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Brazilian legal framework on shellfish safety and its effects on the growth of shellfish farming and commerce

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Abstract

Shellfish are among the most at-risk foods of the occidental culture, requiring special control along all the production chain to provide safe products to the population. *Codex Alimentarius* regulations offer orientations to the control and guarantee of shellfish safety, but the practical application of their indications shall be hampered at the local level by several elements: political, logistic and geographic, as examples. In this article, we provide a comprehensive review of the Brazilian legislative framework on shellfish safety in comparison to those proposed by other trading blocs, mainly the European Community and the USA. Our analysis points out how the simple application of international guidelines on shellfish safety designed for non-tropical areas, the lack of political interest, and scientific orientation, and the concentration of reference laboratories in the extreme south of Brazil, hamper the development of safe and legal shellfish farming and commerce in the rest of the country.

Key words: aquaculture development policies, food safety, risk analysis, risk management.

Introduction

Shellfish production is among the most accessible forms of aquaculture. The ease of breeding, handling, storage, industrialization, and the high aggregated value of some species are an element that may stimulate many producers to begin the activity of shellfish farming. As all animal productions aiming to provide food, the shellfish production chain shall comply with laws regarding food safety according to the 'from farm to fork' concept (EC 2002). This compliance is crucial, as shellfish are filter feeders and shall be consumed raw or lightly cooked (CEFAS 2014). The standardization of control measures applied in the different countries and food inspection procedures is a crucial element to allow international trade of foods among countries belonging to the same trading block or among different trading blocks (Toledo 2014; Rodgers *et al.* 2015). Harmonization should always follow international standards, guidelines, such as those provided by the *Codex Alimentarius Commission* (Codex Alimentarius 2014) and always scientifically based (WTO 2015).

Sanitary inspection of bivalve molluscs differs from that performed on vertebrate animals. The simplicity of the physiology of these animals and the dramatic effects of environmental changes on their health and feeding activity (Morley 2010; Souza *et al.* 2012; Cappello *et al.* 2013) require a holistic vision focused not only on the animal but also on the surrounding environment. As considering the relevance of the environment on shellfish sanity and safety, the laws of different countries include the preventive study of the environment, pollution sources and dispersal as a central element to define the risk of contamination of shellfish, even before the beginning of the breeding process (EU 2012; Fda/Cfsan_Nssp 2016).

The world aquaculture production of molluscs other than cephalopods in 2016 was almost 17 200 tons. The highest shellfish producer countries are in Europe (over 612 000 tons in 2016) with their primary products being mussels (479 351 tons in 2016) and oysters (83 420 tons in 2016). Among South American countries, the main shellfish-producing country in 2016 was Chile: 302 344 tons of mussels, 270 tons of oysters, and 3547 tons of scallops and pectens (these data are estimated according to the FAO website). The 2016 Brazilian production of shellfish was lower than that of Chile: 18 200 tons of mussels, 2700 tons of oysters and according to FAO, no declared production of scallops and pectens (FAO Fisheries and Aquaculture Department 2018).

The production of bivalve molluscs in Brazil is widespread from the extreme south (Santa Catarina State), upward through the states of São Paulo, Rio de Janeiro, Espírito Santo, until the northern region (State of Piauí). The most important species produced in Brazil are brown mussels: *Perna perna* (Linnaeus, 1758), oysters: *Ostrea edulis* (Linnaeus, 1758), and *Crassostrea gigas* (Thunberg, 1793) mostly in the colder waters of the South of Brazil, two native oysters species: *Crassostrea gasar* (Adanson, 1757), and *Crassostrea rhizophorae* (Guilding, 1828) in the warmer waters of the North and Nort-east Brazil, and scallops: *Euvola ziczac* (Linnaeus, 1758) and *Nodipecten nodosus* (Linnaeus, 1758; Rupp *et al*. 2008; Figueredo 2012; Sampaio *et al*. 2017). Most of the Brazilian production of farmed bivalve molluscs (95%) is in the State of Santa Catarina, in the Southern Region of the country. In 2012, this state produced 16 226.6 tons of molluscs: 13 753 tons of brown mussels (*P. perna*), and 2468 tons of oysters: *C. gigas*, and 5.6 tons of scallops (*N. nodosus*; Miotto 2012; Jacomel & Campos 2014; Suplicy *et al*. 2015; Sampaio *et al*. 2017). More recent data referred to the State of Santa Catarina display a substantial reduction in the production of shellfish in 2015 and 2016 as compared to the previous years (21 554 tons in 2014; 20 430 tons in 2015, and 15 381 tons in 2016). Production decrease seems to be associated both with environmental and human causes. In 2015, shellfish commercialization was affected by an extended persistence of red tide. The excessive growth of shellfish (mainly mussels) caused overweight on the ropes of the longlines causing their rupture and the loss of the production. At the same time, regular producers faced the uncontrolled concurrence of illegal harvesters, selling to the public shellfish from polluted or restricted areas (Santos *et al*. 2017).

Since the beginning of the development of shellfish farming in the decade of 1980, Brazil developed a framework of laws intended to guarantee the safety of these products from the sea to the table. Political decisions hampered the implementation of this framework over the last years. The difficulties in complying all current legislation are an obstacle to the legalization of shellfish production and commerce and may difficult the guarantee of the safety when these products are commercialized and offered to the final consumers. Several local studies performed in different parts of Brazil displayed both potentialities and difficulties in the shellfish breeding sector (Suplicy *et al*. 2015; Sampaio *et al*. 2017), but still, a more comprehensive study on the Brazilian legislation on shellfish hygiene was lacking. This paper aimed to provide a critical description of the complete Brazilian legislative framework of shellfish safety and to compare it to correspondent frameworks of other trading blocks, such as the USA and European Union, or specific scientific literature. Through these comparisons, we aim to highlight those parts of Brazilian legislation which could be improved or altered, to provide higher functionality to the entire shellfish inspection process and allow sustainable and legal growth of shellfish breeding along the entire Brazilian coast.

Materials and methods

To perform this survey, we searched different websites from Brazilian and international food safety agencies, web news and official documents from the Brazilian government or from other countries between August 2016, until March 2018. This long survey was necessary as considering the development of Brazilian political situation associated with fishery and food safety.

The survey of Brazilian legislation on shellfish safety was performed by collecting information in the *Ministério da Agricultura, Pecuária e Abastecimento* (MAPA; Brazilian Ministry of Agriculture, Stockbreeding, and Supply) website, and its legislation page: SISLegis; other websites, electronic data from the Brazilian government, and scientific papers dealing on food inspection and fishing products inspection in Brazil. The list of the main websites consulted in the survey is in Appendix I. Keywords for the research among sites in Portuguese were as follows: 'molusco bivalve' (bivalve mollusc), 'ostra' (oyster), 'vieira' (scallop), 'mexilhão' (mussel), 'sanidade aquícola' (aquaculture sanity), 'legislação sanitária' (sanitary legislation), '*lei*' (law).

The survey of international legislation, guidelines, and scientific studies on shellfish inspection was performed by collecting information from different websites of legislation in English and Spanish, such as: Food and Agriculture Organization-Fisheries and Aquaculture Department National Aquaculture Legislation Overview (NALO), *Codex Alimentarius*, European EUR-Lex, British CEFAS, United States Food and Drug Administration (FDA), Chilean Sernapesca, Mexican Cofepris, Canadian Food Inspection Agency, New Zealand Ministry of Primary Industries, and Food Standard Australia. Scientific papers on shellfish safety were searched using NCBI search engine from January 2017, until March 2018. The list of the main websites consulted in the survey is in Appendix I.

Keywords for the search among sites in English and Spanish were, respectively: 'shellfish', 'bivalve mollusks', 'oyster', 'scallops', 'mussel', 'sanity', 'law', 'legislation' and 'moluscos bivalvos', 'ostra', 'vieira', 'mejillón', 'sanidad', 'lei', 'legislación'.

Results

Brazilian legal framework on shellfish safety

Shellfish aquaculture in Brazil began in the State of Santa Catarina in 1987, as the local Federal University (UFSC:

Universidade Federal de Santa Catarina) introduced this activity within the local fishermen community. Since then, the number of shellfish farmers has increased steadily (Suplicy *et al.* 2015). The creation, in 2003, of a specific Secretary for Aquaculture and Fishery (SEAP: *Secretaria Especial de Aquicultura e Pesca*) and the promulgation of a specific Normative Instruction (IN: *Instrução Normativa*) fostered the development of shellfish farming in the State, guaranteeing the availability of public waters for aquaculture (Jacomel & Campos 2014). Together with the Ministry of Environment, SEAP developed a regulation for the local development of sustainable marine aquaculture in the State of Santa Catarina (PLDM: *Planos Locais de Desenvolvimento da Maricultura de Santa Catarina*). The regulation defined specific areas for this activity within the State, by environmental impact, socio-economy and public health (Novaes *et al.* 2010; Suplicy *et al.* 2015).

In 2009 the Brazilian President founded the Ministry of Fishing and Aquaculture (MPA: *Ministério da Pesca e Aquicultura*) which together with the MAPA developed a Federal Legal Framework to organize the sanitary control of mollusc production in 2012.

The central Brazilian laws on the hygiene of the production of bivalve molluscs are as follows: the Decree 9013/2017 (altered by the Decree 9069/2017) on industrial and sanitary inspection of animal-derived foods (RIISPOA: *Regulamento de Inspeção Industrial e Sanitária de Produtos de Origem Animal*) and the interministerial Normative Instruction 7/2012 emanated by MAPA and MPA together (Brasil 2017a,b, 2012a).

The RIISPOA is the leading Brazilian law on the inspection of animal-derived foods. This norm includes all the aspects of food inspection in general: meat and meat products, milk and milk-derived products, eggs, honey, and fishing products. Among fishing products, specific directions rule the inspection of shellfish and shellfish-derived products. In this norm, there are specific requirements for industrial plants for the reception, inspection, cleaning, depuration, labelling, and expedition of shellfish. The law also defines the physical and biochemical features of live molluscs for human consumption and expands the rules of inspection of bivalve molluscs to terrestrial gastropods, and echinoderms.

More specifically, the control of shellfish safety is the theme of the IN 7/2012 and associated laws. IN 7/2012 is the core of the legal framework of shellfish safety in Brazil, establishing the national programme for hygienic and sanitary control of bivalve molluscs (PNCMB: *Programa Nacional de Controle de Moluscos Bivalves*), and the 'minimum required conditions to guarantee safety and quality of bivalve molluscs destined to human consumption and to control and inspect the satisfaction of these conditions' (Brasil 2012a). Besides this, other norms deal with the inspection of shellfish. The Interministerial Ordinance (Portaria: *Portaria*) 204/2012 establishes the procedures for the sampling of microbiological contaminants and toxins in bivalve molluscs, the procedures for the analysis of microalgae potential producers of toxins, and defines the official analytical methods which have to be used (Brasil 2012b). The Portaria 175/2013 provides minor modifications to the previous IN 7/2012 and defines the interpretation of the results of bacteriological and biotoxicologic samplings (MPA 2013a). Besides these laws, MPA produced an operative manual for the application of the PNCMB (Brasil 2012a,b; CGSAP/DEMOC/SEMOC/MPA 2013; MPA 2013a).

Together with the development of the PNCMB, MPA developed reference laboratories responsive for analyses and diagnostics on aquatic organisms and the safety of seafood, called RENAQUA (IN 3/2012). RENAQUA net includes central official laboratories (AQUACEN), specialized official laboratories (LAQUA) and accredited peripheral laboratories (MPA 2012, 2013b). According to the law, there should be two AQUACEN: the one responsive for animal health, the other responsive to the control of residuals and contaminants (MPA 2012). At this moment (August 2018), only the former is active (Aquatic animals diseases diagnostic laboratory at the Federal University of Minas Gerais-UFMG- in the South-Eastern Region of Brazil; MPA 2013b, 2014). Designed LAQUA laboratories are the CIDASC-Joinville in the State of Santa Catarina (Southern Brazil Region) for the diagnosis of aquatic animal diseases (Portaria MPA 125/2012); the laboratory of Research and Monitoring of harmful algae of the Federal Institute of Education, Science and Technology of Santa Catarina (IFSC) in the city of Itajaí (Southern Brazil Region) for the analysis of marine biotoxins (Portaria MPA 122/2012); and the laboratory of diagnosis of diseases of aquatic animals of the State University of Maranhão (Northern Region of Brazil), for the diagnosis of crustacean diseases (Portaria MPA 123/2012; MPA 2013b, 2014).

PNCMB covers shellfish production and processing: through harvesting, transport (logistic) and industrialization. According to this norm, the safety of shellfish and shellfish products depends on microbiologic and biotoxicologic features.

For sanitary purposes, 'breeding or harvesting areas' (*áreas de extração ou cultivo*) are divided into several 'aquaculture parks' (*parques aquícolas*). Each park may contain one or more 'aquaculture areas' (*áreas aquícolas*; CGSAP/DEMOC/SEMOC/MPA 2013; Suplicy *et al.* 2015). MPA manual does not indicate any specific protocol to define the extension and geographic division among 'breeding or harvesting areas', 'aquaculture parks' or 'aquaculture areas'. Microbiologic and biotoxicologic samples should be collected from each breeding or harvesting area.

According to the MPA manual, the election species to be sampled for analyses of bivalve sanity should be the mussels (*P. perna* and related species belonging to the Mytilidae Family). The manual recommends, in the case of absence of these species in the sampling area, either to sample other species or to breed mussels just for sanitary analyses purposes. The veterinarian officer in charge has the responsibility to define the sampling point in each sector used for the breeding or harvest of bivalve molluscs. According to the same document, samples should always be collected from the same positions, identified by the use of GPS (CGSAP/DEMOC/SEMOC/MPA 2013). Sampling points should be as close as possible to sources of contamination of the water, either detected or suspected. In case no contamination source was detected, samples should be collected randomly. The operative manual of PNCMB reports, on the website of the MPA there is a list of all the breeding or harvesting areas that shall be sampled (CGSAP/DEMOC/SEMOC/MPA 2013).

The execution of the PNCMB bases on three processes: (i) microbiological control of shellfish; (ii) biotoxins control of shellfish and monitoring plan for biotoxin-producing algae; and (iii) control of the destiny of bivalve molluscs collected from the sampled areas.

The responsibility for the execution of these controls should belong to State agencies for the control of animal and animal-derived products sanity (CGSAP/DEMOC/SEMOC/MPA 2013).

Microbiological control of shellfish

The microbiological safety of bivalve molluscs is defined by the concentration of *Escherichia coli*, as defined by the *Codex Alimentarius* standard for live and raw bivalve molluscs (Codex Alimentarius 2014).

For the analysis of *E. coli*, the Portaria 204/2012 requires five samples of 100 grams of shellfish pulp. The reference method for the quantification of *E. coli* is defined according to the ISO/IS 16649-3 procedure in five samples of 100 grams of mollusc pulp each, following *Codex Alimentarius* orientations (Brasil 2012b; Codex Alimentarius 2014). According to the same law, following the suggestion of the *Codex*, instead of the ISO 16649-3 method for the analysis of *E. coli* concentration, other equivalent methods may be used, but no one is specified. Samples for microbiological analyses should be sent to 'Laboratories of the official Brazil Government Net' for microbiological analyses, at the maximum temperature of +5°C. The maximum time gap between microbiologic sampling and processing of the samples should not exceed 48 h. At this moment (August 2018), there is no list of accredited laboratories to perform microbiological analyses of shellfish.

Biotoxin control and monitoring plan for biotoxin-producing algae

The reference norm for the analysis of algal biotoxins is the Portaria 204/2012 (Brasil 2012b), later modified by the Portaria 48/2016 (Brasil 2016). These interministerial ordinances define the frequency of periodic sampling for the research of biotoxins in shellfish and algae in seawater. Portaria 48/2016 highlights sampling frequency in the different Brazilian regions shall consider human impact on littoral regions, geography, meteorology and oceanography. As considering these elements, samples should be collected fortnightly in the southern and south-eastern region of Brazil. The frequency of sampling shall vary in the northern and north-eastern regions of the country, where human impact is deemed to be lower. Periodic samples should be two samples of 500 g of shellfish pulp, from sentinel species of molluscs (as defined earlier in the subchapter 3.1) from each breeding or harvesting area. The norm prescribes the research for different types of shellfish poisons: PSP (paralytic shellfish poison), ASP (amnesic shellfish poison), and lipophilic toxins: OA, YTX, and AZA (okadaic acid, yessotoxin, and azaspiracids). The sample size and the list of biotoxins disagree with IN 7/2012 (Brasil 2012a). The reference methods of analysis for biotoxins are defined according to the EC Regulation 1244/2007 and EU regulation 15/2011 (EC 2007a, 2011). The search for biotoxin-producing algae requires 250 mL of marine water. The reference methods are defined according to the EU Regulation 15/2011 and the guide for design and performance of the plan for the control of biotoxins producer algae of the UNESCO (EU 2011; Reguera *et al.* 2011). Shellfish and water samples should be taken on the same day from several breeding areas and sent to the reference laboratory: IFSC laboratory of Itajaí, in the Santa Catarina State. Water and shellfish samples for the analysis of harmful algae and biotoxin should be transported at a maximum temperature of +5°C and the time gap between sampling and analysis should not exceed 72 h.

Destination of the sampled batches according to the results of the analyses

According to the results of the periodic microbiologic and biotoxins sanitary surveillance, IN 7/2012 defines three classes of quality. Molluscs harvest can be: approved, conditionally approved, or prohibited. Table 1 describes the microbiologic and biotoxins criteria for the classification of tested batches of molluscs.

After sampling, live molluscs derived from an approved area shall be destined alive to human consumption after an inspection in a shellfish depuration and processing plant (Brasil 2017a), without previous depuration or any other

Table 1 Microbiologic and biotoxins criteria for the classification of tested batches of bivalve molluscs according to Brazilian laws (IN 7/2012 and Portaria 204/2012, modified)

	Microbiologic criterion	Algal biotoxins criteria/kg				
	MPN *E. coli*/100 g	PSP	DSP	DSP	ASP	AZP
Approved	<230†	<0.8 eq. STX	<0.16 eq. OA	<1 mg eq. YTX	<20 mg DA	<0.16 (eq. AZA1
Conditionally approved	230 < MPN < 46 000	<0.8 eq. STX	<0.16 eq. OA	1 mg eq. YTX	<20 mg DA	<0.16 (eq. AZA1
Suspended	>46 000	0.8 eq. STX	0.16 eq. OA	1 mg eq. YTX	20 mg DA	0.16 (eq. AZA1

†Portaria. 175/2013 defines that, to classify one area as ‘approved’, one among the five samples that must be collected from any fishing area to define its classification shall have MPN values ≥230 MPN and ≤46 000 MPN (MPA, 2013a).
ASP, amnesic shellfish poison; AZP, azaspiracids; DA, domoic acid; DSP, diarrhetic shellfish poison; eq. AZA1, equivalents azaspiracid-1; eq. OA, equivalents-okadaic acid; eq. STX, equivalents-saxitoxin; eq. YTX, equivalents yessotoxin; MPN *E. coli*, Most Probable Number of *Escherichia coli* assessed by the ISO/TS 16649-3; PSP, paralytic shellfish poison.

complementary treatment. Live molluscs derived from a conditionally approved area shall be envied to human consumption after depuration, thermic treatment or the removal of guts and gonads to eliminate pathogenic microorganisms. The choice of the treatment depends on the species of shellfish or to the product to be obtained. Molluscs from a suspended area cannot be destined for human consumption (Brasil 2012a, Art 55). It is interesting to observe, according to Portaria 175/2013, if one among five samples from an approved area has *E. coli* contamination between 230 and 46 000 CFU/100 g of mollusc flesh, molluscs derived from that area still are approved for direct human consumption. It is also interesting to highlight, that the Brazilian norm uses the term ‘depuration’ (*depuração*) to indicate both the decontamination by natural relaying and the depuration performed in a specific centre for depuration. The same norm defines that the efficiency of the depuration process, as described in the HACCP protocol of the processing industry, shall be validated in an official or accredited laboratory ‘during the time of the year, when the risk of organic contamination is higher’ (Brasil 2012b).

Discussion

The first point to discuss is the political responsibility on shellfish safety. The MPA produced the most relevant laws on shellfish safety and production between 2012 and 2013.

In 2015, MPA was closed and transformed into a ‘Secretary of Aquaculture and Fishery’ belonging to MAPA. This transfer of responsibilities and the rearrangement of the MPA website excluded relevant information for shellfish safety, such as the list of harvesting areas or that of accredited laboratories for microbiological analyses. In 2017, the activity of the Secretary of Aquaculture and Fishery passed to the ministry for Industry, Exterior Commerce, and Services (Brasil 2017c). Later this process was stopped, according to the proposal PDC 598/2017 (website available in Appendix I). At this moment (August 2018), a law defines the Special Secretary of Aquaculture and Fishery (SEAP) is under the direct control of the Presidency of the Republic (Brasil 2017d). The following shifts in responsibilities impede the development of plans for the growth and organization of the fishing sector and aquaculture (Santos *et al.* 2017).

The extinction of MPA created a *vacuum* of responsibilities on the inspection and monitoring of shellfish breeding areas. Normative instruction 7/2012 defined, MPA is responsible for inspection and control of microorganisms and algal biotoxins, as long as MAPA inspects the industrialization plants. At now, the field control of the quality of shellfish and the presence of toxic algal blooms is under the responsibility of the state agencies for animal sanitary defence, as had been defined by the 2013 MPA manual for PNCMB (CGSAP/DEMOC/SEMOC/MPA 2013). The recent RIISPOA remarks the responsibility of MAPA for inspection of shellfish industrialization plants, through the stages of shellfish depuration, handling and industrialization (Brasil 2012a, 2017a; CGSAP/DEMOC/SEMOC/MPA 2013). The only State in Brazil where the inspection of shellfish is operative is Santa Catarina, where the CIDASC (Integrated Company for Agriculture Development of Santa Catarina State) periodically controls the safety of shellfish and water by a complete system of shellfish inspection and environmental monitoring. (Suplicy *et al.* 2015).

It is interesting to observe the similar approach of the Brazilian RIISPOA, and European Regulation 625/2017 (EU 2017) on the inspection of foods of animal origin, as a whole. Both norms have a broad view of the inspection of foods, and both define that specific rules on specific matters require specific implementing acts according to scientific and technological developments, which will be available in the future.

Brazilian framework on shellfish safety is firmly influenced by the orientations of *Codex Alimentarius*, as it is with the sanitary food legislation of many other countries: the European Union, Argentina, Mexico, and Chile as examples (Argentina 1968; EC 2004a, 2007b, Cofepris 2009; Sernapesca 2014, 2015, EU 2017). The observation of *Codex* concerns to contaminants concentration, shellfish biotoxins and microbiological monitoring, the counting of *E. coli* using ISO 16649-3 technique (Brasil 2012b; Codex Alimentarius 2014) and the microbiological analysis of shellfishes instead of the surrounding water preconized by US legislation (Fda/Cfsan_Nssp 2016). Several papers analyse the correspondence between these two different strategies for the control of microbial shellfish safety (Taylor *et al.* 2016, 2017).

Among the most critical risks associated with shellfish consumption is microbial contamination (Santos & Vieira 2013). The analysis of the concentration of *E. coli* in 100 g samples of shellfish meat and intervalvular liquid serves as an indicator of potentially pathogenic microbial contamination. *Codex Alimentarius*, European Union, and Brazilian regulations agree, and standardize *E. coli* enumeration by the use of ISO 16649-3 technique (EC 2008; Brasil 2012a; Codex Alimentarius 2014; EU 2015).

ISO 16649-3 is a two steps technique including MPN enumeration and successive confirmation on chromogenic agar media, such as Trypton Bile-X- Glucuronide (TBX) agar, or 5-bromo-4-chloro-3-indolyl-β-D-glucuronide (BCIG) agar. Brazilian legislation, *Codex* standards and European regulation state, alternative methods shall be used, but neither of them indicates which other techniques offer correspondent results (Brasil 2012a; Codex Alimentarius 2014; EU 2017).

The European Union and the European Working Group on Microbiological Monitoring of Mollusc Harvesting Areas define, two alternative techniques for *E. coli* enumeration shall be used instead as the reference method: the impedance method and the direct colony count method according to ISO 16649-2 protocol (EU 2012; CEFAS 2014). Other publications suggest the same techniques as equivalent to the official one proposed by *Codex* being, at the same time less expensive, more straightforward and rapid (Dupont *et al.* 2009; Witte *et al.* 2014; Mooijman *et al.* 2007; Pereira *et al.* 2015). The Brazilian government should also embrace the same position, formally accepting the equivalence between these two methods and the standard ISO 16649-3 technique. The lower cost of analyses and the faster protocol would increase the ease and effectiveness of microbiologic control, without affecting the reliability of the results.

Essential differences between Brazilian and European shellfish safety standards are the definition of classes of microbial risk, the use of sentinel species for microbiological monitoring and the previous classification of the harvesting areas. The lack of correspondence between the European and Brazilian classification of shellfish harvesting area has impeded until now the commercialization of Brazilian shellfish in the European market (Souza *et al.* 2014).

Brazilian standards for microbiological shellfish safety are different from those established by European legislation: ‘conditionally approved’ shellfish according to Brazilian law correspond to both ‘B’ and ‘C’ quality shellfish according to European standards (EC 2004b, 2007b). According to European Union regulations, ‘C’ class shellfish (4600 < MPN < 46 000 per 100 g of shellfish meat and intervalvular water) represent a higher risk of contamination by hepatitis A virus and therefore require long time relaying in clean waters to reduce the risk, or heat treatment. Several studies confirm the long persistence of hepatitis A virus (HAV) in shellfish during depuration processes (Love *et al.* 2010; Diego *et al.* 2013; Sobral *et al.* 2013). Other studies, such as the interesting work of Romalde and collaborators, point out the independence between indicator bacteria contamination and HAV, (Romalde *et al.* 2002). In considering this risk, the heat treatment of ‘conditionally approved’ shellfish should be the best option to guarantee consumers safety, instead of depuration. High contamination by indicator *E. coli* also aware of the possible presence of *Salmonella*. The persistence of the bacteria in depurated shellfish is a matter of discussion. Morrison *et al.* (2011) describe a persistence of *Salmonella* during over 3 days of depuration of shellfish by UV (Morrison *et al.* 2011). The authors criticize the data presented by a previous study performed in Brazil, which highlighted the rapid depuration of oysters (5 h) contaminated with *Salmonella* and depurated using UV, chlorine or a mixture of the two processes (Corrêa *et al.* 2007). To increase the efficiency of the depuration process, US-FDA establishes a minimum depuration time of 44 h (Fda/Cfsan_Nssp 2016). As the risk of *Salmonella* associates to the contamination level of *E. coli* in shellfish, the reduction in the maximum contamination for ‘conditionally approved’ shellfish would provide higher safety for consumers from this risk, similarly as prescribed by the European legislation.

Brazilian legislation suggests the use of ‘sentinel shellfish species’ for microbiological monitoring (CGSAP/DEMOC/SEMOC/MPA 2013), referred to like those, that are more easily prone to microbial contamination. Neither *Codex* nor European legislation suggests a similar approach to breeding sites classification or monitoring. Shellfish have different competence in bacteria concentration, depending on species, size, health, and stress, among other factors (both intrinsic and extrinsic; Burkhardt & Calci 2000; Rasgalla *et al.* 2007; González-fernández *et al.* 2015; Olalemi *et al.* 2016). Olalemi *et al.* (2016) highlight that oysters (*C. gigas*) and mussels (*Mytilus edulis*, Linnaeus, 1758) have a different pattern of bioaccumulation of indicator bacteria and bacteriophages. Stabili *et al.* (2013) compare the microbiological accumulation among marine invertebrates exposed to wastewater. The study points out that mussels (*Mytilus galloprovincialis*, Lamarck, 1819) are the best concentrators of *E. coli* among the species analysed in the paper (Stabili *et al.* 2013). Kershaw *et al.* (2013) instead, point out cockles (*Cerastoderma edule*, Linnaeus, 1758) accumulate *E. coli* at a higher rate than mussels or oysters (Kershaw *et al.* 2013). A more recent document from the same working group highlights, on the contrary, the higher degree of bioaccumulation of faecal coliforms in mussels than in the other species of shellfish (Taylor *et al.* 2016). Italian guidelines on the application of Regulation 853/2004 observe, if different species of shellfish are bred in the same area, the species 'that is more easily prone to bacterial contaminations' (personal translation of the first author from the original text in Italian) might be used as sentinel species (but does not specify any species). In this paper, the use of 'sentinel species' is considered just as an alternative (Presidenza del Consiglio dei Ministri 2010). Australian Shellfish Quality Assurance Programs point out the use of mussels as sentinel species, but only for algal biotoxins (Tasmanian Government 2009). Jin et al. (2016) also compare different Chinese species of shellfish as bioindicators of bacterial contamination and describe *Sinonovacula constricta* (Lamarck, 1818; belonging to the Superorder Solenoidea, Family Pharidae) as the best bioindicator of *E. coli* and aerobic mesophilic bacteria contamination among the species studied.

It is important to underline, shellfish species bred in Europe, Asia, or North America (temperate climates) are different from those produced in Brazil (tropical or subtropical climates). Studies on the comparison of bacterial contamination among Brazilian shellfish species are still lacking, considering both the different shellfish species and environments. One of the few studies on this theme was performed in the state of Bahia and describes the absence of potentially pathogenic *Staphylococcus aureus*, *Vibrio parahaemolyticus* or *Salmonella* spp. in samples of the native oyster *C. rhizophorae* (Neta *et al.* 2015). The diversity of bacterioplankton species (bacterial communities) and assemblages are also peculiar in the temperate and tropical waters (Pereira *et al.* 2015). There is also a substantial lack of knowledge on the best temperature for the transportation of live shellfish until the laboratories. Brazilian laws, following *Codex Alimentarius* suggestions, require a +5°C temperature. Personal experiences suggest, the difference between average seawater temperature (≈+30°C) and transportation temperature shall cause a lethal shock to shellfish. Studies are required to determine the best shipping temperature for tropical shellfish species, especially the most delicate ones, such as the scallops.

Another main difference between the Brazilian legal framework of shellfish safety, the legal framework applied in Europe and North America, and *Codex* orientations are the risk assessment procedures to define the quality of shellfish production areas (EC 2004b; Brasil 2012a; Codex Alimentarius 2012; EU 2012, 2017; Fda/Cfsan_Nssp 2016). This process aims to create a 'base ground knowledge' of the shellfish breeding environment and an epidemiologic knowledge that can help to prevent the occurrence of unexpected high level of contaminations (Canadian Food Inspection Agency 2011; EU 2012; Fda/Cfsan_Nssp 2016). Brazilian laws do not require an assessment of the quality of shellfish based on the quality of successive samplings performed in the same breeding areas, focusing on the quality assessment of the commercialized batches.

Sanitary survey focuses not only on bacteriological analysis but also on broad theoretical and field knowledge of the surrounding shellfish production area, from the 'shore survey', up to the analysis of the entire catchment basin (Codex Alimentarius 2012). This strategy aims to understand the possible sources of contamination (Rice *et al.* 2015), and the analysis of sea currents to understand the movements of the contaminants. The definition of the geographic localization of pollution sources is of extreme relevance to the risk management of bacterial pollution in the breeding areas. Brazilian norms do not define any parameter to define the extension and geographic division among 'breeding or harvesting areas', 'aquaculture parks' or 'aquaculture areas' as previously outlined. The distance from actual or potential pollution sources and the analysis of dispersion of organic pollutants might help do define the risk-based classification of breeding areas to provide instruments for better planning of samplings. Environment analysis is fundamental also to assess the characteristics of the contaminant bacteria, their pathogenic potential, and resistance to antibiotics, (Taylor *et al.* 2011; Alves *et al.* 2014). Advanced techniques of bacterial source tracking cannot be used on a daily basis but shall be a crucial epidemiological tool to have a more profound, and more rapid knowledge of the possible flow of contaminants, both indicator bacteria and specific pathogens (Taylor *et al.* 2011; Harwood *et al.* 2014). The cooperation among producers, the MAPA and Universities could accelerate the environmental knowledge which is fundamental to select a proper site to begin a shellfish breeding.

Even if Brazilian regulation requires neither a prior classification of shellfish breeding areas nor a sanitary survey, there are real experiences of this in the State of Santa Catarina. In this State, there have been experiences with the use of modern and efficient techniques, aiming for the harmonization of Brazilian and European risk assessment procedures (Gallon *et al.* 2011; Garbossa *et al.* 2014; Jacomel & Campos 2014; Souza *et al.* 2014; Suplicy *et al.* 2015). In this case, it is important to point out the cooperation among public authorities, producers, and the Academy (Miotto 2012; LABCAL 2016).

Brazilian laws have specific technical requirements that are very strict, such as the establishment of a unique laboratory for the analysis of algal biotoxins (LAQUA-Itajai, in the state of Santa Catarina, South Brazil) and the logistic requirements for samples submission (CGSAP/DEMOC/SEMOC/MPA 2013). Such demands are strict, considering the vast extension of Brazil, logistic costs and the difficulty to maintain refrigeration temperature for a long period of time in a tropical country. In the same way, bacteriological analyses must be performed in laboratories recognized by the RENAQUA net (MPA 2012). The list of these laboratories is not available, and in many states, there is no laboratory accredited for these analyses. The only microbiological laboratory results available on the Internet are those performed in Santa Catarina State, in the local laboratories of the Federal University of Santa Catarina (LABCAL/UFSC; LABCAL 2016). It is interesting to observe that sometimes the microbiological samples are accepted and processed, even if the recorded temperature of the samples is above the legislative requirement. This observation is crucial not to point out deficiencies in the handling of the samples, but, on the contrary, to highlight the difficulties of shellfish samples transport at a controlled temperature in tropical and sub-tropical regions.

Another hamper to the implementation of the PNCMB is the high cost for the execution of analyses required to guarantee the quality of shellfish and shellfish production areas. Until now, Brazil government accepted no alternative technique to ISO 16649-3 for the enumeration of *E. coli* at the national level. The availability of other techniques could increase the efficiency of the risk assessment procedure.

The implementation of all the aspects of the shellfish monitoring plan in Brazil requires investments for the public system, shellfish breeders and fishers (Cahill & Jouve 2004; Adinolfi *et al*. 2016). Outside the state of Santa Catarina, most of the production of shellfish is performed by small or medium producers, often organized in cooperatives, in a very fragmented market and little possibility for technology application or investments to improve shellfish safety (as a participation of the producers in the cost for the execution of the controls required by the PNCMB; Sampaio *et al*. 2017). The application of PNCMB safety analyses would elevate the price of shellfish cutting out from the market a part of the producers. It is crucial to understand how much shellfish buyers from different social classes would accept to pay for a safer product (Traill & Koenig 2010).

Conclusion

Shellfish breeding in Brazil is still at the beginning in comparison with European or North American countries: it is well developed and concentrated in the extreme South of the country (Santa Catarina State), but it is growing in several other states, along with the entire Brazilian coast. The growth of this sector in the State of Santa Catarina has been possible by local development strategies since the beginning of the production, in the decade of 1980s and by the cooperation among the stakeholders of the shellfish production chain (producers, university, the state agency for the animal inspection and food safety). The concentration of shellfish production in that State oriented the localization of the central reference laboratories for the control of shellfish safety, most especially those for the control of algae and biotoxins.

Several factors hamper the expression of the full shellfish production potential of Brazil: the lack of organization of the production chain in states other than Santa Catarina, the lack of definition of the responsibilities for the inspection of shellfish breeding areas and analyses, and the extreme distance between the production area and the laboratories. This situation could improve by applying several strategies: the strengthening of official control to reduce the commerce of shellfish from illegal harvesting, polluted or restricted areas (Sampaio *et al*. 2017), the opening of local reference laboratories for the control of both microbiological and biotoxicological analyses; the acceptance of a cheaper and faster technique for the enumeration of *E. coli,* and a precise definition of the political responsibilities for the shellfish production chain. In our opinion, these elements will allow the legal development of this activity and the expansion of internal and external markets for the Brazilian shellfish products.

Conflict of interests

The authors declare, there is no conflict of interests regarding the publication of this paper.

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Appendix

Main websites consulted

Shellfish nomenclature: http://www.marinespecies.org/index.php.

MAPA (Ministério da Agricultura, Pecuária e Abastecimento: Brazilian Ministry of Agriculture, Stockbreeding and Supply): (http://www.agricultura.gov.br).

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Food and Agriculture Organization-Fisheries and Aquaculture Department National Aquaculture Legislation Overview (NALO): (http://www.fao.org/fishery/collection/nalo/en).

Codex Alimentarius: (http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/).

European EUR-Lex: (http://eur-lex.europa.eu/homepage.html).

British CEFAS: (https://www.gov.uk/government/organisations/centre-for-environment-fisheries-and-aquaculture-science or https://www.cefas.co.uk/).

United States Food and Drug Administration (FDA): (http://www.fda.gov/Food/GuidanceRegulation/default.htm).

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