Government Regulations Concerning the Use of Chemicals in Aquaculture in Japan

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ABSTRACT

In Japan, fisheries research activity is of a very diversified nature and is overseen by the national and prefectural governments. Regarding the use of chemicals in aquaculture, various regulations exist to protect the safety of cultured aquatic animals intended for human consumption. Under Japan's Drug Laws, certain materials are designated as "medical products" for use in humans and animals, and their usage is strictly regulated. This paper introduces aspects of this legislation as relevant to the aquaculture industry and discusses how they are actually applied on the level of operation. Prefectural fish disease centers and extension services engage in the actual supervision of the use of such designated chemicals. In reference to government research structure, the Ministry of Agriculture, Forestry and Fisheries maintains 29 national research institutes, nine of which are fisheries institutes directly under the Fisheries Agency. The prevention and treatment of fish disease is an important research theme, and programs are being implemented, especially at the National Research Institute of Aquaculture. An auxiliary organ of the Fisheries Agency, the Japan Fisheries Resource Conservation Association operates educational and training programs for employees of prefectural centers and extension services whereby individuals receive certification as fish health specialists.

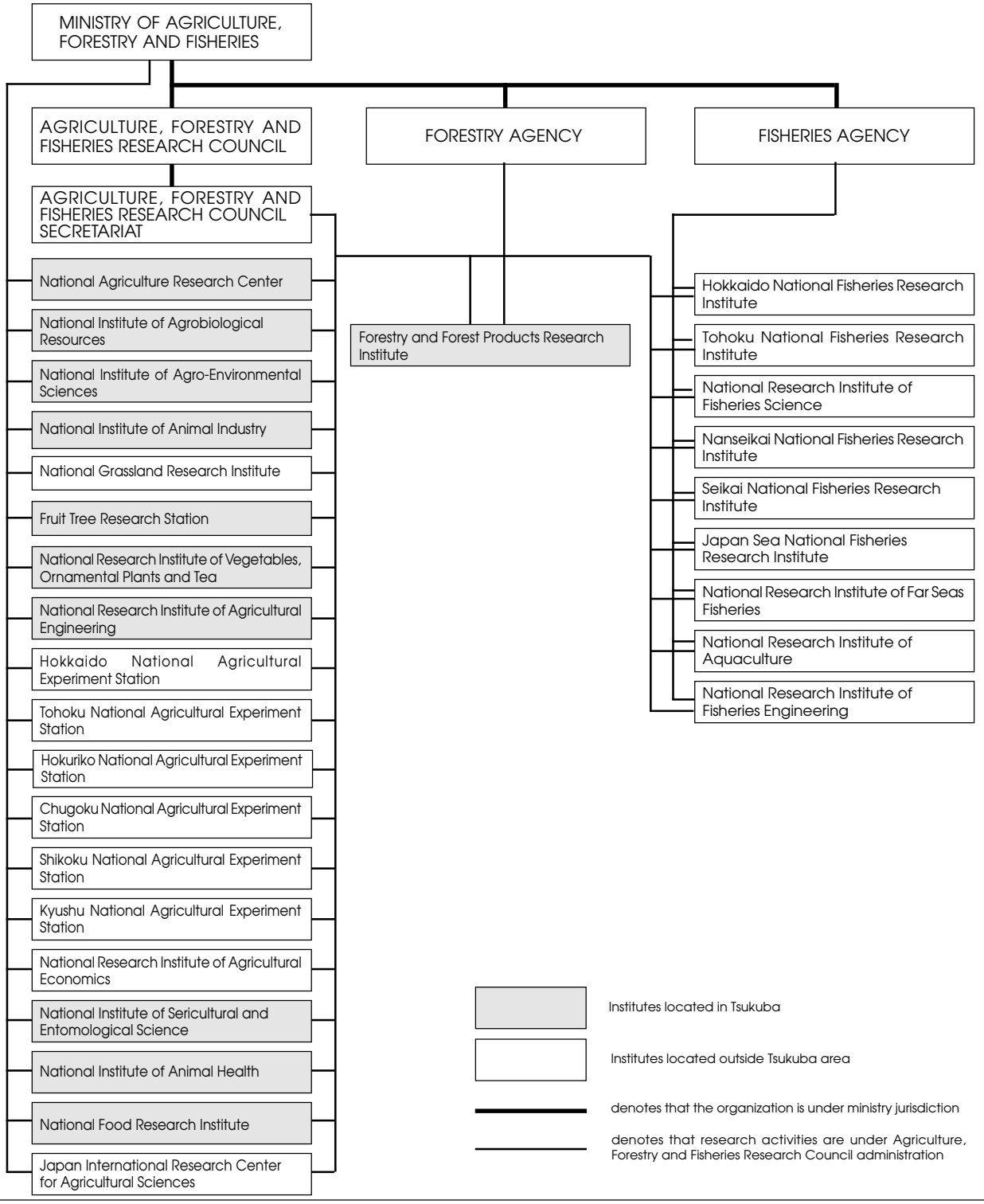
STRUCTURE OF GOVERNMENT-RELATED FISHERIES RESEARCH ACTIVITY IN JAPAN

Fisheries research in Japan is very active and wide-ranging and is carried out principally by national and prefectural government institutions, auxiliary organs, universities and the private sector. This paper will focus on government regulations concerning the use of chemicals in aquaculture in Japan with some discussion about research carried out in this context. The purpose of this section is to introduce the structure and relationships of the government and related agencies that promote and oversee fisheries and aquacultural operations and activities in Japan.

The Government of Japan comprises a number of ministries and agencies; of relevance to this discussion are the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health and Welfare (MHW) (which will be discussed in relation to Japan's food and drug laws). The Fisheries Agency (FA) is under the jurisdiction of the MAFF and maintains nine research institutes, such as the National Research Institute of Aquaculture (NRIA). The institute to which this author belongs, the Japan International Research Center for Agricultural Sciences (JIRCAS) contains a fisheries division but is not primarily a fisheries institute and is therefore under the direct jurisdiction of the ministry. Including the nine fisheries institutes and JIRCAS, the ministry has a total of 29 research institutes (Fig. 1).

Figure 1. General organization of the research institutes of the Ministry of Agriculture, Forestry and Fisheries

Twenty-nine research organizations are affiliated to the Ministry of Agriculture, Forestry and Fisheries: 19 are directly overseen by the AFFRC; 1 forestry and 9 fisheries institutes are under the administration of the Forestry Agency and the Fisheries Agency, respectively.



Generally, the role of these national research institutes is to conduct basic research on their respective fields in tune with the needs of the industry, consumers and agriculturists. In fisheries, dissemination of the thus-developed technologies and related extension services is the realm of auxiliary organs and prefectural institutions. Japan has three major auxiliary organs related to fisheries which carry out their operations in cooperation with the FA. These are the Japan Sea-Farming Association (JASFA), the Japan Fisheries Resource Conservation Association (JFRCA), and the Overseas Fishery Cooperation Foundation (OFCF). The scope of their activities is broad. It includes the management of coastal stocking programs and related research (JASFA), the management of fisheries resources in conjunction with the preservation of the environment (JFRCA), and the promotion of fisheries collaboration between Japan and other coastal countries (OFCF). The activities of the JFRCA as they pertain to the operation of programs related to the control of fish disease and the management of chemical usage in fisheries activities (JFRCA 1995a) will be discussed in detail later. Finally, most prefectures in Japan maintain one or more prefectural fisheries centers. Activities vary with location and needs of the region, as aquaculture species differ according to climate and habitat. However, at most centers, extension and advisory services are available for the local aquaculturists.

OVERVIEW OF JAPAN'S DRUG LAWS

Japan's Drug Laws serve to regulate the use of drugs and medical products intended for human beings or designated animal species which are the objects of human consumption. The Drug Laws contain numerous clauses specifying how products are to be tested and approved, advertised, packaged, utilized and so forth, and under what circumstances they can be prescribed. This legislation is administered by the MHW, but certain clauses contain reference to the MAFF in the case of specifications concerning the use of products or medicines in animals (Noushi 1993). Below is a brief description of the laws.

Medical products are defined as items which, although in themselves may be daily necessities, are products which constitute a group apart from ordinary necessities, in that they have an enormously large impact on the nation's public health, necessitating their regulation and proper usage. Medical products are divided into two groups, those designated for use in humans and those designated for use in animals. The latter group is further divided into items to be used in livestock administration, and those used in fisheries applications. Regarding the use of medical products in animals, legislation is geared so as to guarantee the safety for human consumption of the end product (such as eggs, beef, or cultured fish). The development of the Drug Laws has a long historical background starting from the Meiji Era in 1870. In 1979, major revisions were made to the laws including, for the first time, the inclusion of provisions relating to the use of medical products in animals.

The Drug Laws define which items are medical products (not only drugs, but also equipment and items such as syringes) and are therefore subject to regulation by them. A more detailed explanation is beyond the scope of this paper; however, it will suffice to say that a specific article, Clause 83, states that other clauses and phrases containing the words "Health and Welfare Minister" are interchangeable with "Agriculture, Forestry and Fisheries Minister" and "Ministry of Health and Welfare Promulgation" with "Ministry of Agriculture, Forestry, and Fisheries Promulgation" in interpretation of cases relating to animal-intended products (Noushi 1993). Thus, the same laws are overseen by different ministries depending on whether the product is intended for direct usage in humans or for application to livestock and aquatic species, but the overall aim is the same - to protect public welfare.

APPLICATIONS OF THE DRUG LAWS TO AQUACULTURE

The Fisheries Agency puts out a pamphlet to guide aquaculturists and fish farmers concerning the use of chemicals in aquaculture (Fisheries Agency 1995). This provides a very clear picture of how

drug use is permitted in aquaculture in Japan. Most of the following explanations are based on the contents of this pamphlet.

Medical products for fisheries use are for the treatment and prevention of disease in cultured species, the ultimate objective being to produce a product suitable for human consumption. In accordance with the Food Hygiene Law, foodstuffs may not contain traces of antibiotics or synthetic anti-bacterial agents; however, the majority of fisheries-use drugs contain such materials. Thus, regulations are in place to prevent the occurrence of residues in the final product. In Japan, it is necessary for all aquaculturists to be aware of these regulations.

Table 1 shows all of the fisheries drugs in use in Japan and for which species they may be used. An "O" symbol denotes that the item may be used in a particular species. This implies that the drug has been judged from experimental data that it is effective in treating disease in that species, and that it does not have any deleterious side-effects. It is also known what length of time is required for its clearance from the target animals; i.e., does it leave a residue for a long time or not? On the other hand, items marked with an "X" for a certain species may not be used in that species because their efficacies, side-effects and clearance times are not established.

The heavy frame in Table 1 which encloses species from yellowtail to kuruma prawn, and drugs from amoxicillin to lincomycin hydrochloride indicates "medical products" whose usage is subject to the Drug Laws. This means that the animals in which they are used, the method of administration and quantity, and the time from which administration is terminated to when the product is harvested and out on the market (withdrawal period) are strictly regulated. Failure to comply with the Drug Laws carries a term of imprisonment for up to one year, or a fine of up to 500,000 yen or a combination thereof (Fisheries Agency 1995). Drugs that fall under these restrictions are clearly labeled on their containers or wrapping with a warning that usage is subject to the regulations of the Drug Laws. Items that fall outside of the frame are outside of the regulations of the Drug Laws themselves. This does not mean that they are not regulated. If these items are not used according to the guidelines given, the final product will likely be unfit for the market under the Food Hygiene Law; and, therefore, administrative agencies must supply guidance concerning their use (JFRCA 1992).

For each of the various species targeted for aquaculture, the manner of administration, dosage level and withdrawal period is specified for each drug which can be used in that species (Fisheries Agency 1995). Table 2 presents this information representatively for yellowtail, which has the longest history of aquaculture in Japan; rainbow trout, which is also very popular; and the kuruma prawn. In most instances, the allowed method of administration is oral, by mixing the drug with the feed, although sulfamonomethoxine is given via immersion in rainbow trout. Such information is also given in detail for red seabream, coho salmon, horse mackerel, flounder, carp, eel, sweetfish, tilapia, amago salmon and crucian carp.

GUIDANCE ACTIVITIES AND DISSEMINATION OF INFORMATION

As mentioned above, the actual dissemination of information concerning drug use in aquaculture and guidance in the treatment of fish disease is dispensed by prefectural organizations. Most prefectures maintain their own research stations as well as extension service offices, with guidance and consultation services available to local aquaculturists. Here, fish health specialists advise fish farmers on the proper usage of aquaculture chemicals in conformance with the Drug Laws, give diagnoses and make recommendations. The employees of these prefectural stations and extension centers have a very strong responsibility to understand the Drug Laws, and to supervise aquaculturists on the proper use of these chemicals to ensure a safe product to the consumer and an overall healthy aquaculture industry.

Table 1. Fisheries drugs used in Japanese aquaculture and their target species

	yellowtail	red sea bream	coho salmon	horse mackerel	flounder	carp	freshwater eel	rainbow trout	sweetfish	tilapia	kuruma prawn	amago salmon	crucian carp	other bass species	other herring sp.	other sole sp.	other eel sp.	other salmonids	other carp sp.
amoxicillin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
bicozamycin benzoate	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
ampicillin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	x
erythromycin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
alkyltrimethylammonium oxytetracycline calcium	O	O	X	O	O	X	X	X	X	O	X	X	X	O	X	O	X	X	X
oxytetracycline hydrochloride	O	O	O	O	O	X	O	O	X	O	O	O	X	O	O	O	O	O	X
oxolinic acid	O	O	O	O	X	O	O	O	O	O	O	O	O	O	O	X	O	O	O
oxolinic acid (suspension-forming)	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
oxolinic acid (for immersion bath)	X	X	X	X	X	X	O	X	O	X	X	X	X	X	X	X	X	X	X
kitasamycin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
josamycin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
spiramycin	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
sulfadimethoxine (or sodium salt of)	X	X	X	X	X	X	X	O	X	X	X	X	X	X	X	X	X	X	X
sulfamonomethoxine (or sodium salt of)	O	O	O	O	X	X	O	O	O	O	X	O	X	O	O	X	O	O	X
sulfamonomethoxine (for immersion bath)	X	X	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X	X	X
sulfamonomethoxine/ormethoprine mixture	X	X	X	X	X	X	X	X	O	X	O	X	X	X	X	X	X	X	O
thiamphenicol	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
doxycycline hydrochloride	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
sodium nifurstyrenate	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
sodium nifurstyrenate (for immersion bath)	X	X	X	X	O	X	X	X	X	X	X	X	X	X	X	O	X	X	X
novobiocin salt	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
flumequine	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
florfenicol	O	O	O	O	X	X	O	O	O	O	X	O	X	O	O	X	O	O	X
lincomycin hydrochloride	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
sulfisozole	O	X	X	X	X	O	X	O	O	X	X	X	X	X	X	X	X	X	X
piromidic acid	X	X	X	X	X	X	O	X	X	X	X	O	X	X	X	X	X	X	X
oleandomycin polystrenesulfonate	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X
miloxacin	X	X	X	X	X	X	X	O	X	X	X	X	X	X	X	X	O	X	X
metrifonate (trichlorofane)	X	X	X	X	X	X	O	O	X	X	X	X	O	X	X	X	X	X	X
phosphomycin calcium	O	O	X	O	X	X	X	X	X	O	X	X	X	O	X	X	X	X	X

O: Usage permitted
X: Usage not allowed

Heavy fame encloses items regulated by the Drug Laws

Table 2. Specifics of drug usage in yellowtail, rainbow trout and kuruma prawn

Yellowtail

Drug	Administration	Dosage	Withdrawal period
amoxicillin	oral	40 mg/kg d	5 d
bicozamycin benzoate	oral	10 mg/kg d	27 d
ampicillin	oral	20 mg/kg d	5 d
erythromycin	oral	50 mg/kg d	30 d
alkyltrimethylammonium oxytetracycline calcium	oral	50 mg/kg d	20 d
oxytetracycline hydrochloride	oral	50 mg/kg d	20 d
oxolinic acid	oral	30 mg/kg d	16 d
oxolinic acid (suspension-forming)	oral	20 mg/kg d	16 d
kitasamycin	oral	80 mg/kg d	20 d
josamycin	oral	50 mg/kg d	20 d
spiramycin	oral	40 mg/kg d	30 d
sulfamonomethoxine (or sodium salt of)	oral	200 mg/kg d	15 d
thiamphenicol	oral	50 mg/kg d	15 d
doxycycline hydrochloride	oral	50 mg/kg d	20 d
sodium nifurstyrenate	oral	50 mg/kg d	2 d
novobiocin salt	oral	50 mg/kg d	15 d
flumequine	oral	20 mg/kg d	8 d
florfenicol	oral	10 mg/kg d	5 d
lincomycin hydrochloride	oral	40 mg/kg d	10 d
sulfisozole	oral	200 mg/kg d	10 d
oleandomycin polystyrenesulfonate	oral	25 mg/kg d	30 d
phosphomycin calcium	oral	40 mg/kg d	15 d

Rainbow Trout

Drug	Administration	Dosage	Withdrawal period
oxytetracycline hydrochloride	oral	50 mg/kg d	30 d
oxolinic acid	oral	20 mg/kg d	21 d
sulfadimethoxine (or sodium salt of)	oral	100 mg/kg d	30 d
sulfamonomethoxine (or sodium salt of)	oral	150 mg/kg d	30 d
sulfamonomethoxine (for immersion bath)	immersion	10 kg/1 t saline	15 d
florfenicol	oral	10 mg/kg d	14 d
sulfisozole	oral	200 mg/kg d	15 d

Kuruma Prawn

Drug	Administration	Dosage	Withdrawal period
oxytetracycline hydrochloride	oral	50 mg/kg d	25 d
oxolinic acid	oral	50 mg/kg d	30 d

Heavy frame indicates items regulated by the Drug Laws

To accomplish these aims, JFRCA maintains several programs, including a training and certification course for fish health specialists. The program was originally initiated by the FA to provide certification to prefectural specialists. In 1977, this work was commissioned to the JFRCA. As of 1994, 425 prefectural researchers have been awarded certified status and are taking an active part in disease control management in Japan.

The JFRCA maintains the "Fish Disease Center" on its Tokyo premises where training courses and research pertaining to fish disease are carried out. Of note is JFRCA's "specialist certification course." After completion of this course, and provided that the applicant has at least two years of field experience, a prefectural employee can sit for the certification examination and upon passing, receive the credentials of a fish health specialist (JFRCA 1995b). Other courses are for those already possessing credentials but wishing to receive advanced training in specific areas or to undergo "re-training" to keep abreast of the latest developments. Referring back to the specialist certification course, the course is composed of three segments taught in consecutive years. The first year, various topics such as general disease theory, viral diseases, fungal diseases, and other diseases are taught by university professors. The second year, affiliated topics such as fish physiology and immunology are taught, and practical work in all areas of fish disease is conducted. In the third and final year, applicants study not only scientific areas such as pharmacology, rearing methods, and fish disease diagnostics, but also the specifics of legislation in aquaculture, learning the details of the Drug Laws and the Food Hygiene Law. At present, this system bestows a certification, not a license, as in the case of veterinary certification. Acquiring certification entails rigorous preparation, and at present, the system is serving its purpose in helping specialists to manage fish disease in this country.

STATUS OF DISEASE RESEARCH IN JAPAN

In Japan, numerous areas relating to aquatic animal disease are being investigated; research is of both pure and applied nature. Most basic research is conducted at the national institutes and universities. The National Research Institute of Aquaculture maintains a Fish Pathology Division that is composed of the following sections: Pathogen Section, Pathophysiology Section, Pharmacology Section, and Immunology Section (NRIA 1992). Basic studies are being conducted on:

- the physiology and ecology of viruses, bacteria, and parasites in the context of the establishment of disease prevention measures;
- physiology and immunology of aquatic animals leading to vaccine development and other means of health management; and
- drug metabolism to determine potential utility for disease treatment.

More information can be obtained through the headquarters of the Institute (National Research Institute of Aquaculture, Nansei, Mie 516-01, Japan).

The JFRCA has an in-house applied research program covering prevention, diagnostics, and therapies as pertains to fish disease and, in addition, carries out re-evaluation of fisheries medical products and residue analysis.

CONCLUSIONS

Japan has a well-developed legislation for the regulation of chemicals used in aquaculture that is designed to guarantee safety of the final product to the consumer. Through auxiliary organs of the government's Fisheries Agency, prefectural fisheries experts undergo constant training in order to

supervise and guide the activities of local aquaculturists and fish farmers. Thus, Japan's system is organized from the national level down to the local level with the basic research and law-making activities of the national government being through advisory and extension services at the prefectural level.

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