

Reaching Equivalence through the Application of HACCP

Sirilak Suwanrangsi

*Chief, Fish Inspection Center (Bangkok), Fish Inspection and Quality Control Division,
Department of Fisheries, Thailand*

■ ABSTRACT

Globalization of fish trade has focused on strengthening measures taken to ensure the safety and quality of fish and fishery products. The application of HACCP based control system is the choice of major fish importing and exporting countries, with the expectation that the exporting country will meet similar or equivalent HACCP requirement. However, in practice, there are large differences in the current HACCP-based regulations and system for fish and fishery products. The paper discusses the concept of equivalence as appeared in the WTO sanitary and phytosanitary agreement and various countries' regulations and the procedures for determining equivalence. The relation between HACCP and equivalence agreement, including steps and lesson learnt in reaching equivalence agreement on inspection and control system for fish and fishery products between countries will be elaborated.

■ Introduction

A common issue in all seafood consuming nations is the concern over safe, high quality and accurately described food at the lowest possible price. With increased economic integration of world economies, including expanding trade in seafood as primary and value-added products, the importance of sanitary and quality standards has been elevated. Countries often have elaborate programmes for the assessment and management of risk to determine the measures needed to ensure safe food supplies for humans and to protect consumers' health. The diversification of foods, of non-traditional production methods and of sources of supply have also given impetus to the application of food quality standard, which address attributes other than food safety and which are intended to facilitate commerce and protect consumers against deception and fraud. The WTO recognizes the right of countries to maintain such measures subject to the requirement that

the measures do not arbitrarily or unjustifiably discriminate between countries where the same conditions prevail, or are not a disguised restriction on international trade (Article XXb) (GATT, 1992). The SPS Agreement recognizes that there may be varied ways of ensuring food safety in different countries, but provides that WTO members should accept each other's regulations as equivalent whenever the same level of human, animal or plant health protection is achieved. Thus, mutual recognition agreements acknowledging the equivalence of health protection measures enforced by different approaches are negotiated on a bilateral or regional basis, and can help, for example, overcome any lack of international standards.

The concepts of harmonisation, equivalence, mutual recognition, and food safety assurance measures have a key role to play in international trade of food.

■ Harmonisation of Fish and Fishery Products Standard

Harmonisation of standards means the adoption of the same standards by different countries. Typically, the reason countries seek to harmonise their standards with other countries is so that they may trade more freely with each other. Where harmonised standards are in place, fish and fishery products produced in a country to meet its standards will be capable of being sold freely in another country which applies the same standards. The absence of harmonised standards will result in increased costs for food exporters and importers. Another incentive to international harmonisation is that if countries are able to rely upon a common authoritative source of food standards there will be less need at the national level to devote scarce technical resources to the formulation and validation of unique national standards.

Additional impetus towards harmonisation is given

by the obligation which members of the WTO have accepted under the SPS and TBT Agreements to harmonise their measures with relevant international standards, including Codex norms, wherever appropriate. Under the SPS Agreement, WTO members may be called upon to justify a decision to apply a measure which is more trade restrictive than would be consistent with a relevant Codex standard, guideline or recommendation. Under the TBT Agreement, members proposing to make a technical regulation which is not in accordance with a relevant international standard and which may have a significant effect on trade are required to advise other Members, explain their intentions and take comments into account.

If standards are to be applied in common between different countries they must meet the requirements of each country in terms of protection of consumer health and protection against deceptive or fraudulent practices. Each country has the sovereign right to determine the level of health protection the food standards should provide for their populations, and this level can and does vary from one country to another. Moreover there is great diversity worldwide in dietary patterns and the circumstances in which food is handled and consumed. Despite this diversity it has been possible for Codex to develop international food standards which can and do provide the focal point for harmonisation.

1. Harmonisation: Related activities

To date, there are only 16 Codex standards for fish and fishery products They are:

- Canned Salmon, CODEX STAN 3-1991, Rev. 1-1995
- Canned Shrimps or Prawns, CODEX STAN 37-1991, Rev. 1-1995
- Canned Tuna and Bonito, CODEX STAN 70-1981, Rev.1-1995
- Canned Crab Meat, CODEX STAN 90- 1981, Rev.1-1995
- Canned Sardines and Sardine-Type Products, CODEX STAN 94 –198, Rev. 1-1995
- Quick Frozen Lobsters, CODEX STAN 95-1981, Rev 1-1995
- Canned Finfish, CODEX STAN 119-1981, Rev. 1- 1995
- Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh CODEX STAN 165-1989, (Rev. 1-1995)
- Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets — Breaded or in Batter CODEX STAN 166-1989, Rev 1-1995
- Dried Shark Fins, CODEX STAN 189-1993
- Salted Fish and Dried Salted Fish of the Gadidae Family Of Fishes CODEX STAN 167-1989, Rev. 1-1995
- Quick Frozen Raw Squid, CODEX STAN 191-1995
- Quick Frozen Fish Fillets, CODEX STAN 190-1995
- Quick Frozen Shrimps or Prawns CODEX STAN 092-1982, (Rev. 1-1995)
- Quick Frozen Finfish, Uneviscerated and Eviscerated CODEX STAN 36-1981 (Rev. 1-1995)
- Sensory Evaluation of Fish and Shellfish in Laboratories CAC-GL 31-1999

The Code of Practices for Fish and Fishery Products is currently under revision to incorporate HACCP concepts. The revised Code of Practices includes two standards directly related to ASEAN countries, i.e., Fish Cracker (which was already proceeded for adoption as Codex standard in the 24th meeting in June 2000) and Salted Anchovies (which is pending at step 6, due to the request of Thailand for consideration of not using histamine as a decomposition index). A new standard will be drafted for the 25th session in 2002 which includes standard for scallop meat.

2. Harmonisation: Issues for the future

Codex norms will achieve wider use as a basis for international harmonisation the more effectively they meet the needs of the 165 member countries of the Codex Alimentarius Commission. Member countries need standards which are technically sound and which fully address contemporary risks, whether these risks are to human health or are risks of deception or fraud. In addition, countries need standards which have a high degree of credibility with both consumers and trading partners, and which are capable of being applied by both developing and developed countries. The following considerations are therefore particularly important:

- Codex standards which address health risks must be based on sound science and thorough risk analysis, following agreed principles.
- Codex standards must be based on consensus.
- Codex standards must be developed in a transparent manner which aids acceptance by consumers and therefore by member countries.
- Codex standards must address contemporary health and trade issues, whenever possible anticipating the need for work in new fields.

- Codex standard, in particular fishery product standard should be open for as many species being traded internationally as possible.

On the last of these points, the ASEAN countries need to consider to what extent and how it can assume a leadership role in the development of standards which address regional differences in fish species, products and climate, microbes and new and emerging issues of the region. At present there is, for example, an increasing propensity for countries to develop and implement quantitative limits on microbiological contaminants. Historically, the members of Codex have elected to await the development of a degree of convergence between the separate national approaches of the major developed countries before deciding that an applicable Codex norm should be developed. Such will continue to be the case if the consensus basis of Codex norms is to be preserved. Thus the question is how the framework and mechanisms which the Codex system provides can be better used to facilitate the development of consensus on the basis of which appropriate new norms can be elaborated.

3. Harmonisation: Recommendations

The Codex Alimentarius system has a long history of producing technically credible food standards through a consensus approach. The challenge for ASEAN now is to enhance:

- Participation and inputs of ASEAN countries in CODEX/COA meeting.
- Standards for regional products traded internationally.
- Science based information to support development of standards, practices and control measures.
- Addition of species to existing species specific standards.
- The utilisation of Codex standards at national level.

■ **Equivalence**

The process leading to the preparation of an international standard can be lengthy and costly. Reaching consensus on technical details can take several years. The time gap between the adoption of an international standard and its implementation by national regulators can also be significant. Equivalency is the best option when harmonization of standard is not desirable or when international standards are lacking or inappropriate. For ASEAN countries, which face

climatic, developmental and technological conditions rather different from those prevailing in many importing countries, the recognition of equivalency of their inspection and control system to those applied by importing countries would represent the key instrument to enhance market access for their products.

For these reasons, negotiators introduced in the WTO — TBT and SPS Agreement a complementary approach to technical harmonization, known as equivalence. Technical barriers to international trade could be eliminated if members accept that technical regulations or SPS measures different from their own fulfil the same policy objectives even if through different means.

An importing country usually judge the safety, wholesomeness and other attributes of imported food, but these attributes cannot necessarily be reliably and efficiently ascertained by inspecting products at the time of importation. It is an increasing practice for the regulatory authority of an importing country to rely upon the effectiveness of food inspection and/or certification measures undertaken in the exporting country. However food inspection and certification systems operating in exporting countries often differ from those in the importing country, and such variation may be evident in any component of a food control system. International recognition of the legitimacy of diverse approaches has led to the principle of equivalence being included in trade agreements.

WTO encourages countries to give consideration to accept as equivalent the measures of other members, even if these measures differs from their own or those used by other countries, if the exporting countries demonstrate that its measures achieve the the importing member's appropriate level of health protection (Article 4: "Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own or those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. Members shall, upon request, enter into consultations with the aim of achieving bilateral or multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.")

The TBT Agreement (Article 2.7) states: "Wherever

appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.”

In relation to the application of the principle of equivalence to food, the CAC has adopted *Principles of Food Import and Export Inspection and Certification* which state: “Countries should recognise that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.”

The Codex Alimentarius Committee has also adopted *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* which states (Section 5): “The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines. For the determination of equivalence, governments should recognise that:

- inspection and certification systems should be organised for the risks involved, considering that the same food commodities produced in different countries may present different hazards; and
- control methodologies can be different but achieve equivalent results. Controls on imported food and domestically produced food should be designed to achieve the same level of protection.

Applying the concept of equivalence to different food control sanitary measures used in different countries according to the provisions of the WTO Agreements has a number of benefits such as:

- Maximising food safety outcomes and improvements in public health for a given level of resource input, for both exporting and importing countries.
- Facilitating food control systems that apply innovative, risk-based sanitary measures.
- Decreasing reliance on routine end-product testing (eg at port of entry), which may be of limited effectiveness in protecting public health;
- Decreasing reliance on certification.
- Promoting harmonised food standards in different countries.
- Achieving comprehensive bilateral or multilateral agreements on the equivalence of overall food control systems in different countries.

1. Equivalence: Related activities

Equivalency of regulation is at present taking place, as for example, among the member countries of the European Union (EU), among those of the North American Free Trade Agreement and more recently, between Australia and New Zealand. In case of the EU, even though there is an EU decision explicitly stating that nations were free to maintain and enforce their own regulations for products produced within their jurisdiction but that they could not legally prevent their citizens from consuming the products that meet legal standard of another country, as long as they offered equivalent level of protection of the public interest issues.

However, it seems that where technical regulation play a significant role, equivalency only works if there is a formal arrangement or harmonized standard has been developed. This is particularly the case when there are serious concerns about health and safety. In February 1995, the EU Council agreed to a mandate authorizing the Commission to conduct negotiations with a view to the conclusions of agreements with the third countries on sanitary and phytosanitary measures. Following this mandate, the EU Commission has conducted negotiations with a number of countries. Agreement has been concluded with New Zealand in 1997, USA in 1999 and Canada in 1999, while negotiations are continuing with Australia, Argentina, Uruguay and Chile. Negotiation with Thailand was initiated in 1998, however due to lack of staff and priority from EU side progress has been very slow. The EU agreement with those countries is aimed at facilitating trade in live animal and animal products including fish and fishery products.

The NAFTA Treaty for Mutual Recognition of SPS measures if exporting country’s regulation achieves the importing country’s appropriate level of protection. The burden of proof is on the exporter. If the importing country does not accept the exporting country’s SPS measure as equivalent, then it has to give reasons in writing upon request (Article 714). The final decision about equivalency stays with the authorities of importing country that take decision on a case-by-case basis. Currently, there is no equivalency agreement among NAFTA members on SPS measures. The US and Canada is in the process of developing equivalency agreement on Fish Inspection and Control System. Once the technical issues are solved, there are still the process of drafting the agreement, public hearing and conclusion

of agreement, as required by the procedures set by USFDA in entering into agreement.

Australia and New Zealand have agreed, under the Trans Tasman Mutual Recognition Agreement, to recognize each other's regulation on food. This means that a product legally sold in one market can be sold in the other without having to comply with additional requirements. In the food sector, the two countries have implemented mutual recognition of their respective regulations. A joint food standard system has been in operation since 1999 through Australia—New Zealand Food Authority (ANZFA).

The Government of Canada and Thailand established the Equivalence Agreement on Fish Inspection and Control System in 1998. The agreement aimed at facilitating trade of fishery products between the two countries. Details of this agreement will be elaborated in the following section.

There are guidelines for the recognition of equivalence and development of agreement regarding food import and export inspection and certification systems developed by major importing countries include USA, EU, Australia and New Zealand, Canada and etc. These countries guidelines are based on Codex principles that:

- Legal authority exists to discuss and enter into such agreement.
- Consultation between two parties takes place.
- Importing country provide information on food safety objective to exporting countries.
- Exporting country demonstrates that its own food safety control achieves importing country food safety objective or level of protection.
- Agreed (preferably CODEX) standards, recommendations, and guidelines be used.
- Exchange or review of information that include:
 - Legislative framework

Both responsible authorities should have the authority, based on adequate legislation, to establish and enforce regulatory requirements. Legislation should provide the necessary authority to carry out controls at all stages of raw materials, holding, handling, transporting, processing, packaging, and trade in fish and fishery products.

— Control program and operations

Appropriate policies and procedures for conducting inspections should formally document inspection working methods and techniques.

The inspection program should be based on identified objectives and appropriate risk evaluation. In the absence of sufficient scientific information, inspection programs should be based on the authority's best scientific judgment, taking into account current knowledge and practice. Procedures should be in place to ensure that inspections are carried out using priorities based on risk, to address known or suspected non-compliance situations; and in a coordinated manner between different regulatory authorities, if several exist. Both responsible authorities should identify the main objectives to be addressed by their fish and fishery products inspection and control systems. Where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements should be avoided to prevent legal and commercial problems and obstacles to trade. This system should include, but not be limited to:

- The responsible authority should have in place a management structure that can set priorities, establish policies, decide personnel issues, and monitor that authority's activities.
- The responsible authority should have in place an effective code of ethics for its personnel, addressing both bribery and conflict of interest, with effective means of taking action to prevent or correct problems.

— Decision criteria and actions

— Facilities, equipment, transportation and communication as well as basic sanitation and water quality. The responsible authority should have in place the necessary controls, procedures, standard setting mechanisms, enforcement options, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the fish and fishery products inspection and control program.

— Laboratories, including information on the evaluation or accreditation of laboratories, and evidence that they applied internationally accepted quality assurance techniques. Each party should have in place a system for requiring the reliability of laboratories used for sample analysis. Laboratories should demonstrate that they have consistently acceptable performance through programs that include adequate quality assurance

controls, the use of validated analytical methods, and other measures necessary to document the reliability of test results.

— Details for assuring competent and qualified inspection, through appropriate training, certification and authorization of inspection personnel, the number and distribution of inspectors. Training for inspection personnel should include a standard basic level of training in the procedures and the scientific basis for conducting inspections, including the basic elements of sensory examinations; specialized and/or advanced training for specialists and advisory staff; and a program for continuously maintaining and upgrading the skills of inspection staff. Training for laboratory personnel should include instruction, where appropriate, in regulatory requirements, chemical, microbiological and sensory analytical methods, and maintaining the integrity of evidence.

— Procedures for audit of national systems, including assurance of the integrity and lack of conflict of interest of inspection personnel. Each party should periodically conduct self-assessment or third-party audits at various levels of the fish and fishery products inspection and control system, using internationally recognized assessment and verification procedures.

— Details of the structure and operations of any rapid alert system.

Currently, there are negotiation among countries for equivalence agreement on fish inspection and control system. However, the process are still under development due to the fact that :

- Document review process or side by side comparison is time consuming requiring thorough examination of legislation, authority, policy, procedures, capacity, capability, competence. This process often takes years for both exporting country to prepare the document and years for reviewing of another party.
- Differences in culture and structure of law, make it usually difficult to identify single authority for overall control of system, especially if two-way agreement is being negotiated.
- Differences in policy, procedures, methods is often the case of different inspection and control system, while judgement of equivalency is still qualitative. In most cases it cannot be concluded that different

procedures can produce same level of protection. This often results in compromising measures to deal with differences or each party has to still meet another country's standard or use measures as prescribed by the law of another contracting party.

- Judgement of equivalence of food control systems in different countries is a critical issue. It is evident that international guidelines are needed for systematic application. Codex principles and guidelines associated with determination of equivalence will facilitate this process. In this respect, the Codex Committee on Food Import and Export Certification and Inspection Systems (CCFICS) has developed the Guidelines for the Development of Equivalence regarding Food Import and Export Inspection and Certification Systems, and Guidelines for Judgement of Equivalence.
- Product standard is still being used as appropriate level of protection while there is not always a standard existing for every hazard. In addition meeting standard does not always guarantee safety.

2. Equivalence: Issues for the future

Currently, determination of equivalence is based on qualitative assessment. However, the concept of performance standard based on quantitative risk assessment are being considered, but still under development.

As interest in applying the concept intensifies in exporting countries, so does the need of importing countries for methodology which will allow them to make judgments in an objective and coherent way about whether proposed standards and systems are equivalent to their own internal requirements. Agreed methodology for judging equivalence is urgently needed. International recognition methods is preferable. The absence of guidance from Codex will be a severe disadvantage if a WTO dispute settlement panel or Appellate Body is called upon to rule whether a member country has proceeded appropriately in whether equivalence has been objectively demonstrated by the exporting party.

Usually, importing countries will give priority to negotiate to a country that have significant trade volume and those who have a history of good compliance. All in all, negotiation also depends on politics and trade issues between the two countries as well.

One of the most challenging area in equivalence

recognition is the assessment of equivalence through audit of contracting party's fish inspection and control system. The contracting party must be able to maintain the equivalence. This is usually done by onsite review of fish inspection and quality control system of regulatory agencies and review of industry control performance. To date, there is no standard audit procedures and guidelines for assessment of results. Audit procedures is usually based on ISO 10011 and the Codex Committee on Food Import and export Certification and Inspection System has developed guidelines for audit. The success of the audit will depend on consultation of purposes, objectives, procedures and scope between the two parties, otherwise this exercise will only serve the assurance of compliance to standard or procedures of a single party.

3. Equivalence: Recommendations

Development of Codex guidance on the judgment of equivalence, initially in a generic sense and subsequently in relation to specific topics such as equivalence of inspection and certification systems, and measures to ensure food hygiene.

It should be noted that while such guidance is needed urgently Codex processes are unlikely to allow finalisation of guidelines on this topic until 2003 or later.

ASEAN countries should give attention to the development of the guidelines as well as to prepare the research program on risk analysis to prepare for the development of level of health protection

■ Hazard Analysis and Critical Control Point (HACCP)

In the 1990s, the EU, Canada and the US initiated seafood safety regulations that follow HACCP plans. HACCP principles stress identifying where hazards are likely to occur in a processing chain, the critical control points for the hazards, preventative measures to be taken to keep hazards within critical limits at each critical control point, establishment of monitoring procedures, clear response to deviations of critical limits at each critical control point, record keeping, and continued validation and updating of the HACCP system. Consistent sets of HACCP principles have been set by the United Nation's food standards body, the Codex Alimentarius Commission. While Codex has adopted the HACCP principles, they

do not give detailed guidance on implementation. The plans in place apply to both domestic supplies and imported supplies.

Under the Food and Drug Administration (FDA) procedures, US suppliers of seafood are required to have a HACCP plan of their own, and to obtain HACCP plans from their foreign suppliers or otherwise ensure that the suppliers' programmes are equivalent to the US's. The EU and Canadian plans, while initiated earlier, have a similar focus. For regulators, trade facilitation is an important but secondary goal of HACCP adoption. Importers are required to take affirmative steps to ensure that their suppliers are in compliance with HACCP. The programme offers several ways to meet this requirement, including inspecting overseas plants, obtaining certification of foreign inspections, or testing the product. This requirement is deemed to have been met if the importer's foreign supplier is located in a country that has entered into a mutual recognition agreement (MRA) for seafood with the US. A MRA would establish that the foreign country has in place a mandatory, HACCP-based safety system equivalent to the US system.

1. HACCP: Related activities

Application of HACCP in the seafood industry has caught global interests since 1996. The seafood industry worldwide has responded to the implementation, training and audit of HACCP, while regulatory control agencies has progressively developed a HACCP-based control system.

Training modules and materials, technical information and references, websites on HACCP has been widely available for the industry, government, research and academia.

Training courses on HACCP principles and application, HACCP audit and advanced implementation are available from international organizations, Governments, private consulting firms and academia worldwide.

For the past four years, positive reports from various seafood producing, exporting and importing nations on HACCP implementation has been published and discussed in various regional and international forums. HACCP concepts applied internationally are based on CODEX principles and steps for application. However, as the implementation procedures are left open, there appears to be different

expectations largely from importing nations on:

- Documentation of HACCP programme or HACCP plan, details of information to be maintained or established.
- Training of staff.
- Requirement for prerequisite and hygiene control.
- Hazard to be controlled.
- Hazard analysis procedures.
- CCP determination.
- Control and monitoring procedures to be used.
- Critical limits to be applied.
- Corrective actions and control of process and products required.
- Records to be kept, retention time and procedures.
- Verification of HACCP system and validation of critical limits.

In addition, on the part of regulatory agencies, whether a HACCP regulation is necessary, knowledge

and experience of inspectors, standard procedures for HACCP audit, supported fund and availability of staff.

In relation to harmonization, guidelines for regulatory HACCP audit and HACCP documentation is necessary, to ensure consistent approaches by different countries and authorities.

In relation to equivalency, regulatory HACCP-based programmes becomes an essential part for equivalency determination, especially where importing countries regulate HACCP in their food control measures. Only the USFDA and EU spell out very clearly the requirements of HACCP for imported fish and fishery products. According to US Seafood HACCP regulation, the individual establishment must demonstrate their compliance to HACCP requirements in order to export products to US market. The establishment can demonstrate their compliance in various ways, through the importers (Table 1).

Table 1: Procedures to Demonstrate Compliance to US Seafood HACCP Regulations

Regulation	Description of procedures	References
USFDA	<p>Every importer of fish and fishery products shall either:</p> <ol style="list-style-type: none"> 1. Obtain the fish or fishery products from country that has an active MOU or similar agreement with USFDA that covers fish and fishery products. 2. Have and written verification procedures. The procedures shall list at a minimum: <ol style="list-style-type: none"> 2.1 Product specification that are designed to ensure that the product is not adulterated. 2.2 Affirmative steps that may include any of the following: <ol style="list-style-type: none"> (1) Obtain from foreign processor the HACCP and sanitation monitoring records with specific-to-specific lot of fish or fishery products being offered for import. (2) Obtain either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party. (3) Regular inspection of foreign processors facilities by importers. (4) Maintaining on file a copy (in English) of the foreign processors HACCP plan. (5) Periodically testing the imported products, and maintaining on file a written guarantee from the foreign processors that product is processed under HACCP. (6) Other verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirement. 	21 CFR Parts 123 and 1240; Section 123.12 Section 402 of the Federal Food, Drug and Cosmetic Act

In order for a country to establish a MOU under US Seafood HACCP regulation, the government authority in the exporting country must demonstrate that their HACCP based control programme is equivalent not only to US Seafood HACCP regulation but other regulations as well.

Until now, there is no MOU between FDA and any authority in an exporting country, although the discussions on MOU between USFDA and Canadian Food Inspection Agency were well advanced, and FDA has for the past three years discussed with various countries such as New Zealand, Japan, Thailand, Ecuador, Iceland, etc. According to FDA, none of the 6 affirming step are superior to the rest. FDA has published on 16 April 1998 a "List of Foreign Processors Approved by Governments" covering three countries: Canada, New Zealand and Thailand. The list is based an affirmative steps 2.2 (2). This alternative is an affirmative step that involve the participation of inspection authority in exporting country without reaching equivalence agreement. This step is to avoid the extensive use of certificate from exporting countries.

As for the EU, the approved processors must implement own "check-system" according to EU Directive 91/493 and EC Decision 94/356 to be approved by competent authority and authorized for export by the EU Commission. For harmonized country, where the system of fish inspection of the competent authority is recognized as equivalent to EU, the competent authority is responsible to ensure that the approved establishment consistently complies to EU Directives, as follows:

- EC Directive 91/492/EEC (Health conditions for the production and placing on the market of bivalve mollusc products)
Other relevant legislation include:
- Fishing vessel
- Potable water Directive 98/83/EC
- Drug Residue Directive 96/23/EC
- Additives authorized in fishery products (Directive 95/2/EC)
- Decision 93/140/EEC — Parasite
- Decision 93/351/EEC — Mercury
- Decision 93/51/EEC — Microbiological criteria, shellfish/crustaceans
- Decision 95/149/EC — TVB-N
- Decision 95/328/EC — Health Certificate
- Directive 88/320/EEC — Good Laboratory Practices
- Regulation EC No 2406/96 — Organoleptic criteria

2. HACCP: Issues for the future

Even though application of HACCP in the fishery industry is making progress, it is recognized that the past five years is a learning experience for both the industry and regulatory agencies. It was discovered that there are regulations that does not support the implementation of HACCP existing in all countries, especially those that require lot by lot testing, or regulation that require non safety issues determination.

For industry application, weakness in technical knowledge for hazard identification and analysis do exist. Education, training and information dissemination should still be continued especially for a more quantitative assessment of risk and significance of hazard.

Validation of critical limits is an urgent issue to be complied by the industry. Technical research is urgently needed.

HACCP documentation and records are issues to be sorted at international level. Currently, it seems like the industry is cutting the tree to build the HACCP programme, where a lot of information both useful and non useful are required to be kept and maintained.

Verification of the effectiveness of HACCP plan and programmes must be implemented by the industry or thrid party as appropriate. The industry still relies on regulatory verification and third party. However, the objective of regulatory verification is far broader and is at random, this may not in all cases indicate the effectiveness of industry's HACCP control programs.

Harmonization of regulatory verification at national level, where there are many agencies providing services; at international level or at regional level, where hazards, or production contitions are alike, will serve the effectiveness of HACCP implementation by the industry and the creditibility of regulatory audit as well.

HACCP is often only required for products for export. HACCP concepts should be applied at all levels from primary production through marketing of products. Small scale processors usually face technical limitation, and need to be assisted.

3. HACCP: Recommendations

ASEAN countries should continue to works jointly on hazard identification and hazard analysis for regional raw materials or products. Research work on microbiological and chemical hazards related to raw

materials, process environment and products of the region should be carried out regionally.

Research work to support risk and significant analysis for hazard is useful and should be looked into. ASEAN should consider compiling a regional fishery product hazard and control guides. A harmonized HACCP system for implementation and audit within the region is recommended.

Small scale and domestic processors should be assisted to ensure implementation of HACCP for the whole industry.

■ Conclusion

The establishment of Mutual Recognition Agreements (MRA) on the equivalence of fish inspection and control systems based on HACCP is the aim of fish exporting nations in the absence of harmonized standards. MRA is the outcome of a process of evaluation which leads two or more countries to agree that the standards and/or associated systems employed by each country are such as to allow goods marketed in one country to be freely marketed in another country which is a party to the agreement. The purpose of such agreements is to allow goods to flow more freely in international trade, unimpeded by differences in the national requirements of trading partners, provided that each participating country's appropriate level of protection is achieved. Typically a MRA would facilitate trade by reducing or eliminating the need for inspection control of goods at the point of entry, relying instead on the effectiveness of control systems in the exporting country.

Mutual recognition may apply to all foods traded between countries which are a party to an agreement or only to specified foods, and to all requirements applicable to specified foods (including food standards) or only some (such as conformity assessment procedures). Countries may elect to enter into an umbrella agreement consisting of general provisions and specific sectoral arrangements made under the umbrella agreement.

The feasibility of establishing mutual recognition will be greatest between countries which have broadly similar attitudes to the appropriate level of protection against health risks or deception of consumers, and between countries which have

broadly similar capabilities in relation to the monitoring and enforcement of requirements. Mutual recognition is more likely to be established between countries which are in some kind of political or legal association with each other; often such countries will be neighbours with a long tradition of trading food. To date most MRA is limited to a government to government certification arrangement; examples are EU, Australia and New Zealand, Japan and the trading partners. There are a few cases of equivalence arrangements, where the importing countries agreed that the inspection system of the exporting country deliver an equivalent food safety outcome that is delivered by the system in place in importing countries, such as the MRA between Thailand and Canada.

An exporting country will have to demonstrate and prove that their system can provide acceptable level of protection. Initiative has to be made by importing countries for consultation, exchange of information, evaluation and assessment of equivalence both qualitatively and quantitatively. Assurance of food safety protection cannot be provided by HACCP system alone but HACCP is an integral part. Therefore, implementation of HACCP by industry and an integrated HACCP-based food safety control system operated by the regulatory agency is crucial for MRA development.

■ Mutual Recognition Agreement (MRA): Recommendation

In the development of MRA, the individual country should:

1. Document its legislation, policy and procedures relating to fish safety and quality control. The document must describe all information as recommended by Codex.
2. Law or legislation may need to be reviewed to cover or spell out clearly control from water to marketing, and controlling of non-complying products. In addition, it has to be HACCP based.
3. For some ASEAN countries, authority for inspection and control of fishery products is not by one authority. Technical competent authority usually do not have full legislative authority for inspection and quality control but mainly for research and development as well as conservation enforcement.

This creates an even more difficult position in negotiating equivalence agreement. The authority to establish agreement has to be clear.

4. Laboratory system is one of the components to be also considered for equivalence. The laboratories have to implement quality system equivalent to ISO 17025. Some countries prefer that the laboratories are accredited. More importantly, laboratory collaboration to ensure reliability of test results is a prime concern.
5. Perform the internal audit of the effectiveness of the fish inspection and control system.
6. Maintain competence of personnel involved in the system.
7. Maintain close consultations with importing countries relating to procedures, guidelines, and framework for establishment of equivalence agreement.

Regulatory agencies in ASEAN need to network to cover inspection and control activities so as to strengthen their control system and image as regional bodies, to deal with issues related to technical information, standard, code of practice at international level. This will in the future lead to a regional MRA once the system is well established in all countries. An example of the networking in other region such as the MERCOSUR countries should be followed.

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