ASSISTANCE TO THE SOUTH PACIFIC TO MEET NES FISH-IMPORT REGULATIONS

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UNITED STATES

Background

Approximately 55 per cent of the seafood consumed in the United States is imported. These seafood imports come from 135 countries (FDA Statement, 60 F.R. No. 242, p. 65097).

Not surprisingly therefore, the US seafood safety standards apply both to imported and domestically-sourced seafood. The federal agency with the primary responsibility for assuring seafood safety is the Food and Drug Administration (FDA) which is an institutional component of the US Department of Health and Human Services.

FDA's legislative responsibility as regards seafood is to ensure that seafood either imported into the United States or crossing internal state lines (collectively referred to in the United States as interstate commerce) is safe and wholesome. This responsibility derives from the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.).

Section 402(a) (#21 U.S.C. 342(a)) provides that the FDA can control the production and trade of any 'adulterated' seafood. In the import context this means that the FDA can prohibit from entry into the United States any seafood determined to be 'adulterated'.

To determine whether a seafood product (or other food product) is adulterated, the FDA has employed three regulatory strategies.

First, through formal regulation, the FDA can establish a 'tolerance' that identifies a limit above which a seafood is deemed injurious. As of the early 1990s, only one formal tolerance existed that specifically dealt with seafood and that involved polychlorinated biphenyls (*Seafood Safety*, 1993, p. 288).

Second, the FDA can establish 'action levels' which, although not legally binding and not in the form of a formal regulation, have the effect of establishing limits which seafood must meet. Failure to meet these action levels will result in imported seafood being refused entry into the United States.

Finally, the FDA can control any food where it can provide sufficient evidence that the food constitutes a problem for public health. This authority can be used irrespective of the non-existence of tolerance or action level standards. Microbiological pathogens in seafood are controlled using this third strategy (*Seafood Safety*, 1993, p. 292). Seafood imported into the United States must comply with the same criteria for wholesomeness and safety as imposed on like US products. The FDA has the direct responsibility for inspection (and approval) of imported seafood.

The FDA has developed a strategy of automatic detention for certain fish species (e.g. swordfish, mahi mahi) until the importer can provide assurances that the product is safe. This automatic detention can be extended to products and suppliers that the FDA finds to be inconsistent with US seafood safety standards.

The power to extend automatic detention in this manner derives from the authority of the FDA to refuse admission to any seafood product that 'appears' from examination or otherwise not to be safe and wholesome (i.e. is 'adulterated').

The approaches of the FDA to seafood import monitoring are: reliance on past experience with specific fish species and suppliers; and sampling and testing. The first approach has led to the automatic detention programme for high-risk species and suppliers.

The reliance on sampling and testing to identify the high-risk species and suppliers and to assure safety for non-identified high-risk seafood has been criticised as being ineffectual. To improve the monitoring of seafood safety, make sampling and testing more efficient, and to shift the burden of seafood safety onto the processors and suppliers, the United States developed the Seafood HACCP Regulation. The Seafood HACCP Regulation will come into force in December 1997.

The Seafood HACCP Regulation

There are three mandatory aspects of the US Seafood HACCP Regulation that are of critical importance to exporters of seafood to the United States.

- Every processor (American and non-American) **must**, where an identifiable food-safety hazard is reasonably likely to exist, put in place a HACCP plan consistent with the details of the US regulation. Failure of a processor to have and implement a HACCP plan, where one is necessary, means that the imported seafood is 'adulterated' and the FDA will deny entry of the product into the United States.

- The HACCP plan adopted by a processor (American or non-American) **must** have been developed by an individual who has received training in the application of HACCP principles deemed adequate by the FDA. A HACCP-trained individual must also regularly reassess, modify and review both the HACCP plan and its implementation.

- The US importer **must** be able to verify to the FDA that the seafood seeking entry into the United States has been processed or produced in accordance with an effective HACCP plan. If an importer is unable to show that the seafood product in question has been processed or produced under a HACCP plan, the seafood 'will appear to be adulterated and will be denied entry' (Sec. 123.12(d)).

From these three mandatory aspects of the US Seafood HACCP Regulation come a large number of questions.

Who is a processor that is required to have a HACCP Plan?

A processor is defined as any person engaged, either in the United States or in a foreign country, in processing (Sec. 123.3(l)). The addition of the phrase 'in a foreign country' ensures that the HACCP requirements for seafood production apply outside the United States. Processing is broadly defined as including: handling, preparing, freezing, preserving, packing, dockside unloading or holding (Sec. 123.3(k)(1)).

Harvesting and transporting are not considered processing and the mandatory HACCP requirements do not apply to fishers (except where vessels engage in processing) or the act of transporting processed fish (Sec. 123.3(k)(2)). In the Pacific Island context, canning of tuna is clearly processing, as are the onshore handling and packing of fresh-chilled tuna and other fishery species.

The HACCP plan requirement attaches to acts of processing and the processor rather than the owner of the fish or fish product. If the fish owner is not the processor, the owner, seeking to export to the United States, must utilise a processor that conducts its activities consistent with a HACCP plan.

While it is only a processor that is required by the US regulation to have and operate its activities under a HACCP plan, where hazards to food safety may arise in harvesting or transporting, these activities may benefit from operating pursuant to a HACCP plan.

When is a HACCP plan necessary?

Despite what is stated above, not every processor must have a HACCP plan. More accurately, everyone engaged in processing must conduct a hazard analysis. If such an analysis reveals that food-safety hazards are 'reasonably likely' to occur, then the processor is required to develop and implement a written HACCP plan.

A food-safety hazard is defined as 'any biological, chemical or physical property that may cause food to be unsafe for human consumption' (Sec. 123.3(f)). In analysing the possible existence of food-safety hazards, a processor is to consider that such hazards can be introduced both within and outside the processing facilities and can arise before, during and after harvest. However, it is only food-safety hazards that are 'reasonably likely' to occur that must be identified. The regulation states:

> *A food-safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that it [the hazard] will occur in the particular type of fish or fishery product being processed in the absence of these controls. (Sec. 123.6(a))*

The US HACCP Regulation and the supplementary guide, *Fish & Fisheries Products Hazards & Controls Guide*, give direction as to the types of hazards that may occur for particular fish and processes. The potential food-safety hazard of histamines associated with tuna and mahi mahi is specifically noted in the regulation (Sec. 123.6(c)(1)(vi) and 123.3(m)) and in the *Guide*.

Because food-safety hazards will differ from species to species and depend on the processing activity, a HACCP plan will be unique to each location where fish are processed and to each fish and fishery product being processed. A processor that creates a generic HACCP plan for all facilities, activities and fish is **not** complying with the HACCP plan requirement.

What must be contained in a HACCP Plan?

Consistent with the previously noted seven principles of HACCP, Section 123.6(c) sets out what each HACCP plan, at a minimum, is to contain:

- a list of food-safety hazards reasonably likely to occur;
- a list of the critical control points for each of the identified hazards;
- a list of the critical limits that must be met at each critical control point;
- a list of monitoring procedures to be used at each critical control point to ensure compliance with the critical limits;
- corrective action plans to be used where a deviation from the critical limits at the critical control point occurs (there is a detailed provision that deals with corrective actions, Sec. 123.7);
- a list of the procedures to be employed to verify that the HACCP plan is adequate and effective; and
- provision for a record-keeping system that documents actual values and observations obtained during monitoring of critical control points.

When completed, a HACCP plan is to be dated and signed by the most responsible individual on site at the processing facility or a higher level official. 'This signature shall signify that the HACCP plan has been accepted for implementation by the firm' (Sec. 123.6(d)(1)).

Does having a HACCP Plan fulfill the processor's regulatory obligation?

Just having a HACCP plan does **not** meet the requirements of the US HACCP regulation. There are two parts to implementing the HACCP regulation: establishment of a plan and monitoring how the plan works. The last two of the seven HACCP principles are relevant: verifying the adequacy and effectiveness of the HACCP plan and documenting (record keeping) the key variables at the critical control points. The US regulation is clear, a processor must have and 'implement' a HACCP plan (Sec. 123.6(g)).

Moreover, every processor is to 'verify that the HACCP plan is adequate to control food-safety hazards ... and that the plan is being effectively implemented' (Sec. 123.8(a)). The key to effective implementation is a regular review of the HACCP plan itself where there has been a change in the source of fish product. At a minimum a HACCP plan and its operation is to be re-assessed on a yearly basis. Also, there is a necessity for ongoing assessment of the appropriateness and adequacy of critical control points, critical limits, the procedures used for monitoring and the corrective action plans.

What are the HACCP documentation obligations on a processor?

Given that one of the desired effects of HACCP is to reduce sampling and testing in favour of reviewing and inspecting HACCP plans and their implementation, the documentation of the HACCP plan and its operational effectiveness is critical.

First is the written HACCP plan itself. Second are the records of the monitoring of the critical limits at the critical control points. Third are the corrective-action records that arise where critical limits are not met (the detail of the corrective action plans is in Sec. 123.7). Fourth are the records of the verification procedures.

Together, these four sets of documents constitute the processor's HACCP record. A reviewer or inspector of the documents should be able to determine if a processor has appropriately identified seafood safety hazards, established critical control points and limits and whether these HACCP components are being effectively implemented in such a way that a reviewer or inspector can be assured that particular fish and fish products have been produced or processed in a manner that minimises seafood health risks to the consumer.

It is an important part of the US HACCP Regulation that monitoring records be **reviewed** and that the reviewer sign and date that the review took place. As stated in the regulation:

> *The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within critical limits.* ***This review shall occur within 1 week of the day the records were made*** *(Sec. 123.8(a)(3)(i)).*

The reviewer's assurance that the critical limits have not been exceeded is an important component of the record of the implementation of a HACCP plan. The need for a weekly review of how a HACCP plan is operating is indicative of the emphasis in the HACCP regulation of effective implementation of a paper plan.

Records are to be made of all corrective actions taken where critical limits have been exceeded and where any product testing takes place. As above, these records are to be reviewed either within a week or within a reasonable time. The reviewer is to provide assurances, amongst other things, that corrective action procedures were followed.

The paper record of the HACCP plan and its effective operation is critical if HACCP is to successfully minimise seafood health risks for consumers. Inadequate or incomplete documentation **could** lead the FDA to determine that a HACCP plan is **not** being implemented

and, therefore, that the seafood in question is adulterated.

Who can carry out the numerous HACCP responsibilities?

The Seafood HACCP Regulation specifically directs that certain key HACCP responsibilities must be undertaken by an individual who has appropriate HACCP training. While the wording of the regulation is imprecise, the intent is that key HACCP activities must be carried out by individuals having received training through courses that the FDA recognise as adequate (for the exact wording, *see* Sec. 123.10). The regulation also provides that 'job experience' can qualify an individual to undertake the HACCP responsibilities.

Having a HACCP-trained individual undertake many of the key HACCP responsibilities provides the FDA with increased assurance that the HACCP plan and its implementation are accomplishing the goal of minimising food-safety hazards. It is also part of the overall HACCP strategy of placing the burden of compliance and enforcement of seafood safety on to the processor.

The key tasks that **must** be done by the HACCP-trained individual are:

- developing the HACCP plan;
- reassessing and modifying the HACCP plan as part of the verification process, at a minimum once a year (and when corrective action plans are employed); and
- performing and documenting the record reviews.

Given that the last responsibility regarding monitoring records must be done weekly, the HACCP-trained individual is a critical part of a processing team that is effectively implementing a HACCP plan.

An appropriately HACCP-trained employee can fulfill the above task or the HACCP-trained individual can be a third party. The tasks assigned a HACCP-trained individual can be done by different individuals, provided each is appropriately HACCP-trained.

Will the FDA pre-approve or certify a processor's HACCP Plan?

There is no provision in the regulations for the FDA to provide a certification or approval of HACCP plans. The FDA policy is not to pre-approve HACCP plans. It is not even clear whether the FDA will indicate whether an individual meets the regulatory requirement of being HACCP-trained. The FDA's concern is one of cost (reviewing and approving HACCP plans) and efficiency (the plans and their operation are best reviewed through onsite inspections where possible) (*HACCP Training Curriculum*, 2nd ed., 1997, p. 131).

Who is an importer and what is the importer's role in the US HACCP regime?

Simply stated, the US Seafood HACCP Regulation places on the importer the responsibility for providing adequate evidence to the FDA that the seafood in question has been processed or produced pursuant to an appropriate and effective HACCP plan.

It is the responsibility of the importer to ensure that the HACCP requirements for a foreign processor are met. It is the importers who bear the direct burden of dealing with the FDA, since the importer is **in** the United States while the foreign processor, by definition, is outside the United States.

An importer is defined as a US owner or consignee of the seafood seeking entry or the US agent or representative of the foreign owner who is responsible for offering the goods for entry into the United States (Sec. 123.3(g)). It has always been the responsibility of the importer to offer for entry into the United States only seafood that is unadulterated.

However small a seafood importer's current business, the responsibility on the individual offering the goods for US entry is, in some situations, about to increase since they now must verify that the foreign suppliers meet the requirements of the Seafood HACCP Regulation. An importer is going to have to become proactive in its approach to seafood imports.

The FDA has explained the above in the following terms:

> *Currently, ... the importer is not required to operate in a proactive manner to ensure that it is meeting ... [its responsibility that seafood not be adulterated]. Rather the importer need only offer products for entry ... and thereby place the burden on government to find a problem.*
>
> *[It] is feasible for importers to take steps to ensure that they are not offering adulterated products for entry ... . Requiring such measures will not be a significant added burden for many importers, particularly as HACCP principles become more widely used ...* (FDA Statement, 60 F.R. No. 242, p. 65154*).*

Section 123.12(d) is clear: if an importer cannot provide sufficient evidence to assure the FDA that seafood seeking entry into the United States has been processed under conditions

equivalent to those set out in the Seafood HACCP Regulation, then 'the product will appear to be adulterated and will be denied entry.'

How can an importer verify that seafood has been processed under an appropriate HACCP Plan?

There are two avenues. The first effectively removes most of the responsibility for HACCP verification from the importer. This can occur where there exists a memorandum of understanding (MOU) between the United States and the country where the seafood was processed which results in the FDA recognising that the country of origin has equivalent food safety laws, standards and inspection practices. This MOU option is discussed more fully below (*see* 'The Government-to-Government (MOU) Equivalency Option', pp. 17–20).

Where seafood comes from a country not having a MOU with the United States, then the US importer has the responsibility to satisfy the FDA that the seafood was processed under an effective HACCP plan. The importer is to have and implement written verification procedures to accomplish this goal.

The written verification procedures **must** include 'product specifications that are designed to ensure that the product is not adulterated' (Sec. 123.12(a)(2)(i)). The written verification procedures must also include affirmative steps sufficient to provide evidence that the seafood was processed under an effective HACCP plan. The following is suggestive of what would be appropriate affirmative steps for an importer to take:

- maintain a copy of the foreign processor's HACCP plan and 'a written guarantee' from the processor that the seafood was processed in a manner consistent with the HACCP plan;
- periodically test the imported seafood;
- regularly inspect the foreign processor's facilities to ensure that seafood is being processed pursuant to a HACCP plan;
- obtain from the foreign processor the HACCP monitoring records that relate to the specific seafood sought to be imported;
- obtain a certificate from the foreign country's inspection authority or a competent third party that the seafood was processed under a HACCP plan; or
- other verification measures as appropriate (*see* Sec. 123.12(a)(2)(ii)).

Given that the goal of the written verification procedures is to satisfy the FDA that the seafood has been processed under a HACCP plan as outlined in the Regulation, the importer will of necessity need to collect and verify the accuracy and sufficiency of **most** of the above noted suggested information.

The precise mechanics and the paperwork for the importer to satisfy the FDA of the HACCP requirement are not yet certain. (FDA Statement, 60 F.R. No. 242, p. 65160) At an absolute minimum, however, the importer, if requested by the FDA, must be able to produce the written verification procedures it has established for all imported seafood.

How will the FDA enforce the new regulation?

The ultimate penalty under the Seafood HACCP Regulation is that the seafood will be deemed to be adulterated and thus will be denied entry to the United States. It is irrelevant that an importer, a foreign processor or owner of the seafood seeking entry can demonstrate that the seafood is safe for human consumption. The regulation deems seafood not processed pursuant to an appropriate HACCP plan as adulterated irrespective of the actual safety of the seafood.

The FDA has stated:

> *The purpose of these regulations is to cause processors ... to develop and implement HACCP systems ... . The importer requirements are designed to impose an obligation on importers to ensure that, like domestic products, the products that they are importing are not adulterated ... This requirement means that importers must be able to satisfy themselves, and ultimately FDA, that the fish ... that they are offering for import were produced subject to a HACCP system ... . If an importer does not have evidence that shows that the products were produced subject to such controls, it should not offer the product for import... . The lack of such evidence creates the appearance of adulteration that cannot be overcome by the collection and analysis of a finished product sample by an importer* (FDA Statement, 60 F.R. No. 242, p. 65159).

Although the Seafood HACCP Regulation contains mandatory language (e.g. importers **must** provide evidence of proper HACCP plan processing) and stiff penalties (denial of entry), the legislation is goal-oriented (HACCP plans and safe seafood) rather than rule-oriented. Goal-oriented legislation inevitably involves administrative discretion whether (and how) the legislation shall be enforced. The penalty, denial of entry, is necessary as a deterrent and the ultimate

consequence but can be anticipated to be used sparingly provided importers (and foreign processors) are in substantial compliance and the goal (HACCP plans and safe seafood) is not being compromised. The FDA has commented:

> *FDA expects to exercise broad regulatory discretion in deciding when violations of these regulations warrant regulatory action, just as it does now for other situations. The agency will analyse each case on its merits, based at least in part on the potential for harm that exists* (FDA Statement, 60 F.R. No. 242, at p. 65126*).*

One of the key aspects of HACCP is the shifting of responsibility for seafood safety from the random testing and sampling by governments to the seafood processors themselves. In the case of imports, it is the importers that have the task of enforcing HACCP requirements on foreign seafood processors. The FDA will become more involved in inspecting processes (HACCP plans, monitoring records, reviews, etc.) than in the actual seafood itself.

Of course, random testing, sampling and inspection by the FDA will continue to occur. As has been noted, this shifting of government inspection 'from lot and border checks to the more comprehensive view of HACCP ... constitutes a major change' (Evans, 'Seafood safety—what exporters must know about HACCP', 1995, p. 51). This will be the challenge for the FDA.

Sanitation-control procedures

Good sanitation practices are already mandatory for all foods. A food is adulterated if it is processed under unsanitary conditions (Section 402(a)(4) of the FFDC Act, 21 U.S.C., 342(a)(4)). The Current Good Manufacturing Practice (CGMP) (*see*: 21 F.R. Part 110) provides direction regarding sanitation conditions and practices.

However, after a review, the FDA concluded 'that a significant portion of seafood processors operate under poor sanitation conditions' (FDA Statement, 60 F.R. No. 242, at p. 65146) and that the FDA had 'not succeeded in developing a culture throughout the seafood industry in which processors assume an operative role in controlling sanitation in their plants' (FDA Statement, 60 F.R. No. 242, p. 65147). Therefore, the FDA decided to include in the Seafood HACCP Regulation specific provisions regarding sanitation control by seafood processors (Sec. 123.11).

The sanitation-control provisions in the Seafood HACCP Regulation are to operate simultaneously with the conditions and practices that exist in CGMP regulation and the HACCP requirements. The essence of the new provisions is monitoring. Processors are to monitor, and document the monitoring, of key sanitation conditions and practices that take place in the processing facility.

There are eight key sanitation conditions and practices that are to be monitored and the monitoring documented:

- safety of water (including ice) that comes into contact with food;
- condition and cleanliness of food-contact surfaces, including clothes;
- prevention of cross-contamination;
- maintenance of hand-washing, hand-sanitising and toilet facilities;
- protection of food, food packaging and food contact services from contaminants;
- storage and use of toxic compounds;
- employee health conditions; and
- exclusion of pests from the facilities (for the details *see* Sec. 123.11(b)).

The regulation recommends that each processor have and implement a sanitation standard operating procedure (SSOP) which covers the above-noted sanitation conditions and practices. While an SSOP is not required, it is mandatory that sanitation control records related to the above eight conditions and practices be maintained, as well as the monitoring records (Sec. 123.11(c)).

Sanitation controls and monitoring can be incorporated into the HACCP plan and implementation. Sanitation controls and monitoring may be dealt with separate from the HACCP system. It is important to note that even where a HACCP system is not required (no reasonable likelihood of a food hazard), sanitation controls and monitoring **are required**.

The importer must be able to assure the FDA that seafood seeking entry into the United States has not been processed under insanitary conditions (Sec. 123.12 (2)(i)). Part of the importer's affirmative steps that can (or must) be taken to provide that assurance may include: obtaining from the foreign processor the relevant sanitation monitoring records; obtaining appropriate foreign government or third-party inspection certificates that the sanitation requirements of this regulation were followed; inspection of the foreign processor's facilities; other verification measures appropriate to show foreign processor compliance.

Failure of the importer to provide evidence of a foreign processor's

compliance with the sanitation requirements of the Seafood HACCP Regulation will result in denial of entry of the relevant seafood.

Government-to-Government (MOU) equivalency option

Why MOUs?

The Uruguay Round Agreements on Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade (TBT) obligate their adherents to remove barriers to food trade created by standards, by creating common standards and requiring states to seek bilateral agreements recognising equivalency of food-safety standards.

Moreover, it has already been noted that under the Seafood HACCP Regulation the importer need not be put to the test of assuring that the foreign processor has adopted and implemented sanitation controls and a HACCP plan where the seafood is processed in a country with which the United States has a government-to-government agreement (MOU) through which the United States accepts that the seafood from that country has been processed in a manner equivalent to, and thus in compliance with, the sanitation and HACCP requirements (Sec. 123.12(a)(1)) and 'How can an importer verify that seafood has been processed under an appropriate HACCP regime?').

From the importing state's (United States) perspective, a MOU is desirable since it shifts the principal burden of seafood-safety enforcement and inspection on to the exporting state. The FDA benefits since it will utilise its scarce resources targetting seafood from states which do not have an MOU with the United States since food-safety hazards are more likely to exist with those products. The importer benefits since it need not be concerned with verifying the safety of the seafood seeking entry. The exporting seafood processor benefits since it should find it easier to deal with its local government rather than either the US importer or the FDA.

The only possible loser in the MOU arrangement is the government of the exporter which has to negotiate with the FDA to reach an equivalence (MOU) arrangement and must have in place laws, controls, inspectors, etc. sufficient to assure the FDA that equivalent seafood-safety protection exists.

The FDA approach to MOUs: equivalency

It is important to recognise that the purpose of the MOU exercise is not to have the exporting state mirror or replicate US laws, standards and practices regarding seafood production.

Rather, the purpose is to determine if there exists in an exporting country an **equivalent** level of laws, standards and practices regarding seafood production to those existing in the United States. Duplication may be flattering, but it is neither required nor the goal. The idea of equivalence is paramount in the MOU provision in the Seafood HACCP Regulation—the MOU is to document the equivalency of the foreign and US seafood-safety systems.

The FDA has recently indicated the process and criteria it will be applying in determining equivalency and thus whether an exporting state will be able to enter into an MOU with the United States (FDA Statement, 62 F.R. Vol. 107, pp. 30593–30600).

As a matter of process to determine equivalence, the FDA will do a 'paper review' (side-by-side comparison of US system of laws, regulations, standards, regulatory practices and procedures with that of the exporting country) and an 'on-site verification review' (designed to verify that the foreign regulatory system, including its inspection system, functions as indicated in the paper review).

Regarding the paper review, the test of equivalency involves more than just the written laws, although this is of importance. The food safety law of the United States has the following purposes:

- to prohibit adulterated food entering commerce;
- to establish what constitutes adulterated (or misbranded) food;
- to authorise regulatory agencies to establish standards, to conduct inspections, to issue processing requirements and to take enforcement action.

The FDA has stated that:

> *In order for equivalency to be achieved, a foreign country needs to have laws applicable to food to be exported to the United States that achieve essentially the same objectives and meet US levels of protection. In addition, ..., the foreign country must have the authority to implement the law... and must be, in fact, doing so* (FDA Statement, 62 F.R. Vol. 107, p. 30598).

The US 'levels of protection' relate to the definitions given to 'adulterated' in the Federal Food, Drug, and Cosmetic Act (*see* generally: Sec. 402(a), 21 U.S.C. 342(a)). The manner of achieving the levels of protection are through outcomes (tolerances and levels of contaminant) and conditions of production (sanitation, CGMP, HACCP).

In addition to the written law there are agencies (FDA) which implement (or enforce) the law.

Essential characteristics of these agencies have been identified by the United States as:

- capacity to identify health problems and to establish 'scientifically-based regulatory standards';
- capacity to undertake mandatory inspections and determine if standards are being met;
- a laboratory infrastructure capable of performing appropriate food-safety tests;
- capacity to enforce the law;
- an internal monitoring system to guard against conflict of interest and to promote ethical behaviour (*see*: FDA Statement, 62 F.R. Vol. 107, p. 30598).

An exporting country must be able to demonstrate that its food-safety implementing agencies have equivalent capacities and infrastructure.

Essential to the equivalency comparison is determining whether there exists 'effective implementation'—paper and good intentions are not enough. As the FDA has carefully noted:

> *(Whether equivalence exists will be based on a consideration of whether the foreign country's system as a whole... provides the assurances that are provided by the US system* (FDA Statement, 62 F.R. Vol. 107, p. 30599).

As a general statement on equivalency, the FDA commented: **'US standards will not be relaxed to facilitate a finding of equivalence.'** [emphasis added] (FDA Statement, 62 F.R. Vol. 107, p. 30596).

MOU flexibility

The US MOU arrangements are designed to be government-to-government and are not to be government (FDA)-to-foreign processor.

This is restricting from a foreign seafood-exporter perspective since it cannot deal directly with the FDA. Under the Seafood HACCP Regulation, it is the US importer which must deal with the FDA rather than the foreign processor interacting with the FDA. The restriction on FDA-to-foreign processor MOUs is also consistent with the FDA's approach to not pre-approving or otherwise certifying a foreign processor's HACCP system.

The FDA does accept that the government-to-government MOUs need not be comprehensive food-safety equivalency agreements. The MOUs can be restricted to specific products (seafood or fish species) and/or specific seafood export processors.

The United States is not seeking to impose its food safety standards on an exporting country, rather the United States is seeking to ensure that the food that is imported into the United States meets the same food-safety standards as domestically-produced food (i.e. equivalency).

This flexibility for an MOU could allow exporting states to focus their regulatory/enforcement attention on specific seafood exports (tuna, mahi mahi, deep-water bottom fish—fresh, chilled, canned, smoked) and also target selected processors (those involved in export, rather than all processors).

This MOU flexibility may be of value to countries not having the capacities to create a full, domestic food-safety programme equivalent to the US system. It is important to recognise, however, that even for limited MOUs, the FDA is seeking equivalence and is unlikely to accept any lessening of standards or process requirements.

A further refinement of an MOU relates specifically to HACCP. It may be possible to have a government-to-government MOU which relates solely to the HACCP and sanitary control aspects of the US Seafood HACCP Regulation. The Regulation allows the importer to avoid the onerous verification procedure (*see*: 'How can an importer verify that seafood has been processed under an appropriate HACCP regime?'), where an MOU exists.

The MOU is to document:

- the equivalency of the US system with that of the foreign exporting country or the compliance of the foreign inspection system with that of the United States, and
- that the MOU 'accurately reflects the current situation' (Sec. 123.12(a)(1)).

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