SECTION 5

Research, science and risk analysis

SEAFOODplus: international seafood research

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ABSTRACT

SEAFOODplus is probably the largest ever research project on seafood. It is funded by the European Commission, which contributes four million euro, and European research and industry groups contributing a further 12 million euro. It has a nominal four and a half year lifespan and includes 70 partners in 16 countries. It is organised into six Research and Technology Development (RTD) areas (named 'pillars'), and a further six Information Technology and Development (ITD) pillars. SEAFOODplus has provided a major boost to seafood research in Europe and may spawn similar activities in other regions. Its existence gave the impetus for the formation of a Cooperative Seafood Research Centre in Australia. The strategic objectives of the project are to reduce health problems and increase wellbeing by promoting the consumption of safe and healthy seafood.

INTRODUCTION

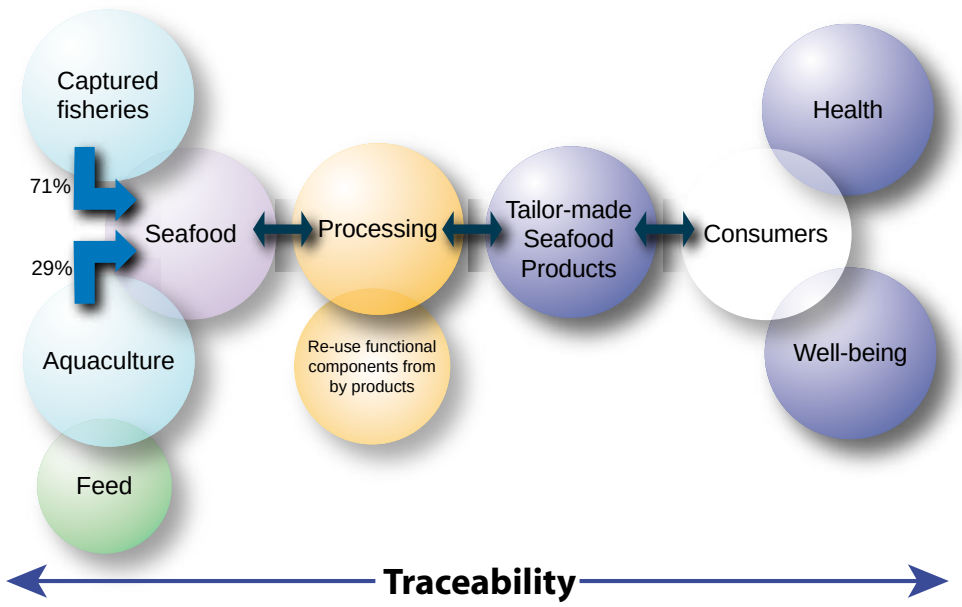
The strategic objective of SEAFOODplus is to reduce health problems and to increase wellbeing among European consumers by promoting the benefits of consuming healthy, safe and high quality seafood products. The term 'seafood' used here encompasses wild and farmed fish and shellfish, both of marine and freshwater origin (see www.seafoodplus.org).

The extent to which a diet rich in seafood can reduce the increasing incidence of cancer, cardiovascular and inflammatory disease, will be assessed by performing dietary intervention and epidemiological studies. Other areas focus on the health of young populations, including the prevention of osteoporosis and postpartum depression in women.

The determinants of consumers' seafood consumption will also be assessed, including the impact of health-related communication strategies on consumer decision-making. This will give information that is useful for adapting seafood products to consumer demands.

The seafood safety components of the research are aimed at making seafood safe for the consumer by identifying risk factors, reducing the risks associated with viral and bacterial contamination as well as biogenic amines, and undertaking risk-benefit analysis. All parts of the seafood industry are covered from traditional fisheries to innovative aquaculture. In terms of aquaculture, one challenge is to find a compromise between intensive rearing and consumer demands for healthy, high quality seafood that is ethically produced with minimal environmental impacts. Validated traceability systems will also be assessed in an attempt to apply a total food chain approach: tracing the live fish to the final consumer product, and back, from fork-to-farm. Figure 1 shows the components of the total food chain approach and its 'fork-to-fish' traceability objective.

FIGURE 1
Conceptual diagram using the approach to a total food chain of the relationships between activities in SEAFOODplus



SEAFOODPLUS: BACKGROUND AND ORGANIZATIONAL ARRANGEMENTS

The European Union (EU) wanted to tread new paths in its sixth research framework programme. Instead of the usual small projects for which administrative input tends to be high and the development boost low, they were looking for a project with better cost/benefit ratios and with integrated sub-projects directed towards common goals. To this end, it was able to build upon a well-established European network of institutes and scientific facilities, namely WEFTA, the Western European Fish Technologists Association. For 30 years WEFTA had been promoting practical research in the fish sector. Following a year of monthly meetings to establish structures and content, partners from the fields of nutrition, medicine and consumer science were invited to join technologists to create a truly multidisciplinary research consortium.

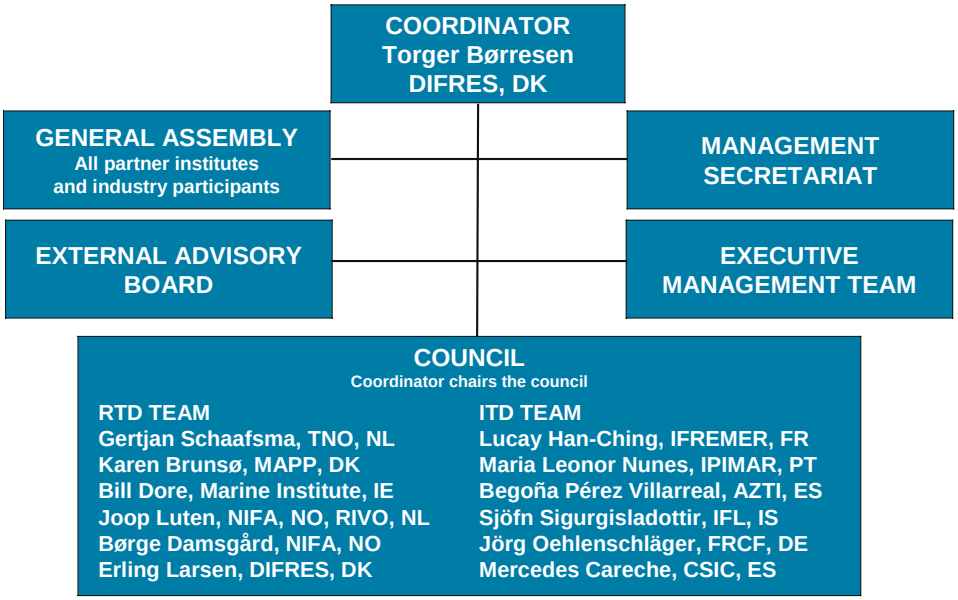
The European Commission (EC) in Brussels confirmed the work programme for SEAFOODplus in October 2003, the necessary contracts were signed at the end of 2003 and activities proper commenced in 2004. In contrast with traditional research approaches, the starting point for the SEAFOODplus research is the consumer. Contemporary consumers demand healthy, safe products that are produced using modern yet sustainable, environmentally sound, production methods.

SEAFOODplus was one of the few programmes selected by the EC, from the nearly 900 original projects submitted. Only six proposals out of 69 were selected for grants in the food area of its sixth research framework programme. The points in favour of SEAFOODplus were the high scientific standard, the strong links between the sub-projects, the complexity of the multidisciplinary programme, and the meaningfulness of the anticipated results. About 70 partners from 16 European states, among them both research facilities and small and middle-sized companies, are involved in one or other of the 20 sub-projects. Some non-European partners are also involved, including the Canadian enterprise 'Aquanet'.

Organizational structure

Figure 2 outlines the organizational structure and governance relationships of SEAFOODplus, which have been designed for maximum integration of activities, full transparency and adequate oversight. All coordination of technical activities as well as legal, contractual and administrative activities at consortium level is performed by the Council, whereas the management of technical details of RTD activities is done within the RTD pillar and at project level respectively. Issues related to industry training, information dissemination, and intellectual property protection, are managed by the ITD team.

FIGURE 2
The overall organizational structure of SEAFOODplus



Internal information exchange between project teams

The integration of research streams and adequate information flows between projects is achieved through a comprehensive spectrum of measures and methods, including training courses, the handling of research topics by several teams, exchanges of personnel, workshops, the joint use of data bases and information exchange via an Intranet site.

Commercial companies integrated within the project

Cooperation with small and middle-sized companies is important for ensuring that results will be commercially useful and subsequently used. The faster the results can be translated into action, the sooner the high personnel and financial costs of SEAFOODplus can be justified. Significant results are immediately available on the website, including to the public, even while the programme is ongoing. This applies in particular to findings related to new technologies, which could create economic benefits for users. The intention is that some findings may lead to the setting up of new companies and thus to the creation of jobs.

Fast distribution of results

A special working group is charged with the distribution of research results. It targets politicians, consumers and companies, using for example, specialist publications, the Internet, leaflets, being present at conferences and trade fairs, interviews and press releases.

Close contacts with processing companies, aquaculture enterprises, and the European associations of seafood processors, mean that they can also be used to distribute information quickly to their networks. Information stands and presentations at important European seafood exhibitions and trade fairs are part of the dissemination and publicity strategy. Seafood retailers are a particularly important target group as they have direct, daily contact with customers. The 'Dissemination' team offers support in translating the scientists' technical jargon into everyday, generally comprehensible language.

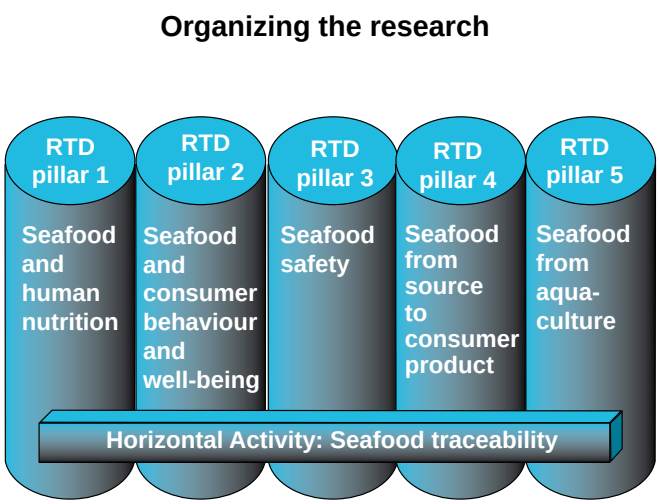
Integration activities

Research is conducted by groups familiar with seafood as a commodity and by groups that are more associated with a particular scientific discipline. Both research environments need to be integrated. The instruments for doing this include training, exchange of personnel, PhD projects, joint studies, common work-ins, establishment of shared databases, and the operation of shared websites. In addition to training activities for researchers, a programme is also being prepared for the training of key personnel in industry, particularly small - and medium - sized enterprises (SMEs), thus integrating the research and industry environments, and assuring that any outcome from the SEAFOODplus research and development activities will be utilized by industry. To encourage the industrial exploitation of results, a special demonstration programme has also been established.

Research structure

SEAFOODplus research is organized into five Research and Technology Development (RTD) areas, called RTD pillars, and one horizontal activity spanning all RTD pillars (Figure 3). Each of the RTD pillars deals with a specific discipline oriented research area, but there is a strong interdependence between them.

FIGURE 3
The research pillars in SEAFOODplus



The challenge: To have researchers from very different scientific areas closely together

RTD pillar 1: seafood and human nutrition

The major causes of premature morbidity and mortality in Europe are cardiovascular disease (approximately 40 percent) and cancer (approximately 25 percent). Epidemiological studies provide convincing evidence that seafood consumption can improve health and reduce the risk of chronic diseases. Increasing evidence supports an important role for long chain n-3 polyunsaturated fatty acids from seafood. There is increasing concern that the ratio of the n-6/n-3 fatty acids in the diet in some European

populations is too high, in the region of 12:1 where a desirable level is estimated to be nearer to 6:1, or according to some scientists even lower. By consuming more seafood could this imbalance be rectified?

The research in this pillar addresses the question: 'How important is seafood consumption for the health of the consumer?' On the basis of mainly epidemiological research there are strong indications that regular seafood consumption could help to reduce gastrointestinal diseases, such as colon cancer and inflammatory bowel disease, and other diseases with an inflammatory component, such as diabetes type 2 and osteoporosis. Seafood consumption may play a significant role in weight management, and help in the prevention of obesity. There is good evidence that regular seafood consumption reduces cardiovascular mortality.

These beneficial effects of seafood need to be verified and the underlying mechanism elucidated. This can only be done through intervention studies in humans. In this pillar, three projects are focused on the physiological effects of seafood protein and seafood fatty acids. All involve intervention studies in humans to explore the effects of seafood consumption and how it works to improve health. Indications of a preventive effect of seafood against postpartum depression, a disease affecting 5-20 percent of childbearing women, will also be studied epidemiologically, as will the effects of seafood on colon cancer. An attempt will be made to distinguish between the effects of seafood protein versus seafood lipids, the results of which will feed into the development of seafood products that deliver the greatest possible health benefits to the consumer. In a later stage of SEAFOODplus, the links to other pillars, especially to pillar 4, will be developed with the efficacy testing of seafood based functional foods.

RTD pillar 2: seafood and consumer behaviour and wellbeing

It is generally agreed that seafood is a valuable resource for human nutrition. Epidemiological studies indicate that seafood contributes to a healthy diet, and populations that eat seafood regularly have a lower risk of coronary heart diseases, hypertension and cancer. Seafood may thus play an important role in a healthy diet, and in securing consumer health and wellbeing in Europe. However, seafood consumption seems to be declining in several European countries. No information is available to explain this decline due to lack of valid and comparable data at the European level. Thus, from a European health policy perspective, knowledge on what determines the consumption levels across Europe from a cross-cultural consumer perspective will be crucial for attempts to change or increase seafood consumption.

Attempts to modify consumption patterns might be aimed at either adapting seafood products to changing consumer demands or at changing consumer attitudes or perceptions of seafood. Both require a better understanding of what determines seafood consumption in Europe. In general, studies on the determinants of food acceptance or choice have distinguished between three types of factors; properties of the food product, factors related to the consumer, and environmental factors. Most research on food and seafood choice has tested the effects of a single type of determinant. Future research should take a more comprehensive and integrated approach.

In RTD pillar 2, four unique consumer projects complement each other, and together will reach new scientific insights and provide methodological innovations in relation to consumer research. At the core, a consumer survey will provide the basis for describing and predicting consumer preferences and attitudes towards seafood on an aggregate level. This project provides results to the other three projects as well as to other pillars in SEAFOODplus. The three other projects all extend this knowledge in relation to three crucial areas related to seafood products: on the eating quality of seafood, on consumer perceptions of new seafood products, and on consumer perceptions of information about seafood.

RTD pillar 3: seafood safety

Although seafood is generally regarded as a wholesome, safe, and nutritious food, it sometimes poses consumer risks. This pillar conducts research towards identifying and reducing the potential risks associated with seafood.

From reviews of international epidemiological data, the most clearly identified consumer risks from seafood are from human enteric viruses contaminating bivalve molluscs, pathogenic bacteria such as *vibrio* species, the formation of biogenic amines (histamine poisoning) in certain fishery products, and marine biotoxins. Other potential risks have been described, including, bioaccumulation through the food chain of persistent organic pollutants and heavy metals through environmental or aquaculture food contamination, and residues of veterinary medicines used in aquaculture.

Management of the consumer risks from seafood in the EU is either through direct legislation requiring monitoring and control, through prescribed standards for specific risks, or through generic controls using Hazard Analysis Critical Control Point (HACCP) procedures. Such risk management options are usually underpinned by risk assessment, but this approach is currently underdeveloped in the seafood safety area. Health statistics and continuing EU Rapid Alerts relating to seafood, suggest that despite the controls in place, the risks persist and seafood consumers continue to suffer illness.

The partners within the SEAFOODplus consortium have a wealth of experience with seafood safety risks and, collectively, constitute a unique pool of expertise within Europe. Following extensive consultation among key European fisheries institutes, SEAFOODplus has developed an integrated package of proposals for research in the seafood safety area. The projects build on existing knowledge and experience and aim to provide a very practical contribution towards improving consumer protection within the European Union. Projects cover the following areas:

- the development of improved test methods for both viral and bacterial contaminants of seafood (projects 3.1 and 3.3);
- the development of HACCP procedures for better control of viral pollution risks in shellfish harvesting areas (project 3.2);
- a better understanding of why EU consumers still continue to experience histamine food poisoning leading to predicative models; and
- improved industrial processing measures (project 3.4).

These projects are underpinned by a comprehensive risk assessment, which will provide risk managers and consumers with targeted and contextual information on risks associated with seafood (project 3.5). Overall the projects comprise a balanced and integrated package addressing key issues that should facilitate the development of better controls for seafood production and lead to less consumer illness.

RTD pillar 4: seafood from source to consumer product

Consumers are concerned about the sustainability of fish stocks. They are also concerned about the increasing amount of byproducts from the seafood production chain due to a growing aquaculture sector in various European countries. Although the majority of byproducts are used for feed production, manufacturing byproducts into human food with beneficial health effects represents a larger and a more challenging potential. This full utilization approach would contribute to a positive consumer image of the fishery chain.

Seafood byproducts are an important source for protein hydrolysates (bioactive peptides), n-3 lipids, nucleotides, collagen, gelatin, chitosan and mucosapolysaccharides, with proven and potential positive health beneficial effects. However, the recovery and utilization of byproducts from wild fisheries and aquaculture could be improved. The potential health benefits of new components from seafood byproducts also need to be tested.

The market for convenience food is growing and in the case of seafood this may help to overcome some barriers for seafood consumption, such as the off-putting presence of bones or the inexperience of consumers in seafood preparation. Convenience seafood products tend to be lightly (semi) preserved. Safety issues are therefore of great importance, due to the potential contamination with pathogens. Different methods, including ionisation or chemical preservatives, have been tested for killing or inhibiting the growth of unwanted micro-organisms in food, but they all affect flavour or texture and are not compatible with the 'fresh' image of these foods. The synergistic combination of subtle preservation factors or advanced technologies, including the use of protective bacterial culture (biopreservation), anti-microbial active food-packaging and non-thermal processes such as 'pulse light', to control, destruct or inactivate undesirable micro-organisms may help to overcome these problems.

Another problem affecting consumer acceptance of seafood is rancidity and softening of the texture of seafood. Oxidation reduces the already limited amount of n-3 lipids in diets, and renders the use of these fatty acids as bioactive functional food ingredients difficult. During oxidation the fatty acids are converted into radicals and hydroperoxides that are further transformed into a wide array of (non)-volatile end products. Radicals, both hydroxyalkenals and aldehydes, are found to be highly reactive and can affect colour, protein functionality and enzyme activity. Enzymatic degradation of proteins in seafood after slaughter affects texture. Until recently softening was mainly ascribed to two groups of proteases, namely the cathepsins and the calpains. Lately there has been a growing interest in the protease, 20S proteasome. However, the mechanisms and kinetics of these processes, leading to deterioration of sensory properties and nutritional quality, are not understood. This knowledge will ensure the high nutritional and sensory quality of seafood.

The current interest in the role of seafood in human health relates to n-3 lipids that are highly susceptible to oxidation. The prevention of oxidation by a natural marine anti-oxidant, which has an additional beneficial health effect as dietary fiber, is one of the options for developing seafood products as functional food beyond the existing intrinsic nutritional value of seafood. Dietary modulation of farmed seafood is another option. Compounds like Se-(alkyl)cysteines present in, for example, alliums are of significant importance in combating cancer, as has been shown already in human intervention studies. However, feed modulation using this vegetable selenium source to change the selenium content and bioavailability of selenium in farmed fish, has not yet been investigated. The idea of developing functional seafood products with benefits beyond their intrinsic nutritional value is an unexploited area.

Research will be consumer driven to ensure that the resulting seafood products fulfill the needs and demands of target consumers, especially with respect to their being healthy and convenient.

RTD pillar 5: seafood from aquaculture

Seafood from capture fisheries is limited and in some cases not sustainable. Future demand for seafood will have to be met from aquaculture sources. There are some major consumer concerns about seafood from aquaculture, including:

- its poor taste and texture compared to wild fish;
- its potential contamination from fish feed;
- the ethics of the intensive production and slaughter of farmed fish;
- the sustainability of marine fish feed sources;
- the adverse environmental impacts of pollution; and
- the potential environmental impacts from interaction with wild stocks.

Projects in pillar 5 directly address these concerns to help overcome consumer resistance to aquaculture products. Some key elements need to be better understood. Seafood from aquaculture can potentially overcome the problem of the over exploitation

of scarce wild resources. It can potentially deliver a product of defined quality and composition to the market throughout the year, thereby enabling a greater penetration of 'healthy foods' in the diet of Europeans. Moreover, increasing intensification offers an ability to determine the quality of the product in several ways, allowing more tailor-made seafood products. Similarly, high seafood quality can be linked to ethically acceptable husbandry practices and aquaculture systems, both in reality and in the perceptions of consumers.

It will be important to diversify farming away from salmon to various white fish species, such as cod and carp. Research on how genetic background, growth and husbandry affect the biological properties of the muscle and hence eating and processing quality traits will be particularly useful.

Unless these quality problems are resolved there will be a decline in the consumption of healthy seafood. The research in pillar 5 focuses on major deficiencies in scientific understanding, which must be addressed. The relevance of the research proposed is shown by the participation of SMEs in the work packages.

RTD 6: Horizontal activity on seafood traceability to ensure consumer confidence

The seafood sector faces considerable challenges in the next few years as full traceability is introduced into the EU area. However, it is an outstanding opportunity to introduce traceability not only as a defensive system, but also as a proactive tool to ensure and verify the credibility of new seafood products.

Against this background, RTD 6 has been created as a horizontal activity to develop a traceability tool for the whole project, in particular as a support for RTD pillars 3, 4 and 5. The results of RTD 6 will also feed into RTD 2, with a focus on the consumer as the end user of the traceable data. The overall objective is to develop validated traceability systems for seafood and seafood products tracking them from consumers and retailers back to fishers.

This is a multi-scientific and multi-technological task ranging from methodology through implementation to validation. Electronic solutions are the only option for a practical and feasible traceability system. A range of scientific and technological problems must be solved before a validated traceability system can function in an open EU marketplace. Until now, general definitions of traceability for fish and fish products have come out of EU project QLK-2000-00164 'Tracefish'. RTD 6 builds on this work to develop a uniform methodology with a universal vocabulary as well as operational guidelines for traceability. This requires an extensive study of data capture equipment, data flow, development of management models, validation methods and analyses of selected seafood chains.

The technology transfer and information dissemination from this activity will be important especially given EU legislation requiring the implementation of traceability systems by all players in the seafood production chain (from January 2005). While there is no requirement for these systems to be validated, the system will have limited value and inadequate credibility without validation.

Information technology and development (ITD)

ITD activities are organized in pillars analogous to those of RTD (Figure 4).

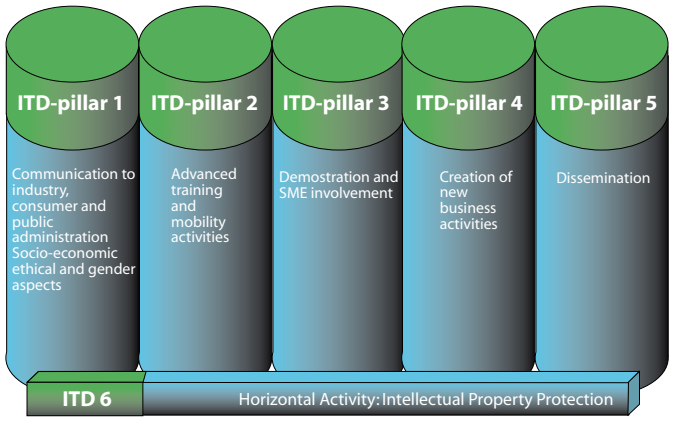
Dissemination

The dissemination plan is designed to disseminate the results of research beyond the consortium, including through publications, a website, specialized leaflets, editorial pages, conferences (especially those with an emphasis on innovation), press releases, interviews, exhibitions and trade fairs. These activities also include training activities, such as workshops and conferences, providing operational manuals, an e-learning

platform, and the provision of consultancy and advisory services. Information will be tailored to particular groups such as consumers and their associations, industry groups, trade and retail organizations, the government sector, medical doctors and nutritionists and the research community (universities and public research institutions).

Information about SEAFOODplus, including progress to date, training courses and conferences offered, important milestones reached which are of particular interest to the scientific community is available at www.seafood.plus.org.

FIGURE 4
The organization of the ITD activities into pillars



THE AUSTRALIAN SEAFOOD COOPERATIVE RESEARCH CENTRE (SEAFOODCRC)

Following two years of intensive collaboration between the Australian seafood industry, government agencies and research providers, it was agreed to establish the Australian Seafood Cooperative Research Centre (Seafood CRC), to commence operations from 1 July 2007 (see www.seafoodcrc.com). SEAFOODplus provided a convincing model of a large integrated research project between industry and research organizations.

Seafood CRC will be Australia's first national entity to stimulate and provide comprehensive seafood-related research and development. Its competitive advantage was seen as follows:

- it has the support of the industry's major wild-harvest and aquaculture sectors, key companies and industry leaders throughout the value chain, and the nation's leading fisheries, aquaculture and seafood research institutes;
- it will improve on the successful collaboration and knowledge gained from other CRCs and programme such as those of the Fisheries Research and Development Corporation;
- it will build on existing private and public infrastructure investments to address institutional and market failures in the seafood industry; and
- it will attract and develop research and vocational capabilities required to support the value chain beyond production.

These advantages will enable Seafood CRC to advance research in seafood well beyond what is currently being undertaken in pursuit of the overall outcome of a "substantially improved contribution to national economic growth by a profitable, internationally competitive, robust Australian seafood industry".

The structure will be as follows:

- Research Program 1: Value chain profitability. Outcome: Increased profitability and industry value through production innovation and efficient delivery of Australian seafood to the consumer.
- Research Program 2: Product quality and integrity. Outcome: Increased access to premium markets by meeting consumer demands for safe, high quality, nutritious Australian seafood.

- Research Program 3: Health benefits of seafood. Outcome: Increased demand resulting from consumers' improved recognition of the health benefits of Australian seafood.

Two further programmes, Education and Training, and Commercialization and Utilization, are designed to support the outcomes of these three research programmes.

CONCLUSIONS

SEAFOODplus has provided a major boost to seafood research both in Europe and elsewhere. The full measure of its success will not be seen until its research is completed and results are disseminated. Progress to date suggests that it will achieve it overall objective of ensuring that consumers have access to healthy, safe and high quality seafood, and that in the long term this will have positive impacts on the general health and wellbeing of the European population. By providing the impetus for similar activities in other countries, such as the Cooperative Seafood Research Centre in Australia, the benefits of SEAFOODplus are likely to extend well beyond Europe.

Tailoring farmed Atlantic salmon with low levels of dioxins

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ABSTRACT

Norway is a major exporter of seafood, including of around 500 000 tonnes of farmed fish annually. To ensure the continuity of this trade it is essential to be able to clarify the effects, from 'feed to fork', of the undesirable substances and of the beneficial nutrients found in that fish. Since safe and healthy production of farmed fish starts with fish feed, the development of fish feeds with low levels of undesirable substances has become pivotal. The typical undesirables derived from marine feed ingredients are persistent organic pollutants (POPs), which are associated mainly with fish oil. In farmed salmon, the fat-soluble polychlorinated dioxins and furans (PCDD/F) and dioxin-like PCBs (DLPCB), commonly known as 'dioxins', are among one of the greatest challenges to food safety. Strategies are being developed to produce fish that are low in undesirables, by designing diets and optimizing feeding strategies while also taking into account issues of cost-efficiency and fish welfare. There are three main approaches that singularly or in combination can reduce the levels of PCDD/F and DLPCB in fish feed and farmed fish:

- selecting marine feed materials with relatively low natural levels of dioxins;
- using of alternative, terrestrial feed materials with naturally low levels of dioxins;
- technical removal of undesirable substances from marine fish oils.

The selective use of marine oils with low natural levels of organic pollutants reduces the level of dioxins in farmed fish, but has a lesser effect on the level of PCDD/F than DLPCB (Lundebye *et al.* 2004). The use of vegetable oils effectively reduces the level of both PCDD/F and DLPCB, but may also affect the positive nutrients normally found in marine fish (Berntssen *et al.* 2005). The use of purification techniques has the potential to reduce the level of lipid soluble organic pollutants while maintaining the high nutritional value of the marine ingredients used in fish feeds.

This paper gives an overview of current and potential strategies to control and reduce the levels of dioxins in farmed salmon. Research examples and a discussion of two previously published articles will also be presented.

INTRODUCTION

Norway is a major exporter of seafood. In 2004, around 500 000 tonnes farmed fish were exported. For major exporters of seafood such as Norway, it is of utmost importance to clarify the levels and the effects, from 'fjord to fork', both of the undesirable substances and the beneficial nutrients found in this fish. Since safe and healthy production of farmed fish starts with fish feed, the development of fish feeds with low levels of undesirable substances has become pivotal. Typical undesirables

derived from marine feed ingredients used in fish feeds are persistent organic pollutants (POPs). There is currently considerable focus on food safety aspects of persistent organic pollutants (POP) in farmed fish (for example, Hites *et al.* 2004). In salmon culture, dioxins (polychlorinated dibenzo-*p*-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF)), as well as dioxin-like polychlorinated biphenyls (non-ortho PCB and mono-ortho PCB), are among the greatest challenges.

Dioxins (PCDD/F) and dioxin-like PCBs (DLPCB) are highly persistent, and fat-soluble environmental pollutants that are ubiquitous in the marine ecosystem and are readily biomagnified in the food chain. Fish oils, extracted from marine pelagic fish species, used in high energy fish feeds are considered to be the main source of these lipophilic organochlorines in farmed salmon (WHO 1999; Jacobs *et al.* 2002).

Several strategies are being developed to produce fish low in undesirables by designing diets and optimizing feeding strategies, while taking into account cost-efficiency and fish welfare concerns. There are three main approaches that singularly or in combination can reduce the levels of PCDD/F and DLPCB in fish feed and farmed fish. One is to select marine feed materials with relatively low natural levels of dioxins (Isosaari *et al.* 2004; Lundebye *et al.* 2004). Besides seasonal variation, there is a large variation in fish oil PCDD/F and DLPCB levels depending on factors such as fish species, age, or geographical origin (EC 2000, NORA 2003). Another strategy is to substitute fish oil with alternative, terrestrial feed ingredients that contain lower levels of dioxins than fish oils. Vegetable oils have lower PCDD/F and DLPCB levels than most commonly used fish oils, and substituting fish oil with vegetable oil has great potential to reduce the level of dioxins in farmed salmon (Bell *et al.* 2005; Berntssen *et al.* 2005). Finally, several techniques exist to remove POPs from fish oils (deKock *et al.* 2004; Breivik and Thorstad, 2004) without affecting the nutritional status of the oils.

This paper gives an overview of current and proposed strategies to control and reduce the levels of dioxins in farmed salmon. A summary of research examples and a discussion of two previously published articles (Lundebye *et al.* 2004 and Berntssen *et al.* 2005) on the selective use of fish oils or substitution of fish oils with vegetable oils in salmon feeds will also be presented.

MATERIAL AND METHODS

Experimental design

The potential to reduce the levels of persistent organic pollutants, such as PCDD/F and DLPCB was investigated in a series of experiments using different approaches. In the first experiment, Atlantic salmon (*Salmo salar* L) with a initial mean weight of 1.8 kg was fed one of four diets with graded dioxin and dioxin-like PCB content for 7.5 months, in triplicate (final mean weight was 4.9 kg). The graded levels of dioxins and DLPCB were obtained by using two different fish oils: of Pacific origin (low dioxin) and of Baltic origin (high dioxin). The composition of the oil in the four diets was as follows:

- Diet A: 100% Pacific
- Diet B: 75% Pacific and 25% Baltic
- Diet C: 25% Pacific and 75% Baltic
- Diet D: 100% Baltic fish oil (for details see Lundebye *et al.* 2004).

In the second experiment Atlantic salmon were fed a fish oil based feed or a 100 percent substituted vegetable oil-based feed throughout an entire life cycle (from start feeding at 0.5 g until slaughter size at 2.2 kg), in triplicate for 22 months. The life cycle study included seven different feeding periods, with a different feed size for each feeding period. Fish and feed were sampled for all feeding periods from both vegetable oil (VO) and fish oil (FO) fed fish. The relative importance of several biological factors (growth, lipid deposition etc.) for the final contaminant levels in the fish, was

assessed by partial least square regression (PLS) modelling (for details see, Berntssen *et al.* 2005). In both experiments, fish and feed were analysed for those PCDD/F and DLPCB congeners that have been assigned Toxic Equivalency Factors (TEFs) by the World Health Organization (WHO), and results are given in WHO-TEQ. Feed–to-fish assimilation efficiencies were calculated for the various PCDD/F and DLPCB congeners after correcting for biological factors (for details see Berntssen *et al.* 2005).

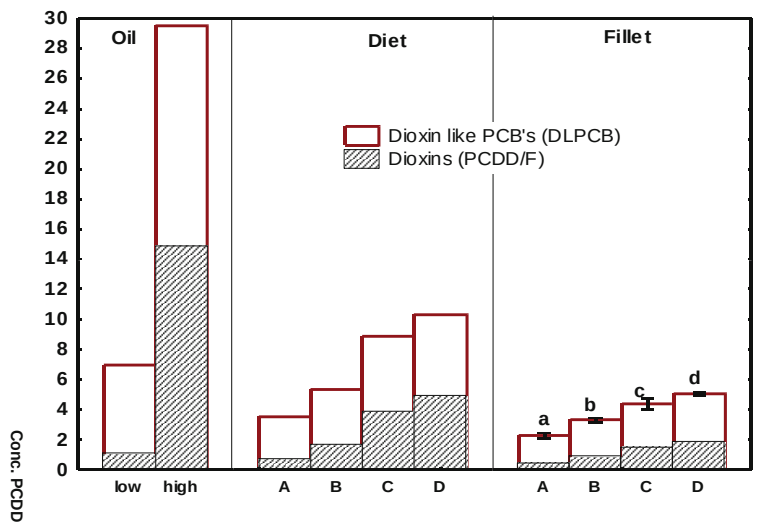
Dioxin analyses

Concentrations of PCDD/F and DLPCB were analysed using the following method (Berntssen *et al.* 2005). Briefly, fish and feed samples were homogenised and freeze-dried. Sample material was pressure solvent extracted using a Dionex accelerated solvent extractor (ASE 300™ Dionex, USA), at 125°C and 1500 PSI. To quantify the PCDD/F and DLPCB congeners, the extracts were spiked with ^{13}C labelled PCDD, PCDF, non-*ortho*- and mono-*ortho*-PCB standards (Cambridge Isotope Laboratories, Canada). The extracts were purified in a Power-Prep System™ (Fluid Management System, Waltham, MA, USA) using a sequence of columns (H_2SO_4 on silica, multilayered silica, basic alumina, and carbon column, respectively, FMS, Waltham, MA, USA) to separate and clean different groups of PCDD/F and DLPCB congeners. After extraction, the samples were concentrated by pressurised vaporation (Turbovap II™ Zymark,, USA). Prior to analysis, a mixture of ^{13}C labelled PCDD and PCB was added to the purified extract to provide relative recovery data on injection.

Analysis was performed by high-resolution gas chromatography/high resolution mass spectrometry (HRGC/HRMS, MAT 95XL Thermo Finnigan, Bremen, Germany), equipped with a fused silica capillary column (RTX-5SILMS, Restek, Bellefonte, USA). Quantification of each congener was based on the isotope dilution methods (1613 and 1668) of the US EPA (US EPA 1994, 1999). The congeners analysed included the 17 PCDD/Fs and 12 dioxin-like PCBs for which WHO has established TEFs for human risk assessment (Van den Berg *et al.* 1998). The concentrations of PCDD/F, dioxin-like PCB, or sum–TEQ of PCDD/F and DLPCB are expressed as pg upper-bound WHO-TEQ g^{-1} wet weight. Upper-bound is defined using the limit of quantification for each non-quantified congener to the TEQ (EC 2002)

FIGURE 1

Mean concentrations (in WHO-TEQ pg g-1 wet weight) of dioxins (PCDD/F; top open bar) and dioxin like PCB (DLPCB; bottom hatched bar), as well as total-WHO-TEQ PCDD/F and DLPCB (total bar as mean, standard deviation as error bars) in two different oils with low or high contamination level (left panel), four diets with different inclusion level of these oils (middle panel), and Atlantic salmon (Salmo salar) (mean initial weight 1.8 kg) fed on these diets for 30 weeks (right panel). Bars with different superscripts are significantly different from each other (P<0.005). (Lundebye *et al.* 2004.)



RESULTS

Reducing dioxins and dioxin-like PCB by selecting fish oils.

The mean PCDD/F and DLPCB concentrations in two different fish oils (high and low), feeds and

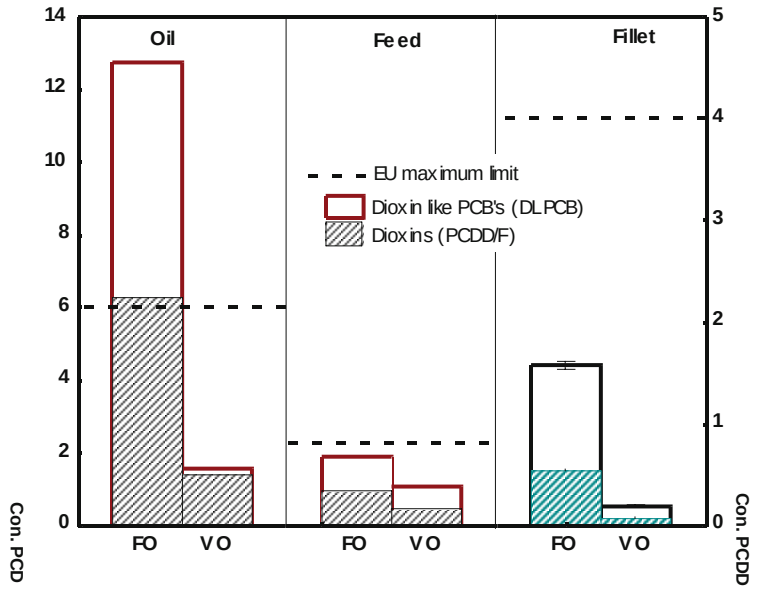
fish fillets (n=3 pooled samples per diet) at 30 weeks of the feeding trial (with four different diets, A-D) are given in Figure 1. The concentrations of PCDD/F and DLPCB in the fish reflected the levels present in the feed, and DLPCB contributed a greater proportion to the total TEQ than PCDD/F. After 30 weeks of dietary exposure, there were significant differences ($p<0.05$) in the concentrations of PCDD/F and DLPCB in the salmon fillets among all dietary treatments. The contribution of DLPCB to the total TEQ decreased with increasing concentration in feed and fillet. The decline was less apparent in fillet (from 79 percent to 63 percent) than in feed (from 79 percent to 52 percent).

Reducing dioxins and dioxin like PCBs by substituting fish oils with vegetable oils

The mean PCDD/F and DLPCB concentrations in feeds based on fish (FO) or vegetable oils (VO), and fish fillets (n=3 pooled samples per diet, per sampling time) after 22 months exposure are given in Figure 2. At the end of the experiment the levels of dioxins and dioxin-like PCBs were significantly ($p<0.05$) lower (8 and 12-fold, respectively) in the fillets of Atlantic salmon fed on VO compared to FO diets. As was the case for the fish fed on different fish oils, the contribution of DLPCB to the total TEQ was lower in feed (34 percent) than the fillet (64 percent).

FIGURE 2

Mean concentrations (in WHO-TEQ pg g-1 wet weight) of dioxins (PCDD/F; top open bar) and dioxin like PCB (DLPCB; bottom hatched bar), as well as total WHO-TEQ PCDD/F and DLPCB (total bar as mean, standard deviation as error bars) in fish oil (FO) and vegetable oil (VO) (left panel), diets based on these oils (middle panel), and Atlantic salmon (Salmo salar) fed on these diets from start feeding until slaughter weight (2.2 kg) (right panel and x-axis). Bars with different superscripts are significantly different from each other (P<0.005). Dotted line gives the current European Union (EU) upper limit for PCDD/F only in fish oils, fish feed and fish products. (Berntssen *et al.* 2005.)

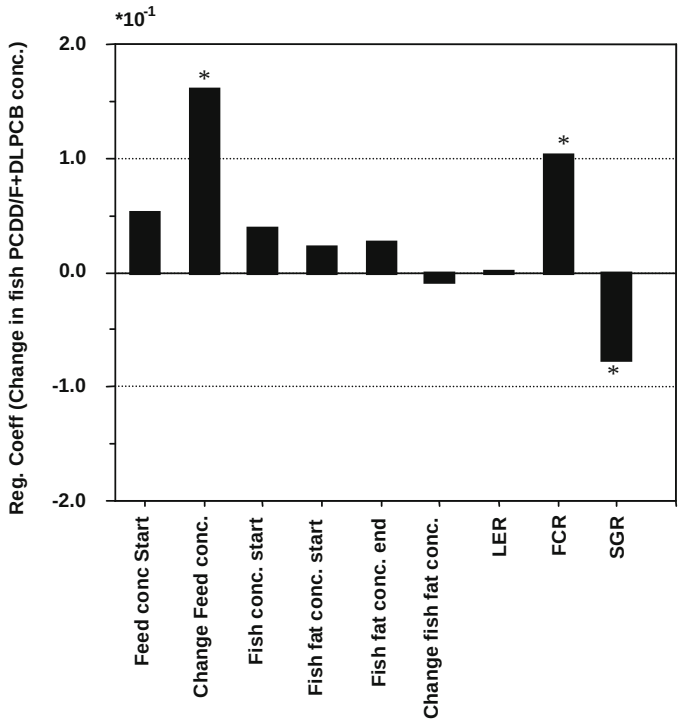


Other factors influencing dioxin levels

A long term study on the levels of total-TEQ PCDD/F and DLPCB in fish fed on vegetable oil and fish oil diets during an entire production life cycle showed that the changes in PCDD/F and DLPCB levels were related to other factors in addition to total TEQ PCDD/F and DLPCB levels in the feed. Periods with low growth (expressed as specific growth rate, SGR) and poor food utilisation (expressed as feed conversion ratio, FCR) caused the PCDD/F and DLPCB levels in the fish to increase and vice versa. A PLS (partial least square regression) model showed that the relative changes in total-TEQ PCDD/F and DLPCB levels over time was significantly correlated to the changes in feed concentrations, specific growth rate (SGR) and feed conversion factor (FCR) (Figure 3). Whole fish lipid content, changes in lipid content,

and lipid efficiency ratio (LER) had no significant effect on changes in whole body sum-TEQ PCDD/F and DLPCB levels (Figure 3).

FIGURE 3
Positive and negative correlations of different variables on the change of sum-TEQ dioxins and dioxin like PCBs (pgWHO-TEQ/g ww) in salmon during a life cycle (22 months). Effects of variables are expressed by regression coefficients in a PLS model. Variables that significantly affect levels in fish (change in feed concentration, specific growth rate [SGR] and feed conversion rate [FCR]) are marked with an asterisk. (Berntssen *et al.* 2005.)



Accumulation efficiencies

Accumulation efficiencies were calculated for 2.2 kg Atlantic salmon (Table 1), and were corrected for the additional factors that influenced tissue levels such as growth and feed utilisation. The accumulation efficiency for dioxins (sum PCDD/F congeners) was significantly lower (2-fold) than for dioxin-like PCB (sum DLPCB congeners). For dioxins, congeners with a lower degree of chlorination (4-5 chlorines) and higher WHO-TEF had a higher accumulation efficiency than dioxins with a higher degree of chlorination (6-8 chlorines), and lower WHO-TEF. For dioxin-like PCB no significant differences were observed among the dioxin-like PCB congeners with the chlorines in non-ortho position (higher WHO-TEF) compared with mono-ortho position (lower WHO-TEF). This difference in accumulation explains the relative increase of dioxin-like PCBs over dioxins in feed compared to fish that was observed in the two aforementioned feeding trials. This has also been reported for rainbow trout (*Oncorhynchus mykiss*) fed commercial fish feeds and feeds based on Baltic herring (Isosaari *et al.* 2002)

TABLE 1
Accumulation efficiencies (♋ %) for dioxins and dioxin-like PCB congeners in Atlantic salmon fed a fish oil diet (n=3, mean ± SD). Dioxins are divided into a group with a low degree of chlorination (Tetra-Penta chlorine) and a low range of WHO-Toxic Equivalency Factors (WHO-TEF), and high chlorination (Hexa-Octa) and high WHO-TEF. Dioxin-like PCBs were divided into non-ortho chlorinated PCB with a higher range of WHO-TEF and mono-ortho PCB with a lower range of WHO-TEF among the DLPCBs. (Berntssen *et al.* 2004.)

Congeners (chlorination)	TEF WHO	♋[1] (%)	Congeners (chlorination)	TEF WHO	♋[1] (%)
Dioxins	1.0-0.0001	43±6[a]	**Dioxin like PCB**	0.1-0.00001	74±9[a]
Tetra-Penta	1.0-0.5	49±7[a]	Non-ortho	0.1-0.0001	72±9[a]
Hexa-Octa	0.1-0.001	27±5[b]	Mono-ortho	0.0005-0.00001	75±8[a]

[1]Values in columns with the same superscripts are not significantly different (ANOVA, Tukey's *t*-test, P<0.05).

DISCUSSION

Feed to fish transfer of 'dioxins'

The potential threat to human health is not related to a single chemical component, but to a mixture of several related congeners of different chemical ground structures. For dioxins (polychlorinated dibenzo-*p*-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF)) and dioxin-like polychlorinated biphenyls (non-ortho PCB and mono-ortho PCB) a total of 17 out of 210 dioxin congeners (135 PCDF and 75 PCDD congeners) and 12 out of 209 PCB congeners are considered to have a common toxic. Dioxin and dioxin-like PCB concentrations can be expressed in terms of WHO Toxic Equivalents (WHO-TEQs), which are generated by applying Toxic Equivalency Factors (TEFs) to the 29 congeners. These factors are related to the toxic potential of the individual congeners in relation to the most toxic dioxin congener, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (Van den Berg *et al.* 1998). 'Dioxin' concentrations are occasionally expressed as the sum of all 29 PCDD/F and DLPCB WHO-TEQs.

The profile of these 29 congeners, and hence the sum WHO-TEQ, in feed is often not reflected in the fish. Some congeners (such as dioxin-like PCB) are more predominant in the fish than in the feed compared to other congeners. This can be explained by the difference in accumulation efficiency observed among certain congeners. The accumulation efficiency of PCDD/F and DLPCB have been reported in detail for both rainbow trout fed commercial fish feeds and feeds based on Baltic herring (Isosaari *et al.* 2002), Atlantic salmon fed on Pacific and Baltic fish oil (Isosaari *et al*. 2004) and Atlantic salmon fed vegetable oil and fish oil based diets (Berntssen *et al.* 2005). The accumulation efficiency of DLPCB in these studies was two to three-fold higher than that of PCDD/F (Isosaari *et al.* 2004; Berntssen *et al.* 2005), and seemed to be independent of feed contamination levels (Isosaari *et al.* 2004). Within the PCDD/F congener groups, tetra- and penta-chlorinated congeners were preferentially accumulated in salmon, whereas hepta- and octa-chlorinated dibenzo-p-dioxins were excreted in the faeces (Isosaari *et al.* 2004). Substitution patterns that were associated with a preferential accumulation of PCB in salmon included non-ortho substitution and tetra-chlorination (Isosaari and others 2004). The different carry-overs show the complexity of aiming for a "feed to fork" control of undesirable substances along the food chain. When selecting new feed resources to tailor a fish low in certain contaminants, differences in feed-fish transfer among the many contaminant congeners have to be taken into account.

Biological factors affecting dioxin levels in farmed fish

Generally, the PCDD/F and DLPCB burden in fish correlates with the level of lipid included in the diet, as shown for Atlantic salmon and rainbow trout (Karl *et al.* 2003; Berntssen *et al.* 2005). From ecotoxicological studies it is well-known that growth rate, which is strongly influenced by the feeding rate, also seems to be one of the predominant factors in determining PCB accumulation in wild fish (Nakata *et al.* 2002). Growth rate (leading to growth dilution of persistent organic pollutants (POPs)) is negatively correlated, and feed conversion ratio (increased deposition of POPs) is positively correlated with PCDD/F and DLPCB levels in fish (Berntssen *et al.* 2005). In addition to the reduction in the level of contaminants in the feed, the maintenance of an efficient feed conversion and high growth rate can be used to keep the level of dioxins as low as possible in farmed fish.

Tailoring farmed fish low in contaminants

Selective use of marine fish oils with naturally low levels of dioxins and dioxin-like PCBs, such as oil obtained from fish in the Pacific Ocean, has been reported to reduce the levels of dioxins, and to a lesser degree dioxin-like PCBs in farmed Atlantic salmon

(Isosaari et al. 2004; Lundebye et al. 2004). The relatively low reduction in dioxin-like PCB by using 'low dioxin fish oils' to reduce fillet contamination, is the combined effect of the relatively high contribution of DLPCB to the total WHO-TEQ level in these oils, and the dominant carry over of DLPCB from feed to fish. Salmon fed a 'low dioxin' fish oil diet had a total-TEQ PCDD/F and DLPCB level of 2.9 ng WHO-TEQ kg-1ww, which was not lower than the 'typical' level found in Norwegian farmed Atlantic salmon fillets on the market (approximately 2.5 ng WHO-TEQ kg-1 ww (Hites et al. 2004). Data from monitoring studies include randomly sampled Atlantic salmon farmed in Norway that have most probably been fed different types of feeds, which may therefore vary in the source of fish oil, fish meal, and may include alternative feed resources (see Norwegian Seafood data base at www.NIFES.no).

CONCLUSIONS

Substitution of marine oils with vegetable oils has been shown to be an effective approach to reducing the levels of both dioxins and dioxin-like PCBs in fish feeds and in Norwegian and Scottish farmed salmon (Bell *et al.* 2005; Berntssen *et al.* 2005). The full substitution of fish oil with vegetable oil gave a sum-TEQ PCDD/F and DLPCB level (Berntssen *et al.* 2005) that is eight to nine times lower than the current level found in Norwegian farmed Atlantic salmon fillets on the market. The use of vegetable oils seems to be a valuable tool for tailoring farmed Atlantic salmon low in dioxins and dioxin-like PCBs, and can therefore reduce the total intake of these contaminants by the consumers of farmed fish.

However, the increased use of vegetable oils in fish farming will also reduce the levels of health promoting nutrients such as very long chain omega-3 poly unsaturated fatty acids (VLCn-3 PUFAs) (Bell *et al.* 2005; Berntssen *et al.* 2005). Clearly, there is a trade-off between reducing undesirable substances and maintaining the nutritive status when tailoring farmed fish to be low in contaminants by using vegetable oils in the diet.

An approach to reconstituting the typical marine fatty acids in salmon fed on vegetable diets, is feeding with a full fish oil diet as a finishing diet during the last phase of salmon culture, until market size. Feeding fish oil diets to salmon previously fed on vegetable oil diets for six months nearly completely (80 percent) restored flesh VLCn-3 concentrations, while the dioxins and dioxin-like PCB concentrations were still 60 percent and 47 percent lower than salmon fed fish oil diets throughout the production cycle (Bell *et al.* 2005).

Decontamination of fish oils by the technical removal of POPs while maintaining the beneficial nutritive status (deKock *et al.*2004, Breivik and Thorstad 2004), is a further option that may support the production of Atlantic salmon low in contaminants and high in health promoting nutrients.

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International risk assessment for *Vibrio cholerae* in seafood

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ABSTRACT

Seafood exports are a major source of foreign exchange for many Asian countries. However, this trade is affected when there are reports of cholera in one or other of those seafood-exporting countries. This paper summarizes the results of a risk assessment for *Vibrio cholerae* in warm water shrimp processed for export. It concludes that the risks to human health are very low. It is hoped that this risk assessment will help regulatory agencies in importing countråies to take more appropriate risk management measures, and in particular to avoid making false alerts when non-01/non-0139 *Vibrio cholerae* are detected in raw shrimp.

INTRODUCTION

Seafood exports are a major source of foreign exchange for many Asian countries. Cholera is endemic in some of the seafood exporting Asian countries. Exports are affected whenever there are reports of a cholera outbreak. Shrimp constitute the major seafood commodity that is affected. In 2003, there were 4.3 million tonnes of shrimp in international trade, of which 70 percent was warm water shrimp. Considering the importance of shrimp from warm waters in international trade, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) set up a joint expert committee to perform a risk assessment for *Vibrio cholera* in warm water shrimp processed for export. This paper summarizes the findings of the FAO/WHO Drafting Group[1].

VIBRIO CHOLERAE: A PROFILE

Vibrio cholerae is a heterogeneous species consisting of over 220 serotypes. The disease cholera is caused only by serotypes O1 and O139. These are also referred to as choleragenic *V.cholerae* . Strains belonging to non 01/non-0139 serotypes of *V.cholerae* are widely distributed in the aquatic environment and they are mostly not pathogenic to humans, though occasionally, they may be associated with sporadic cases of gastroenteritis (Kaper *et al*., 1995; Desmarchelier, 1997). Choleragenic *V.cholerae* are characterized by their ability to produce a cholera toxin that is a complex protein consisting of A and B subunits. The production of cholera toxin is encoded by *ctx*AB

[1] For the complete risk assessment document, see FAO/WHO Microbiological Risk Assessment Series No 9, Risk Assessment of choleragenic Vibrio cholerae O1 and O139 in warm water shrimp in international trade.

genes. The *ctx* gene is present in a filamentous bacteriophage that infects *V.cholerae* through a pilus called toxin co-regulated pilus (TCP) (Waldor and Mekalanos, 1996; Faruque *et al*., 1998). Since the *ctx*AB gene is phage encoded and there may be loss of bacteriophage in some environmental strains, it is possible to isolate non-toxigenic *V.cholerae* O1 from the environment, and occasionally from seafood like shrimp (Colwell *et al*., 1977; Kaper *et al*., 1979; Dalsgaard *et al*., 1995). Serotyping alone is inadequate to detect choleragenic *V.cholerae* due to serological cross-reactions. Therefore the use of molecular techniques, such as polymerase chain reaction or DNA probe hybridization, have become important in determining the presence of choleragenic *V.cholerae* in seafood (Koch *et al*., 1993; Karunasagar *et al*., 1995)..

In the aquatic environment, *V.cholerae* may be associated with copepods. However copepods are planktonic organisms and shrimp are demersal organisms and therefore *V.cholerae* are generally not associated with shrimp in their natural environment. Under an FAO sponsored shrimp microbiology project during late 1980s, shrimp surface and shrimp gut were tested for the presence of *V.cholerae* in a number of countries such as India, Thailand, Sri Lanka, Indonesia, Malaysia and the Philippines. The data indicated an absence of choleragenic *V.cholerae* associated with shrimp (Karunasagar *et al.,* 1990; Fonseka, 1990, Rattagool *et al.,* 1990; Karunasagar *et al.,* 1992). Though one study in mid 1990s detected O1 *V.cholerae* in tropical shrimp, molecular studies indicated that the isolates were non-toxigenic (Dalsgaard *et al*., 1995).

RISK ASSESSMENT

For risk assessment, it would be important to consider the prevalence and concentration of choleragenic *V.cholerae* in shrimp during all stages of the food chain, from farm to fork. Warm water shrimp intended for export is handled according to Hazard Analysis and Critical Control Point (HACCP) guidelines. This involves the use of adequate clean ice to cool shrimp immediately after harvest, the use of potable water to make ice, and hygienic practices in handling and processing etc. Studies conducted in Peru during an epidemic of cholera in 1991 show that contamination of seafood with *V.cholerae* can be prevented by adopting HACCP measures.

Freshly harvested shrimp have a bacterial count of about 10^3-10^4 cfu/g, and diverse bacterial groups are present (Karunasagar *et al*., 1992). If contamination with *V.cholerae* occurs in raw shrimp, the organism has to compete with other natural flora on the surface of the shrimp. Indeed, studies indicate that *V.cholerae* is unable to multiply in raw shrimp (Kolvin and Robert, 1992). Studies conducted in our laboratory show that icing and storage in ice for 48 hours could lead to 2 log reduction in *V.cholerae* levels, even if the organism was present on shrimp before icing (Table 1). Studies conducted in Argentina show that freezing and frozen storage of shrimp could lead to 3-6 log reduction in levels of *V.cholerae* (Reilly and Hackney, 1985; Nascumento *et al*., 1998). Moreover, shrimp are usually consumed after cooking. *V.cholerae* is sensitive to heat with a D value of 2.65 minutes at 60°C. Thus it can be expected that there will also be about 6 log reduction in numbers during the cooking of shrimp.

For risk assessment, dose response data would be important. The data based on human volunteer studies conducted in United States of America in connection with cholera vaccine trials (Cash *et al*., 1974, Black *et al*.1987; Levine *et al*., 1988), indicate that the infective dose would be 10^6 choleragenic *V.cholerae*. Data on the prevalence of choleragenic *V.cholerae* in warm water shrimp was based on 'port of entry testing for *V.cholerae*' in Japan, the United States of America and Denmark. Out of 21,857 samples of warm water shrimp tested, only two were positive (0.01%) for choleragenic *V.cholerae.* The risk assessments assumed that 90 percent of warm water shrimp are eaten cooked and 10 percent are eaten raw (sashimi etc). Qualitative risk assessment indicated that the risk to human health is therefore very low. The risk of the organism

occurring in shrimp is low, and the organisms would need to multiply in the product to attain infectious levels, but during processing of warm water shrimp (icing, freezing, cooking), significant reductions in level are expected to occur (Table 2). Moreover, epidemiological evidence shows no link between imported warm water shrimp and cholera in importing countries. Semi-quantitative risk assessment using Risk Ranger (Ross and Sumner, 2002) estimated one case per century in Japan, 0.4 cases per century in the United States of America and 0.1 cases per century in European shrimp importing countries.

TABLE 1
Effect of processing on levels of choleragenic *V. cholerae* in shrimp

Processing step	Temperature distribution	Time distribution	Effect on population of *V. cholerae* O1
HARVEST **Handling time before icing**	15-35°C	0-1 hrs	No effect
Aquaculture shrimp **Wild caught shrimp**	10-30°C	0-3 hrs	0-1 log increase
WASHING **Washing and icing of aquaculture shrimp**	0-7°C	1-4 hrs	1 log reduction
Washing in seawater of wild caught shrimp	0-30°C	1-4 hrs	
ICING **Icing during transport (including on board fishing vessel for wild caught shrimp) to processor**	0-7°C	2-16 hrs (aquaculture) 2 – 48 h (wild caught)	2-3 log reduction
WATER USE **Water use during handling at processing plant**	4-10°C	1-3 hrs	No effect
TEMPERATURE **Temperature during processing before freezing**	4-10°C	2-8 hrs	No effect
COOKING **Cooking at processing plant**	>90°C	0.5-1.0 min (This is the holding time at >90°C)	>6 log reduction
FREEZING **Freezing of cooked and raw products, storage, and shipment time**	-12 to -20°C	15-60 d	2-6 log reduction

TABLE 2
Qualitative risk assessment for choleragenic *Vibrio cholerae* in warm water shrimp

Product	Identified hazard	Severity	Occurrence risk	Growth in product required to cause disease	Prod^{n}/process/ handling ↑↓→ hazard	Consumer terminal step	Epidemiological link	Risk Rating
Raw shrimp	*V. cholerae*	II	Low	Yes	↓ Inactivation during washing, icing, freezing	No	No	Low
Shrimp cooked at the plant and eaten without further heat treatment	*V. cholerae*	II	Low	Yes	↓ Inactivation during washing, icing, cooking (optional), freezing	No	No	Low
Shrimp cooked immediately before consumption	*V. cholerae*	II	Low	Yes	↓ Inactivation during washing, icing, (optional), freezing, thawing and cooking	Yes	No	Low

Source: FAO/WHO (2005) Risk assessment of choleragenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade. Microbiological Risk Assessment Series, No. 9. Rome.

CONCLUSIONS

The findings of this risk assessment are very important for risk managers in shrimp importing countries. For some shrimp importing countries, the term ' *V.cholerae* ' means the causative agent of cholera. However, the FAO/WHO risk assessment has clearly shown the differences in pathogenicity and the relative health risks due to choleragenic *V.cholerae* and other non- 01/non-0139 *V.cholerae*. It is hoped that this risk assessment will help regulatory agencies in shrimp importing countries to take appropriate risk management measures to avoid making false alerts when non-01/non-0139 *V.cholerae* are detected in raw shrimp. The evidence suggests that the risks to human health are actually quite minimal.

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Cost-benefit analysis and risk management

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ABSTRACT

The paper presents a general review of cost-benefit techniques applied to public health regulations. It reviews those techniques from the perspective of official government agencies having jurisdiction, from the perspective of industry, and from the perspective of society as a whole. In the formulation of new food safety regulations government agencies can assess the costs and benefits of regulatory alternatives in order to select those that maximize net benefits. Compliance with a regulation represents a cost to industry, albeit partly offset by preventing product rejections, consumer illness, and potential liability. The benefit exists only if the system works properly and ensures continued market access for those products. However, industry typically seeks additional profitable uses for the information and/or the systems that the specific regulation obliges. Cost-benefits to society are assessed using two indices: willingness-to-pay (WTP), which measures how much individuals are willing to pay in exchange for the reduction of a risk to their health; and the cost-of-illness (COI), which estimates the cost of disease in the population. In general WTP is greater than COI.

INTRODUCTION

Methods for analyzing the costs and benefits of food safety regulations can be classified into two broad groups: (i) methods of interest to public health agencies when studying the cost-benefit of new or revised regulations and, (ii) methods of interest to industry. Public health agencies are more interested in the overall cost-benefit picture, "including potential economic, environmental, public health and safety and other advantages; distributive impact and equity" (US Federal Register, 1993). The industry is more interested in methods that allow assessment of specific cost-benefits. In both cases, cost-benefit analysis is a key tool for analyzing different risk management alternatives.

In the United States regulations require agencies not only to assess the costs and benefits of regulatory alternatives, but also to select those that maximize net benefits. Similar provisions can be found in Australia (Council of Australian Governments, 2004) and Canada. This raises the question of what is the most appropriate method for estimating the costs and benefits of a risk management decision from the point of view of society overall. Public health agencies aim to systematize and eventually standardize methods in order to achieve transparency and consistency between and within government agencies (Kuchler, 2001). Transparency and consistency are essential to allow estimates to be reviewed and discussed by interested stakeholders, such as industry, consumer associations, political parties, government control bodies, academia, and foreign commercial partners, etc.

A regulatory requirement represents a cost to industry; the benefit exists only if the system works properly (preventing product rejections, and consumer illness, injury or

death) and reduces eventual (or potential) liability costs. These kinds of benefits, as well as affecting market access, are perceived by industry as common benefits; accruing to all companies that implement the requirements. Industry management is particularly interested in identifying additional uses for the information and/or the systems that the specific regulation obliges them to have; uses that could provide an additional comparative advantage to their company. It should be possible to verify results in practice, based on information obtainable at the company level (Zugarramurdi et al., 2000). This focus on tangible benefits does not mean that the industry lacks vision or social commitment; it is part of the legitimate approach of any company attempting to deliver safe food in compliance with regulatory requirements.

This paper presents a general review of cost-benefit techniques applied to public health regulations, from the industry perspective as well as from the perspective of society as a whole.

COSTS OF ACTUAL FOOD OUTBREAKS AND COST-BENEFIT ANALYSIS

The consequences to the consumer of a food incident can range from simple diarrhoea to premature death. In monetary terms the overall costs could range from the cost of an anti-diarrhoeal pill and a temporary decrease in an individual's productivity (with no direct cost to the company responsible), to several million and even billions of US dollars (in fines, compensation, legal costs, etc.), or even the bankruptcy of the company found liable. Some costs of food outbreaks, associated with *C. botulinum* toxin in fish appear in Table 1.

TABLE 1
Costs of botulism associated with canned fish products (Todd, 1985)

Year	Product	Where eaten	No of fatal cases	Total costs (US$ of 1986)
1963	Canned tuna	USA	3	167 300 600
1978	Canned salmon	UK	4	6 277 650 [1]
1982	Canned salmon	Belgium	2	150 181 900

[1] The negative economic impact of this incident on the UK fishery industry was estimated in some additional US$4 million.

Evaluation of the costs of food outbreaks in Canada and the United States of America, based on all available information, show that company losses and legal action are much higher than medical/ hospitalization expenses, lost income or investigational costs (Todd, 1989a). In addition, the average cost for industrial food processing incidents is found to be 70 times higher than the average costs of incidents linked to food-service establishments, markets, homes, farms and communities (Todd, 1989b). Depending on the country's regulations and its compliance with due diligence, products can be seized, injunctions can be presented, companies and executives fined, licences withdrawn and, in extreme situations, those responsible can be prosecuted and imprisoned (Todd, 1987) (Zugarramurdi, et al. 1995). However, safety regulations are also intended to protect the industry, particularly the industry that is in compliance with regulations, from unfair competition and undesired economic effects of food outbreaks. The information presented in Table 1 is useful to measure the economic impact of actual food outbreaks but not to estimate *a priori* normal costs or benefits for specific risk management measures.

The challenge raised by new regulations is that of assessing *a priori* normal costs and possible benefits. The economic significance of any failure is linked to the efficiency and effectiveness of the specific food safety methods adopted, rather than to the normal costs and benefits inherent in the method chosen. Something equivalent could be said from the industry perspective. Avoidance of failure is a hypothetical and general benefit derived from compliance with the law, but it can not be taken *a priori* as a benefit. Different methods have been proposed to analyze costs-benefits *a priori* in the

case of food safety regulations (Caswell, 1991, 1995 and 1998) (Kuchler and Golan, 1999) (Wilson and Crouch, 2001) (Kuchler, 2001). In particular, the economics of food traceability (not specifically for fish and fish products), in the United States context, has been studied by Golan et al. (2004a and 2004b).

COST-BENEFIT ANALYSIS FROM A REGULATORY POINT OF VIEW

Caswell (1998) reviewed different monetary and non monetary benefits and costs of improved safety and nutrition. Kuchler and Golan (1999) examined five different methods of cost-benefit analysis. The Economic Research Service of the United States Department of Agriculture (USDA) utilizes two monetary methods to research the cost-benefits of food safety regulations: the willingness-to-pay (WTP) and the cost-of-illness (COI) (USDA, 2001). The WTP is the preferred method for analyzing cost-benefit at the United States Food and Drug Administration (FDA) (Williams and Jessup; 2004)[1]. The main features of both methodologies are as follows:

Willingness-to-pay (WTP): measures how much individuals are willing to pay in exchange for the reduction of a risk to their health. Information on willingness-to-pay is worked out from a number of different sources such as: how much people are actually spending in fire alarms, life insurance premiums and coverage, etc.

Cost-of-illness (COI): Estimates the cost of disease in the population, including medical costs and lost income, without the provisions of a given food safety regulation, and then estimates the same kinds of costs with the regulation in place. The difference between the two is considered the regulation's benefits. In the case of the COI for those who die during either the acute illness or with chronic organ failure (extreme situation), the present value of the reduced stream of earning is calculated. The "Value of Statistical Life" (VSL) proposed by Landefeld and Seskin (1982) is represented by the equation:

Value of statistical life = α (1)

Where:

T = remaining lifetime

t = a particular year

Yt = after tax income, including labour and non-labour income

r = individual's opportunity cost of investing in risk-reducing activities (e.g. 0, 02 – 0, 05)

α = risk aversion factor ($\alpha > 1$) (this factor is not accepted by all the authors)

Formal comparisons of costs and benefits, with regulatory purposes, are not straightforward, as has been discussed by different authors (Kuchler and Golan, 1999) (Wilson and Crouch, 2001) (Kuchler, 2001). Some difficulties are of a technical and conceptual nature while others, like the need to define the "Value of a Statistical Life" (VSL), may trigger discussions on ethical and political issues. These issues are outside the scope of this paper.

In general WTP is greater than COI and some authors have suggested that COI is the lower boundary of WTP (Caswell, 1998). Viscusi (1993) reviewed different studies and suggested that the VSL is somewhere between US $2 million and US $8 million, from the overall range of US $100,000 to US $10 million. From this range of estimates, the VSL utilized by the different agencies of the United States Federal Government was US $5.9 million (1997 US$ dollars) (Shogren et al., 2001). An example of a regulation that has been introduced in the United States of America, following this type of analysis is the USDA-FSIS regulation on *"Nutrition labelling of meat and poultry products"* in 1993. In this case the benefits were estimated at US$ 1.75 billion, whereas the costs were estimated in the range of US$ 218-272 million. The depreciation was taken over 20 years, and discounted at 7 percent (US Federal Register, 2003).

[1] There are other monetary and non-monetary methods not discussed in this paper.

BOX 1

Possible scheme for cost-benefit analysis from a regulatory point of view

(1) Determine the number of people affected per year (e.g. hospitalizations, sequel and premature deaths) *without any new* regulatory intervention (risk management option) (*). Base of reference, to check against epidemiology records.
(2) Determine the number of people affected per year with risk management option 1 (*).
(3) Determine the number of people affected per year with risk management options 2, 3, etc. (*).
(4) Determine the difference in people affected for each risk management option.
(5) Based on the differences found in step (4) calculate the benefits for each risk management option (either based on COI or WTP).
(6) Calculate the costs for implementing each risk management option, including regulatory costs. These costs will depend on the cost of the technological alternatives associated with each risk management option.
(7) Find the difference between benefits and costs for each risk management option. Concentrate on options that maximize net benefits.
(8) Analyze trade-offs and risk-risk situations that may be created by each risk management option (e.g. solutions that require increased transport by road will increase the risk of people killed in road incidents).
(9) Analyze to determine if there is more than one technological alternative to produce about the same net benefits. If there were more than one alternative, then probably the regulation would not need to prescribe a specific technological method.
(10) Open the results to scrutiny by stakeholders (consumers groups, industry, and academia).

(*) A proper quantitative risk assessment would be necessary. Most traditional food regulations are based on hazards for which there isare already strong epidemiological evidence.

The USDA has an online "foodborne illness cost calculator" (USDA, 2003) that allows examination of the impact of different assumptions on cost estimates and risk rankings. It is also possible to introduce one's own data to predict the potential costs of foodborne illness for new conditions.

INDUSTRY AND REGULATORY REQUIREMENTS

Faced with new regulatory requirements even the smallest industry will conduct some sort of cost-benefit analysis, to determine if it can bear the cost, or investment. The fact that a given regulation might be advantageous for society overall does not mean that it would be economically advantageous, or feasible, for a specific industry. Regulators cannot assume that the whole industry will seek to comply with a new or modified regulation. The industry has, in practice, a number of initial options such as the following:

(i) stop production: to quit the industry by stopping operation of the product/ line/ plant;
(ii) change products: to move operations to a product with lower safety requirements (for example, from value added to (just) frozen fillets to frozen fish to fresh fillets];
(iii) change markets: to shift production to a market without the new requirement (either international, regional, national);

(iv) stall: take advantage of the inevitable long explicit or implicit implementation time (no regulation is enforced overnight);
(v) fake compliance: pretend to have achieved compliance; and
(vi) become compliant: achieve compliance because it is profitable (in some way) for the industry.

The quit option actually occured in developing countries following the introduction of the requirement for Hazard Analysis and Critical Control Point (HACCP) based systems for export; the number of fish exporters was drastically reduced. The amount of fish exported may eventually reach the former level but it would come from a smaller number of exporters. The effect of the HACCP in the international market was to consolidate the offers from the exporter country and in some cases to reduce intermediation.

Options (ii), (iii) and (iv) have also occured in practice. Option (v) is the "gambling" option; since detentions and rejections continue it is clear that a part of the fish industry opts for it. Option (vi) is the most positive from the point of view of the *status-quo* of the overall existing market, however, actual implementation could depend of many factors, including the nature of the specific regulation and what is asked for in practice (e.g. in terms of new equipment, procedures, labour) to achieve it. The decision to achieve compliance is, in turn, based on one of the following:

- assuming the costs as a (bearable) market entrance fee (pure cost);
- capitalization of possible marketing advantage (e.g. quality claim, consumer assurance);
- capitalization of possible reduction in production costs; improvements in productivity and/ or management associated with the methods to achieve compliance;
- some combination of the previous two.

As discussed above, the first advantage to industry of compliance with regulatory requirements is market access. The second advantage is the prevention of crisis situations resulting from rejections, recalls and withdrawals. Industry naturally prefers that the costs of implementation and the operation of a new regulatory system are covered by the benefits it generates or that it creates additional benefits.

COSTS AND BENEFITS FOR SOCIETY

Since COI and WTP as well as VSL are strongly influenced by local and national conditions, calculations in two different countries will yield different values. Large differences in such values are *de facto* at the root of misunderstandings related to food safety regulations between (developed) importing and (developing) exporting countries. For most developing countries it is likely that:

[Average VSL developed country] >> [Average VSL developing country]

However, the implementation costs, particularly if investment and new technologies are required, will be the same or even higher in developing countries, particularly if the new technology must be imported.

In a developing country, under this situation new food safety regulation may either not be adopted or only adopted for export foods. This is particularly so for HACCP where a large number of developing countries meet European Union (EU), United States, Canadian and Australian HACCP-based regulations but have not yet adopted a HACCP regulation at national level. This asymmetry creates a number of practical problems that are likely to become more critical as developed countries adopt more regulations and decisions based on systematic risk analysis. Under this scenario individual regulations are not isolated one from the other, because they are all targeted

with the express purpose of achieving FSOs (Food Safety Objectives) consistent with a risk analysis approach.

COSTS AND BENEFITS FOR THE INDIVIDUAL INDUSTRY

Cost-benefit analysis from the point of view of industry can also vary depending on regulatory requirements. However, the fishery industry in developing countries may still gain additional benefits from implementing safety regulations (Zugarramurdi et al., 2000). Lower labour and other costs can give a comparative advantage compared with developed countries but it is improved productivity that will ensure a sustainable place in the international fish market. The costs of machinery (refrigeration and freezing, processing), stainless-steel components, and energy are more or less equivalent throughout the world.

Over the last decade the export fishery industry in developing countries has become technologically similar to the industry in developed countries. This is not only because of pressure from external regulations, but also the need to achieve comparable productivity levels both in physical and economic terms. As a result, the safety and quality of fish and fish products in many developing countries has improved, despite not having an explicit HACCP regulation at national level in such countries.

Difficulties may also arise due to the lack of equivalence or harmonization in international fish regulations. This can occur when each importing country sets slightly different requirements, and in particular procedures and records, which can increase the cost to the fishery industry in exporting countries without the potential to develop additional sources of income. For instance, the costs of traceability required by the United States FDA Public Health and Bioterrorism Preparedness and Response Act, are paid for by companies in exporting countries[2], but have no benefit in terms of improving supply-side management for individual companies. They are also irrelevant in relation to the 'traceability' that has to be provided, for instance, to European importers. For the exporting company the costs of such traceability represent a new market access cost, with no corresponding returns.

Other potential conflicts with the costs and benefits of regulatory requirements for developing countries are those that may affect artisanal capture and aquaculture production and live bivalve exports. Many regulations (e.g. in the United States of America and the EU) incorporate chapters on "flexibility" in their food safety regulations in relation to their own artisanal and small-scale production. However, these provisions are not extended to producers in developing countries. As noted by Buzby (2003) there is definitely a need for further studies on the economic impact of food safety regulations on international trade. The costs and benefits of improved fish (and food) safety regulations in developing countries also merit further research.

CONCLUSIONS

It is definitely advantageous to analyze food safety regulations from the point of view of their costs and benefits, both in monetary and non-monetary terms. From the literature it is clear that this view permits a different understanding than can be reached by consideration of food safety, processing, politics and even marketing. The analysis of costs and benefits is a useful tool for assigning resources both at the level of industry and for society overall. Although cost-benefit analysis is a very powerful tool in risk management, final decisions may depend on other value criteria both at the regulatory level as well as at industry level.

It is possible to separate the analysis of costs and benefits of regulatory measures in a cost-benefit analysis for society and for an individual company. In the case of cost-

[2] The cost of such traceability system for the industry is in the order of US $ 450 per year to keep the mandatory communication agent in the USA plus US$ 29.95 per shipment (record) (FDA Registrar, 2005).

benefit analysis of regulations for society, there are already some methods in use in developed countries. Of particular interest for individual companies are the benefits that could be earned, other than those resulting from market access, from compliance with regulations. However, there are currently no specific methods for analyzing for these additional benefits.

Cost-benefit analysis cannot be extended from developed to developing countries. There is a need for developing countries to develop their own capability in relation to regulatory measures, both to assist the introduction of relevant safety regulations at national level as well as to improve their position in international trade. There is a need for further analysis of the impact of food safety regulatory measures on international fish trade

A conscious cost-benefit analysis of regulatory measures by industry could lead to proactive measures to mitigate the potential risks to consumers of unsafe products. In the particular case of developing countries exporting fish and fish products, such an approach could also improve the safety of fish and fish products destined for the internal market, even where there is an absence of HACCP-based regulations applying to production for local consumption.

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[3] Initially issued by the Clinton Administration it was reaffirmed by the Bush Administration. The Executive Order lays out the principles and procedures that govern centralized regulatory oversight in the USA.

[4] Chapter 8 is devoted to Quality and Safety Economics in the context of the fishery industry.