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Introduction to the analysis of regulations and texts of interest to safety of fish products from aquaculture

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SUMMARY – Aquaculture is the fastest growing food production system of the last decade. The expansion of fish markets for aquaculture products is a need; however, this expansion will be possible if a number of factors can be met. One of the key factors is quality, and within the concept of quality, safety is the first necessary condition to fulfil. Consumers are increasingly interested in safety and quality aspects and the EU and USA, for instance, put new safety regulations in force. New regulations have introduced the Hazard Analysis and Critical Control Point (HACCP) system, which is basically the control of food safety during food production and processing. There is a notorious change of paradigm regarding the previous system based on control through the analysis of samples of the final product. HACCP-based regulations regarding the safety of fish products apply to fish and fish products from aquaculture. However, aquaculture fish presents particular characteristics that are taken into account in safety regulations like residues of veterinary drugs. At the same time, aquaculture in itself is regulated as an economic activity, and this set of regulations is centred on the health of the cultured fish. Both visions should not necessarily be in contradiction; however, in practice the situation of both views is not completely harmonised. In the coming years we may expect an evolution of regulations, in order to have a more consolidated view of aquaculture production and to accommodate the introduction of new concepts like those derived from risk assessment, and codes of practice of responsible aquaculture and good animal feeding. This paper briefly reviews the current status of food safety regulations as they apply to aquaculture fish, according to EU and USA regulations, and discusses the structure of national regulations and international documents that apply to fish safety.

Key words: Fish safety regulations, HACCP.

RESUME – "Introduction à l'analyse des réglementations et textes d'intérêt pour la sécurité des produits de l'aquaculture." L'aquaculture est le système de production alimentaire qui connaît la plus grande croissance de cette dernière décennie. L'expansion des marchés pour les produits aquacoles est une nécessité ; cependant cette expansion ne sera possible que si l'on peut atteindre un certain nombre de facteurs. L'un des éléments déterminants est la qualité, et dans le concept de qualité, la sécurité est la première condition nécessaire à respecter. Les consommateurs portent chaque fois plus d'intérêt aux aspects de sécurité et de qualité, et l'UE et les USA par exemple ont mis en oeuvre de nouvelles réglementations concernant la sécurité. Des nouvelles réglementations ont introduit le système d'Analyse des Risques et des Points de Contrôle Critiques (ARPC), qui consiste essentiellement à contrôler la sécurité alimentaire pendant la production et la transformation des aliments. Il y a un changement paradigmatique notable par rapport au système précédent basé sur le contrôle à travers l'analyse d'échantillons du produit final. Les réglementations basées sur l'ARPC concernant la sécurité des produits de pêche s'appliquent au poisson et produits à base de poisson provenant de l'aquaculture. Cependant les produits aquacoles présentent des caractéristiques particulières qui sont prises en compte dans les réglementations de sécurité, comme les résidus de médicaments vétérinaires. En même temps, l'aquaculture en soi est réglementée en tant qu'activité économique, et cette série de règlements est axée sur les conditions sanitaires des produits d'élevage. Ces deux visions ne devraient pas nécessairement être contradictoires ; cependant dans la pratique la situation de ces deux approches n'est pas complètement harmonisée. Pendant les années à venir nous pouvons nous attendre à une évolution des réglementations, visant à une approche plus rigoureuse de la production aquacole et à préparer l'introduction de nouveaux concepts tels que ceux dérivés de l'évaluation des risques, et des codes d'usages pour une aquaculture responsable et une alimentation appropriée des animaux. Cet article passe brièvement en revue l'état actuel des réglementations sur la sécurité alimentaire, d'application aux produits de l'aquaculture, d'après les réglementations de l'UE et des USA, et discute la structure des réglementations nationales et des documents internationaux appliqués à la sécurité des produits de poisson.

Mots-clés : Réglementations sur la sécurité des produits de poisson, ARPC.

Introduction

Aquaculture and fish safety is creating one of the most interesting and challenging situations in the

fishery industry. Aquaculture production has increased at an average rate of 9.6% per year during the last decade, which makes it one of the fastest growing food production systems. This will ultimately change the way we perceive fish as food. From a wild source of food to a cultured one. This will reshape the international and national fish markets. The "aquaculture revolution" is a rather interesting process in itself. However, possible expansion of production is not enough, the markets for cultured fish will have to expand too, and this will be possible if a number of factors are present. One of the keys factors for this market expansion is "quality".

Quality is a rather complex concept that encompasses a number of different elements, one of which is safety. However, safety is a necessary (*sine qua non*) condition for quality, and the first aspect to take into account. On the other hand, food safety in general and fish safety in particular is one of the ends of millennium problems. The problem has been called appropriately the "food safety paradox". Probably never before in the history of mankind has such an amount of safe food been produced. However, the epidemiology data from developed countries indicates a rise in the number of food outbreaks in absolute and relative terms.

Why this increase in food outbreaks occurs (or how to solve the paradox) is a matter of discussion and many explanations have been proposed. Perhaps an acceptable explanation is the increased urbanisation of the human society; coupled with the increased concentration of food production and distribution systems that amplifies the possibilities of food outbreaks. Whereas the reasons for the "safety paradox" exist, the consumer is increasingly worried about the perceived lack of food safety. This is reflected first in the press, then in politics and finally in regulations. Safety is related to public health and therefore law enforces the minimum requirements.

By the end of the 80's developed countries arrived at the conclusion that classic fish (and food) inspection based on the analysis of samples of the final product and on generic hygiene measures was not enough to provide the necessary level of protection to consumers. A preventive system called "Hazard Analysis and Critical Control Point" (HACCP) was adopted and governments started to shift their regulations to HACCP-based systems (ICMSF, 1988) (FAO/WHO CAC, 1997). If one word has to be chosen to explain HACCP in short, it is prevention.

How to look at food (and fish) safety regulations

Today, for non-specialists and even specialists, there is certain difficulty in looking at food (and fish) safety regulations. The main reason for the difficulty in reading and understanding regulations lays in the change in the paradigm of food safety control, *from the inspection and analysis of samples of the final product, to the control of food safety during the food production and processing*. This change of paradigm is determined by the incorporation of the HACCP (*Hazard Analysis and Critical Control Point*) system in current food (and fish) safety regulations.

In the first approach we were looking for problems in the final product. In the second approach production is programmed and controlled in order to prevent safety problems occurring. In this second approach procedures to produce safe food are the key aspects of regulations.

However, the current situation is one of transition. The old and new approaches to control food safety co-exist to a certain extent. This means that further changes in regulations can be expected in the coming years. This paper focuses on the HACCP approach, as it is the current prevailing approach and future developments will be based on extensions of the HACCP system.

The next important point is the growing importance of international agreements that involve food (and fish) safety aspects. About 40% of all fish produced are traded internationally, which means that there is a search for common criteria that allows for the issue of clear compliance rules. The tendency is towards harmonisation of national regulations, which means regulations that *could assure an equivalent level of food protection to consumers*. This is a relatively easy concept to understand, but very difficult to implement and validate in practice. In turn, this increases the importance of internationally accepted guidelines, recommendations and standards as those of the Codex Alimentarius. The provisions of the GATT Agreement related to food trade compound that tendency and all these aspects are inter-linked.

The collection of regulations, agreements and guidelines of interest to safety of aquaculture products is becoming rather complex. To facilitate the study we may divide them in two large groups; international and national texts, and in turn each group could be divided in two groups; general texts (for food or for fish as food) and specific texts (aquaculture).

Relevant texts at international level

The GATT Agreement on the Application of Sanitary and Phytosanitary Measures

At international level there is no agreement on food or fish safety, however there are agreements on food trade with implications on food safety and quality matters. The important one regarding food safety is the "Agreement on the Application of Sanitary and Phytosanitary and Measures" (SPS) (GATT, 1994).

This agreement introduces two very important concepts. The first is that "to harmonise sanitary and phytosanitary measures on a wide basis as possible Members (countries) shall base their sanitary or phytosanitary measures on international standards, guidelines and recommendations, where they exist..." (Art. 3). The same Agreement establish that regarding food safety "international standards, guidelines and recommendations" to be taken as reference will be those "established by the Codex Alimentarius Commission (CAC) relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling and guidelines of hygiene practice" (GATT, 1994).

The standards, guidelines and recommendations of the Codex Alimentarius Commission (CAC) are voluntary; they can have legal value only when incorporated into national regulations. However, the GATT agreement gave them a *de facto* legal value at international level, in the sense that they are taken as a first reference on food trade international controversies. At the same time, the national regulations are increasingly incorporating the CAC guidelines and recommendations. However, incorporation of CAC standards in regulations does not conduct necessarily to an immediate harmonisation of regulations.

The second important point of the SPS Agreement is the adoption of the criteria that risk assessment shall be the base to determine the appropriate level of sanitary and phytosanitary protection. In this case the SPS Agreement is imposing a strong condition on national regulations which are not yet accommodated to this criteria. Current HACCP-based regulations include a "hazard analysis" step, but risk assessment, which should be a part, is performed only qualitatively, and country regulations do not refer to risk assessment explicitly. Future development and evolutions of regulations will be in this direction.

The basic Codex Alimentarius Commission (CAC) texts on food (and fish) safety

The SPS Agreement is therefore the support at international level of two basic documents that can be called upon to ascertain the safety of an aquaculture product in case of trade disputes. The first, of a general nature, is the *"Recommended International Code of Practice. General Principles of Food Hygiene"* (FAO/WHO CAC, 1997) that includes the *"Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application"* (which is at the basis of current national regulations). The second specific one would be the *"Code of hygiene practice for the products of aquaculture"*, currently under discussion at the CAC Committee on Fish and Fishery Products.

It should be said that in Codex the HACCP system is an Annex to the principles of food hygiene, whereas in country (or EU) regulation hygiene is a part of the HACCP regulation. For this, and other reasons, in general "HACCP system" which is the system defined according to Codex, and "HACCP-based systems", which are presented in actual regulations.

The Codex text on the HACCP system is about food in general. It is not specifically aimed at fish or to aquaculture fish. It is possible that a specific HACCP system for fish in general and fish in aquaculture in particular will be issued in the future.

Some FAO and WHO texts of relevance to aquaculture fish

In addition, FAO and WHO international texts are of importance. These texts are not mandatory or covered under the SPS criteria (they are not CAC documents). However, they are increasingly taken as reference at national and international levels, particularly regarding aspects dealing with fish safety issues.

The first important document is "*Aquaculture development. FAO Technical Guidelines for Responsible Fisheries*" (FAO, 1997a). This document can be retrieved from: <ftp://ftp.fao.org/fi/document/techguid/fishaqu5.pdf>

This document is based on the "Code of Conduct for Responsible Fisheries", adopted at the FAO 32nd Conference in 1995, which includes one thematic article on "Aquaculture development". The Code and Guidelines have been formulated so as to be interpreted and applied in conformity with relevant rules of international law.

Other important FAO and WHO texts of relevance to aquaculture fish that include references and recommendations regarding fish safety are the following:

"*The Code of Practice for Good Animal Feeding*" (FAO, 1997b) which may be obtained from: <http://www.fao.org/news/1997/970507-e.htm>

"*Food safety issues associated with products from aquaculture*" (FAO/NACA/WHO, 1999).

"*Biotechnology and food safety. Report of a Joint FAO/WHO Consultation*" (FAO, 1996). This text can be retrieved from: <http://www.fao.org/WAICENT/faoinfo/economic/esn/biotech/tabconts.htm>

The last three documents mentioned deal with very important fish safety issues for aquaculture. As these texts consolidate the knowledge in relevant areas of food and fish safety of interest to aquaculture, and have been discussed at international level in a UN forum, they may be taken as first reference at international level.

National level

A large number of countries now have specific HACCP-based regulations regarding the safety of fish and fish products, including products from aquaculture. Approximately 65% of the total international fish trade are performed under HACCP-based regulations. The large exception is the Japanese market. Japan, which accounts for about 32% of the total international fish market (demand) but has no HACCP regulations yet. The EU and USA were first in adopting the HACCP-based regulations of fish and fish products as presented in this paper.

In this paper EU regulations are taken as "national" regulations, however, individual EU countries may have additional relevant regulations that are not considered in this text. For instance, France and Spain have their own microbiological criteria. EU regulations may be applied directly, however the contents of the regulations must be first transferred into national laws of EU member countries.

HACCP-based regulations for fish and fish products in the EU

The regulation that introduced the concept of "own health checks" (HACCP in terms of the EU regulation related to fish products) is the *Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products* (EU, 1991c).

This Directive has been modified partially by *Council Directive 95/71/EEC*; however, the most important changes and clarifications were introduced by: *Commission decision 94/356/EC laying detailed rules for the application of Council Directive 91/493/EEC* as regards own health checks on fishery products (EU, 1994).

These two texts are the basic kernel of the current HACCP-based regulations for fish and fish products in the EU. There is also a general regulation on the food hygiene, which also refers to HACCP: *Council Directive 93/43/EEC on the hygiene of foodstuffs* (EU, 1993).

Council Directive 91/493/EEC *applies to aquaculture products* as established in Art. 3 (3). If the product is live bivalve mollusc (an important aquaculture product), there is a general *Council Directive 91/492/EEC "laying down the health conditions for the production and placing on the market of live bivalve molluscs"* (EU, 1991b).

The central core of HACCP-based regulation is, in turn, complemented by a number of other Directives, Decisions and regulations that should be taken into account according to the type of product specie, situation, and possible hazard, etc. A *non-exhaustive list* of these complementary texts could be as follows:

Decision 93/51/EEC	Microbiological criteria – Crustaceans and shellfish
Decision 93/140/EEC	Parasites
Decision 93/351/EEC	Mercury
Decision 93/383/EEC	Biotoxins – Laboratory tests and conditions
Decision 93/25/EEC	Heat treatment – bivalve molluscs and gastropods
Decision 95/149/EC	Total volatile basis Nitrogen (TVBN)
Decision 96/340/EC	Snail and frog legs – Requirements
Directive 80/778/EEC	Potable water (to be in contact with fish products) ¹
Directive 88/320/EEC	Good laboratory practices
EEC Regulation 103/76	Sensory criteria (some fish species)
EEC Regulation 33/89	Sensory criteria (some fish species)

In general the previous paragraphs give an idea of the complexity of the subject when analysed at national regulations level. We can say that we have two types of regulations. The first type is Council Directive 91/493/EC and Decision 94/356/EEC defines *the HACCP-based system*; this means the general setting to achieve safe production. The remaining regulations fix in general specific conditions. They include regulatory limits, methods of analysis, operative practices (including type of certificates to put into use), processing conditions, etc. Although they are not always written in such a way, they could be defined in general as *regulatory standards*, which are the precise procedures and limits that the system should observe or accomplish.

In any case, the regulatory system and "standards" define a large "family" of regulations. In turn each type of fish or product has, in general, a "reduced" or partial "family" (or specific regulatory profile), according to the legislator perceived hazards of such specie or product.

The main task of each plant is to identify this "specific regulatory profile". This task is basically achieved when, according to the HACCP system, the Hazard Analysis is performed. *Perhaps, this aspect more than others, clarify the difference between classic fish inspection and safety control, from the application of the HACCP system.*

In classic fish inspection there were also "regulatory standards", however, they were not always rational. All the relevant hazards were not always taken into account, and very often a number of non-existent hazards required the attention of processors and fish inspectors, increasing the costs of appraisal and generating a sense of false safety.

When applying HACCP, all the relevant hazards should be looked into and once identified, it is necessary to establish the corresponding Critical Control Point (CCP) at plant level (in the EU regulations CCP are called "Critical Points"). First of all, we should consider the hazards that regulations specify to take into account (e.g. histamine), however, we should also consider the hazards, for the consumer that may not be clearly specified in the regulations. Aquaculture fish is a type of raw material where this type of situation can arise very easily.

EU regulations regarding health conditions for aquaculture animals and products

Aquaculture production, have in the EU, their own regulation: *Council Directive 91/67/EEC*

¹ During 1999 a new EU Directive was issued on potable water, however, it will not enter into force immediately.

concerning the animal health conditions governing the placing on the market of aquaculture animals and products (EU, 1991a).

This Directive relates to health conditions of animals from aquaculture. The basic principle of the Directive is to avoid the spread of infectious or contagious diseases. Fish intended for the market "must show no clinical signs of disease on the day of loading". Production for marketing of aquaculture products is only possible from approved zones or farms.

Council Directive 91/67/EEC in turn generates a "family" of regulations. For instance *Council Directives 93/54/EEC and 95/22/EC and 95/70/EC* have successively amended Directive 91/67/EEC. The CD 93/54 clarifies the requirements concerning the approval of zones and animals not belonging to the susceptible species and reviews the list of diseases. The CD 95/22 lays down criteria to protect farms against the introduction of fish diseases IHN (Infectious Hematopoietic Necrosis) and VHS (Viral Hemorrhagic Septicaemia). The CD 95/70 introduces minimum measures to control certain diseases affecting bivalve molluscs in order to protect shellfish farming. Reference laboratories for diagnosis of diseases are included.

The Council Directive 91/67/EEC also is related to other regulations for instance the *Council Directive 92/118/EEC (amended by the Council Directive 96/103/EC)* includes fishmeal in the definition of processed proteins intended for animal feed.

This "family" of regulations *is basically aimed to the control of fish diseases*; they are only in the second instance complementary with the HACCP-based regulations aimed to prevent human diseases. The accomplishment of the regulations related to the aquaculture production do not imply the accomplishment of the fish safety regulations that shall also be accomplished. Although, there are not contradictions between both families of regulations the correspondence and co-ordination between them will surely increase with time.

It has been suggested to introduce the HACCP system, with all the specific characteristics, to the aquaculture production in national regulations, which is probably one of the developments of the coming years.

There is an important point to take into account which the GATT Agreement discussed in point 3.1, in addition to public health, and that is the possible risk that food traded products could have on animals and plants.

HACCP-based regulation for fish and fish products in the USA

The shifting to the HACCP-system imposed by regulations is not an EU phenomenon. All developed countries and a large number of developing countries have already shifted to HACCP-based systems. The basic regulation that makes mandatory the implementation of the HACCP system in fish and fish products in the USA: *US Food and Drug Administration (FDA, 1995). 21 CFR Parts 123 and 1240 Procedures for the safe and sanitary processing and importing of fish and fishery products: final rule. US Fed. Regist. 61, 65096-65202, 18 December.*

The US regulation does not mention specifically fish from aquaculture. However, it is included implicitly in the definition of "fish" ("where such animal life is intended for consumption") and in other paragraphs of the regulation (e.g. when list "drug residues" as one of the possible hazards to take into account). However, the regulation does not apply to aquaculture production in itself, and the regulation is specifically centred on processing.

The processor is legally responsible and should look into all the possible hazards that a given cultured fish may have (e.g. antibiotic residues). This triggers a chain. The processor is primarily responsible for fish safety, and should therefore seek for legally valid assurances from the primary producer. In this situation the HACCP system will also be applied to the fish farm, as the only (economic) way to provide the desired assurance.

A very important document to be used in conjunction with the above-mentioned regulation is the *"Fish and a fisheries product hazards and controls guide" (2nd Ed.) (FDA, 1998)*. The text of this

document can be retrieved from <http://vm.cfsan.fda.gov/~dms/haccp-2.html> .One of the chapters of this guide (Chapter 11) refers specifically to Aquaculture drugs.

Although the US HACCP-based regulation for fish and fish products appears to be more concise than the EU regulation, in part because it does not include fishing vessels, there are also a number of other regulations that should be accomplished. For instance, producers (and exporters) should comply with Section 402 of the Federal Food, Drug and Cosmetic Act. This in practice means to accomplish with what we called the "*regulatory standards*". A table encompassing all the requirements is included in the "Fish and fisheries products hazards and controls guide" (FDA, 1998) previously mentioned (Table #A-3 FDA & EPA Guidance levels). This table includes 36 lines of different guidelines/tolerances to be taken into account, which *de facto* generates a "large" family of regulations. In turn for each type of specie / product it is possible to define a "restricted" family of regulations.

Implicit references to cultured fish appear again in the Table mentioned in the previous paragraph. For instance, the tolerances for oxytetracycline (2 ppm) and the combination sulfadimethoxine/ormetoprim (0.1 ppm), whereas it is specifically mentioned that no residue is permitted for sulfamerazine. In particular the table mentions that no residue of unsanctioned drugs is permitted.

As it was discussed regarding the EU regulations, the 21 CFR Parts 123 and 1240 regulation represents "*the HACCP-based system*", that shall be complemented in practice with a number of other related regulations.

The future of fish safety regulations

From the previous points the complexity of discussing in detail fish safety regulations is clear. At the same time, regulations are changing very quickly. For instance, the EU regulation on aquaculture products, as mentioned above, varied three times between 1991 and 1995. Further changes, and probably new regulations, can be expected in the years to come regarding cultured products, particularly in relation to feedstuffs, veterinary drug residues (in particular antibiotics) and contaminants. These changes are unavoidable since regulations should be reputed to be in a transitory state, and changes to accommodate new scientific and operative knowledge shall exist.

However, a further large change in the kernel of fish (and food) safety regulations can be expected with the introduction of quantitative risk assessment (ICMSF, 1998). Although based on the basic HACCP system, HACCP-based regulations from the different countries are not fully equivalent from the point of view of the analysis of regulatory texts. However, this is not the main problem. Two different regulations can lead to two somewhat different HACCP plans, however, the HACCP plans could be equivalent in terms of risk (or protection) for the consumer. The possibility of proving this equivalence depends on the development of practical ways to assess quantitatively the risk associated with each possible hazard.

The hazard analysis included in the current regulations, is a qualitative hazard analysis, even if not explicitly acknowledged, and this makes it impossible to judge the possible equivalence in terms of risk (statistical probability of occurrence of a given hazard). It should be noted that the same happens within a given regulation when we want to compare the relative safety of two different plants producing the same product.

Therefore future regulations will tend to include either direct quantitative risk analysis of the relevant hazards associated with a given product or some indirect measurement of those risks. This would be valid for all types of fish sources, including aquaculture.

Conclusions

This paper presents a very brief analysis of current EU and USA HACCP regulations of fish and fish products based on the HACCP system with particular reference to aquaculture products. In particular the analysis is centred on the EU and US regulations and reference is made to texts of importance at international level.

As a general conclusion it may be said that regulations are structured around a basic regulation that defines the HACCP-based system, and this basic regulations is complemented by a number of regulations defined in this paper as "regulatory standards". Each specie and product may be defined as a "family" of regulatory texts that outline the minimum regulatory requirements for each particular case.

Fish and fish products from aquaculture are included explicitly or implicitly in the HACCP-based regulations. However, whereas the HACCP system for processing steps, once fish is taken out of the water is well defined, the application of the HACCP system to all the production aquaculture chain does not appear to be so clearly established in regulations. Development in relation to these regulations can be expected.

Further evolution of the fish safety regulations may be expected with the introduction of new technical, scientific and operative knowledge and in particular regarding mandatory quantitative risk assessment.

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