

Preliminary Review of the Legal Framework Governing the Use of Chemicals in Aquaculture in Asia

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“States should regulate the use of chemical inputs in aquaculture which are hazardous to human health and the environment” (CCRF, 9.4.5)

ABSTRACT

This preliminary review looks into legislation governing the use of chemicals in aquaculture in Asia. Brief assessments are made of the legislation relating to chemical contamination and the use of veterinary drugs and feed additives, a section is dedicated to trade in aquaculture products, and a few conclusions are then drawn. While mandatory measures of control are desirable and feasible, soft law instruments, such as codes of practice and conduct, allow an element of flexibility to be maintained while avoiding undue legislative restraints on scientific and technical progress.

INTRODUCTION

National legislation on the use of chemicals in aquaculture is not abundant, and is characteristically scattered in various legislative texts, including that of basic and subsidiary legislation, which does not permit a detailed and accurate legal analysis of the use of chemicals in aquaculture. While basic legislation laying down general principles applicable to the use of pesticides, veterinary drugs, food products, etc. as a whole could be collected by the author, it was more difficult to find the subsidiary regulations, including the “vertical measures” dealing with specific categories of products (in the present case, aquaculture products), the latter often being drafted by ministerial departments or subsidiary authorities.

The study of legislation relating to the use of chemicals in aquaculture brings with it two distinct legal issues. One relates to the problem of water pollution and the contamination of the general aquatic environment by aquaculture chemicals, and the second contemplates the controls on the lawful use of a range of chemicals for medicinal, pesticidal and other uses in aquaculture.

Like all producers of food crops, aquaculturists are driven to minimize stock loss in order to maximize profitability. Moreover, countries exporting fish and fish products destined for human consumption are concerned because importing countries may no longer accept their products without a guarantee that the products contain no chemical residues of concern.

CHEMICAL CONTAMINATION

Aquaculture operations, and the farms that often adjoin them, are usually dependant on properly used chemicals to minimize problems and maximize harvests. Unfortunately, when chemicals are improperly used, or when they are accidentally discharged into waters used by aquaculture operations, they can contaminate the water and harm the product. Serious threats to aquaculture water come from herbicides used to control aquatic vegetation in fish ponds; runoff of pesticides, herbicides, and fertilizers from fields adjoining aquaculture ponds; and aquifer contamination due to pollution of the recharge water.

Aquaculture Chemicals

To a certain extent, it may be difficult for aquaculturists to avoid the risk of chemical contamination from aquaculture products. This contamination may come from neighboring, as well as distant farms. An informed aquaculturist can, however, minimize the risks by considering these issues at the time of site selection and by avoiding the creation of dangerous situations on his property.

The best way for the careful aquaculturist to avoid the risk of chemical pollution is to follow strictly the instructions for use of fertilizers and chemical pesticides. Many countries in the region have set up regulatory procedures to control trade practices and the production and use of pesticides under a “pesticide-related legislative text.”

It should be noted that the term “pesticide” is not common in all countries: the Republic of Korea uses the term “agrochemical products;” Japan speaks of “agricultural chemical products;” India has endorsed the term “insecticides;” and Pakistan, Malaysia, Sri Lanka and Hong Kong China use the term “pesticides.”

Needless to say, these terms are defined differently in different countries. In some countries, they refer to plant health products only (e.g., Republic of Korea); in others, to plant health products and veterinary products (e.g., Malaysia, Pakistan); and in others, to substances to be used to control human disease carriers (e.g., Sri Lanka, Thailand). In the case of Sri Lanka, the term covers, in addition to the above, all products used to control all forms of plant or animal life likely to affect public health and human ecto- and endoparasites. In Malaysia, the following criteria allow to identify a pesticide: its (a) chemical name, trademark and commercial name; (b) ingredients; (c) formulation; (d) manufacturer; and (e) technical features. It is sufficient for even one of these elements to differ between two pesticides under comparison for the two pesticides to be deemed to be different substances.

In order to distinguish between products in terms of the hazards that they represent, they are usually classified on the basis of the risks to which they give rise. Along with the classification, control systems on their use and/or import may be more or less severe i.e., pesticides may be either authorized, restricted or banned.

An analysis of the pesticide laws in several countries in the region (see Annex I) shows that most pesticide control systems involve authorization schemes: (i) registration procedures and appeal, including treatment of proprietary information and post-registration monitoring; (ii) licensing procedures and appeals; (iii) charges and taxes related to registration and licensing schemes, including those for pesticide analyses; and (iv) special aspects concerning manufacturing and trade, including importation (licenses, border inspections, certificates, rejection or destruction and compensation thereof), exportation and re-exportation. Provisions are also made with regard to labeling requirements and, of course, for offences and administrative or penal sanctions, including powers of the designated authority and the liability of enforcing officers, where applicable.

Several countries distinguish between the commercial activities relating to pesticides and the registration of pesticide products (e.g., Japan, Republic of Korea, Pakistan, Malaysia, Myanmar, the Philippines, Thailand). The purpose of registration is to ensure that pesticides, when used according to registered label directions, will be effective for the purposes claimed, and safe (see for example, FAO's "International Code of Conduct on the Distribution and Use of Pesticides" (FAO 1990). This enables authorities to exercise control over quality, use levels, claims, labeling, packaging and advertising. The purpose of licensing is to strengthen the control on traders in these products and the facilities and infrastructure which they use.

Registration may also occur in stages. To this effect, some countries provide for an experimental authorization, either for a limited period (e.g., Myanmar - two years; Indonesia - one year; Malaysia - six months) or for an unspecified period (e.g., Sri Lanka). Other countries have set up a system of Provisional Authorization for Sale (PAS) (e.g., India, Indonesia, Myanmar, the Philippines, Sri Lanka). As a consequence, the product can be sold, but only in limited quantities and over a limited period of time. Registration may also be subject to conditions (e.g., Malaysia). A PAS is often granted for a poorly known product, whereas a conditional registration is granted for a well known product.

The registration or licensing of a pesticide implies the existence of pesticide control institutions and the conduct of examinations or tests. The relevant authorizing authority may be an official or a committee (e.g., Malaysia) or an official upon recommendation of a committee (e.g., Pakistan, Ministry of Agriculture and the Agriculture Pesticide Technical Advisory Committee; Sri Lanka, Registrar and Pesticide Committee). It is to be noted that an authorizing officer may be subject to powerful pressure on the part of the applicant(s) which might prevent him from contemplating the application in an objective manner. On the contrary, it may be more difficult for an applicant to exercise pressure on a group. Furthermore, a joint decision implies a joint responsibility.

The duration of the registration may be limited to a certain period (e.g., India - two years; Malaysia - three years; Myanmar - 10 years) or remain unspecified in the law (e.g., Sri Lanka, Republic of Korea).

The registration procedure is subject to a fee to cover administrative costs incurred by the authority when assessing the product. The fee is usually paid when the application is filed. It is to be noted that in the Republic of Korea, the law provides for the establishment of a Pesticides Management Fund to provide the resources needed to conduct all the tests to evaluate pesticides. The fund has its own financial resources. Every manufacturer or importer is required to pay 2 % of their total sales revenues into the fund's reserves every year. Nevertheless, revenues from the sale of products tested at the expense of the manufacturer or importer may be completely or partially excluded from this requirement. The fund is used to cover, amongst others, the following: (a) the cost of training and safety campaigns regarding the use, handling and management of pesticides and (b) the management costs.

As highlighted above, many countries have a twin system: registration and license/permit. Two types of permits can be identified: (1) permits for import/sale and (2) those for manufacture/packaging. Import of pesticide may be forbidden without a permit (e.g., Sri Lanka, Malaysia). The manufacture/packaging permit may relate to a control of the technical know-how in possession of the applicant.

Labeling is important and, in particular, clear and accurate labels are needed, as they often constitute the only contact between the manufacturer/supplier and the user of the product. In practically all of the legislation studied, there are provisions concerning the requirement for labels to be perfectly affixed to (or integrated into) the package of the pesticide, and for their text to be clearly visible and legible by ordinary people under normal conditions. In most cases, there are detailed rules as

to size requirements (e.g., Malaysia, Hong Kong China). Mandatory information to be reproduced on the label relates to (i) product identification, (ii) instructions for use, and (iii) warnings as to potential hazards (e.g., Malaysia, Thailand, Sri Lanka, Hong Kong China).

Misuse of approved pesticides and the use of unapproved pesticides are examples of offences which may lead to criminal penalties or fines. The latter vary depending on the type of infringement. Penalty for infringement can also involve the withdrawal of the registration or the license. Moreover, provisions for the seizure of products which do not conform to the statutory provisions are sometimes provided (e.g., Malaysia, Sri Lanka).

Chemical Discharge

Aquaculturists should be aware that chemical drift or runoff may lead to them being legally liable in respect of the consequences caused. This might occur either under a theory of “chemical trespass” in certain jurisdictions, or more generally, as a result of an action for private nuisance.

Growing concern over the potential adverse effects of chemicals released in aquaculture effluents is being observed. As an example, the legislation in Sri Lanka can be cited. Under the National Environment Act, several tools have been developed for the purposes of control of aquaculture activities, to prevent water pollution and the alteration of water quality. The Central Environment Authority has set standards for emissions (discharge of effluents) into inland surface, brackish and marine coastal waters, in particular, for the discharge of aquaculture waste waters as described below:

- “Standards for discharge of effluents into inland surface waters” (National Environmental (Protection and Quality) Regulations, No 1 of 1990, schedule 1)
- “Tolerance limits for aquaculture waste water discharged into irrigation waters”
- “Tolerance limits for aquaculture waste water discharged into inland surface waters”
- “Soil and water quality parameters suitable for brackish aquaculture”

Regulation of Pesticides at the International Level

For many years, FAO has been the center of efforts to establish a world-wide system of cooperation to control pesticides through the exchange of technical information and administrative decisions. By Resolution 10/85, the FAO Conference adopted in 1985 the *International Code of Conduct on the Distribution and Use of Pesticides* (FAO 1990). One of its primary objectives (see Article 1.1) is to “set forth responsibilities and establish voluntary standards of conduct for all public and private entities engaged in or affecting the distribution and use of pesticides, particularly where there is no or an inadequate national law to regulate pesticides.”

The code provides for standards on pesticide management, testing, availability, use, distribution, trade, advertising, labeling, packaging, storage and disposal. The code deals with activities for reducing health hazards, regulatory and technical requirements from governments and the industry, the principles of information exchange and the prior informed consent and their respective procedures, the monitoring of the code itself, etc. National laws should “translate” the contents of the code and allow for its implementation. Guidelines have been set up to this effect (see FAO 1985a,b, 1989).

The term “pesticide” provided for in the code¹ implies that the latter (i) not only applies to pesticides in the strict sense, but also to other categories of products (e.g., desiccation agents), (ii) contemplates in addition to plant health products, also veterinary products and substances to be used to control human disease carriers, (iii) embraces pesticides to be applied for the protection of inanimate products (foodstuffs, feedstuffs, wood, wood products), and (iv) thus aims at protecting

products intended for human or animal consumption in every phase of food production.

Also of interest for this study is the definition of label and the objective pursued by the latter. Article 2 of the code defines “label” as: “the written, printed or graphic matter on, or attached to, the pesticide; or the immediate container thereof and the outside container or wrapper of the retail package of the pesticide.” In the guidelines relating to the labeling of pesticides, a label constitutes “the means of achieving a consistently high standard of communication from supplier to purchaser” and in this regard, it is recommended what information should appear on the label.

Regulations Concerning the Use of Pesticides for the Specific Purposes of Aquaculture

Specific rules for the use of pesticides in aquaculture could not be found. What made the task difficult relates partly to the author’s lack of knowledge in identifying and evaluating when a product qualifies as a pesticide and, to a lesser extent, whether or not it is used in aquaculture. Nevertheless, the general impression is that few pesticides have been registered specifically for use in aquaculture, although they may have been registered for other uses.

VETERINARY DRUGS

Each country in the world has its own legal framework governing drugs and feed additives. In general, legislation sets controls on the sale and use of drugs of all kinds for treatment of either humans or animals, including fish. Conditions of use, dosages, and species for which use of a compound is approved vary from drug to drug among countries. Other critical parameters are withdrawal times and detection methodology. For the purposes of this paper, the term “veterinary drug” refers, in general, to any preparation produced in quantity or in series and offered for sale as a therapeutic, prophylactic, diagnostic, or growth-promoting agent to be applied to animals. It includes narcotics, drugs which induce anesthesia, antibiotics, anabolics, sera, vaccines, and herbal remedies (see Wilcke and Hill 1995).

The general legal approach involves the subjection of veterinary drugs to a requirement of product registration (e.g., Indonesia, Japan, Republic of Korea, Pakistan, Philippines) and/or licensing (e.g., Indonesia, Malaysia, Pakistan) before a drug may be sold or used for any kind of treatment of either humans or animals, including fish.

Both systems involve a license or a registration certificate being issued before the veterinary drug may be sold, supplied or manufactured in the country. Applications for the product registration or licenses are submitted to the appropriate licensing/registration authority (e.g., Indonesia - Director General of Livestock Services, Ministry of Agriculture; Japan - Animal Health Division of the Ministry of Agriculture, Forestry and Fisheries; Republic of Korea - Animal Health Division of the Ministry of Agriculture, Forestry and Fisheries; Pakistan - Registration Board; the Philippines - Bureau of Food and Drugs, Department of Health; Thailand - Drug Control Division, Food and Drug Administration) in a prescribed form along with full supporting data relevant to the

¹For the FAO Code of Conduct on the Distribution and Use of Pesticides, the term pesticide means “any substance or mixture of substances intended for preventing, destroying or controlling pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products, or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.”

determination of the application relating to the safety, efficiency and quantity of the product for the purposes for which it is to be used (e.g., Japan, Pakistan, Thailand). Specifically, in relation to the consideration of “safety,” the following elements are to be evaluated by the competent authority: capacity of the substance to cause danger to the health of the surrounding environment, the harmful residue which it may leave in the animal (e.g., Republic of Korea, Japan, Thailand), the already banned ingredients which it includes (e.g., the Philippines) and safety to the animal. “Effective” often means that the product is expected to do what it is claimed it will do consistently. To this effect, the data may have to originate from adequate and well-controlled studies (e.g., Japan, Republic of Korea, Pakistan), the “dose response” relationship may have to be defined (e.g., Thailand) or studies may have had to be performed in several locations as to evaluate any geographic or environmental impacts (e.g., Malaysia). The burden of proof of the safe and effective character lays most often with the manufacturer and importer (e.g., Thailand). To this effect, foreign studies may be accepted (e.g., Thailand, Indonesia, Republic of Korea).

It is rather uncommon in the countries examined that, by law, adverse impacts of, or reactions to, an approved veterinary drug must be reported by manufacturers and importers. Exceptions, however, exist (e.g., in Japan, Republic of Korea and Thailand). On the contrary, manufacturers and importers are most often required to report post-registration (e.g., Thailand (except for feed additives), Japan (only side effects and results in the case of new drugs), Pakistan, Republic of Korea).

FEED ADDITIVES

Substances which are added to feeds to promote growth and to maintain fish health appear to be separately regulated in some countries (e.g., Japan, Indonesia, Thailand, the Philippines, Singapore). Generally speaking, such regulations refer to substances which, by their very nature or their intended uses, may become components of animal feeds or which may affect the characteristics of animal feed.

Controls upon their use and import may include registration (e.g., the Philippines), licensing (e.g., Thailand, Singapore) or listing of authorized additives. In the latter case, the use of additives in fishfeed must occur in accordance with specific regulations defining the substances which may be added (e.g., Thailand, Singapore, Malaysia, Pakistan, Indonesia, the Philippines).

Sometimes, when feed additives are added for medicinal purposes (“medicated feedstuff”), they tend to be covered by the legislation governing drugs, and thus subject to registration (e.g., Japan, Korea, Malaysia) and withdrawal periods. The citing of a withdrawal period seems generally accepted amongst the labeling requirements. Occasionally, an indication on the withdrawal period is to be provided as supporting data during the application process.

Given the importance of assuring that the feed produced meets intended specifications and is not adulterated, it should be noted that in Pakistan, local manufacturers are required to comply with the Standards of Good Manufacturing Practices (GMP). The latter provide guidance for local feed manufacturers (in particular, medicated feed manufacturers) to ensure that their products meet the identity, strength and quality which they should possess with respect to their ingredients, in particular, their drug contents. In the case of imported products, applicants for the use and sale thereof are to provide a certificate asserting the Good Management Practice standards of the manufacturer abroad or authorization to sell under the US Food and Drug Act.

Likewise for veterinary drugs, the application for registration and licensing occurs in a prescribed form. Supporting data that must be provided include information on chemical identity, animal and human safety, intended physical effect, etc.

Enforcement activities include actions to correct and prevent violations, remove illegal products or goods from the market, and punish offenders. The types of enforcement vary with the nature of the violation. Violators found guilty may be subject to penalties and to imprisonment specified by law. Criminal prosecution is sometimes preceded by warning the firm or the individual(s) involved. Other regulatory actions may involve seizure of the product(s) to remove it from the channels of commerce.

Significantly, in relation to the above, the rapid increase of aquafeed production and the need for feed additives such as growth promoters, hormones, probiotics, etc. have led to the adoption in several countries of rules relating to the control of aquafeeds (e.g., Thailand, Agricultural and Cooperatives Ministerial Regulation, 1991 and Aquafeed Regulations; Indonesia, Decree of Minister of Industry No 37/M/SK/3/1992 on standards for the shrimpfeed industry; the Philippines, Feed Control Law and Administrative Order No 84, Series of 1990).

TRADE IN AQUACULTURE PRODUCTS

Restrictions on Commerce

In addition to restrictions on the use of certain chemicals, states also have laws that require food products to be safe if they are to travel in commerce and to be branded properly (e.g., Malaysia, Pakistan).

Often the legislation regulating the quality of aquaculture food products may prohibit contaminated or adulterated food from being marketed. As the primary purpose of food legislation is the protection of the consumer, a need exists to provide the public with legal safeguards against anything that may adversely affect its health or abuse its trust. The term “adulterated” often refers to fish products that contain chemical residues in amounts beyond a level that is considered safe, or ingredients that are not approved by the competent authorities. The term “misbranded” refers to labeling aspects that may be false or misleading. Transporters of adulterated food are subject to criminal sanctions, even if they are unaware of the violation.

In all cases where food is concerned, standardization (i.e., precise requirements against which product conformity can be checked) are defined and codes of practice are present. Undoubtedly, it is in the interest of the aquaculture industry that the quality of fish from aquaculture be acceptable in both national and international trade.

Standards as a Principle of “Food Law”

The trend towards generalized standards is reflected at the national level, and also at the international level in the Joint FAO/WHO Food Standards Programme - Codex Alimentarius Commission. The Codex Alimentarius is a “collection of international food standards adopted by the commission and presented in a uniform manner.” (see FAO/WHO 1995). As such, it contemplates, amongst others, provisions in respect to food additives, pesticides residues, veterinary drugs residue and for fish and fishery products, including last but not least, for the “products of aquaculture.”

A draft *Code of Hygienic Practice for the Products of Aquaculture* has been prepared and amended/re-drafted since 1990 by the FAO Fish Utilization and Marketing Service and discussed recently at the Codex Committee on Fish and Fishery Products in Norway. The scope of this Draft Code of Practice is limited to “finfish and crustaceans produced by commercial aquaculture and intended eventually for direct human consumption.” It contains general guidelines for setting up and conducting production under the most essential requirements of hygiene up to harvesting live fish and loading for transport to market. The slaughtering process is not considered (see FAO/WHO 1996).

It is not the purpose of this survey to enter into the merits of the draft code, but the author would like to stress that the code is intended “for information purposes and as a guideline for the elaboration of national quality standards, quality control and fish inspection regulations in countries where these, as yet, have not been developed. In addition, it could be used for training of fish farmers and employees of the aquaculture sector. In other words, the implementation of the Code of Practice will have to be adapted to national and local needs, priorities and requirements.

It is clear that in order to increase the international trade in aquaculture products, governments have interest in reaching an “agreement” on the composition of these products intended for export and thus, in harmonizing their national rules governing labeling, quality, use of pesticides, feed additives, veterinary drugs, etc. likely to be used in the production process of aquaculture products. Undoubtedly, the more the relevant rules are harmonized, the more complete and effective the eradication of “technical” (non-tariff) barriers (disguised and arbitrary restrictions on trade) will be.

Codex and GATT²

Of relevance to the Codex Alimentarius Commission and to this study are two separate agreements, namely the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the “SPS Agreement”) and the *Agreement on Technical Barriers to Trade* (the “TBT Agreement”) adopted by GATT members following the Uruguay Round. The SPS Agreement deals with measures necessary to protect human life or health, while the TBT Agreement contemplates other technical measures, such as those to prevent deceptive practices. The basic objective of the two agreements is to limit the use of measures that do, or may, restrict trade to those that are justified to provide importing countries the level of protection that is necessary. Temporarily, nevertheless, Members maintain the fundamental right to protect themselves, at the level they determine necessary.

As a result of the Uruguay Round Agreements, major emphasis and greater importance is given to the work of the Codex Alimentarius Commission. Full recognition is given to the important contribution that international standards, guidelines and recommendations can make with regard to the development, adoption and enforcement of sanitary and phytosanitary measures. The use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by relevant international organizations including the Codex Alimentarius Commission, is encouraged. Nevertheless, Members may “introduce or maintain” such measures “which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification...” or where the decision to do so is based on a risk assessment, appropriate to the circumstances (see Article 2 of the SPS Agreement, GATT 1994).

As far as the TBTs are concerned, the objective is to guarantee that they do not create unnecessary obstacles to, and to minimize their impact on, international trade. The latter, when introduced should be the least disruptive measures possible, and should be of a temporary nature. Where Codex standards exist and are relevant to the circumstances, GATT members must base their measures on them.

Both agreements dedicate a crucial role to “transparency” in the development and application of trade-restrictive (regulatory) measures. This embraces requirements for notifying an intention to introduce such a measure at an early stage, whenever an international standard, guideline or

² The text of the Final Act that embodies the results of the Uruguay Round of Multilateral Trade Negotiations was finalized and came into effect in April, 1994 with its signing at the Marrakech Ministerial Meeting by ministers representing Members in the General Agreement on Tariffs and Trade (GATT).

recommendation does not exist or the content of the proposed measure is not substantially the same as the content of an international standard, guideline or recommendation, and such measure may have a significant effect on trade of other Members (see Annex B of the SPS Agreement, GATT 1994). Undoubtedly, the notification procedures and requirements enclosed therein seem intended to perform as an incentive toward adoption of international standards, guidelines and recommendations, where they exist.

The incorporation of references to Codex standards and codes of practice in GATT agreements should substantially contribute to the development of international trade in food products and reduce problems emerging from differences in national legislation (see Ronk and Dodgen 1991). It should also increase coordination and integration between Codex and the national systems and approaches for approving food additives or for establishing tolerances for contaminants.

Aquaculture Products Producers and Processing

Quality ought to be a characteristic of all commodities, basic (agricultural), processed (industrial) and traded. As for other products, an aquaculture product should not constitute a health hazard or pose threat to consumer safety. The quality control of domestically produced or imported food tends to rely on the governments, for they are responsible to protect citizens against health hazards and commercial fraud. Controls are exercised to ensure compliance of products with relevant national legislation.

A new trend is notable whereby food quality control is left to the parties concerned i.e., to the producers, in a first instance, and to the administration, as a second-tier control. In other words, in order to detect chemical residue or chemical contamination, the aquaculturist must screen the product during the food processing stage. In the interest of producers, it is highly recommended that such controls be undertaken in accordance with an “officially” recognized procedure. Today, the Hazard Analysis Critical Control Point (HACCP) system is the most widely accepted procedure for assuring safe quality of food products. Elements of this system could be found in the legislation of Pakistan (“Good Manufacturing Practice” system), Hong Kong China and the Republic of Korea.

CONCLUSIONS

A few observations can be drawn from the foregoing preliminary analysis of selected legislation governing the use of chemicals in aquaculture in the Asian Region.

Generally speaking, aquaculturists can minimize the risks to their food products by adhering to regulations relating to the distribution and use of chemicals. But, as shown by the present preliminary study, several of the “chemicals” used in aquaculture appear to be subject to various pieces of basic and subsidiary legislation. Moreover, few regulations seem to exist which are specifically drafted or well designed for the purposes of aquaculture. This appears particularly true with regard to pesticides and veterinary drugs and, to a lesser extent, with regard to feed additives and food quality control. Typically, the relevant legal provisions are widely scattered in various legislative instruments covering subject matters like agriculture, plant protection, pesticides, animal health, veterinary drugs, consumer protection, etc. Undoubtedly, this will create confusion and regulatory burdens on the aquaculturist having to comply with all of them and, also, among administrators having to enforce them.

As with the legislation, it appears that the aquaculturist has to cope with various ministries and departments dealing respectively with agriculture, fisheries, animal health, consumer health, and the environment. Indeed several “chemicals” used appear to be hazardous substances which are

controlled under different regimes by various governmental agencies. Again confusion, overlap and conflicting situations are likely to arise which may be detrimental to both the aquaculturist and the consumer. A risk of marketing “unsafe or hazardous” aquaculture products exists.

Legal aspects are essential to the control of use of chemicals in aquaculture and to the quality control of the end product. Nevertheless, this study also shows that there is a need for more scientific and legal interaction. Knowledge of a wide range of technical items is a prerequisite for drafting legislation and setting up appropriate institutional frameworks which will establish an effective system of control on the use of chemicals in aquaculture products. Undoubtedly, the legislator will often be involved in transforming technical norms into nationally binding rules. In addition, the needs of the aquaculturists should be met.

Recent trends in international, regional and sub-regional trade show that a Code of Practice could constitute an essential tool towards eradicating non-tariff barriers. The potential benefits of a Code of Practice relating to the subject matter discussed in this forum should not be underestimated. A code might promote not only rational production, but also competitiveness among producers and consequently, boost exports and protect the interest of consumers. From a legal point of view, a code offers the advantage of grouping into one document measures which are usually scattered throughout different national legislative instruments. As such, a code would likely constitute a basis for the preparation of vertical measures dealing specifically with aquaculture and thus contribute to widely differing national legislation.

RECOMMENDATIONS

In the light of the above, the following recommendations are made:

- Mandatory measures of control are desirable and feasible, but once a government has decided to introduce them, it is absolutely vital that (i) lessons are taken from experiences in the neighboring countries; (ii) adequate care is taken to involve scientists, aquaculturists and, last but not least, legal experts and administrators in the drafting process; and (iii) where possible, harmonization is sought with relevant laws and regulations of the other countries in the region and/or world wide. Harmonization does not imply altogether identical laws and regulations, rather, it is the adoption of similar and compatible approaches and provisions in the domains which could benefit all concerned (manufacturers, producers, traders, importers and exporters).
- The preparation of a Code of Practice relating to the use of chemicals in aquaculture could be critical to boost national and international trade in aquaculture products. Such a code could be based on one of several models. One possibility is a code like the *International Code of Conduct for Responsible Fisheries* (FAO 1995), which sets out general principles which require significant further elaboration through technical guidelines before being suitable for adoption in national legislation. Another possibility is the *International Code of Conduct on the Distribution and Use of Pesticides* (FAO 1990), which has been drafted in such a way that its provisions can be easily incorporated into national legislation. Most probably, it is the latter model that will have the greatest application to the present subject matter. It is recommended, therefore, that consideration be given to the formulation of a code or codes for the use of chemicals in aquaculture.
- Meanwhile, and in view of the above, the preparation of a more in-depth study could be most useful. For an environment in which science and technology continually confront aquaculturists with existing and new regulatory challenges and changing expectations, an in-depth analysis of the current situation is not only desirable, it is essential. It should focus on

the chemicals used in aquaculture and their respective legal status and related approval process. To this effect, it would be beneficial if authorities from countries involved in this exercise would compile and provide information with respect to each product used using a standard format, an example of which is given in Annex II.

REFERENCES AND SUGGESTED READING

- Barberis G, Chiaradia-Bousquet J-P. 1995. Pesticide registration legislation. FAO Legislative Study No. 51, 88 p.
- Chiaradia-Bousquet J-P. 1995. Legislation governing food control and quality certification - authorities and producers. FAO Legislative Study No. 54, 125 p.
- Clausen E. 1985. Regulation of pesticide residues in food : addressing the critical issues. Food Drug Cosmetic Law J. 40: 494-498.
- FAO. 1985a. Guidelines for the registration and control of pesticides. FAO Rome.
- FAO. 1985b. Guidelines on good labeling practice for pesticides. FAO, Rome.
- FAO. 1989. Guidelines for legislation on the control of pesticides. FAO, Rome.
- FAO. 1990. The International Code of Conduct on the Distribution and Use of Pesticides. amended version, FAO, Rome. 34 p.
- FAO. 1995. Code of Conduct on Responsible Fisheries. FAO, Rome. 41 p.
- FAO/WHO. 1995. Codex Alimentarius. 2nd Edn.
- FAO/WHO. 1996. Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission: Proposed draft code of hygienic practice for the products of aquaculture. Codex Alimentarius Commission, CX/FFP 96/7.
- GATT. 1994. The results of the Uruguay Round of Multilateral Trade Negotiations - the legal texts. GATT Publication.
- Gonzalez Vaque L. 1987. Pesticide labelling legislation. FAO Legislative Study No. 43, 129 p.
- New M, Tacon AGJ, Csavas I. 1994. Farm-made aquafeeds. FAO Fisheries Technical Paper No. 343, 434 p.
- Ronk RJ, Dodgen D. 1991. Food standards: an overall strategy for common requirements applicable to all foods. FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade. ALICOM 91/6.
- Silva Repetto R. 1995. The role of pesticide legislation. FAO-LEGN Study. FAO, Rome.
- Wilcke JR, Hill SA. 1995. Compendium of regulations and authorities for registered veterinary products. Virginia Maryland Regional College of Veterinary Medicine, Virginia Polytechnic Institute and State University, Blacksbourg, Virginia, 24061 USA.

Summary of National Legislation Related to the Use of Chemicals in Aquaculture for Selected Countries of the Asian Region

(available with FAOLEX, FAO's Legal Database, maintained by the Legal Office at
FAO Headquarters in Rome, http://faolex.fao.org/faolex_eng/faolex.html)

Hong Kong China

- L.N. 422 of 1990: Agricultural Pesticides (Amendment) Regulations 1990
- The Pesticides Ordinance, amended 79 of 1990

India

- The Insecticides Act, 1968
- The Insecticides Rules, 1971

Indonesia

- Government Decree on the Control of the Distribution, Storage and Use of Pesticides, 1973
- Ministerial Decree on the Procedure of Application for Registration and Approval of Pesticides, 1973
- Ministerial Decree on the Packaging and Labelling Requirements for Pesticides, 1973
- Decree of Minister of Industry No 37/M/SK/3/1992 on standards for the shrimpfeed industry
- The law No. 8 of 1967, concerning the principle of provision of animal husbandry, distribution and administration of animal vaccine, sera, and biological diagnostic substances
- The Government Regulation No. 15 of 1977 concerning repulsion, prevention, and eradication and treatment of animal diseases
- The Government Regulation No. 78 of 1992 concerning veterinary drugs
- The Decision of Minister of Agriculture No 432/kpts/UM/8/10/974 concerning examination and control regulations for vaccine, sera, and biological diagnostic substances
- The Decision of Minister of Agriculture No. 539/Kpts/Um/12/1977 concerning licensing regulation of veterinary drug production, provision, and distribution
- The Decision of Minister of Agriculture No. 24/Kpts/Um/DJP/Deptan/1978 concerning veterinary drug registration procedures

Korea, Republic of

- The 1957 law on the handling of agricultural chemical products as amended by Law No 33 22 of 31/12 1980; and the subsidiary legislation for its implementation
- Decree No 11372 of 29/02/1984 - the Pharmaceutical Affairs laws

Malaysia

- Pesticides Act No 149, 1974 and subsidiary legislation (in particular, the Regulations governing the registration of pesticides (1976), the instrument governing exemption from registration (1979), the Regulations relating to the import of pesticides for educational and research purposes (1981), and the Pesticides (Labelling) Regulations (1984)
- The Control of Drugs and Cosmetics Regulations, 1984
- The Sale of Food and Drugs Regulations, 1952
- Poisons Act, 1952 (Revised, 1989)
- Act 366, (covers the importation of veterinary drugs)
- Animals Ordinance, 1953: Act 17 (covers the importation of veterinary biologics)
- Veterinary Act, (proposed) (covers the importation, manufacture, sale and use of veterinary biologics and drugs)

- Animal Feeds Act, (proposed) (covers the importation, manufacture, and sale of animal feeds)

Pakistan

- The Agricultural Pesticide Ordinance, 1971
- Agricultural Pesticides (Amendment) Ordinance, No XII of 1979
- Agricultural Pesticides Rules, 1973
- The West Pakistan Foodstuffs (Control) Ordinance, 1975
- The Fish Meal (Grading and Marking) Rules, 1973
- Drugs Act, 1976
- Drugs (Licensing, Registering and Advertising) Rules, 1976

the Philippines

- Feed Control Law and Administrative Order No 84, Series of 1990
- Act No. 3720 relating to the use and distribution of veterinary drugs

Sri Lanka

- Control of pesticides Act, No 33 of 1980

Thailand

- Agricultural and Cooperatives Ministerial Regulation, 1991 and Aquafeed Regulations

Guide for the Collection of Information for a Detailed Legal Survey on the Use of Chemicals in Aquaculture

Product classification

pesticide

veterinary drug

medicated feedstuff

feed additive

poison

other (specify under which circumstances it belongs to one or another category)

Manufacturer's name

Product name

official

scientific

Registration number

License number

Approved uses

Label code

Active ingredient, common name and content

Applicable mandatory rule:

basic law

regulation

ministerial decision or order

Fee(s) (amount)

Agencies (ministry, department, committee, etc.) involved in the approval process (registration, license or other)

central

local

other

Agencies (ministry, department, committee, etc.) involved in the enforcement process

Data to be provided for the application for an authorization

on chemical and physical properties

on efficacy

on toxicity for assessment of human health hazards

on residues

on possible environmental impacts

Reporting obligations post-authorization

Additional information deemed relevant