consumers.

Overall, RASCS has demonstrated to be an extremely valuable opportunity to improve our skills within the RA of contaminants in seafood. The activities within RASCS have stressed how important is for experts to improve our awareness on RA associated knowledge, by listening to other experts, and how important are the synergic efforts of experts from different fields that converge in the same room to discuss on emerging issues on food safety, for which important gaps require action.

# 5. Consortium evaluation of the RASCS Partnering Grant and Impact

RASCS Partnering Grant has allowed to reach three main goals: i) Significantly improve the participant's knowledge within the subject of RA of contaminants in seafood, ii) Increase awareness on EFSA's goals and tools regarding RA, and iii) Strengthen links among institutions and experts.

As it can be seen in this report, the levels of exchange of information and experiences have been intense, and all partners have taken great benefit of this exchange in a reciprocal sense, either as provider or as receptor of information, experiences and strategies. We could strengthen a point of very constructive exchange between two "types" of partners: individuals whose day-to-day work focuses more closely on specific contaminants in nature and seafood, some implementing deeply specialized analytical skills, other studying their toxicological effects or evaluating the specific risk for the impacted population, with individuals that are focusing their work closer to consumers and communication. In this sense, we value this Partnering Grant as a way of improving our skills within RA of contaminants in seafood, and enlarging our vision of RA beyond our specific professional experience, with a more wholistic approach to RA. Questionnaires focusing on the implementation of monitoring programs and consumer surveys were sent to EU agencies, and this allowed to retrieve and organize existing data and methods to work. In addition, a consumer survey specific to contaminants in seafood was set in three countries (Belgium, Spain and Poland).

Regarding the improvement of the consortium awareness of EFSA's goals and tools regarding RA, RASCS has definitively offered valuable opportunities to be acquainted of EFSA's documents, strategies and initiatives particularly focusing on RA of contaminants in seafood.

RASCS has definitively improved the connections among individual partners, strengthening a multidisciplinary network of professionals dedicated to RA of contaminants in seafood. Although some participants in the RASCS consortium had already established collaborations in several international projects and activities, RASCS has allowed to create a "new" network of professionals, increasing a shared vision on the benefits that a multidisciplinary approach can provide to RA. This network has allowed to identify, within institutions that were already known, new experts that have enlarged our vision on RA with their particular expertise and vision of RA. This is leading, beyond RASCS, to favor new experimental work, the writing of new research proposals and scientific publications. It has overall increased the knowledge and expertise on contaminants in seafood across European institutions.

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# Abbreviations

| | |
|---|---|
| AAS | Atomic absorption spectroscopy |
| ANSES | French Agency for Food, Environmental and Occupational Health & Safety |
| AOP | Adverse Outcome Pathway |
| ASC | Aquaculture Stewardship Council |
| AZAs | Azaspiracids |
| BfR | German Federal Institute for Risk Assessment |
| CBA | Component-Based Approaches |
| CLEFSA | Climate change as a driver of emerging risks for food and feed safety, plant, animal health and nutritional quality |
| CLP | Classification, Labelling and Packaging |
| CP | Ciguatera poising |
| CREDA | Center for Agro-Food Economics and Development |
| CTX1B | Ciguatoxin congener CTX1B |
| CTXs | Ciguatoxins |
| DALYs | Disability-Adjusted Life Years |
| DTXs | Dinophysistoxins |
| ECHA | European Chemical Agency |
| EPA | Environmental Protection Agency |
| EURL | European Reference Laboratories |
| FAIR | Findable, Accessible, Interoperable, Reusable |
| FAO | Food and Agriculture Organization |
| FBO | Food Business Operators |
| FFQ | Food Frequency Questionnaire |
| FPQ | Food Propensity questionnaire |
| GC-HRMS | Gas chromatography coupled to high-resolution mass spectrometry |
| GC-MS | Gas chromatography-mass spectrometry |
| GC-MS/MS | Gas chromatography coupled to tandem mass spectrometry |
| HBGV | Health Based Guidance Values |
| HBVs | Health-based values |
| HI | Hazard Index |
| HILIC-MS/MS | Hydrophilic liquid chromatography coupled to tandem mass spectrometry |

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| HQ | Hazard Quotient |
| IATA | Integrated Approach to Testing and Assessment |
| ICP-MS | Inductively coupled plasma mass spectrometry |
| ICP-OES | Inductively coupled plasma optical emission spectrscopy |
| IPCC | Intergovernmental Panel on Climate Change |
| IPCS | International Programme on Chemical Safety |
| IPMA | Portuguese Institute for the Sea and Atmosphere |
| IRTA | Institute of Agriculture and Food Research and Technology |
| KE | Knowledge Exchange |
| LC-FLD | Liquid chromatography coupled to fluorescence detection |
| LC-MS/MS | Liquid chromatography coupled to tandem mass spectrometry. |
| LC-UV | Liquid chromatography coupled to UV detection |
| LOD | Limit of Detection |
| LOQ | Limit of Quantification |
| MCs | Microcystins |
| MoA | Mode of Action |
| MoE | Margin of Exposure |
| MPLs | Maximum permitted levels |
| MRLs | Maximum Residue Levels |
| MS | Member State |
| MSC | Marine Stewardship Council |
| NAMs | New Approach Methodologies |
| NGRA | New Generation Risk Assessment |
| NRDC | Natural Resources Defence Council |
| NRLs | National Reference Laboratories |
| OA | Okadaic Acid |
| OECD | Organisation for Economic Cooperation and Development |
| PAHs | Polyaromatic hydrocarbons |
| PCBs | Polychlorinated Biphenyls |
| P-CTX-1 | Formerly used for Ciguatoxin congener CTX1B |
| PFASs | Perfluoroalkyl substances |
| PFHxS | Perfluorohexane sulfonic acid |
| PFNA | Perfluorononanoic acid |
| PFOA | Perfluorooctanoic acid |

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|---|---|
| PFOS | Perfluorooctane sulfonic acid |
| POPs | Persistent Organic Pollutants |
| QALYs | Quality-Adjusted Life Years |
| RA | Risk Assessment |
| RASCS | Risk Assessment Strategies for Contaminants in Seafood |
| RPF | Relative Potency Factor |
| STXs | Saxitoxins |
| TDI | Tolerable Daily Intake |
| TEF | Toxic Equivalent Factor |
| TEQ | Sum of dioxins and PCBs, expressed as toxin equivalents |
| TDS | Total Diet Studies |
| ToS | Training on Spot |
| TTC | Thresholds of Toxicological Concern |
| TTX | Tetrodotoxin |
| WHO | World Health Organisation |
| WMA | Whole Mixture Approaches |
| YTXs | Yessotoxins |

# Appendix list:

**Appendix A: MONITORING PROGRAM QUESTIONNAIRE (FILE NAME: RASCS APPENDIX A MONITORING PROGRAM QUESTIONNAIRE)**

In this task, Anses elaborated a questionnaire jointly with IRTA and BfR, to collect information on the monitoring programs for contaminants in seafood in the MS represented in the consortium, namely Belgium, France, Germany, Italy, Portugal and Spain. Appendix A is the template of the monoitoring questionnaire sent to the different institutions.

**AppendiX B : QUESTIONNAIRE CONSUMPTION SURVEYS (FILE NAME : RASCS APPENDIX B QUESTIONNAIRE_CONSUMPTION_SURVEYS)**

A questionnaire was prepared to identify and make an inventory in-house dietary surveys on seafood. National dietary surveys on the general population, including but not specifically dedicated to seafood, were targeted, as well as specific studies on seafood consumers. Appendix B is the template of the survey questionnaire sent to the different institutions.

**AppendiX C: RISK ASSESSMENT INSTITUTIONS (FILE NAME: RASCS APPENDIX C RISK ASSESSMENT INSTITUTIONS)**

A survey was carried out among the RASCS partners, to identify institutions dealing with RA in seafood products (non-exhaustive). Appendix C is the list of the RA Institutions identified.

# ANNEX A: 76 SURVEYS

**List of the 76 surveys from the EU Comprehensive database that include consumption data on seafood, and survey information.**

| Country | Start Year | Survey name | Number of subjects | Min-Max age range (years) | Dietary methods | Reference publication |
|---|---|---|---|---|---|---|
| **Austria** | 2010 | Austrian Study on Nutritional Status 2010-12 - Adults | 615 | 18-80 | 24-hours dietary recall | Elmadfa I et al. Österreichischer Ernährungsbericht 2012. 1. Auflage, Wien, 2012 http://www.bmg.gv.at/cms/home/attachments/4/5/3/CH1048/CMS1348749794860/oeb12.pdf |
| **Austria** | 2010 | Austrian Study on Nutritional Status 2010-12 - Children | 387 | 6-15 | Food record | Elmadfa I et al. Österreichischer Ernährungsbericht 2012. 1. Auflage, Wien, 2012 http://www.bmg.gv.at/cms/home/attachments/4/5/3/CH1048/CMS1348749794860/oeb12.pdf |
| **Austria** | 2014 | EU Menu Austria: Food consumption data for Austrian adults | 2250 | 18,02-64,89 | 24-hours dietary recall | Rust P, Hasenegger V, König J: Österreichischer Ernährungsbericht 2017. https://broschuerenservice.sozialministerium.at/Home/Download?publicationId=528 ; Hasenegger, V., Rust, P., König, J., Purtscher, A., Erler, J., & Ekmekcioglu, C. (2018). Main sources, socio-demographic and anthropometric correlates of salt intake in Austria. Nutrients, 10(3), 311.; EFSA supporting publication 2019:EN-1754. 21pp. doi:10.2903/sp.efsa.2019.EN-1754 |
| **Austria** | 2016 | EU Menu Austria: Food consumption data for Austrian pregnant women | 302 | 19,46-47,76 | 24-hours dietary recall | Rust P, Hasenegger V, König J: Ernährungsverhalten von Schwangeren in Österreich. 2019 ; EFSA supporting publication 2019:EN-1754. 21pp. doi:10.2903/sp.efsa.2019.EN-1754 |
| **Austria** | 2018 | EU Menu Austria: Food consumption data for Austrian adolescents | 657 | 10,06-17,99 | 24-hours dietary recall | EFSA supporting publication 2019:EN-1754. 21pp. doi:10.2903/sp.efsa.2019.EN-1754 |
| **Bosnia and Herzegovina** | 2017 | Bosnia-Herzegovinian Dietary Survey of adolescents, adults and pregnant women | 1384 general population/134 pregnant women | 10-64 | 24-hours dietary recall | https://doi.org/10.2903/sp.efsa.2021.EN-6993 |

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|---|---|---|---|---|---|---|
| **Belgium** | 2002 | Regional Flanders | 661 | 2,5-6,5 | Food record | Huybrechts I, Matthys C, Pynaert I, De Maeyer M, Bellemans M, De Geeter H and De Henauw S, 2008. Flanders preschool dietary survey: rationale, aims, design, methodology, and population characteristics. Arch. Public Health 66: 5-25. |
| **Belgium** | 2004 | Diet National 2004 | 3245 | 15- | 24-hours dietary recall | De Vriese S, Huybrecht I, Moreau M, De Henauw S, De Backer G, Kornlitzer M, Leveque A and Van Oyen H, 2005. The Belgian food consumption survey: aim, design and methods. Arch Public Health. 63, 1-16. |
| **Belgium** | 2014 | Belgian national food consumption survey in children, adolescents and adults | 1027/2278 | 3-64 | Food record, 24-hours dietary recall | EFSA supporting publication 2018:EN-1468, 2018:EN-1467; De Ridder K, Bel S, Brocatus L, Cuypers K, Lebacq T, Moyersoen I, Ost C & Teppers E. De con-sumptie van voedingsmiddelen en de inname van voedingsstoffen. In: Bel S, Tafforeau J (ed.). Voedselconsumptiepeiling 2014-2015. Rapport 4. WIV-ISP, Brussel, 2016. https://fcs.wiv-isp.be/nl/Gedeelde%20%20documenten/NEDERLANDS/Rapport%204/Rapport_4_NL_finaal.pdf, De Ridder K, Bel S, Brocatus L, Cuypers K, Lebacq T, Moyersoen I, Ost C & Teppers E. La consommation |
| **Bulgaria** | 2007 | NUTRICHILD | 1723 | 0-4.92 | 24-hours dietary recall | Petrova S, Ovcharova D, Rangelova L, Duleva V, Angelova K, Kalinov K, Dimitrov P, Bojilova D, Baikova D, Vatralova K, Popivanova A, Marinova M, Antonova Z and Duneva Z, 2009. National survey on nutrition of infants and children under 5 years and family child rearing. A Report for UNICEF Bulgaria. NCPHP, pp 1 – 361 (In Bulgarian). Available from: http://ncphp.government.bg |
| **Cyprus** | 2003 | Childhealth | 303 | 11-18 | Food record | Not available |
| **Cyprus** | 2014 | National dietary survey of the adult population of Cyprus | 812 adults/ 204 pregnant women | 10 (pregnant 17.1)-76.86 (pregnant 43.26) | 24-hours dietary recall | EFSA supporting publication 2018:EN-1458 |
| **Cyprus** | 2014 | National dietary survey of the children of Cyprus | 848 | 0,02-9,99 | Food record | EFSA supporting publication 2018:EN-1464 |
| **Czechia** | 2003 | Czech National Food Consumption Survey | 1751 | 4- | 24-hours dietary recall | Ruprich J, Dofkova M, Rehurkova I, Slamenikova E, Resova D. 2006. Individual food consumption - the national study SISP04. CHFCH NIPH in Prague. Available from: http://www.chpr.szu.cz/spotrebapotravin.htm |
| **Germany** | 2001 | Consumption Survey of Food Intake among Infants and Young Children | 804 | 0,4-5 | Food record | Banasiak U, Heseker H, Sieke C, Sommerfeld C, Vohmann C. Abschätzung der Aufnahme von Pflanzenschutzmittel-Rückständen in der Nahrung mit neuen Verzehrsmengen für Kinder. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz (2005) 48: 84-98. |

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|---|---|---|---|---|---|---|
| **Germany** | 2006 | Dortmund Nutritional and Anthropometrical Longitudinally Designed (DONALD) Study 2006-2008 | 926 | 1-10 | Food record | Kroke A, Manz F, Kersting M, Remer T, Sichert-Hellert W, Alexy U and Lentze MJ, 2004. The DONALD Study. History, current status and future perspectives. Eur. J. Clin. Nutr. 43: 45-54. Sichert-Hellert W and Kersting M, 2004. Fortified food with folic acid improves folat intake in German infants, children and adolescents. J. Nutr. 134: 2685-2690. |
| **Germany** | 2006 | Eating Study as a KiGGS Module (EsKiMo) | 1234 | 6-11 | Food record | Stahl A, Vohmann C, Richter A, Heseker H, Mensink GBM. Changes in food and nutrient intake of 6 to 17 year old Germans between the 1980s and 2006. Public Health Nutrition. 2009 12: 1912-1923. doi:10.1017/S1368980009004844 |
| **Germany** | 2007 | National Nutrition Survey II | 13926 | 14-80 | 24-hours dietary recall | MRI (Max Rubner-Institut), 2008. Ergebnisbericht der Nationalen Verzehrsstudie II - Teil 1 (in German: Report of the National Nutrition Survey II - Part 1). Karlsruhe (Germany), (p. 144). Available from: http://www.was-esse-ich.de/uploads/media/NVS_II_Abschlussbericht_Teil_1_mit_Ergaenzungsbericht.pdf ; Krems C, Bauch A, Götz A, Heuer T, Hild A, Möseneder J and Brombach C, 2006. Methoden der Nationalen Verzehrstudie II. Ernährungsumschau. 53 (2): 44-50. |
| **Denmark** | 2000 | Danish Dietary Survey | 4118 | 4-75 | Food record | Lyhne N, Christensen T, Groth MV, Fagt S, Biltoft-Jensen A, Hartkopp H, Hinsch H-J, Matthiessen J, Møller A, Saxholt E and Trolle E, 2005. Dietary habits in Denmark 2000-2002, Main results Copenhagen: Danish Institute for Food and Veterinary Research, Department of Nutrition. |
| **Denmark** | 2005 | The Danish National Dietary survey 2005-2008 | 2700 | 4-75 | Food record | Pedersen A, Fagt S, Groth MV, Christensen T, Biltoft-Jensen A, Matthiessen J, Andersen NL, Kørup K, Hartkopp H, Ygil K, Hinsch HJ, Saxholt E, Trolle E (2009). Danskernes kostvaner 2003-2008. DTU Fødevareinstituttet. |
| **Denmark** | 2006 | Danish National Dietary survey among infants and young children 2006-2007 | 1743 | 0,5-3 | Food record | Trolle E, Gondolf UH, Ege M, Kørup K, Ygil KH, Christensen T (2013). Danskernes kostvaner. Spæd- og småbørn 2006-07. DTU Fødevareinstituttet |
| **Estonia** | 2013 | National Dietary Survey among 11-74 years old individuals in Estonia | 3049 | 10,97-75 | 24-hours dietary recall | EFSA Supporting publication 2017:EN-1198 |
| **Estonia** | 2013 | National Dietary Survey among children up to ten years old and breastfeeding | 1598/384 | 0,29-10,97 | Food record, 24-hours dietary recall | EFSA Supporting publication 2017:EN-1199 |

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| | | mothers in Estonia | | | | |
| **Spain** | 1998 | Food patterns of Spanish schoolchildren and adolescents | 382 | 1-14 | 24-hours dietary recall | Serra-Majem L, García-Closas R, Ribas L, Pérez-Rodrigo C and Aranceta J, 2001. Food patterns of Spanish schoolchildren and adolescents: The enKid Study. Public Health Nutr. 4: 1433-1438. |
| **Spain** | 1999 | Spanish Agency for Food Safety (AESAN) Survey | 418 | 18-60 | Food record | Requejo AM, Ortega AM, Lopez Sobaler AM, Navia B, Andres P, Jodral M, Quintas E, Redondo R, Menendez L, Perea JM, Aparicio A, Lozano MC, Bermejo L, Mena C, Faci M, Lolo JM, Rodriguez N, Cocho M, Diez C and Alvarez C, 2002. Estudio sobre dietas y habitos alimentarios en la poblacion Española. Consejo de Seguridad Nuclear. 1-303. |
| **Spain** | 2004 | Encuesta de nutrición 2005 | 1050 | 4-18 | 24-hours dietary recall | Larrañaga Larrañaga N, Amiano Etxezarreta P, Gorostiza Garai E, Pérez Díez Y, Bidaurrazaga Van-Dierdonck J, Sarasqueta Eizaguirre C, Arrizabalaga Abasolo JJ, Espada Sáez-Torres M and Méndez Navas I (2006). Encuesta de nutrición 2005. Hábitos alimentarios y estado de salud de la población vasca de 4 a 18 años. Primeros resultados. Vitoria-Gasteiz, Servicio Central de Publicaciones del Gobierno Vasco, DL. Available from http://www.euskadi.net/r33-2288/es/contenidos/informacion/sanidad_alimentaria/es_1247/adju |
| **Spain** | 2009 | Spanish Agency for Food Safety (AESAN) - FIAB Survey | 1068 | 17-60 | 24-hours dietary recall | Ortega RM, López-Sobaler AM, Ballesteros-Arribas JM, Pérez-FarinósN, Rodríguez- Rodríguez E, Aparicio A, Perea JM and Andrés P, 2010. Estimation of salt intake by 24-hour urinary sodium excretion in a representative sample of Spanish adults .Br J Nutr. |
| **Spain** | 2012 | Spanish National dietary survey on children and adolescents | 1780 | 0,5-17 | Food record, 24-hours dietary recall | EFSA Supporting publication 2015:EN-900; Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) Marcos Suarez, V.; Rubio Mañas, J.; Sanchidrián Fernández, R.; Robledo de Dios, T. (2015). |
| **Spain** | 2013 | Spanish National dietary survey in adults, elderly and pregnant women | 824/144 | 18-74 | 24-hours dietary recall | EFSA Supporting publication 2016:EN-1053; Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) Marcos Suarez, V.; Rubio Mañas, J.; Sanchidrián Fernández, R.; Robledo de Dios, T. (2016) |
| **Finland** | 2000 | Special Turku Coronary Risk Factor Intervention Project | 250 | 7-8 | Food record | Simell O, Niinikoski H, Rönnemaa T, Raitakari OT, Lagström H, Laurinen M, Aromaa M, Hakala P, Jula A, Jokinen E, Välimäki I and Viikari J, 2009. Cohort Profile: The STRIP Study (Special Turku Coronary Risk Factor Intervention Project), an infancy-onset dietary and life-style intervention trial. Int. J.Epidemiol. 38: 650-655. |

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|---|---|---|---|---|---|---|
| **Finland** | 2001 | Diabetes Prediction and Prevention Nutrition Study (DIPP) 2001-2009 | 1750 | 0,5-6 | Food record | Virtanen SM, Takkinen HM, Nevalainen J, Kronberg-Kippilä C, Salmenhaara M, Uusitalo L, Kenward MG, Erkkola M, Veijola R, Simell O, Ilonen J, Knip M. Early introduction of root vegetables in infancy associated with advanced β-cell autoimmunity in young children with human leukocyte antigen-conferred susceptibility to type 1 diabetes. Diabetic Medicine 2011;28:965-71. Virtanen SM, Nevalainen J, Kronberg-Kippilä C, Ahonen S, Tapanainen H, Uusitalo L, Takkinen HM, Niinistö S, Ovaskainen ML, Kenward MG, Veijola |
| **Finland** | 2003 | Diabetes Prediction and Prevention Nutrition Study (DIPP) 2003 - 2006 | 1448 | 1-6 | Food record | Räsänen M, Kronberg-Kippilä C, Ahonen S, Uusitalo L, Kautiainen S, Erkkola M, Veijola R, Knip M, Kaila M and Virtanen SM, 2006. Intake of vitamin D by Finnish children aged 3 months to 3 years in relation to socio-demographic factors. Eur. J. Clin. Nutr. 60: 1317-1322. |
| **Finland** | 2007 | National Findiet Surveys | 2038 | 25-74 | 48-hours dietary recall | Paturi M, Tapanainen H and Reinivuo H, Pietinen P (Eds.) 2008. The National FINDIET 2007 Survey. (In Finnish, summary, figures and tables in English) Publications of the National Public Health Institute, B23/2008. Helsinki: National Public Health Institute. Available from http://www.ktl.fi/attachments/suomi/julkaisut/julkaisusarja_b/2008/2008b23.pdf ; Reinivuo H, Hirvonen T, Ovaskainen M-L, Korhonen T and Valsta LM, 2010. Dietary survey methodology of FINDIET 2007 with a risk assessment perspective. Publ H |
| **Finland** | 2007 | Nutrition and wellbeing of secondary school pupils | 306 | 13-15 | 48-hours dietary recall | Hoppu U, Lehtisalo J, Kujala J, Keso T, Garam S, Tapanainen H, Uutela A, Laatikainen T, Rauramo U, Pietinen P. (2010) The diet of adolescents can be improved by school intervention. Public Health Nutr 2010;13:973-9. Hoppu U, Lehtisalo J, Tapanainen H, Pietinen P. (2010) Dietary habits and nutrient intake of Finnish adolescents. Public Health Nutr 2010;13:965-72. |
| **Finland** | 2012 | National FINDIET 2012 Survey | 1708 | -74 | 48-hours dietary recall | Helldán A, Kosonen M, Tapanainen H, et al, 2013. The National FINDIET 2012 Survey. (In Finnish, summary, figures and tables in English) Helsinki: National Institute For Health and Welfare. Report 16/2013. |
| **Finland** | 2017 | FINDIET 2017 | 1773 | 18-75 | 24-hours dietary recall | doi:10.2903/sp.efsa.2020.EN-1914$http://urn.fi/URN:ISBN:978-952-343-238-3 |
| **France** | 2007 | Individual and national study on food consumption 2 | 4079 | 3-79 | Food record | Agence Française de Sécurité Sanitaire des Aliments (AFSSA), 2009. Report of the 2006/2007 Individual and National Study on Food Consumption 2 (INCA 2). Synthèse de l'étude individuelle nationale des consommations alimentaires 2 (INCA 2), 2006-2007. 1-44. Lioret S, Dubuisson C, Dufour A, Touvier M, Calamassi-Tran G, Maire B, Volatier JL and Lafay L, 2010. Trends in food intake in French children from 1999 to 2007: results from the INCA (Etude Individuelle Nationale des Consommations Alimentaires) dietary survey |
| **France** | 2014 | The French national dietary survey (INCA3, 2014-2015) | 4874 | 0-79,8 | Food record, 24-hours dietary recall | https://www.anses.fr/en/content/inca-3-changes-consumption-habits-and-patterns-new-issues-areas-food-safety-and-nutrition ; EFSA supporting publication 2017:EN-1351. 33pp. doi:10.2903/sp.efsa.2017.EN-1351 |

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| **United Kingdom** | 2000 | National Diet and Nutrition Survey | 1724 | 19-64 | Food record | Henderson L, Gregory J and Swan G, 2002. National Diet and Nutrition Survey: Adults aged 19 to 64 years. Volume 1: Types and quantities of foods consumed. TSO, London. Available from: http://food.gov.uk/multimedia/pdfs/ndnsprintedreport.pdf |
| **United Kingdom** | 2008 | National Diet and Nutrition Survey - Years 1-3 | 3073 | 1,5- | Food record | Bates B, Lennox A, Prentice A, Bates C, Swan G (eds) (2012) National Diet and Nutrition Survey: Headline results from Years 1, 2 and 3 (combined) of the rolling programme (2008/09-2010/11) Available online: https://www.gov.uk/government/publications/national-diet-and-nutrition-survey-headline-results-from-years-1-2-and-3-combined-of-the-rolling-programme-200809-201011 |
| **United Kingdom** | 2011 | Diet and Nutrition Survey of Infants and Young Children, 2011 | 2683 | 0,33-1,5 | Food record | Lennox A, Sommerville J, Ong K, Henderson H, Allen R (2013) Diet and Nutrition Survey of Infants and Young Children, 2011. Available at: https://www.gov.uk/government/publications/diet-and-nutrition-survey-of-infants-and-young-children-2011 |
| **Greece** | 2004 | Regional Crete | 874 | 4-6 | Food record | Linardakis M, Sarri K, Pateraki M, Sbokos M and Kafatos A, 2008. Sugar-added beverages consumption among kindergarten children of Crete: effects on nutritional status and risk of obesity. BMC Public Health 8: 279. |
| **Greece** | 2005 | Diet Lactation GR | 65 | 25-39 | Food record | Antonakou A. et al. European Journal of Nutrition 2012 52(3):963-973. |
| **Greece** | 2014 | The EFSA-funded collection of dietary and related data in the general population aged 10-74 years in Greece | 791 | 10-75 | 24-hours dietary recall | EFSA supporting publication 2018:EN-1499 |
| **Croatia** | 2011 | Croatian food consumption survey on adults | 2002 | 18-64 | 24-hours dietary recall, 48-hours dietary recall | EFSA supporting publication 2017:EN-1297 |
| **Hungary** | 2003 | National Repr Surv | 1360 | 18- | Food record | Rodler I, Biró L, Greiner E, Zajkás G, Szórád I, Varga A, Domonkos A, Agoston H, Balazs A, Mozsary E, Vitrai J, Hermann D, Boros J, Nemeth R and Zsuzsanna K, 2005. Taplalkozasi vizsgalat Magyarorszagon, 2003-2004. (Dietary survey in Hungary, 2003-2004) Orvosi Hetilap, 146. Evfolyam, 34, 1781-1789. |
| **Hungary** | 2018 | Hungarian national food consumption survey | 2689 | 1-74,98 | Food record, 24-hours dietary recall | doi:10.2903/sp.efsa.2020.EN-1981 / doi:10.2903/sp.efsa.2020.EN-1982 |

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|---|---|---|---|---|---|---|
| **Ireland** | 1997 | North/South Ireland Food Consumption Survey | 958 | 18-64 | Food record | Kiely M, Flynn A, Harrington KE, Robson PJ and Cran G, 2001. Sampling description and procedures used to conduct the North/South Ireland food consumption survey. Pub Health Nutr. 4:1029-1035. ; Harrington KE, Robson PJ, Kiely M, Livingstone MBE, Lambe J and Gibney MJ, 2001. The north/south Ireland food consumption survey: survey design and methodogy. Pub Health Nutr. 4: 1037-1042. |
| **Ireland** | 2008 | National Adult Nutrition Survey | 1500 | 18-90 | Food record | Irish Universities Nutrition Alliance (2011) National adult nutrition survey. Summary Report. Available at http://www.iuna.net/wp-content/uploads/2010/12/National-Adult-Nutrition-Survey-Summary-Report-March-2011.pdf |
| **Italy** | 2005 | Italian National Food Consumption Survey INRAN-SCAI 2005-06 | 3323 | 0,1- | Food record | Leclercq C, Arcella D, Piccinelli R, Sette S, Le Donne C and Turrini A, 2009. The Italian national food consumption survey INRAN-SCAI 2005-06: main results in terms of food consumption. Publ Health Nutr. 12(12): 2504 –2532. |
| **Italy** | 2017 | Italian national dietary survey on children population from three months up to nine years old | 825 | 0.25-9,97 | Food record | https://doi.org/10.2903/sp.efsa.2020.EN-7087; https://doi.org/10.3389/fpubh.2021.590315 |
| **Italy** | 2018 | Italian national dietary survey on adult population from 10 up to 74 years old | 1203 | 10.04-74,95 | 24-hours dietary recall | https://doi.org/10.2903/sp.efsa.2022.EN-7559; https://www.frontiersin.org/articles/10.3389/fnut.2022.954939/full |
| **Latvia** | 2008 | National Dietary Survey | 2070 | 7-66 | 24-hours dietary recall | Šantare D, Ozoliņš G and Joffe R, 2008. Latvijas iedzīvotāju pārtikas patēriņa pētījums: mērķi, norise, metodes. LU Raksti, Jelgava, iesniegta publicēšanai. |
| **Latvia** | 2011 | Dietary survey on pregnant women in Latvia (LGPPP) | 1002 | 15-45 | 24-hours dietary recall | PVD 2012: Latvijas grūtnieču pārtikas patēriņa pētījums (2011). Available: http://www.pvd.gov.lv/lat/augj_izvlne/iedzvotjiem_un_uzmjiem/ptjumi_un_apskati |
| **Latvia** | 2012 | Latvian National Dietary survey | 3595 | 0,08-80 | Food record, 24-hours dietary recall | EFSA Supporting publication 2017:EN-1307 |
| **Montenegro** | 2017 | Montenegrin National Dietary Survey on the | 1513 general poulation/201 pregnant women | 10-74 | 24-hours dietary recall | https://doi.org/10.2903/sp.efsa.2022.EN-7196 |

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|---|---|---|---|---|---|---|
| | | general population | | | | |
| **Republic of North Macedonia** | 2018 | National dietary survey on the children population in the Republic of North Macedonia | 1079 | 1-9 | Food record | https://doi.org/10.2903/sp.efsa.2022.EN-7169 |
| **Netherlands** | 2003 | Dutch National Dietary Survey 2003 | 750 | 19-30 | 24-hours dietary recall | Ocké MC, Hulshof KFAM and Van Rossum CTM, 2005. The Dutch national food consumption survey 2003. Methodological issues. Arch Public Health. 63: 227-241. |
| **Netherlands** | 2006 | DNFCS-Young-Children | 1279 | 2-6 | Food record | Ocké MC, Van Rossum CTM, Fransen HP, Buurma EJM, de Boer EJ, Brants HAM, Niekerk EM, Van der Laan JD, Drijvers JJMM and Ghameshlou Z, 2008. Dutch National Food Consumption Survey - Young children 2005/2006 (350070001). Bilthoven: National Institute for Public Health and the Environment (RIVM). Available from http://www.rivm.nl/ |
| **Netherlands** | 2007 | Dutch National food consumption survey 2007 - 2010 | 3819 | 7-69 | 24-hours dietary recall | Van Rossum CTM, Fransen HP, Verkaik-Kloosterman J, Buurma-Rethans EJM, Ocké MC. Dutch National Food Consumption Survey 2007-2010. Diet of children and adults aged 7 to 69 years. Bilthoven: RIVM; 2011. ReportNo.: 350050006. |
| **Netherlands** | 2010 | Dutch National Food Consumption Surveys - Older Adults | 739 | 70- | Food record, 24-hours dietary recall | M.C. Ocké, E.J.M. Buurma-Rethans, E.J. de Boer, C. Wilson-van den Hooven, Z. Etemad-Ghameshlou, J.J.M.M. Drijvers, C.T.M. van Rossum Diet of community-dwelling older adults. Dutch National Food Consumption Survey-Older adults 2010-2012. Bilthoven: RIVM 2013. RIVM rapport 050413001/2013 (Report DNFCS-older adults 2010-2012) |
| **Netherlands** | 2012 | Dutch National Food Consumption Survey 2012-2016 (DNFCS) | 4313 | 1-80 | Food record, 24-hours dietary recall | EFSA supporting publication 2018:EN-1488 $ https://wateetnederland.nl |
| **Portugal** | 2015 | National Food, Nutrition and Physical Activity Survey of the Portuguese pregnant women | 166 | 17-46 | 24-hours dietary recall | EFSA supporting publication 2017:EN-1341 |
| **Portugal** | 2015 | National Food, Nutrition and Physical Activity Survey of the | 6429 | 0,34-84,98 | Food record, 24-hours | EFSA supporting publication 2017:EN-1341 |

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| | | Portuguese general population | | | dietary recall | |
| **Romania** | 2012 | Dieta Pilot Adults | 1508 | 19-92 | Food record | Not available |
| **Romania** | 2019 | Ad-hoc consumption survey for Romanian pregnant women | 148 | 19-49 | 24-hours dietary recall | doi:10.2903/sp.efsa.2020.EN-1924 |
| **Romania** | 2019 | Ad-hoc consumption survey for Romanian vegetarian adults | 277 | 12-74 | 24-hours dietary recall | doi:10.2903/sp.efsa.2020.EN-1923 |
| **Romania** | 2019 | Romanian national food consumption survey for adolescents, adults and elderly | 1730 | 10-74 | 24-hours dietary recall | doi:10.2903/sp.efsa.2020.EN-1925 |
| **Serbia** | 2017 | Serbian Food Consumption survey on children | 576 | 1-9.89 | Food record | https://doi.org/10.2903/sp.efsa.2021.EN-6994 |
| **Serbia** | 2019 | Serbian Food Consumption Survey on adults | 2737 general population/145 pregant women | 10-75.4 | 24-hours dietary recall | https://doi.org/10.2903/sp.efsa.2022.EN-7401 |
| **Serbia** | 2019 | Serbian Food Consumption Survey on vegetarians | 281 | 18-74.8 | 24-hours dietary recall | https://doi.org/10.2903/sp.efsa.2022.EN-7401 |
| **Sweden** | 1997 | Swedish National Dietary Survey - RIKSMATEN 1997-98 | 1210 | 18-74 | Food record | Becker W and Pearson M, 2002. Riksmaten 1997-98. Kostvanor och näringsintag I Sverige. Metod-och resultatanalysis. (Dietary habits and nutrient intake in Sweden 1997-98) Livsmedelsverket (National FoodAdministration). 1-201. |

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| **Sweden** | 2003 | National Food Administration | 2495 | 3-18 | 24-hours dietary recall | Enghardt-Barbieri H, Pearson M and Becker W. Riksmaten. 2003. Livsmedels - och näringsintag bland barn i Sverige (with a summary in English). Uppsala: Livsmedelsverket; 2006. |
| **Sweden** | 2010 | Swedish National Dietary Survey - Riksmaten adults 2010-11 | 1797 | 18-80 | Web-based dietary record | Amcoff E, Edberg A, Enghardt Barbieri H, Lindroos AK, Nälsén C, Pearson M, Warensjö Lemming E (2012) Riksmaten – vuxna 2010–11 Livsmedels- och näringsintag bland vuxna i Sverige Resultat från matvaneundersökning utförd 2010–11. Livsmedelsverket. Available at: http://www.slv.se/upload/dokument/rapporter/mat_naring/2012/riksmaten_2010_2011.pdf |
| **Sweden** | 2016 | RIKSMATEN ADOLESCENTS 2016 | 3099 | 10.12-21.22 | Web-based dietary record | Moraeus et.al. Riksmaten adolescents 2016-17: a national dietary survey in Sweden – design, methods and participation. Food Nut Res 2018;62 |
| **Slovenia** | 2017 | Slovenian national food consumption survey | 2119 adults/946 children | 0,25-74 | Food record, 24-hours dietary recall | EFSA supporting publication 2019:EN-1728, 2019:EN-1729 |

# ANNEX B: BARCELONA WEBINARS

## WEBINARS AGENDA, ABSTRACTS AND DEBATES

Risk Assessment of Contaminants in Seafood - RASCS WEBINARS, Barcelona, November 2022

**Wednesday, November 23rd**

**13:45-14:00** Welcome by the Catalan Agency of Food Safety and the European Food Safety Authority.

**14:00-15:30** Processing of Seafood - Impact on contaminant concentration and compliance with maximum levels. (Astrid Spielmeyer, BfR).

***15:30-16:00*** *COFFEE BREAK*

**16:00-17:30** Alternative screening methods for marine toxins. (Mònica Campàs, IRTA)

**Thursday, November 24th**

**9:00-10:30** Scientific approaches for the definition of optimal sampling in monitoring programmes. (Jorge Diogène, IRTA)

***10:30-11:00*** *COFFEE BREAK*

**11:00-12:30** The risk assessment of multiple chemicals contaminating seafood. The harmonised procedures according to EFSA guidance. (Emanuela Testai, ISS)

***12:30- 13:30*** *LUNCH*

**13:30-15:00** The impact of climate change on seafood contamination. (Maura Manganelli, ISS; Pedro Reis IPMA)

***15:00-15:30*** *COFFEE BREAK*

**15:30-17:00** Balancing risks and benefits: approaches applied to seafood consumption. A Comparative Analysis of Different Approaches to the Risk-Benefit Assessment in Seafood: Deterministic vs Probabilistic and Intake Threshold Focus vs Dose-Response Focus. (Carlos Cardoso, IPMA)

SOCIAL ACTIVITIES

**Friday, November 25th**

**9:00-10:30** The assessment of risk and benefit perception and the role of such perception on consumer purchase decisions. (Djamal Rahmani, CREDA).

***10:30-11:00*** *COFFEE BREAK*

**11:00-12:30** Balancing risk and benefit communication about seafood consumption. (Fien Minnens, Christine Yung Hung, UGENT)

**12:30-13:00** Wrap-up of the Webinars (FOR RASCS ONLY)

Risk Assessment of Contaminants in Seafood - RASCS

WEBINARS, Barcelona, November 2022

# ABSTRACTS AND DEBATES

**Wednesday, November 23rd**

**14:00-15:30 Processing of Seafood - Impact on contaminant concentration and compliance with maximum levels. (Astrid Spielmeyer, BfR).**

Limits of marine biotoxins in live bivalve mollusks (LBM) are set out in Regulation (EC) 853/2004. The respective values refer to unprocessed food and a weight base (e.g., µg toxin equivalent per kg). Processes such as steaming of LBM cause changes of the food composition and weight, mainly due to the loss of water. Depending on the physical-chemical properties of the marine biotoxins, this water loss can lead to a decrease or increase of the marine biotoxins' contents in the final edible product. Consequently, processed food products might exceed limits of Regulation (EC) 853/2004, although the initial products were compliant. In case of lipophilic marine biotoxins in molluscs, the Standard Operation Procedure (SOP) of the EURL for Marine Biotoxins contains measures how to deal with processed food (Annex C). These include the addition of a defined amount of water to the mussel tissue to correct for water loss during processing.

The seminar will provide an overview of literature studies dealing with the impact of processing on marine biotoxins' contents in mussel and shellfish tissue. In this context, the current praxis of Annex C of the SOP will be discussed.

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.

2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

▼M23

(a) for paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalents diHCl per kilogram;

▼C1

(b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;

▼M23

(c) for okadaic acid and dinophysistoxins together 160 micrograms of okadaic acid equivalents per kilogram;

▼M14

(d) for yessotoxins, 3,75 milligrams of yessotoxin equivalent per kilogram;

▼C1

and

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

Regulation (EC) No. 853/2004; Annex III, Section VII, Chapter V

## DEBATE

The topic and the questions raised from the presentation have been considered as important and relevant regarding analytical and regulatory perspectives by the consortium. The most important outcomes of the fruitful discussion on this topic are listed below.

Analytical/research aspects:

- It was suggested that SOPs regarding the extraction of lipophilic toxins from processed mussels as provided in Annex C of the "EU harmonized SOP for determination of lipophilic marine biotoxins in molluscs by LC-MS/MS" should be available for the most common matrices. The most common shellfish species may be identified via the questionnaire on monitoring programs provided by ANSES (Task 2.1) at least for the countries which are included in RASCS.

- Another important point raised from the discussion was the fact that although there is just limited data on chronic effects from repeated ingestion of marine biotoxins, they might however be relevant. Accordingly, sufficient data on chronic effects is needed to be considered in RA if necessary. The assessment of chronic effects also depends on analytical data; therefore, analytical methods should be harmonized, especially for the analysis of processed food (e.g., consider processing factors or not).

- Further research needs to be considered regarding RA of marine biotoxins are: information on toxikokinetics e.g. possible bioactivation or detoxification of mother compounds as well as of derivates or conjugates, or the conversion of e.g. STXs /AZAs to more or less toxicological potent analogues. The extent to which processing might have an effect on bioavailability should also be investigated.

Regulatory/toxicological aspects:

- It could be possible that FBOs might have data on processing factors as they have to provide them to national surveillance authorities according to the European regulation and as they have to ensure that the products they place on the market are compliant with EU regulations.

- The point was raised that EFSA stated in their opinions of 2008/09 on different groups of marine biotoxins that in most cases (except for YTXs) the current limit values in the European Union are not sufficient to avoid acute toxic effects due to consumption of seafood and therefore do not ensure a high level of consumer protection. EFSA showed that the respective acute reference doses may be exceeded due to consumption of negotiable products. As the underlying calculations have been made for adults, it is additionally notable that children have even a higher risk to exceed acute reference doses due to their relatively high food intake in relation to their comparably low body weight.

- In relation to this topic it was discussed, if the consortium members have information on intoxication cases, e.g. on an annual basis which might support the need of re-evaluation of the current limit values. This is not the case, as there are almost no intoxication cases known which are related to the ingestion of (regulated) marine biotoxins via

contaminated food. However, the consortium agreed that this is probably due to the fact that the consumers are in generally not aware that gastrointestinal symptoms from seafood consumption might be related to intoxication instead of microbial issues. Additionally, it is assumed that most consumers will not consider seeing a physician due to occurrence of mild gastrointestinal symptoms. Accordingly, the consortium assumes a high number of unreported intoxication cases with marine biotoxins.

- The idea was raised that it might be more useful to set additional maximum limits for processed food commodities instead of incorporating the use of processing factors or lowering the existing limit values for live bivalve molluscs. Therefore, sensitive analytical methods and robust data based on occurrence data are needed. As processed foods are investigated within TDS – which are targeted at the assessment of chronic risks - this might be a relevant source for data generation. However, marine biotoxins are generally not included in these studies as their chronic risks for human health have been hardly studied yet.

Which recommendations can be made for the risk management?

- High frequency of official controls considering a risk-based sampling (e.g., samples from countries with high contamination risks due to environmental conditions)
- Filling research gaps on behaviour of toxins during processing, toxikokinetics, and chronic effects
- Re-evaluation of existing limit values or consideration of setting limit values for processed food in addition to existing limit values on raw materials
- Draw attention of the consumer to the possibility that gastrointestinal symptoms from seafood consumption may occur from intoxication with marine biotoxins and that consumers could/should give samples of the suspected food responsible for the occurrence of symptoms to local authorities for further investigation.

**16:00-17:30 Alternative screening methods for marine toxins. (Mònica Campàs, IRTA)**

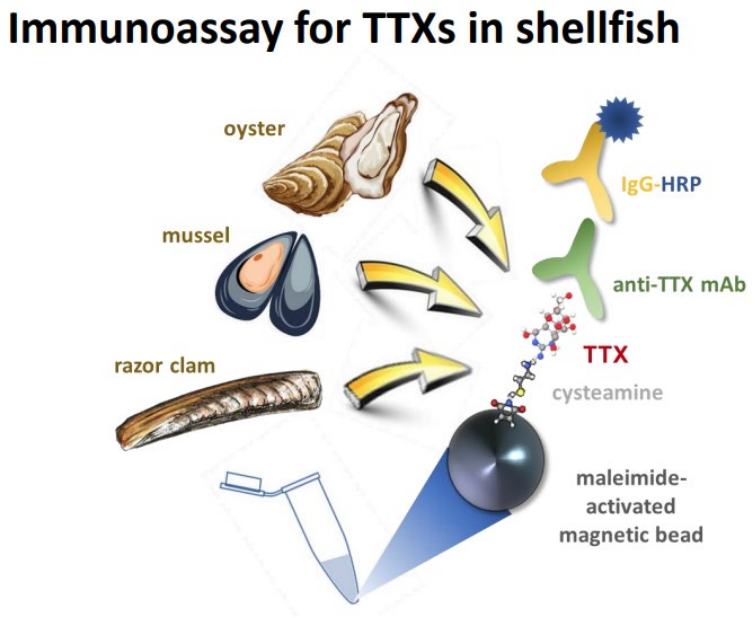
Marine toxins are complex chemical compounds, produced as secondary metabolites by microalgae and bacteria. They are present in numerous organisms and may play an important role in community structure and interspecies interactions within the ecosystems. Some marine toxins are extremely potent and are responsible for serious seafood poisoning events.

Mouse bioassays (MBAs) have been for years important tools to manage seafood safety and prevent risk situations for consumers. Although with ethical concerns, they may be of interest to understand the toxic potential and mechanism of action of new marine toxins and may also contribute to unexplained toxicity of seafood. Nevertheless, European authorities, having specific regulations that forbid the use of laboratory animals when equivalent alternative methods exist, encourage and facilitate the development of such methods.

As for other contaminants, instrumental analysis methods have been applied to detect and quantify some marine toxins in order to fulfil regulations. For some toxins, like CTXs, the application of an instrumental analysis method in routine is difficult due to the lack of certified material, the structural complexity of this toxins group, and the low sensitivity of the current

instrumentation, since these toxins are extremely powerful and may be hazardous at concentrations in fish that are difficult to detect. Alternative methods can provide a higher sensitivity or may have other advantages such as shorter analysis times or lower cost, and may be used as screening or quantification tools to facilitate the evaluation of multiple samples in due time and at regulatory levels.

Cell-based assays, biochemical assays (i.e. immunoassays, enzyme assays and receptor binding assays) and biosensors are promising alternative tools to overcome MBA drawbacks and to complement instrumental analysis techniques, because of their selectivity, sensitivity, ease-of-use and low cost. Alternative methods, once validated, may become excellent screening tools, and even contribute to quantify toxins or restricted groups of toxins. In any case, the combination of techniques with different recognition principles is usually the best approach to quantify marine toxins in seafood and evaluate their risk




**DEBATE**

AT: there is a lot of open questions that probably have not an answer. We need to know the purpose and then focus the efforts to get what we need. Is there a need within RA? Some systems are very specific and/or very sensitive but, are they really appropriate and applicable?

MC: biosensors are versatile, and you can optimize them according to your needs. Of course, in the examples I have shown, we apply them to a few samples to demonstrate that they work, but for their use in specific applications, much more exhaustive validation studies would be necessary.

MM: there are several factors that must be considered. Are these systems economically viable? Some systems may be difficult to be applied by citizens. The portable device seems a very good

option for those countries with low resources and to be used by people that are not trained/skilled.

MC: Yes, nevertheless colorimetric assays may be easier and cheaper to use than biosensors. They also have the advantage that you can perform multiple analysis at the same time (with biosensors this is a bit more difficult). It is also important to take into account the geographic area where you want to apply your biosensor. For examples, the immunosensors for CTXs (Designed with antibodies against Pacific CTXs) may not be valid for countries that have Caribbean CTXs.

ET: there is not a universal method. Biosensors may be too sophisticated. A simple colorimetric assay, e.g. ELISA, may be enough, depending on your purpose. I do not think these technologies can be transferred to citizens, as society is not still prepared (contamination could be a big issue). In one of the examples, the differences on TTX contents among techniques are considerable. How can this be explained?

MC: important matrix effects were responsible for the discrepancy in the immunoassay. We have to take into account that techniques have different detection principles and the reason behind the differences may be due to the cross-reactivity of the different congeners. We need to join people with different background (including engineers) to make the portable biosensors really useful (like the glucometers), but the market behind is relatively small, compared to the human diagnosis field.

ET: there is not an optimal technique, each technique has advantages and limitations.

JD: the more analytical techniques are available, the better the global vision will be, and this contributes to understand the complexity of samples. It is good to have techniques that will provide toxicological and structural information of samples. It is good to advance in the new biotechnologies; later on, we will be able to adapt them to the specific needs or questions to be solved.

PR: everything is possible, the future is today. Would it be useful to have systems such as the Environmental Sample Processor in Europe, for example for OA? They could be useful to protect and help producers and consumers.

MC: these systems are very expensive but are really interesting. They are also able to detect several analytes simultaneously (not only marine toxins, but also toxic microalgae). We need to know what our purpose is to see if they fit our needs.

AT: it can be very useful to develop models and have predictive tools if the final objective is to reduce the risk. To know if biosensors can be applied to real situations, we need to know first which is the objective. Is your objective to reduce the risk?

MC: I like to play with technologies. My objective is providing new bioanalytical systems. Of course, they can later be tuned according to the specific needs.

ET: it is very good to have people focused on making progress on this direction and providing new technologies.

CYH: these tools could also be applied to reduce food waste.

JD: it is important to have in mind that some biorecognition molecules are not commercially available.

MC: yes, and in fact, those that are commercially available may be very expensive and limit the number of experiments to perform (compared with when some colleague gives you an antibody).

ET: what about the differences between biomolecule batches?

MC: yes, we have observed this problem, for example with protein phosphatases.

**Thursday, November 24th**

**9:00-10:30 Scientific approaches for the definition of optimal sampling in monitoring programmes. (Jorge Diogène, IRTA)**

Monitoring of contaminants in seafood is of major importance to ensure a safe food system that can guarantee maintaining public health standards and a prosperous food industry. Current regulations on contaminants in seafood (or in food to a wider extent) are appropriate frameworks that fix legal standards and are the basis to design the structure of monitoring programmes. Nonetheless, these regulations may not define all the critical points that are needed to conduct an efficient monitoring programme. The risk analysis approach is the main axis to consider when transposing the current regulations into monitoring programmes. Hence, risk assessors and risk managers involved in the design of monitoring programmes should consider the particularities of the area where the monitoring programme has to be implemented. In addition, the design of monitoring programmes needs to take into account, not only the legal requirements, but also ongoing scientific results and technical advancements that may not yet be considered in regulatory texts. Science, technology and monitoring activities can walk hand in hand to provide society with the most efficient tools to protect consumers and the seafood industry.


**DEBATE**

RB: are these volunteered procedures from fishermen effective?

JD: in the Canary Islands, the systems is working.

FM: the communication strategy is very important.

ET: what about the recovery periods? This should be studied. If you know when you can open the area again, the management can be better.

JD: in the Canary Islands, ciguatera was not described until 2004. Then, it started suddenly. They started to control it using a method, but it was not appropriate. When they saw that the method was not reliable, they shifted to neuro2a assay with our support and training. In some

projects, we are focusing of fish with weight lower than that of the official control, to better understand ciguatera. We are also working on the detection of *Gambierdiscus* and their toxicity.

MM: can you see *Gambierdiscus* blooms?

JD: You need to go to the benthos. In the water it is not that visible, although sometimes it is also possible. We also try to harmonize the sampling (scratching the rock, taking the macrophytes, etc.). There is an official monitoring for CTXsin the fish, but it would be very difficult to have a monitoring for Ciguatera poisoning just based on the microalgae in the water.

MM: it would be good to know the dynamics of the blooms.

JD: we are running a project co-financed by EFSA (EUROCIGUA 2), where one of the objectives is modelling and prediction.

AT: although there may be good data, the problem is to establish the link between the presence in the market and the exposure. Traceability is also an issue.

JD: sampling may be expensive. In Catalonia, IRTA is not working with products in the markets, but with the producers and harvesting areas, while the department of Health focuses on the market. In Galicia, the same lab works for the fisheries department and for the health department and this is interaction to make the link between the market and the consumers and have information about the real exposure of consumers.

AT: heterogenicity of batches is also an issue and, therefore, it is necessary to consider it and optimize the sampling. The definition of batch may change according to the producer.

ET: I fully support this observation. It is necessary to harmonize and apply the same strategies to make comparisons. Depending on your aim or the characteristics of the area, you may have slight differences, so a bit of flexibility should be allowed.

JD: if we can harmonize, we should try to do so. Sometimes management procedures are not optimized. Irregularities or bad practices may be observed.

NA: ANSES optimized the monitoring program for lipophilic marine toxins for the French Ministry, but the French Ministry considers the procedure too complicated. ANSES provided different options in a RA study, but the managers are not trained, and they cannot choose among the different options.

JD: in case of doubts, you need to increment the sampling effort, but this means more economic resources.

ET: it would be good to interact more between the different systems, such as with the people working with bathing water, not to duplicate the sampling, but to work in a collaborative way. More dialog between administrations that work on similar things could be beneficial and provide more data.

DR: the risk is not only at the production level, but also along the value chain. Is it possible to prevent the contamination?

JD: definitively. You may have predictive models according to the levels of microalgae in the water. For particular situations when the system is very well known, the predictive tools may be very efficient. For other contaminants, such as microbiological contaminants, meteorological analysis can also be useful.

ET: this is also applicable to other contaminants, such as chemical contaminants. You can also take into account the information about the industrial activities of an area.

AT: machine learning is another way to predict, and it is data-costly. It is working well, but we do not know exactly how it works and why is able to give good predictions. You can use it as an alert system. Machine learning is probable the future, particularly for climate change scenarios.

**11:00-12:30 The risk assessment of multiple chemicals contaminating seafood. The harmonised procedures according to EFSA guidance. (Emanuela Testai, ISS)**

The EU Chemicals legislation, in common with the situation in other parts of the world, is based predominantly on assessments carried out on individual substances. However, in reality humans are exposed to a wide variety of chemicals throughout their lives. Hence, there is increasing concern in the general public about the potential adverse effects of the interactions between those substances when present simultaneously in a mixture. This is the case of marine toxins in fish or seafood.

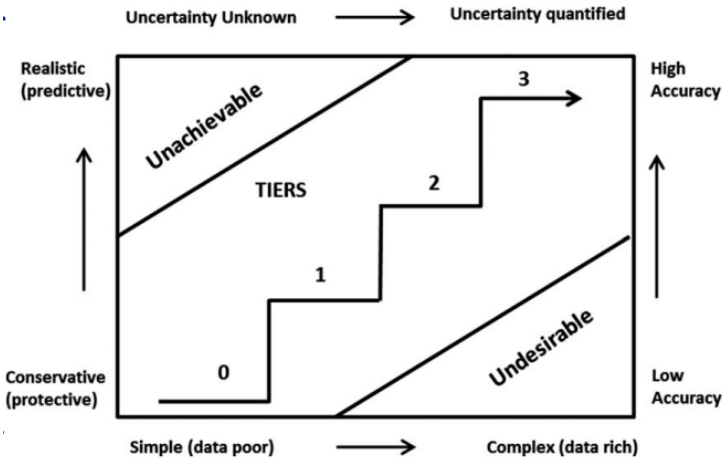
Many documents have been adopted by the major international Agencies dealing with human health risk assesment. In its Guidance document adopted in 2019 EFSA describes harmonised framework for RA and related methodologies for combined exposure to multiple chemicals for all relevant areas within EFSA's remit. The framework is based on the RA steps, with tiered and stepwise approaches for both WMA (when the mixture is treated as a single entity, similar to single chemicals, and so requires dose–response information for the mixture of concern or a sufficiently similar mixture) and component-based approaches CBA (when the risk of combined exposure to multiple chemicals is assessed based on exposure and effect data of the individual components). The extent of characterisation of a mixture is an important factor in determining the approach to RA.

Testing of "real world" complex mixtures is rarely feasible (unless they are intentionally produced as for formulated products), due to the huge number of possible combinations and the variability of mixtures composition over time. Therefore in most case the CBA is used; for this reason specific considerations to CBA are given in the EFSA MixTox Guidance including the grouping of chemicals into common assessment groups, the use of dose addition as a default assumption, approaches to integrate evidence of interactions. Another EFSA opinion (2021) has been then focussed to the identification and refinement of assessment groups.

Chemicals with common modes of action will act jointly to produce combination effects that can be described by dose/concentration addition. For chemicals with different modes of action (independently acting), no robust evidence is available that exposure to a mixture of such substances is of health concern if the individual chemicals are present at or below their no effect levels. If no MoAinformation is available, the dose/concentration addition method should be preferred over the independent action approach. Prediction of possible interaction requires expert judgement and hence needs to be considered on a case-by-case basis.

With regard to the assessment of chemical mixtures, a major knowledge gap at the present time is the lack of exposure information and the rather limited number of chemicals for which there is sufficient information on their MoA. Currently, there is neither an agreed inventory of MoA, nor a defined set of criteria how to characterise or predict a MoAfor data-poor chemicals.

These general principles will be esemplified by using some natural toxins occurring in fish or seafood as case studies.




## DEBATE

Djamel Rahmani (CREDA): How should we proceed for risk benefit?

Emanuela Testai (ISS): The risk benefit analysis is independent on the fact that you have a single chemical or a mixture. When you have derived the risk for a mixture, you can proceed with risk/benefit procedures in the same way as for a single chemical.

DR: Which indicator should we calculate?

ET: The RA for a mixture gives you the indication of a potential risk which is comparable to the one obtained for the single chemical. The only further attention is possibly related to understand which is/are the component (s) responsible for the risk (in other words whose weight to the overall toxicity is higher)

Luciana Tartaglione (University of Naples): Data reporting mussel contamination with high levels of MCs are impressive. Are those contamination level considered accurate?

ET: The results showed comes from the literature search coming from an EFSA project results. We collected all the literature available, selecting only those papers presenting a sound methodology (for the sample preparation and for the analytics). The data showed are clean and reliable.

LT: I was wondering if there are so few data because the papers are unreliable or the mussels contaminations is understudied?

ET: For cyanotoxins the problem of food contamination is in general understudied, only four 'good quality' papers were on mussels, and few more in other food items. One of the problems is the lack of robust analytical methods for complex matrix (methods are available for water). We used only reliable data and for sure they were not representative of the real situation, although it seems they show a particularly high contamination. It is not possible to base a RA on such a scant data base, but our aim was just to flag a possible problem to EFSA.

LT: I agree, maybe some cyanotoxins monitoring in mussels could be a crucial point to underling what you are saying.

Nathalie Arnich (ANSES): In France we have a specific programme for monotoring MCs in mussels (10/12 monthly sampling points) so we have more reliable data. But we collect data just to see trends.

Jessica Dietrich (BfR): About the toxicological properties, in most cases the problem with contaminants is that we don't have enough in vivo data to make a sufficient outcome for AOP for example, what role do you think can play NAMs or in silico methods for this?

ET: They should be the future. You cannot rely only on very costly and time-consuming in vivo experiments, ethical issues aside. I think there are many NAMs that are really powerful, but none of them can be used as stand alone. In every case you should think to a testing strategy by using the NAMs being the best fitting to answer your question. Think about the estimate for the internal exposure: you can think to very complicate PBPK modelling, but if you don't have good in vitro data to be used as an input they are useless. Sometimes it is very easy to have good in vitro data. We must be smart in building testing strategies, if this is done, we will proceed, even if slowly, to use NAMs in RA. Then we have to prepare the risk managers, because at the very end they ask you a result which is understandable to them (often a number): if they don't understand the methods you are using they won't trust the results. Talking to risk managers is often a crucial point, it is necessary to train them so that they are familiar with these new methodologies.

JD: I agree that we have to go on with the in vivo and in vitro data until we are sure that the NAMs could give us reliable results.

NA: A comment, a common MoA or a common target organ is what is looked for in some ongoing work on mixtures. And so, a target organ is selected that is not the most interesting one. We should not forget the risk characterization of the compound individually. Because we need a global picture of the mixture, but we don't have to forget the single chemical.

ET: When a health-based guidance value is established for a single chemical considering the critical organ (or effect) there is protection not only towards the effects on the critical organ, but no other toxicity is expected, because it occurs at higher exposure level. But when they are in a mixture they can contribute because adopting dose addition, they sum up with other components having the same target. However, their contribution is expected to be lower and in the prioritization you have to consider this: the weight of those compounds to the overall toxicity will be lower.

Carlos Cardoso (IPMA): In this concept of equivalent of toxicity, is bioaccessibility considered?

ET: Not always. In the TEFs obtained with in vitro test could be used to demonstrate the common target (for example for dioxin like compounds the binding to the nuclear receptor is considered): in this case the kinetics is not considered. A compound can bind very rapidly and tight to the

receptor without reaching the target of toxicity. But kinetics is more and more considered now in the RA.

Anne Thebault (ANSES): It is strange not to consider multi-target effects. As if liver is affected, kidney will have more work, and so on. If an organ is damaged, it is as if it is exposed to a higher dose. Moreover, the differences within the population must be taken into account. This approach is very chemical oriented. Shouldn't all these variables be taken into account?

ET: I agree, but multi-target or human variability are only rarely implemented even for a single chemical. In PARC and in some EFSA projects some consideration on the inter-individual variability will be taken up in the kinetic part (modelling including the human variability). This is something that is starting to be present in the RA. Once we will have more information on what happens for a single chemical than it will be easier to apply it to the mixtures.

AT: I see that you also talk about repeated exposure, has it been considered for cyanotoxins?

ET: No, I don't think it has been considered. Maybe it's something similar to alcohol consumption. In that case you can have accumulation of the damage without bioaccumulation of the chemical. In general, every time you have a different perspective you have something different to be considered.

NA: About the open question, in WP1 we work to the list of priority contaminants to be considered in the project, maybe we can go a little further and add some relevant mixture. Considering also data on co-occurrence we could refine our exposure assessment considering the concrete co-exposure in food.

ET: Yes, for the key study to be run in WP3 would be very useful to have good co-exposure data coming from the exposure WP.

Jorge Diogene (IRTA): A management question. We can imagine how managers can react to the complexity of this issue of co-occurrence of contaminants. Can we help to simplify measure and define scenarios where the situations could be at higher risk regarding types of contaminants, combination of food?

ET: A risky combination considering specific scenarios can be foreseen and could be of help. For sure there is a need to simplify a complex issue for the managers: for example, a proposal has been done and it's still under discussion at REACH level regarding the introduction of an additional uncertainty factor, a mixtures assessment factor (MAF), for any chemicals as any compound could be in a mixture. For me this approach is scientifically unjustified (just adding more uncertainties) and has no sustainability because useful compounds can be banned without a solid ground.

NA: In the ANSES report on MCs, the RA for MCs has been based on effects on the male reproductive system. Are you aware of that?

ET: Yes, I know. But those effects have been described in papers characterized by many flaws and not consistent one to the other, not being robust enough to be used as point of departure . This was the conclusion we reached within the WHO WG analyzing the data for setting the

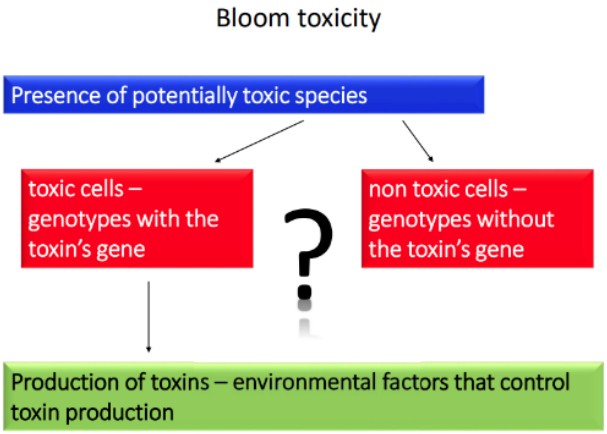
Guidance values for drinking water and working on the WHO book 'Toxic cyanobacteria in Water' in 2021.

**13:30-15:00 The impact of climate change on seafood contamination. (Maura Manganelli, ISS; Pedro Reis IPMA)**

Climate change can affect seafood contamination and the risk of human exposure to toxins and chemical contaminants through the food chain, by either changing the occurrence of toxins/chemical contaminants or changing the organisms' physiology and response to the presence of toxins/chemical contaminants.

Temperature increase:
Occurrence of toxins/chemical contaminants
- diffusion in the Mediterranean Sea of tropical organisms potentially toxic or new toxins
- faster growth and biomass increase of toxic organisms (bacteria, dinoflagellates and cyanobacteria in water, fungi on feed)
- impact on toxin production rate and on toxicological profile (in terms of variants produced)
- melting of polar ice/warming and increase of mercury concentration
Physiological response of organisms
- change in metabolism rate and uptake of contaminant – what about elimination? Differential rate?
- interaction of stress condition and contaminants
Water acidification:
Occurrence of contaminants
- changes in speciation of metals – changes in bioavailability
Physiological response of organisms
- reduction of buffer capacity of organisms with respect to the increase in metal concentration
- interaction of stress condition and contaminants
Floods and discharge of nutrients and contaminants:
Occurrence of toxins/contaminants
- coastal eutrophication and increase of opportunistic organisms potentially toxic
Variation of toxicity
- coexposure of seafood to multiple contaminants (natural toxins from cyanobacteria, chemicals from anthropized lands)
ISS will present examples on the changes in toxins and contaminants occurrence and IPMA would present examples on physiological responses of seafood.

If someone from the consortium has some data on all these possible effects, and more specifically on changes in speciation of metals and changes in bioavailability and on possible changes in consumers habits is more than welcome to share during the discussion.




## DEBATE

Ronel Bire (ANSES): Regarding the toxins, you showed that producers can be influenced by global warming. The drivers will mainly affect bioaccumulation. CC will affect more natural toxins production than the athropogenic ones?

Maura Manganelli (ISS): For anthropogenic contaminants you can act for a reduction of the occurrence of these compounds, but you cannot do anything to reduce the production of natural toxins as we don't know how to control the processes involved.

Pedro Costa (IPMA): Toxins production can be affected by CC and also the uptake. But it probably depends on different species.

Anne Thebault (ANSES): From a pragmatic point of view if we don't know anything is it better to make more sampling or go through modelling for a predictive approach?

MM: More sampling? Not sure, looking at the case study it seems not. We should go for a mechanicistic explanation considering both data coming from monitoring and from the laboratory studies, also complex studies which consider more variables at the same time.

Emanuela Testai (ISS): Mechanisms is the answer. If you know why a phenomenon occurs it is easier to focus on the specific issue, try to understand why and give the modelers the correct data.

PC: just a comment. It is easier to measure changes than investigate and describe mechanisms of accumulation, or the mode of transport.

Jorge Diogene (IRTA): When you deal with anthropogenic contaminants the source of the contaminant is easy to be followed, while for marine biotoxins, and all natural toxins ecology has a great importance. For CC we have to make efforts in different directions. Laboratory studies to understand physiological aspects. Physical and chemical parameters other than T and pH are relevant for the ecological species (turbulence, presence of organic matter in the water, light, turbidity in coastal area etc.). Toxin amounts depend on the ecosystems and this should be

considered. It could be useful to establish "sentinel" field sampling site to study how the system evolves over years. We should be more systematic with the field monitoring.

MM: I agree, being this an ecological problem we need very long term studies. We also should consider the bacteria community that plays a fundamental role and it is often ignored.

Anne Thebault suggests the possibility to use the site "Copernicus" to produce models to forecast the effects of climate changes on some variants.

**15:30-17:00 Balancing risks and benefits: approaches applied to seafood consumption. A Comparative Analysis of Different Approaches to the Risk-Benefit Assessment in Seafood: Deterministic vs Probabilistic and Intake Threshold Focus vs Dose-Response Focus. (Carlos Cardoso, IPMA)**

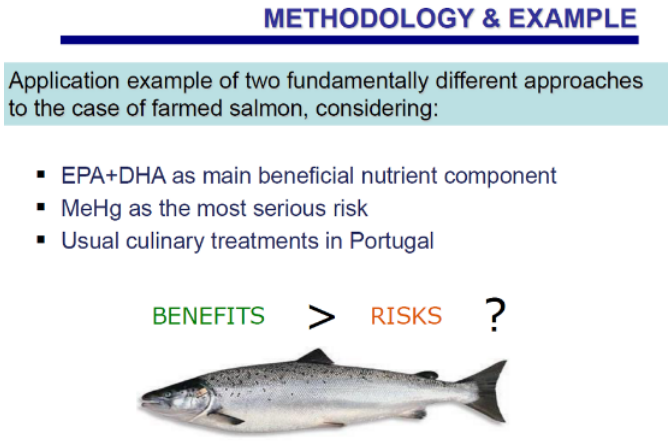
Seafood consumption is recommended on the basis of the associated health benefits, being rich in omega 3 polyunsaturated fatty acids —which prevent diseases such as cognitive disability—, in some essential elements —such as selenium (Se), which, among other benefits, mitigate toxic metals effects, e.g., methylmercury, MeHg—, and other bioactive nutrients. On the other hand, seafood may be a dietary source of MeHg, exposure to which can affect the neurocognitive development of children. Thus, it is important to weigh benefits versus risks in seafood consumption.

For this risk-benefit assessment, different strategic approaches are possible: either a simple deterministic calculation or a full-blown probabilistic estimation (accounting for all data variability in constituent contents in seafood and consumption patterns). Moreover, another dichotomy between a switch on-off evaluation using a frontier/threshold value for a specific constituent intake and a continuous and progressive increment of risk/benefit with increasing doses of a given constituent. For each approach, different methodologies and models are required, varied metrics/units are used for expressing results, and alternative interpretation planes are possible.

Methodological tools comprise: (i) the mathematical-statistical modeling of constituent concentrations and consumption frequencies by fitting specific distribution functions (e.g. log-normal); (ii) the combination of function generated data by Monte-Carlo or hypercubic algorithms; (iii) the application of the Extreme Value Theory for the modeling of the tail portion of a Pareto-like curve —thereby enabling the calculation of a probability for exceeding a specific threshold—; (iv) and the application of dose-response curves (based on scientific studies linking dietary patterns and specific intakes to occurrence of particular health outcomes). In the last case, a common universal metric for weighing health benefits against health negative effects and calculating a net health impact, such as Disability-Adjusted Life Years (DALYs) or Quality-Adjusted Life Years (QALYs) is another essential tools that depends on previous studies quantifying the probability of death (and associated reduction of life expectancy) and the equivalence of quality life losses in terms of life years.

These alternative approaches to risk-benefit assessment may all be useful to public authorities, stakeholders, and researchers, informing the formulation of products, proposal of specific meal combinations, and issuing of overall dietary recommendations. The analysis and interpretation

possibilities also vary according to each approach and affect the risk-benefit communication.




## DEBATE

Q - Jessica Dietrich: Jessica Dietrich asked about the formation of harmful compounds during culinary treatment (for instance, grilling) and desired to know if these aspects were studied.

A: Carlos Cardoso recognized that these compounds, also known as artefactual molecules, would be highly relevant, especially for the most drastic thermal treatments, but they were not the subject of his studies at IPMA. In any case, they should be considered in the future and inform any advice concerning cooking of seafood.

Q - Emanuela Testai: Emanuela Testai referred that recommendations to the general population require more information and a broad encompassing of many different constituents and contaminants.

A: Carlos Cardoso agreed with Emanuela Testai and referred to the analytical capabilities of his institute (IPMA) and the need of focusing on some nutrients and contaminants deemed more relevant in seafood. These would be probably the major determinants of any net health impact of seafood consumption. In any case, further studies and more extensive collection of data as well as the study of other constituents and contaminants (including so-called emerging ones) would be of paramount importance.

Q - Emanuela Testai: Emanuela Testai pointed to the fact that some beneficial constituents may also exert a negative effect on health and thus become a risk source and she asked whether such situation was also studied.

A: Carlos Cardoso agreed about the importance of this aspect and mentioned that at IPMA this was also studied in some cases. In particular, he exemplified with iodine in seaweed, which due to its high content in some seaweed species could easily become a risk with apparently modest daily consumption frequencies. There are iodine-deficient populations and seaweed recommendations can be issued in order to address this problem, but care should be taken to also provide upper consumption frequencies, whose surpassing could raise serious concerns.

Q - Emanuela Testai: Emanuela Testai also referred that too much emphasis was placed on bioaccessibility and bioavailability should be the decisive aspect.

A: Carlos Cardoso concurred and mentioned that bioaccessibility was used due to be easier to study and as a first estimate and proxy for bioavailability, since it is an upper ceiling for bioavailability. There are *in vivo* studies underway, but they are more recent and require adequate animal models in the case of the contaminants.

Q - Nathalie Arnich: Nathalie Arnich mentioned that final recommendations regarding seafood consumption frequencies cannot be issued without thorough studies covering all hazards and benefits and she also gave the PCBs subject as an example.

A: Carlos Cardoso acknowledged that the PCBs in seafood were not studied at this institute (IPMA), but that their quantification and risk-benefit assessment treatment would be relevant. On the other hand, he also emphasized that the presented recommendations in his studies come with a whole set of outlined assumptions, drawbacks, and caveats. Among these, the necessity of accounting other constituents and contaminants in seafood is stated. The recommendations are to be read as estimates and approximations conditional on available information and passible of revision. Moreover, there are emergent contaminants, which may comprise novel pollutants, citing the issue of micro- and nanoplastics, whose content in the marine environment and seafood has been increasing. Accordingly, any recommendation is always provisory.

Q - Veronique Sirot: Veronique Sirot asked which previous studies led to the choice of specific seafood meal sizes in the performed risk-benefit assessment studies.

A: Carlos Cardoso answered that there is an additional category between deterministic and probabilistic risk-benefit assessment studies, which are the semi-probabilistic studies. These only allow for variability in the constituents or contaminants contents in seafood and use a fixed average seafood consumption in the population. This corresponds to the definition of scenarios, such as, for instance, three weekly meals of seafood and, typically, these scenarios also assume a specific meal size, which can be different for adults and children. In these cases, due to the lack of population consumption surveys, hypotheses and central scenarios using reference values and guidelines (for instance, 50 g meal size for preschool children) or estimates with diverse origins.

Q - Djamel Rahmani: Djamel Rahmani asked whether it would be possible to translate the conveyed risk-benefit assessment data into a more understandable message that could be transmitted to the general population, namely, alluding to the possibility of applying a color code.

A: Carlos Cardoso replied that it would be possible, since it is easier to simplify and streamline whenever there is plentiful and detailed information.

**SOCIAL ACTIVITIES (From our own private budget)**

**Women's FC Barcelona-FC Bayern München**

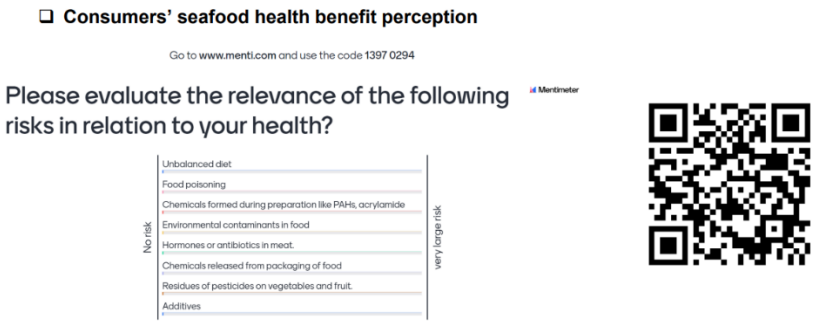

**Friday, November 25th**

**9:00-10:30 The assessment of risk and benefit perception and the role of such perception on consumer purchase decisions. (Djamal Rahmani, CREDA).**

Consumer perceptions of seafood risk and benefit is a determinant driver of food choices. Understanding such perceptions is a key factor in developing effective risk benefit communication. The present session will try to improve our understanding of the assessment and the role of risk and benefit perceptions. The objectives of this session include:

- Assessing the different approaches mostly used for seafood risk benefit analysis.
- Identify the most relevant factors influencing risk and benefit perceptions.
- Assessing the role of such perception on consumer purchase decisions.
- Sharing some preliminary results of the consumers' survey.

Research showed that consumers/citizens have different risk perceptions than experts due to several reasons. An excise will be conducted with partners using an interactive platform (Mentimeter) to assess their risk perception and the results will be discussed and compared with those from consumer survey.




## DEBATE

Djamel Rahmani started his presentation with some examples of health risks and benefits of seafood consumption. Then, he listed different methods used to measure seafood health risk and benefit perception. Next, he listed the drivers of seafood health risk and benefit perception. Finally, he explained how these perceptions affect seafood consumption.

Participants discussed possible ways to provide consumers with information on risk and benefit of seafood consumption. In particular, they discussed the feasibility of developing a tool similar to "Nutriscore" to provide consumers with the balance between the risk and benefit of seafood products.

Participants also highlighted the importance of the choice of the correct words (concepts) when measuring the risk and benefit perception of seafood consumption. They discussed the difficulty for consumers to understand the questions and the best way to prepare the questions in order to avoid any misunderstanding.

Participants also discussed the methods used when conducting consumer surveys to select the target. They highlighted the importance of considering some relevant factors. They also discussed the way to select the samples and to compare the results in cross-country studies.

**11:00-12:30 Balancing risk and benefit communication about seafood consumption. (Fien Minnens, Christine Yung Hung, UGENT)**

This webinar will shed light on current communication strategies regarding seafood health benefits and risks, discuss their shortcomings and reveal opportunities in the communication landscape.

RA is only the first of three pillars of risk analysis, and should not be detached from the other two: risk management and risk communication. While scientists and risk managers are redesigning RA approaches considering new knowledge, tools and the changed environments, the same should be done for the EU's approach to risk communication about seafood.

Due to the diversity in seafood products, preparations, diets of consumers and contaminants and the ever-changing environment, communicating about the nutritional-toxicological conflict to consumers can be challenging. A lot of efforts go into establishing dietary guidelines about seafood, however they are very diverse among EU countries. When analysing the communication landscape, several actors can be identified that communicate about risks and benefits of seafood consumption. The different actors and their communication message are discussed from the point of view of the general population and the different vulnerable groups.


ONLINE ATTENDANCE UPON INVITATION

(IRTA will provide the link on the same week)

# ANNEX C: PRIORITIZATION WEBINAR

**WEBINAR on Prioritization (March 13, 2023, online)**

Abstract : Before implementing preventive measures to ensure food safety, it is crucial to prioritize the chemical and microbiological hazards that can contaminate foods. To do this, ANSES has developed a multi-hazard and multi-food health prioritization method following a two-step process:

- First step: identification and selection of 35 biological hazards (21 bacteria, toxins or metabolites; 10 parasites, 4 viruses and non-conventional transmissible agents), 11 families of chemical contaminants (POPs, pesticide residues, etc.) and hundreds of relevant food-hazard pairs.

- Second step: definition of prioritization criteria based on the probability of occurrence of the hazard (number of new cases of disease per year, estimated number of cases associated with consumption of the food, etc.) and the severity of the associated adverse effects (mortality, morbidity, carcinogenic, neurotoxic effects, etc.). The relative importance given to each criterion is determined by risk managers based on their objectives.

The developed method has been tested for ranking several food-hazard pairs. It is now being deployed on a broader scale.

# ANNEX D: ToS ROME

# Training on Spot: "Institutional approach to Risk Assessment, RA"

**Hosting Istitution:** ISS (Istituto Superiore di Sanità), Viale Regina Elena, 299 - 00161 Rome (Italy)

**Date:** 16 and 17 February 2023

**Participant:** Testai Emanuela (ISS), Scardala Simona (ISS), Manganelli Maura (ISS), Diogène Jorge (IRTA), Dietrich Jessica (BfR), Hung Yung Christine (UGent) and Reis Costa Pedro (IPMA).

**Proposed Agenda:**

16th February,
14h-17:30h: meeting for scientific and institutional approach to RA at the ISS

17th February,
9h-13:00h: Meeting for scientific and institutional approach to RA at Ministry of Health
14:00-16:30 Visit of EU reference laboratory for chemical elements in food - ISS

**16th February**

**14:00-15:30:** Dr. Emanuela Testai made a wide presentation to describe the organization of ISS, the approach and activities related to RA in food safety in Italy with a focus on ISS, the flow of information, and two case studies. From the discussion that followed several similarities with other partners emerged, especially with the BfR, which has a very similar mandate, even if focused only on health and not on the environmental part; but also important differences. How plant protection products are managed is a good example: in Italy they are under the responsibility of the Ministry of Health (as Competent Authority) and not under the Ministry of Agriculture, or the Ministry of Economics, showing that health is considered more important that the than to the economic/agricultural aspects.

**15:30-15:45:** Dr. Simona Scardala briefly presented how Italy manages the Italian Multi Annual National Control Plan (MANCP, a legal requirement regarding Reg. (EC) no. 882/2004) and the Annual Report, required by the MANCP itself, in which data from peripheral laboratory are critically analysed by the Ministry of Health, by means of a specific data-base for which Dr. Michele De Martino (a Ministry of Health's food safety data manager) is responsible. This introduced the virtual meeting with him.

**15:45-16:30:** Virtual meeting with Dr. Michele De Martino who is also the Italian contact point for EFSA in relation to food safety data flows. He manages the RaDISAN database (the collector of analytical data of official control in food safety) and is co-author of the MANCP Annual Report.

Dr. De Martino explained the data flows from the periphery to the database up to the competent authorities. He described also the type of data collected and the statistical use of the database. The data from official control is available to the general public as well.

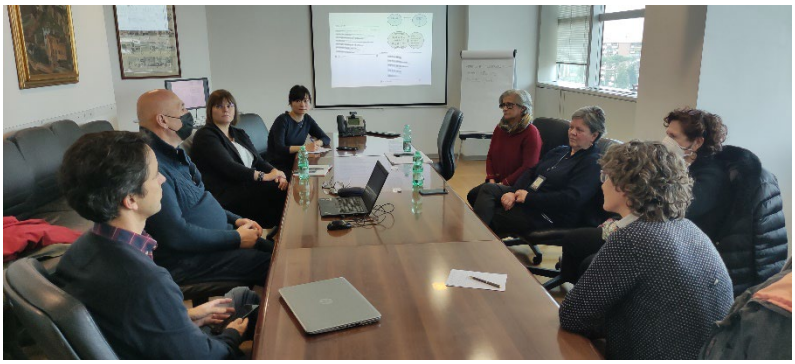
**16:30-17:00:** Dr. Maura Manganelli presented a national project on TTX in seafood that will start in April 2023, in which the ISS is participating as a work package on RA as an example of possible approach to RA and link between some research activity and institutional kind of work. ISS will also cure the communication of risk to stakeholders interested to the project outputs (fishermen, aquaculture manager, public, local authorities involved in control on the market...). A debate on the communication strategies followed.

**17:00-17:30**: Dr. Emanuela Testai presented the portal "ISSalute", the portal of the Istituto Superiore di Sanità that offers health information in simple words: it is in Italian only and is addressed to the general public. ISSalute includes: A-Z health topics, a section on life styles, nutrition and environment, and a section to contrast fakenews and hoaxes. As an example, the page on Mercury was discussed, since it addresses also information related to fish consumption.

## 17th February

**10:00-13:00:** Meeting at the Ministry of Health with Dr. Simonetta Bonati, Head of Office 2 (Food safety RA) of the Directorate General of Collegial bodies for health protection and Dr. Maria Girolama Falcone, Senior Veterinary Officer - Office 2.

The Directorate-General for Collegial bodies for health protection (DGOCTS) is the national EFSA contact point. It is responsible for the physical, chemical and biological RA for food safety. It is also the national contact point for the Food Safety National Committee. It is responsible for the coordination and planning of actions aimed at assessing risks in the food chain, as well as of the



activities of the Committee of Consumers and Producers Associations, in collaboration with the Directorate-General for hygiene, food safety and nutrition (DGISAN).

Exactly as the ISS also the Ministry of Health is not allowed to answer directly to citizens' questions, however the collaboration with the Committee Consumers and Producers Associations makes the Ministry aware of the problems that can be particularly interesting for Citizens. In addition, the Opinions produced by the Ministry are also discussed during the Committee with Consumers and Producers Associations and other ministries. However, these Opinions have no legal value but can be used by legislators and normally have an abstract also intended for citizens. A discussion followed to highlight differences and similarities among the different participants.

**13:00-14:30:** Lunch

**14:30-15:15:** Visit to the Italian National Reference Laboratory for Metals and Nitrogenous Compounds in Food, at the ISS. The purpose of the Laboratory is to ensure, within the system of official food controls, the harmonization of the methods of production and management of analytical results at national level with those of other EU member countries and with the indications of the EURL-MN.

**15:15-16:00**: Dr. Angela Sorbo (Researcher at the Department of Food safety, nutrition and veterinary public health at ISS and responsible for the NRL) presented the activities of the National Reference Laboratory for metals and nitrogenous compounds in food. She also described the ISS approach to harmonise and improve the methods of analysis and their use by the official control laboratories also organising inter-laboratory comparative / proficiency tests, and ensuring their follow-up communicating the results of tests and follow-ups to the competent authorities.

During the discussion the need and usefulness of harmonisation of procedures between MS has emerged. For smaller countries, such as Portugal, but for some specific targets also for Italy, organizing Proficiency Tests can be complicated, not having an adequate number of national laboratories able to participate. Cooperation between MS become, therefore, very important.

**16.00-16:15:** Wrap-up, planning future steps and end of the activities

All the documents (and presentations) presented during the ToS will be made available, in the TEAMS folder, for all the partners in RASCS.

## ROME, Attendants considerations:

**Jorge Diogène:** The TOS was very fruitful and provided an excellent opportunity to have a direct contact with persons implicated in Italy in RA of contaminants. In addition, it allowed to understand the overall organization of RA in Italy, the direct contact with active professionals

was certainly rewarding. I understood that the organization on RA among countries might be different, according to responsibilities among ministries, but that may not be a limiting factor since the internal organization is sometimes based on Governmental priorities, but as long as competent people are implicated in RA, which I believe is the case, the good practices of RA are ensured. Important to say that there was clear communication among ministries in different commissions. I also felt that there was a good link between the administration and research on RA, which is definitively important. The Data base on data on contaminants within official control programmes was certainly RaDISAN, or the ISSalute portal, are also good examples that the information flows and reaches the society. The TOS also ensured an exchange with participants from ISS, BfR, UGENT, IPMA and IRTA and their own perspectives.

**Jessica Dietrich:** The ToS in Rome at the ISS – Insituto Superiore di Sanità - was very vell organized and focused on the institutional approach on RA at ISS and further on risk management, risk communication and the official control of food in Italy. During the ToS, the participants from BfR, CREDA, IPMA and UGent had the opportunity to get in contact with different persons in charge of the above mentioned fields of food safety and had fruitful discussions with them on the areas of their work. For me it was particularly interesting that the ISS works on decree on the Italian Ministry of Health pointing out that the main focus of food safety in Italy is on consumer health and protection. In addition, it is a crucial task of the Ministry to further consider environmental and economic interests. Fruitful discussions comparing differences regarding the national organization of food safety in the partner countries raised at different timepoints within the ToS. Another important point to me was that both, ISS and the ministry of Health make great efforts to communicate issues on public health and food safety in easy language to the general population. Furthermore, the efforts that are made to make data from official food control available to the gernal public impressed me a lot. In total, the exchange of knowledge and experience during the ToS between RASCS partners and external experts from Italy was an awarding experience regarding networking and capacity building.

**Pedro Reis Costa:** The ToS in Rome at the ISS - Istituto Superiore di Sanità was very well conducted allowing the participants to understand the overall process of RA in Italy, its internal organization between different authorities and to compare differences and similarities between EU MS. The Italian mode of organization based on the Health Ministry making a bridge between the Economy and the Environment was discussed. Also important, and well highlighted by the organizers, is the fight against fake news regarding food safety. A Web Portal for fake news and official indications were presented, which was viewed by the participants as crucial for the years to come. A Web Portal, the RaDISAN, containing data, freely available, from the food safety official control was also shown. Finally, some issues were identified and shared by some participants, for example the difficulties to perform inter-laboratory comparative studies when only a low number of laboratories is available. At the end, fruitful discussions were carried out making evident the importance of knowledge and expertise exchange.

**Christine Yung Hung:** The ToS was a successful KE event in many ways. It offered insights into the implementation of food safety RA, organization of risk management decisions between authorities, and integration of risk communication into the overall process in Italy. The ISS plays a critical role in disseminating food safety and health-related information and safeguarding the

public from fake news and hoaxes through ISSalute. From the perspective of risk communication to consumers, the ToS underscores barriers and opportunities in matching the information needs of public with food safety information. While social media have been a powerful communication tool and offer lots of opportunities, It might be challenging for scientists to use such tool to deliver easily understandable, frequent and timely messages. That is exactly why programmes like this ToS are valuable in bringing the international experts together, bridging the gap between natural and social science, and inspiring future initiatives that ensure accessibility, comprehensibility and relevancy in the context of food safety RA and communication.

# ANNEX E: ToS LISBOA

# Training on Spot: "Risk-Benefit Analysis"

## Hosting Institutions:

- IPMA (Instituto Português do Mar e da Atmosfera), Avenida Alfredo Magalhães Ramalho, 1495-165 ALGÉS (Portugal)

- ASAE (Autoridade de Segurança Alimentar e Económica), Laboratory of Food Safety, Estrada do Paço do Lumiar, Campus do Lumiar 22 - Edifício, F - 1ºandar, 1649-038 LISBOA (Portugal)

**Date:** 28th February and 1st March 2023

**Participants:** Cardoso Carlos (IPMA), Reis Costa Pedro (IPMA), Marques António (IPMA), Dietrich Jessica (BfR), Rahmani Djamel (CREDA-UPC), Testai Emanuela (ISS), Scardala Simona (ISS), Manganelli Maura (ISS), Nabais Pedro (ASAE), Carmona Paulo (ASAE), Lopes Sofia (ASAE), Monteiro Sarogini (ASAE), Oliveira César (ASAE), and Vieira Rafael (ASAE).

## Proposed Agenda:

28th February:
14h00-17h30: Presentation/Meeting regarding the approach to risk-benefit analysis at national level by the Portuguese food safety authority at ASAE and visit to national reference laboratory also at ASAE

1st March:
9h00-13h00: Theoretical exposition of the application of alternative risk-benefit assessment methodologies to seafood case-studies
14h00-16h30: Practical session on the application of statistical tools in the risk-benefit assessment

## 28th February

**14h00-16h00:** Dr. Pedro Nabais dealt with the issues of RA, management, and communication at ASAE. He started with an overview of the nature, structure, mission, competences, and responsibilities of ASAE. Afterwards, the components and procedures of RA by ASAE were expounded. Examples of paradigmatic cases demanding special attention and a careful RA were shown. The issues of sustainability and fight against food waste were also presented. The specific challenges and difficulties of risk communication were addressed, being cited the example of a leaflet formulating dietary recommendations for the consumption of fish. The foodborne incident investigation carried out in Portugal was also brought to the fore in the subsequent part of the presentation. The new National Crisis/Emergency Plan was discussed after mentioning the problems detected in the previous plan. A summary of all these ideas was finally given.

**16h00-16h30:** Dr. Paulo Carmona addressed the Food Control Sampling Plan implemented by ASAE. It was stressed that this plan is aimed at ensuring that foodstuffs in the market are safe and do not endanger the safety and health of consumers, as well as safeguarding the consumer

best interests. The Risk Matrix and the parameters (namely, the Risk Priority Number) used by ASAE were presented. An overview of the results of the sampling plan with a diachronic perspective was also given. The non-compliant results were discussed.

**16h30-17h00:** Discussion of the presentations held by Dr. Pedro Nabais and Dr. Pedro Carmona with expounding of the experience and views of the colleagues from ISS, BfR, and CREDA-UPC as well as those assisting from IPMA (Carlos Cardoso and Pedro Reis Costa). There were also questions directed to the two ASAE experts related to the analyses, activities, mission, and strategy of ASAE. These questions focused on the significance of the sampling in the Food Control Sampling Plan and the adequacy of the communication approach by ASAE, being emphasized the importance of a balanced risk-benefit analysis by the IPMA participants.

**17h00-17h30**: Visit to national reference laboratory dedicated to the analysis of dioxins and other organic contaminants in food matrices, also at ASAE. The participants put forward some questions regarding the operation of this laboratory and the methodological challenges related to emergent organic contaminants. The responsible technician for this specific laboratory answered these questions and expounded his view regarding the future of this laboratory.

## 1st March

**9h00-9h30:** The external participants in the ToS were welcomed by Dr. António Marques, who guided them in a short visit to various laboratories of the Division of Aquaculture, Valorisation, and Bioprospection at the IPMA premises in Algés. A succinct overview of the scientific activities carried out in these laboratories was provided and some questions were answered.

**9h30-12h45:** Dr. Carlos Cardoso performed a presentation of the theoretical aspects concerning the context, assumptions, and case-studies for the assessment of the risk-benefit dichotomy. A first part dealt with the issues of bioaccessibility and bioavailability in seafood and their importance for the risk-benefit assessment. In this context, the methodological alternatives were considered and the essentiality of *in vitro* studies was underlined. In the second and main part, the risk-benefit analysis of seafood consumption was presented. This included a revision of the background, regulatory framework, challenges and difficulties, assumptions, and alternative approaches/methodologies for the risk-benefit analysis. The differences between deterministic, semi-probabilistic, and probabilistic approaches to risk-benefit assessment were highlighted. The possibility of using scenarios and the advantages of adequate consumption surveys were also addressed. In addition, the application of statistical function fitting to concentration and consumption data and the Extreme Value Theory to the quantification of risk- and benefit-associated probability was explained. As case-studies, besides a paradigmatic case-study developed at IPMA (tuna consumption by the Portuguese population and its health implications), other previous studies developed at IPMA and based on extensive analytical databases were shown. The integration of bioaccessibility and bioavailability data into the risk-benefit assessment was also addressed. Finally, the possibility of calculating net health impacts by expressing risks and benefits into a common measure, such as DALYs, was explained and exemplified as another alternative approach.


**12h45-14h00:** Lunch

**14h00-16h15:** Dr. Carlos Cardoso carried out a set of practical activities aiming at translating theoretical principles into real case situations and at presenting risk-benefit assessment statistical-mathematical tools to the participants. There was a direct computer session with a paradigmatic case-study (mercury in fish and exposure scenarios and in the Portuguese population). The fitting of statistical distributions, the combination of distribution functions through Monte-Carlo and/or Hypercubic algorithms, and the Extreme Value Theory probability calculation routines were shown. The required software and the Excel interface were also highlighted. The application of dose-response functions, estimation of life years lost equivalences, and the calculation of a net health impact by application of a common metric were also treated and discussed. Finally, several questions were put forward, responded, and discussed, being also addressed the particular assumptions and key problems and taken into account the particular participant experiences regarding the evaluation of risk-benefit associated to seafood consumption.

**16h15-16h30:** Wrap-up, discussion of future steps, and end of ToS activities.

All the documents (and presentations) presented during the ToS will be made available, in the TEAMS folder, for all the partners in RASCS.

## LISBON, Attendants' considerations:

**For BfR (Jessica Dietrich):**

The ToS in Lisbon organized by the RASCS project partners from IPMA - Instituto Português do Mar e da Atmosfera – had two emphases: on the first day, the participants from BfR, CREDA and

ISS visited the Portuguese food safety authority ASAE. There, we had a very fruitful and rewarding discussion with our hosts from ASAE and IPMA on the national structure of food safety in Portugal, including approaches in RA, risk communication as well as sampling strategies for the official control of food. The institution unites the three pillars of food safety in one authority: risk management, RA and risk communication which is interesting to me as in Germany risk management and RA are located in different authorities. I learned that both concepts have advantages as well as disadvantages e.g. regarding collaboration opportunities or conflicts of interest. In addition, it was interesting to me that the Portuguese authority faces similar problems regarding the official control of products from online commerce as it is the case in Germany. The second day at IPMA was about the institutional approach on risk benefit assessment. Dr. Carlos Cardoso explained comprehensively deterministic and (semi-)probabilistic models to evaluate the risk and benefits upon certain food consumption. The participants discussed the potential and challenges raising from these approaches. Overall, the ToS offered a great opportunity for capacity building, KE and networking between RASCS partners and external experts from ASAE.

**For ISS (Emanuela Testai, Maura Manganelli, Simona Scardala):**

The ToS in Lisbon organized by IPMA (Instituto Português do Mar e da Atmosfera, Portuguese Institute for the Sea and Atmosphere) within the RASCS project, in which also colleagues from ASAE (Autoridade de Segurança Alimentar e Económica -Food and Economic Safety Authority in Portugal) participated, perfectly reached the goal of increasing the KEand networking between participants: discussion was very alive and fruitful, in a very informal and friendly atmosphere. It was useful to understand how the Food safety issue is dealt with in Portugal, with the intervention of different Institutions, with specific roles, comparing it with the situation we have in Italy. Worth of note, here the food safety issue is under the responsibility of the Ministry of Health, although other ministries are also involved, while ASAE, the competent authority ensuring the implementation of Food Safety official controls for food of animal origin throughout all the food chain, is under the responsibility of Ministry of Economy and IPMA follows the responsibility of the Ministry of Economy and Sea and Ministry of Agriculture and Food.

General procedures adopted as well as specific case studies were discussed, realizing that although the general organization is different very similar problems have to be faced in different countries in the area of RA and the approach taken is similar as well. Issues related to Risk Communication and Management were also presented and discussed. The second day at IPMA was also very informative, providing a general overview of the various methodologies used for the risk benefit analysis. Dr. Carlos Cardoso, thanks to his wide experience in the field, guided us through deterministic and (semi-)probabilistic models to evaluate the risk and benefits, applied to fish consumption (benefit) vs contamination with e.g. Hg (risk). The participants discussed the potential and challenges of the approaches, especially in relation to the amount of data necessary to properly apply them to different cases. We learn a lot to be used in our professional life, but we also enjoyed the social side of the ToS, for which we thank our host.

**For CREDA-UPC (Djamel Rahmani):**

"Risk-Benefit Analysis" organized by IPMA (Portuguese Institute for the Sea and Atmosphere) and ASAE (Food and Economic Safety Authority) was a great success with a very interesting and

useful KEbetween participants. I really acquired useful knowledge about risk-benefit assessment approaches and challenges, as well as how consumption data from national surveys are used in probabilistic models to evaluate the risks and benefits. I really enjoyed the discussion we had about several issues and challenges (*For example, our discussion about the difference between a hazard and a risk. Emanuela gave an excellent example: A shark is a permanent hazard in the sea, however, swimming near a shark is a risk*). Thank you to IPMA and ASAE for the fantastic organization and to all of the participants for their useful contributions.

# ANNEX F: ToS BARCELONA

## Training on Spot: "Dissemination and outreach"

### BARCELONA

At the ToS organized in Barcelona on **April 11 and 12**, some of the participating partners of the European RASCS project met to discuss some of the topics related to WP5 "Dissemination and outreach", the one lead by CREDA and IPMA. During these days, there was the participation and presentations of experts from different sectors.

**Tuesday 11/04/2023**

**Influence of communication on perception: aquaculture as a case study**

**Lourdes Reig**, PhD in Marine Sciences, presented her work on 'The influence of communication on perception: Aquaculture as a case study'. Reig began with an activity to involve all the participants in the study, through a word association test, the doctor proposed three nouns (fish, fisheries and aquaculture) to which they had to respond with the first concepts that came to mind. Once the experiment was done, Reig compared and analyzed the results obtained with a study that was carried out in Denmark, with the same concepts.

Afterwards, the doctor continued with her presentation talking about aquaculture, what it is, how it has changed and what society knows about it. To explain this situation, Reig relied on some studies carried out, such as one that was carried out in Barcelona with a sample of 300 people to know whether they knew aquaculture and whether they recognized the fish that had been produced by this technique.

The results showed that there is a lot of ignorance around this sector of activity, at least in Spain. To base these conclusions, Reig showed an analysis of 1,077 articles and the topics that each of them dealt with. To conclude her presentation, the doctor denied some of the myths that always arise around fish farms, such as the lack of quality in their products, and the results that exposure to information can generate in society: the more information, the more appreciation and consumption of aquaculture fish.

**Public Food Safety Communication**

Afterwards, we had the participation of **Raquel Arpa**, representing the **Catalan Food Safety Agency (ACSA)**. During her speech, Arpa explained whatthe task and position of the agency is as it is an agency belonging to the Department of Health of the Generalitat of Catalonia. Its main objective is to keep under control all food poisoning alerts and maintain a constant transmission of information between producers and sellers, in order to avoid situations of excessive risk.

In the presentation, Arpa explained how they act in the agency in different situations and what are the protocols to follow, since several actors involved in the sector must be informed such as citizens, economic operators and risk managers. Thus, Arpa explained how communication from platforms of this type should be constant and daily, because not only food alerts should be spoken of, but also of studies, consultations, results and even fake news.

Arpa presented some of the situations that have been experienced in Catalonia so far, in which a certain level of risk has been detected and reports have had to be issued: Histamine in tuna, large consumption of panga, smoked salmon, presence of microplastic, etc. For the ACSA, the objectives depend on the recipients, but in general it seeks to provide security, have a balanced perception of risk and promote good hygiene practices. After her presentation, Arpa showed the 'Map of Dangers' generated by the ACSA at the time, in which the different species of animals and the dangers of all kinds (chemicals, bacterias, etc.) are exposed.

At the end of the presentation of Arpa, the first day was ended. The second day of conferences collected most of the presentations in which many topics were discussed in relation to risk and benefit communication and how to make use of it.

**Wednesday 12/04/2023**

**Private Sector Communication on** Seafood **Benefits**

**Garazi Rodriguez**, head of production and marketing plans at the **Spanish Association of Aquaculture Growers (APROMAR)**, presented an exhibition on 'Communicating the benefits of fish and seafood in the private sector' to talk more deeply about what aquaculture is and how it is carried out.

Rodriguez explained how the sector is currently in Spain presenting data that showed large fluctuations over the years. In addition, according to the data, the most produced species in Spain are mussels, sea bass, rainbow trout and sea bream, some of the most characteristic products of the country.

Once the structure and operation of the association was presented, Rodriguez announced some of the actions that APROMAR had carried out to promote the production and consumption of water products throughout the region. Campaigns such as 'Crianza de nuestros mares', have helped to better detect the species that have been produced in Spain since 2015, by including a distinctive label on the products.

Other campaigns and actions have also been carried out that have fostered knowledge of this sector such as: collaboration with 'influencers' to recognize their figure as brand ambassadors; the creation of a press kit for those occasions when events or press conferences are organized; the realization of advertising actions in markets and supermarkets with promotional screens and posters; or the creation of content for social networks and the promotion of raffles of products related to the sector.

Finally, Rodriguez presented some strategies that APROMAR have carried out to boost brand awareness and highlighted how adaptation to new technologies has helped reach more people.

**Public-Private Sector Communication on Risks and Benefits**

After her presentation, we met the **Barcelona Fish Wholesalers Guild**, led by the group's veterinarian, **Laura Caldentey**, who spoke about how the market intervenes in the communication of risk and benefit of fish.

Being a veterinarian, Caldentey began by talking about the different risks that we can find in the different varieties of fish and water animals. To deal with poison alerts, there are different entities that must be contacted in order to have a greater reach: AESAN, SCIRI, RASFF and INFOSAN; both at regional and European level.

In her presentation, Caldentey gave some advice on how they act within the Guild in alert situations. First, the veterinarian presented tables that follow the official records of the health authorities which must be completed in case of alert and stated that in this type of situation it must be specified to which customer was sent the affected product. On these occasions, the main problem is that the products are perishable, so, according to the established systems, when officially communicated the normal thing is that the product has already been consumed.

On the other hand, the Guild also realized the little appreciation that children have toward eating fish and thought how they could solve this problem. Caldentey explained that the answer was the 'Creix amb el Peix' project, an action that aims to guide children between 8 and 10 years old toward their future consumption of fish. To carry out this project, a kind of museum has been created in which children carry out different learning activities. The results indicated that fish consumption was increased by 1.8 servings per week in families and the willingness to try new species was higher.

**Communication During Food Incidents: Successes and Failures**

After the interventions of external personnel to the CREDA, the participation of internal personnel specialized in different areas was given to reinforce the knowledge and learning of the different topics. First, biologist **Saray Ramirez** presented some cases of success and failure of communication during food incidents. To illustrate which methods are more effective than others,

Ramirez presented as success the communication of health alert in tuna cans in sunflower oil in Spain. This was because despite the sale of the product, only four people were intoxicated, even so, communication to final consumers was slow.

According to the biologist, another successful case was that of Listeria in smoked salmon from Andalusia, in this case there was no affected thanks to rudimentary controls and rapid communication. Another situation was that experienced in Italy by poisoning of fresh tuna, since, on this occasion, the authorities were informed quickly, but the information did not reach the consumers and the number of people affected increased.

Faced with cases of this type, Ramirez showed how in other countries, such as the United States or Portugal, good communication is made to encourage the consumption of water products. In both cases, advertising is true, false promises or non-existent benefits are not expressed, but rather the product and what it can really bring are exposed: 'Seafood is simple, healthy, delicious'. In the same way, organizations such as WWF have created campaigns to prevent excessive consumption of certain products, since this can generate its extinction.

Finally, the biologist explained that in certain situations communication has not been completely efficient and has generated a situation of risk and false crisis, as was the case of the consumption of panga imported from Vietnam.

**Are Consumers More Sensitive to Price Changes During Food Scares?**

The day continued with the intervention of **Chema (José M.) Gil**, director of CREDA, who presented a study on how risk communication can affect consumer sensitivity to product prices. In his speech, Gil explained that price is something that always affects the decisions of consumers, whether there is a food crisis or not, and therefore, they wanted to study the variations in the choice of products in Spain during the years 2015 and 2017.

The director presented how after the analysis they saw that the good results were not communicated in the media and this was something that did not generate confidence in consumers, on the other hand, when things go wrong, we find excessive communication that makes the population afraid. Thanks to an analysis of the messages published on Twitter, Gil was able to create a communication index that indicated that society was reacting immediately to fear, a fact that produced an instant change in consumer consumption.

Thus, the director presented the results obtained that showed how by increasing communication, the consumption of tuna and hake also increased. In addition, they also observed how the price was not so relevant: when communicating a risk in one species, its price is not very relevant, but it is that of the rest of species. These situations led Gil to determine that communication should not be excessive, otherwise society can panic.

**Experiment in a Natural Ambiance in a Lunch Restaurant**
**Tools to Assess the Effect of Information on Consumer Behaviour**

Reaching the end of the conference, **Djamel Rahmani**, PhD in Economic Analysis and Business Strategy, presented some studies carried out to analyze the behavior of consumers to have more or less information about a specific product. First, Rahmani presented some tips that could serve to communicate both risk and benefit to society: texts, videos, narratives, etc.

Once the communication strategies were introduced, the doctor presented a series of experiments that were carried out to different consumer groups on products such as wine, crispr tomatoes and fresh hen eggs. In these experiments, consumers began to fill out surveys with little information about the product, and as they progressed they were given more information relevant to different aspects.

In the case of wine, 3 bottles were presented without any identification and responded to three classes: conventional, organic and vintage supreme organic; the respondents had to choose which they preferred, and so on each round in which a little more information was given. In this way, Rahmani wanted to know which details affect consumers most when choosing a product.

After presenting the experiments carried out, the doctor conducted an experiment with 30 students of the UPC to find out if the provision of information on seafood risk and benefit would affect their decision to consume this product in the canteen of the university. After lunch time, the results showed that the students with the benefit information consumed more fish than the previous time, but the students who received negative information maintained their abstention from fish consumption.

Before ending the RASCS conference, the head of communication of the CREDA, Cristina Poyato, presented a summary of how corporate communication and risk communication work on social media when we are part of an entity with informative power and influence.

Poyato presented some advice for all types of entities or organizations that have access to information relevant to risks or benefits that can affect the health of society, in order to help

share content on social media in the most appropriate way to each of these platforms, since depending on the social network we talk about, we must address one segment of the population or another.

To finish her presentation, the head of communication recalled the basic and necessary points that any entity should have in mind when using this type of platforms as a means of communication, but she also stressed that both online and offline communication are important for any person or organization, and therefore, both must be on the agenda of these entities.

# BARCELONA, Attendants' considerations:

## For IRTA (Mònica Campàs, Jorge Diogène):

The ToS at CREDA presented different approaches on Risk Communication from different actors. From the Catalan Food Safety Agency, with whom we are quite interrelated at IRTA since we are on continuous collaboration, we received a clear pattern of transparency and clarity when approaching communication of hazards to society, a field that we are not so aware about. We could certainly understand how the scientific data are crucial to support the appropriate messages to be given. As attendants from the research sector, we are also rarely exposed to risk communication from the market perspective, and we were very positively surprised by the deep preparation, the creative initiatives and a very professional overall approach to risk communication set by APROMAR from the production aquaculture sector and the Barcelona Fish Wholesalers Guild. Certainly, after these presentations, we will foresee to strengthen the links between our research activities on RA and the aquaculture sector. Regarding academia, in this case CREDA, the presentations of several researchers helped us also to understand how important the scientific communication to society is, including through social media, and to learn about the different strategies to improve the perception of consumers towards safe and valuable aquaculture products, for example. We were also exposed to the experimental design of consumer surveys and interpretation of their replies as very powerful tools to take commercial and communication decisions regarding safe seafood consumption.

## For ISS (Manganelli Maura, Scardala Simona)

The ToS "Dissemination and outreach" hosted by CREDA presenting different approaches on Risk Communication has been very interesting and formative being quite outside of our expertise. Different approaches were illustrated by CREDA but also by other Institutions: The Catalan Food Safety Agency, the Spanish Association of Aquaculture Growers and the Barcelona Fish Wholesalers Guild. All these institutions consider risk communication from different perspectives and the detailed presentations showed how much the different aspects are related and interconnected. As researchers in the field of RA, it was very interesting to have an overview of the approach to risk-benefit communication at the institutional level but also by the private sector, especially when referring to the population. The importance of an adequate and balanced communication of risks and benefits has been highlighted, even with an experiment carried out with 30 students of the UPC to find out if the provision of information on seafood risk and benefit would affect their decision to consume this product in the canteen of the university. That experiment, although with all the limitations given by the short time available within the ToS, gave an idea of the effects of the different types of messages. Surely, we will consider the input received in this experience in our future works.

## For IPMA (Carlos Cardoso)

The presented communications and the various questions and discussions during the ToS "Dissemination and outreach" hosted by CREDA enabled to achieve for IPMA a broad overview of the different approaches on Risk Communication, thereby being quite helpful for me as experienced risk assessor. Indeed, since my area of expertise lies in the quantification and pondering of risks and benefits associated to seafood consumption, this training and updating on Risk Communication was totally new and invaluable to me as well as for IPMA, where we miss the existence of a group with a core competence on communicating risk. More specifically, it was

very enriching and enlightening for understanding the challenges and critical points of communicating risk to a broader public and to particular targeted groups in the population. Furthermore, this was even more so due to the input of entities external to CREDA, such as the Barcelona Fish Wholesalers Guild, the Catalan Food Safety Agency, and the Spanish Association of Aquaculture Growers. Given their different nature, these entities approach risk communication from different angles and bring to the fore different themes and items that must be addressed if a proper communication to the overall public (and specific population segments) is to be achieved. Finally, it was also very interesting to note the very systematic and experimental approach to risk communication at CREDA as exemplified by an exercise involving CREDA students, which tried to evaluate the impact of different messages concerning food risk and benefit in the students behavior and also enabled to highlight the specific difficulties of these studies and, at the same time, their importance for a more objective construction of risk-concerning messages directed to the broad public and specific cohorts and groups. All in all, the whole ToS "Dissemination and outreach" enabled me to enlarge my horizons and it still may prove seminal in the development of work on Risk Communication at IPMA.

# ANNEX G: ToS PARIS

**Training on Spot: "Anses experience: From laboratory to risk assessment and beyond"**

**PARIS**

Meeting at Anses of the European RASCS project

A training session was held at Anses headquarters in Maisons-Alfort on 11 and 12 May 2023. It was organised by the Anses members of this consortium, namely Nathalie Arnich (DER, UERALIM), Véronique Sirot (DER, UME), Anne Thébaut (DER, UME) and Ronel Biré (LSAl, UPBM), in order to share their experience with six other scientists of the consortium: Jessica Dietrich (BfR, Germany), Jorge Diogene (IRTA, Spain), Christine Hung (UGENT, Belgium), Maura Manganelli and Emanuela Testai (ISS, Italy), Pedro Costa (IPMA, Portugal). The agenda alternated presentations, case studies and practical exercises, while exchanging on the approaches of the various agencies in the field of chemical contaminants (and marine biotoxins) in seafood, from data acquisition to health RA and communication. Two days rich in exchanges, placed under the sign of conviviality.

**11 May 2023**

**Nathalie ARNICH** provided a general presentation of Anses, its missions, the methodology of work for the health RA based on a collective expert appraisals, its ethical framework, with a focus on the work conducted by the Expert Committee on chemical risks in food.

Then, **Nathalie ARNICH** presented in details Anses work on the health risks assessment associated with pinnatoxins (PnTXs) in shellfish. A particular attention was given to the description of the toxicity data and the construction of the provisional acute heath-based guidance value. She shared her experience on assessing the quality of a toxicity study with the use of a grid developed at European level by the JRC (Joint Research Centre). The software-based tool "ToxRTool" (Toxicological data Reliability Assessment Tool; https://joint-research-centre.ec.europa.eu/scientific-tools-and-databases/toxrtool-toxicological-data-reliability-assessment-tool_en ) provides comprehensive criteria and guidance for evaluations of the inherent quality of toxicological data, thus making the decision process of assigning reliability categories more transparent and harmonised. The attendees were invited to a hands-on exercise with ToxRTool and one of the key toxicity studies on PnTX G.

In the presentation, provided by **Veronique SIROT**, the importance of collecting consumption data for RA was underlined. Veronique SIROT presented different types of consumption surveys with examples of surveys conducted in France for the general population as well as seafood consumers, and examples of data generated, currently used at Anses to perform RA. Methods, advantages and limits of the different approaches were discussed as well as lessons from previous results.

To conclude this first day of the training, **Ronel BIRE** invited the attendees for a guided tour of the French Reference Laboratory on Marine Biotoxins and the French Reference Laboratory on trace elements in food (Maisons-Alfort).

**12 May 2023**

The first presentation was given by **Nathalie ARNICH** on Anses work related to a guidance level for brevetoxins (BTXs) in French shellfish. A focus was given on toxicity, occurrence data in shellfish and on an update on the microalgae known or suspected to produce BTXs. The hazard characterisation based on human cases of intoxication and the derivation of the guidance level of BTX in shellfish were discussed, taking into account national seafood consumption data and a representative mean body weight for the French population. The last parts were dedicated to research needs to fill data gaps and on ecotoxicity of BTXs for the wildlife.

Then, **Veronique SIROT** shared experience on food sampling for chemical RA, through the example of TDS. The general method was presented, with a particular focus on the food selection method (based on consumption data presented the 1st day) and on the sampling plan design. The need of data and the combination of data coming from different sources was underlined, as well as the compromises to be done between means (budget and time), objective of the sampling, and availability of information. Examples of results were presented regarding contamination data, exposure and RA, and use in the definition of food-based dietary guidelines and mixtures identification.

**Anne THEBAUT** gave a presentation on cost(simplified)-benefit (acute exposure reduction) approach in shellfish production area. The efficiency of monitoring system can be assessed in term of sensitivity and specificity of the definition of periods at risk. Different ANSES opinions illustrate this approach. Dose-response modelling based on epidemiological data for acute risk, allow to estimate the number of human cases in relation with a dose received, combination of consumption (portion-size) and contamination data. An illustration is made with published dose response in PSP (https://www.mdpi.com/2072-6651/10/4/141 , research work at ANSES). For a "sea to fork" approach, we can use historical data or simulated data, in combination with quantitative RA approach, to illustrate the efficiency of monitoring/management system to avoid human cases and costly day of closure in production areas. This presentation was followed by a practical exercise in excel and in Rstudio cloud, for different scenarios of monitoring/management and theoretical data of phytoplankton bloom and shellfish contamination.

The last point of the agenda was a discussion about potential examples.

# PARIS, Attendants' considerations:

### For IRTA (Jorge Diogène):

The ToS at ANSES provided a wide description of ANSES contributions to RA of food safety issues. I valued the wide spectrum of responsibilities within ANSES and their solid organization linked to five ministries. I could perceive the systematic approach to food safety hazards, in a well-structured institution. In addition, as perceived in other ToS, the relevance of the staff in the day-to-day work, proved to be crucial in how departments work. For example, at ANSES, the RAt group on food is more implicated in research activities that other branches at ANSES on other subjects on RA. The quality of the presentations was very high, with a lot of details and time to openly discuss. Two examples of emerging marine toxins (Pinnatoxins and Brevetoxins) were used to describe the EMERGETOX program in France, an original and effective approach to non-regulated toxins. The presentations on consumer surveys and TDS, allowed me to better

seize the complexity of these fields and provided me with strategies and tools to achieve these goals. Two different practical exercises to evaluate the acceptability of toxicological studies, and the efficiency of monitoring programs were extremely useful to understand a systematic approach to analysis and decision-taking. A visit to the laboratory facilities of ANSES was also very valuable to identify potential improvements in our own laboratories.

**For ISS (Emanuela Testai and Maura Manganelli)**

By means of two real examples of the RA carried out by ANSES for two emerging marine toxins (Pinnatoxins and Brevetoxins) it has been possible to see in detail the procedures applied by ANSES and discuss some specific aspects. It has been particularly interesting to see that experts external to ANSES are invited to join the ANSES staff and a WG is generally responsible to address the requests, following a procedure which is similar to the one adopted by EFSA. A visit to the lab in charge of detecting marine and freshwater toxins as well as metals, complemented the first day of the ToS. The practical exercise on the use of the ToxRtool to evaluate and ranking the quality of a specific paper in a systematic and harmonised way was very appreciated, The presentations on the methodologies to get reliable information on food consumption in general and seafood (e.g. consumer surveys and TDS) and the practical exercise on the possible tool to predict the best period for monitoring an area interested by marine biotoxin contamination were very informative and increased our knowledge on the complexity of the issue of calculating the actual exposure of the population. The ToS was another excellent opportunity to deep into some aspects of the RA in which we have lower familiarity.

**For UGent (Christine Yung Hung)**

The ToS organised by ANSES offered comprehensive insights into seafood RA of with very well-thought and useful hands-on exercises. This KE bridged the gap between technical scientific content and its effective communication to the public. The exchange enables us to correctly simplify complex concepts of health RA and toxicology, thereby promote a better understanding of public health implications and safety measures. We also engaged in discussions regarding the design and application of consumption surveys and cost-benefit analyses, underscoring the importance of socioeconomic nuances in data collection and interpretation. This experience will guide our future efforts in prioritising and formulating communication strategies for risk management systems. Such multi-disciplinary strategies will ensure that information about the monitoring of seafood production and potential risks is accessible, transparent, credible, and timely, fostering a broader understanding among the public, and in turn contribute to consumer protection and public health outcomes.


# ANNEX H: RASCS FINAL WORKSHOP

**Risk Assessment of Contaminants in Seafood – RASCS FINAL WORKSHOP**

**PARMA, 7th and 8th of June 2023**

Meeting at EFSA of the European RASCS project

The final workshop was held at EFSA headquarters in Parma on 7 and 8 of June 2023, with all the institutions attending physically and 15 attendants. The meeting was also offered online for other RASCS members that were not on site.


A first part of the meeting was dedicated to the activities held during the RASCS project, including a revision of the final report draft and analysis and discussions on the **Questionnaires on Monitoring programmes** and the **Consumer Surveys** held in Poland, Belgium and Spain. The meeting allowed to go deeper in the analysis of data, since the final report draft only contained preliminary data on the Consumer Surveys.

A second part of the meeting focused on additional dissemination activities of RASCS, including communications in conferences and the writing of manuscripts for publications.

In the third part of the meeting, a World Coffee was conducted on PFAS, since starting in 2023 new regulations require to conduct PFAS evaluation in seafood. Four topics were addressed:

- *Origin of PFAS, toxicology and regulation on seafood.*
- *Presence of PFAS in the environment and data gaps.*

- *PFAS, another requirement for the industry: economic impact, risk increase of restrictions.*
- *PFAS: consumer perception in front of a new hazard. How to handle a new restriction.*

This exercise allowed an intense knowledge exchange since the awareness on the different topics related to PFAS was far from homogenous among partners before the exercise. The format of the exercise was certainly efficient and favored active participation of all attendants. It allowed collecting available information and identifying gaps and major priority actions that should be considered in the near future, in which our institutions could be involved.

The workshop closed with an evaluation of the RASCS outcomes and potential perspectives among RASCS partners for future collaborations.