Functional Food and Nutraceutical Registration Process in Japan and China: Similarities and Differences

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ABSTRACT – Purpose. This paper looks into the functional food and nutraceutical registration processes in Japan and China. The Japanese have developed the Foods for Specified Health Use (FOSHU) registration process whereas the Chinese have put into place the Health Food (HF) registration process. The aim of this paper is to compare the regulation processes between the two countries. **Method**. The study was conducted using secondary sources. The literature surveyed covered academic journals, trade journals, magazine and newspaper articles, market reports, proceedings, books and web pages of relevant regulatory authorities and regulatory consultants. Information from the more recently published sources was used over older sources. Indeed Official regulations as well as the Chinese SFDA (State Food and Drug Administration) and the Japanese MHLW (Ministry of Health, Labour and Welfare) websites were also consulted. **Results**. The two diagrams of the registration processes respectively in Japan and China clearly show that there are similarities and differences. There are six categories under which these can be found: (1) the scientific evidence required; (2) the application process; (3) the evaluation process; (4) the law and the categories of products; (5) the labels and the types of claims; and finally (6) the cost and the time involved. **Conclusions**. The most noticeable similarity is how the overall process takes place whereas the most noticeable difference is in the number of steps and the structures put into place by each country.

INTRODUCTION:

With the development of science and technology the fundamental concept of food is also changing from merely feeding the basic survival needs of people to helping people to remain in good health and to prevent diseases. There is a growing concern in the links between food and health by public health officials, consumers, as well as by people from the food industry. Functional foods and nutraceuticals have been among the growing trends in recent years [1, 2, 3, and 4]. To ensure that the products are safe and that the firms involved are not misleading consumers, governments from various countries have put complex regulation systems into place. Indeed government's authorities must ensure that functional foods are regulated in a manner that maximises health benefits and minimizes health risk for consumers and that claims that are made by the firms producing and selling them are genuine. However the assortment of regulatory regimes creates much uncertainty for the firms seeking to benefit from developing foreign markets. Indeed the lack of familiarity and poor knowledge regarding the regulatory situation in the destination market increases the risks of failure. Due to a lack of standardisation in the functional food and nutraceutical regulatory regimes, with each additional target export market, the firm must incur additional costs and assume further risks [5, 11, 12, and 14]. The research presented in this paper should provide valuable information to biotech, pharmaceutical, and nutraceutical companies developing their market entry strategy in Japan and China. There are few national and international studies of drug registration application processes but even fewer comparative studies of functional food and nutraceutical registration application processes. This paper compares and contrasts two regulatory systems and since little is generally known about them, particularly within North America, it provides a useful introduction to regulations other than the US and European systems. In light of a dearth of information of other regulatory regimes, this paper aids in highlighting the lack of consistency internationally. Insight into regimes other than the US system should aid in improving current regulatory structures related to "Functional Foods" and "Nutraceuticals".

The study was conducted, primarily using secondary sources. Two strategies were used to analyze the data: (1) narrative strategy - detailed story built from the raw data, and (2) visual mapping strategy - the presentation of large quantities of information in relatively little space. These strategies are particularly attractive for the analysis of process data because they allow the simultaneous representation of a large number of dimensions and they can easily be used to show precedence, parallel processes and the passage of time [7]. The terminology related to functional foods is still not clearly defined and disagreement exists among experts. Differing understandings of what functional and health-enhancing foods were found.

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The literature sources used the term “functional food” in varying ways ranging from a strict definition of “scientifically proven to elicit physiological benefits beyond regular nutrition” to a much broader definition to include anything from fortified and low-fat products to capsules and extracts. As a result, comparisons between countries are never easy [8].

Nutraceutical Registration Process in Japan

Foods for Specified Health Uses (FOSHU) are foods that are composed of functional ingredients that affect the structure/function of the body. These foods are used to maintain or regulate specific health conditions, such as gastro-intestinal conditions, blood pressure, and blood cholesterol level [9]. FOSHU are divided into four groups (Table 1) depending on the level of claim and scientific evidence. Different levels of claims are allowed, from A to C, depending on the strength of the supporting data [20]. Regular and Disease risk reduction FOSHU require A grade evidence where evidences are both medically and nutritionally established from a scientific view. Standardised FOSHU requires B grade evidence, where evidences are confirmed at the level previously required for the approval of existing FOSHU. For Qualified FOSHU, C level of evidence is acceptable where evidences are not established but the efficacy is suggested [13].

FOSHU health claims are allowed in several categories designated by the government – gastrointestinal health, cholesterol moderation, hypertension moderation, lipid metabolism moderation, sugar absorption moderation, mineral absorption and bone health and tooth health. However, new claims and combination of claims are approved on a regular basis [20].

Overseas applicants file their applications directly with the MHLW. The calendar is divided into four quarters. Applications are accepted every three months (usually March, June, September and December) [21, 33]. The process of regular FOSHU registration is shown in Figure 1. The application requirements are listed in Table 2. It indicates that information must be provided on safety, efficacy, processing, formulation, analytical method, and chemical and physical analysis, as well as other specifics. Product samples and proposed labels with proposed claims must also accompany the application. All information submitted must be in Japanese language. At least some of the clinical data must come from Japan involving Japanese subjects. Publication of information in a Japanese scientific journal is also required [9, 28].

Table 1. Japanese FOSHU Categories

Regular FOSHU	**Reduction of Disease Risk FOSHU**
"Regular" FOSHU refers to foods intended for consumer products, whose safety and efficacy regarding health claims have been proven by a series of safety/stability tests and clinical trials and have been approved by the MHLW (Ministry of Health, Labour and Welfare) to make health claims for the specific product.	If the efficacy has been medically and nutritionally established, this category allows claims on the product label that describe the efficacy in disease risk reduction.
Standardized FOSHU	**Qualified FOSHU**
The Standardized FOSHU represents foods that contain certain active ingredients that are proven to meet the standards and specifications for a specific health claim, ingredient and/or quality standard. Food that has an accumulation of scientific evidence (more than 100 cases of past approvals as FOSHU) can be approved as a Standardized FOSHU upon sole review of MHLW, without needing an individual review by the examination council.	Refers to foods with certain effectiveness, but whose scientific data are less conclusive than those required for the existing FOSHU standard. The application process is simpler and less stringent. Labels for Qualified FOSHU products can include this sort of statement: ‘This product includes (name of substance), which may be appropriate for (health claim), although the grounds for this effectiveness have not necessarily been established.’

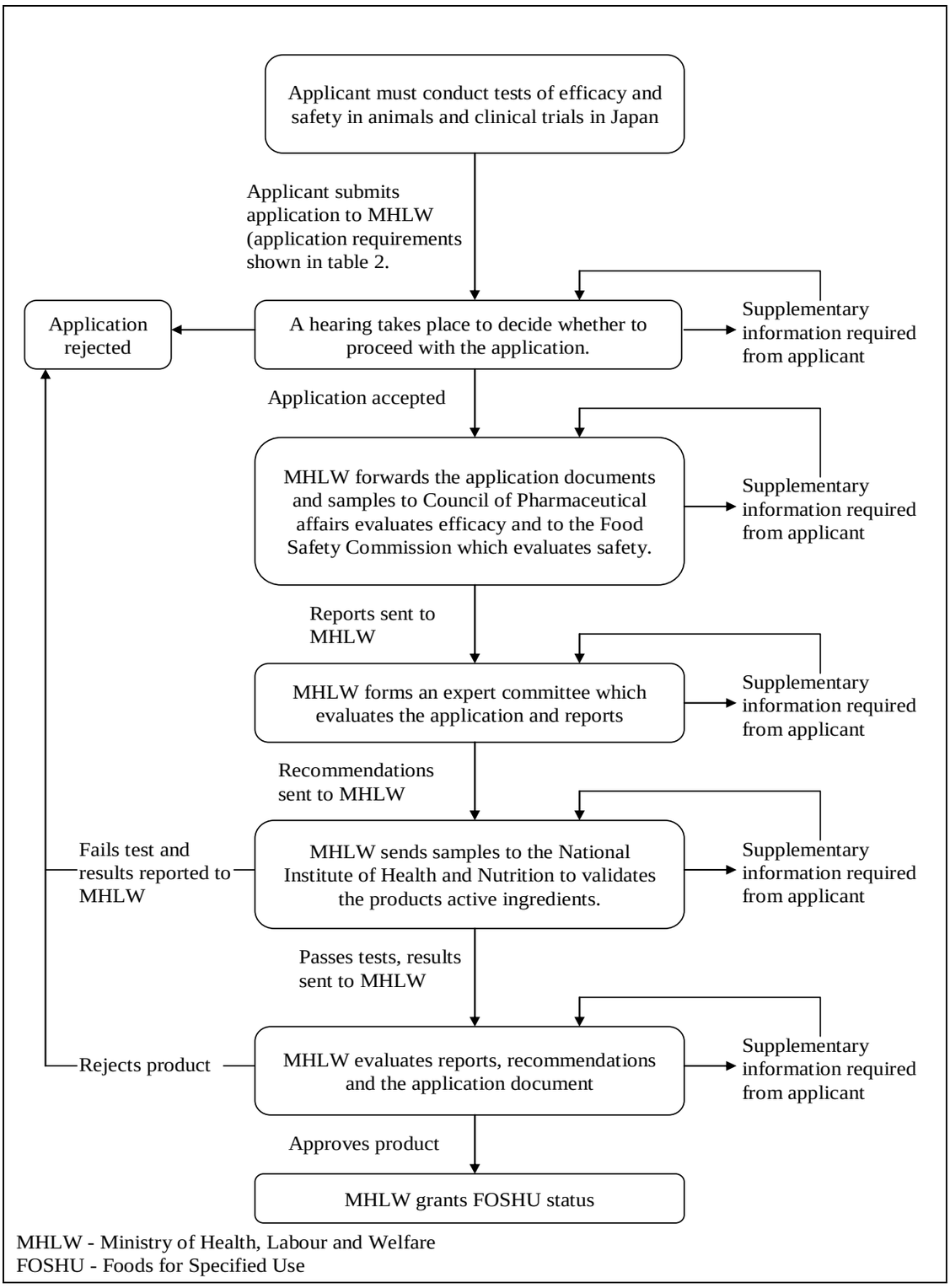

Figure 1. Japanese FOSHU Registration Process

MHLW reviews the application in a hearing and decides whether to proceed further with the application. If the application is accepted, MHLW passes on the application and the product samples to three groups: (1) the Council of Pharmaceutical Affairs, (2) Food Safety Commission and (3) the National Institute of Health and Nutrition. The Council of Pharmaceutical affairs evaluates the efficacy of the product and the Food Safety Commission assesses its safety [10, 21,22]. Regarding standardised FOSHU, an application under this category does not require the consultation steps covering effectiveness and safety [16]. The National Institute of Health and Nutrition validates the analytical method for testing the active ingredient [21]. Each group sends back its report to the MHLW. Then the MHLW forms a committee of experienced specialists in medical, nutritional, food hygiene, and pharmaceutical fields, whose members are generally chosen from the Japanese academic community. Depending on the health benefit being claimed for the product, the application is assigned to the appropriate committee for review and comment. The committee then decides whether more data are needed, or if the application can be forwarded to MHLW with a recommendation of approval [9, 10].

Table 2: FOSHU Application Requirements

- Name of applicant (representative) and the address
- Name and address of head office and factory
- Product name
- Shelf life
- Content amount
- Reason for seeking approval and how the intake contributes to the improvement of one's diet and the maintenance/enhancement of health of the entire population
- Health claims the applicant wishes to seek approval for
- List of ingredients and composition percentage
- Considerations and precautions at intake
- Instructions for preparation, storage, or intake of the product
- Product sample
- Sample of the entire package with labels and health claims
- Documentation that shows clinical and nutritional proof of the product's functional effects for the maintenance of health
- Documentation that shows clinical and nutritional proof of the intake amount of the product or its functional components
- Documentation concerning the safety of the product and its functional components, including additional human studies regarding the eating experience
- Documentation concerning the stability of the product and its functional components
- Documentation of physicochemical properties and the test methods for the product's functional components
- Results of the quantitative and qualitative tests of components of the functional component, and their testing method
- A report describing the analysis of the designated nutrient constituents and the product's energy content
- Description of the production method, factory equipment, and an explanation of the quality control system
- Reasons for not attaching any of the above
- Other information to support the application

Once the process has been completed, the MHLW makes its decision to grant approval for the product under FOSHU. During the course of evaluation, the MHLW office can ask for further documentation and amendments. If granted approval the applicant can use the FOSHU mark (Figure 4) on its label. It symbolizes 'jumping for health' [21].

Nutraceutical Registration Process in China

The Chinese regulation system defines health foods as foods with specific health functions that are suitable for consumption by specific groups of people and that has the effect of regulating human body functions without treating diseases. The application must be done by the firm's representative office or authorized agent in China [17]. Prior to submission, the following forms must be obtained from the INFS (Institute of Nutrition and Food Safety), the Chinese Centre for Disease Control in Beijing: report of toxicology safety assessment, report of functionality evaluation, analytical report of active ingredient, report of product stability study and report of sanitary inspection [19]. There are 27 categories of function claims that are allowed. (Table 3)

Figure 2. FOSHU Symbol

The minimum period required by the approval process is 6 months. It begins with receipt of the application by the MHLW. However, this period does not include extra time required by the various inquiries from the office of the MHLW, the committee, and the Council, as well as the time necessary to respond to these inquiries. Usually the minimum period is 12 months [21]. That does not include the efficacy and safety tests required which can take between 4 and 12 months. Thus the registration process can take between one and two years. The entire FOSHU approval process including gathering the scientific evidence can cost around US$1million. The fees for FOSHU applications and tests are only $1,600. Most of the costs are associated with producing safety tests and demonstration of efficacy [23].

Table 3: Function Claims for China Health Foods

1. *Enhancing immune systems*
2. *Sleep improvement*
3. *Alleviating physical fatigue*
4. *Enhancing anoxia endurance*
5. *Irradiation hazard protection function*
6. *Increasing bone density*
7. *Assisting liver protection against injury*
8. **Alleviating eye fatigue**
9. **Eliminating acne**
10. **Eliminating skin pigmentation**
11. **Improving skin ability to retain moisture**
12. **Improving skin oil content function**
13. Assisting blood lipids reduction
14. Assisting blood sugar reduction
15. Antioxidative function
16. Assisting memory improvement
17. Alleviating lead excretion
18. Improving throat function
19. Assisting blood pressure reduction
20. Facilitating milk secretion

Table 3 Continued…

21. Assisting weigh control
22. Improving child growth
23. Improving nutritional anemia
24. Regulating gastrointestinal flora
25. Facilitating digestion (regularity)
26. Facilitating bowel movement
27. Protection of gastric mucosa

Note:
Italics: Animal study only,
Bold: Human study only,
Normal: Animal and Human studies are required

Other new functions can be claimed if the applicant can prove that the food delivers what it claims with complete details of the research process. The government requires that full "evidence" be presented to support health food claims. That means that health food must be tested on animals and/or humans. Each product can be certified for no more than two health functions. Therefore, if a firm can prove that its product can achieve more that two functions, it must decide which two are the best to use in order to market the product [17]. Furthermore Table 3 shows whether animal and/or human studies are required for the claims. For instance for a product that would claim to enhance immune systems the tests would need to be conducted on mice for 30-45 days. The testing parameters are body weight, organ/body weight ratio, cell immune function, fluid immune function, mono-nuclei phagocyte function and natural killer cells activity [19]. Once the INFS (Institute of Nutrition and Food Safety) reports have been obtained, the application for imported health food product must be submitted directly to the SFDA with the requirements of the application as listed in Table 4.

Table 4: Health Food Certificate Application Requirements

- Application Form for Imported Health Foods, which requires
- -Product Name
- -Manufacture
- -Manufacturing address
- -Applicant name and contact details
- - Health functions claimed
- Product formula and scientific evidence of formulation
- Active ingredients and analytical procedure for the active ingredients;
- Manufacturing process with a flow chart that describes the process clearly and in detail
- Product quality specifications (industry standard)
- Test certificate issued by an Authorized Testing Institute
  -toxicology safety, functionality evaluation, active ingredient analysis, product stability, sanitary inspection reports
- Product insert sheets with health claims and specifications
- Product packaging with all labels that will be used for the product in the marketplace
- Certified/notarized documentation that show the applicant is empowered to act on behalf of the submitting organization
- Documents that shows the product is allowed to be produced and sold in the manufacturer's country or region of origin
- Three samples of the product as they will be packaged and formulated for the market (these samples are strictly for visual inspection; samples for testing should be submitted separately)
- Any other documentation that can be used to support the claim and approval processing.

Figure 3 shows the application process for health food registration in China. The application should include the product name, list of ingredients, active/marker ingredients and their content, health care functions, people who can use it, a list of health conditions that should lead to avoid using the product, dosage and usage, specification, best before date, storing method, and precautions (article 68 Decree of the State Food and Drug Administration No. 19).

Each document should include one original copy and 13 photocopies [19]. With the exception of the manufacturer's address, all other items submitted in a foreign language must be accompanied by corresponding translations in Chinese [24]. The Chinese translation of the documents should be notarised by a Chinese notary [19]. The SFDA will give applicants a response within five working days if either the application has been accepted, rejected or supplementary materials are required. Next, if the SFDA believes it necessary, they will visit the overseas site(s) to take samples and inspect production processes. The SFDA will also send samples to a designated testing agency to carry out further tests, samples and confirm previous results. That must be completed in 50 days after which the reports of these tests are submitted to the SFDA (article 30, 31 Decree of the State Food and Drug Administration No. 19) [17]. Next, an expert committee arranged by the SFDA will review the claims and reports from the testing laboratories. The SFDA will organise a quarterly evaluation and approval committee meeting in the last two weeks of each quarter. The evaluation and approval committee is a pool of experts from food hygiene, nutrition, toxicology, medicine and other related professions around the country. The calendar is divided into four quarters. All applications accepted by the end of the second month of each quarter are considered at the meeting [17,19]. The SFDA will then approve or reject the application or may ask for supplementary materials. If supplementary material is required the applicant has five months to supply it and the committee must review the material within 30 days of receiving it (articles 13 and 14 Decree of the State Food and Drug Administration No. 19).

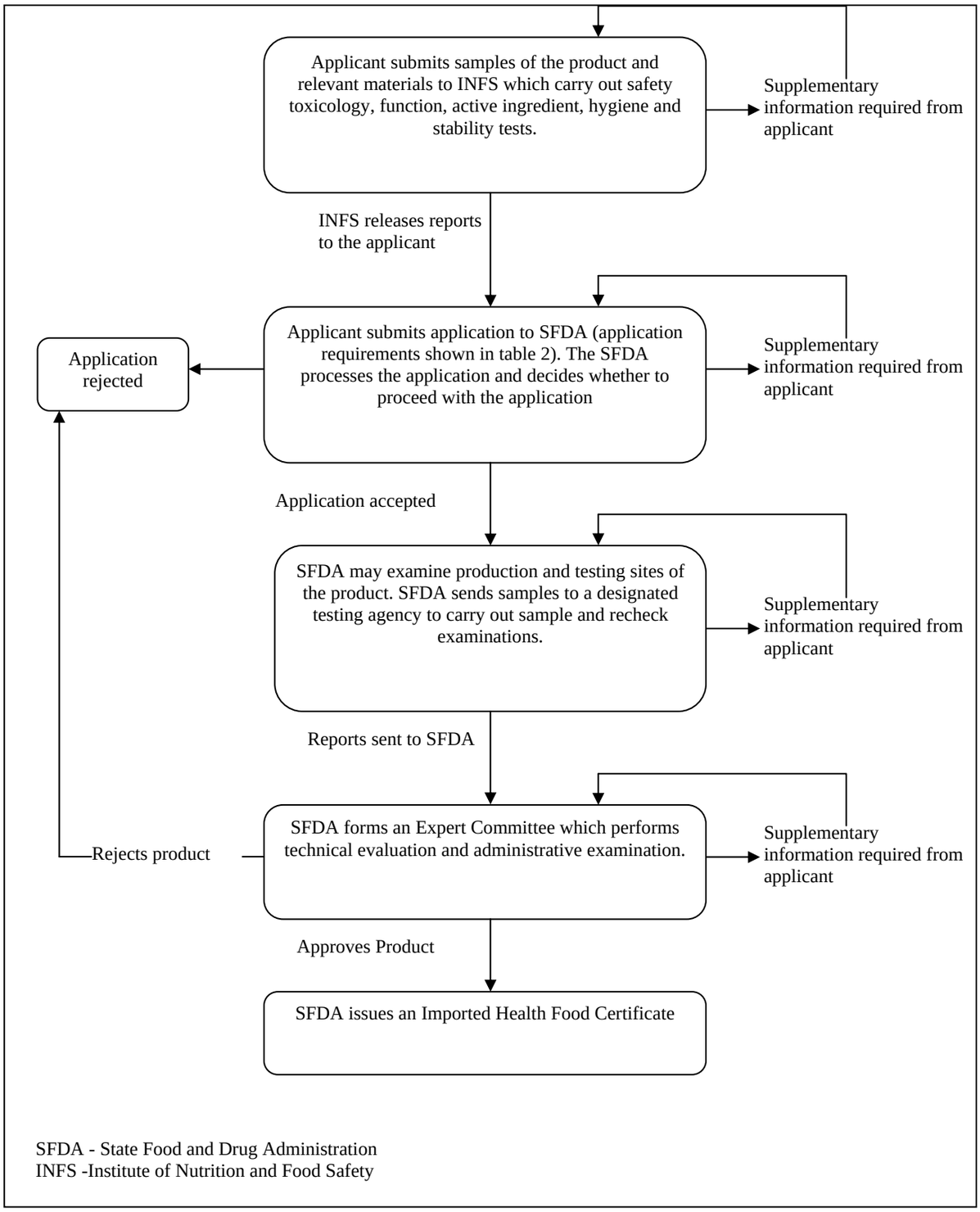

Figure 3. Chinese Health Food Registration Process

Once the application has been approved the SFDA will issue an Imported Health Food Certificate to the applicant after which the applicant may sell its health food product in China [17]. The certification expires five years from the date of official certification, and must be recertified.

Quality control and testing can take 6 to 12 months depending if human clinical trials are required. The application is then submitted to the SFDA. If all runs smoothly the application can be approved within 3 months. However if further information is needed it can take longer, from 9 to 19 months. Indeed the main cost is conducting the tests ranging from US$14 500.00 to US$ 29 000.00 (Authors to reconcile this with their statement in the conclusions. The application fee is only about US$ 1200.00. [17, 24]

DISCUSSION

The two diagrams of the registration processes respectively in Japan and China clearly show that there are similarities and differences between the nutraceutical registration processes of these countries. There are six categories under which these similarities and differences can be found (Table 5): (1) the scientific evidence required; (2) the application process; (3) the evaluation process; (4) the law and the categories of products; (5) the labels and the

types of claims; and finally (6) the cost and the time involved.

The Similarities

Scientific evidence is required as part of the application for nutraceutical registration in both countries; China and Japan. The scientific data required in both countries are very similar regarding the safety, the efficacy, and the stability profiles. They further require the identification of the active ingredients as well as a statement in regard to their analytical method. In both countries the test method provided by the applicant is validated and then used to test the active ingredient. Where clinical trials are required, the clinical trials must be conducted with either Japanese or Chinese subjects in their respective countries. Most of the application requirements are similar in both countries such as the description of the manufacturing process, the proposed health claims, the dosages, the product packaging and labels, the samples, the applicant and manufacturer details and the product formula. Both countries accept other evidence, information or documentation that may support the application. For example clinical trials overseas in non-Japanese and non-Chinese subjects are welcome. All documents that are submitted must be accompanied by a translation in the national official language as documentation in English alone is not accepted.

Further similarities exist in the evaluation process of the Japanese and Chinese registration systems. In both countries there is an initial step where a decision is made by the relevant authority as to whether the application is acceptable or not. If accepted the application may proceed further. In both countries evaluations are held four times a year in March, June, September, and December. Both authorities send documents and samples to centres outside the SFDA or the MHLW to evaluate the efficacy, safety, and the active ingredients of the products. In both registration processes expert committees are formed. They are made up of various experts from around the country in areas such as food hygiene, nutrition, medicine, toxicology and other related professions. At any stage of the registration process supplementary information can be requested and the applicant is kept informed of the development of its application by the SFDA and MHLW throughout the process. Both countries allow function claims. Whereas Japan has always allowed product specific claims, China allows them since 2005 only. Before 2005 a catalogue of pre-approved claims listed the only claims that were allowed for health foods.

Another interesting similarity between Japan and China is in the legislation that regulates the processes. When the FOSHU system was first introduced it was put under the umbrella of the already existing Nutrition Improvement Law. That was the Law that was regulating the Enriched Foods and Foods for Special Dietary Uses (FOSDU). FOSDU included Foods for the Sick, Formulated Milk Powder for Infants, and Food for Aged Persons. The new products were simply added under another FOSDU category without the need for a new law (Bailey 2005a). However the health foods regulatory system was reformed in 2001 and put under the Food Sanitation Law. The Chinese health foods system introduced in 1996 comes under the Food Hygiene Law.

The Differences

In Japan, clinical trials are mandatory for ordinary FOSHU approval whereas in China depending on the health claim, animal tests alone are sufficient. Another major difference is who can conduct the tests and trials. While Japan allows the manufacturers to conduct their own tests, in China samples of the product must be submitted to one of the SFDA authorized testing institutes such as the INFS that will carry out the tests. Furthermore, the two countries have different ways to ensure the validity of the tests. In China the tests are conducted by an authorised testing institute and therefore the validity of the test is secured by the independence of the testing source. In Japan, since the law was changed in 1998, the obligation that the companies must certify that their scientific evidence has been reviewed by outside experts has been removed. It was replaced by the pre-requisite that the studies be published in a Japanese scientific journal. However industry-sponsored journals are accepted according to the MHLW [27]. To test the data relating to the active ingredients, the MHLW send samples and documentation on the analytical method to the NINH to validate.

A major difference in the processes between Japan and China is the cost of obtaining approval for nutraceuticals registration. In Japan, regular FOSHU approval can cost up to US$1,500,000. In China the health food approval costs range from $17,500 to $34,500. Authors to reconcile with previously stated US$14 500.00 to US$ 29 000.00 It does not seem that the difference in costs can be explained by the size of the market in each country. Current market size in Japan is US$17 billion (US$6 billion FOSHU) and in China is US$6 billion [15, 18]. FOSHU approvals require clinical trials that are much more expansive. However the regulations have recently been changed to introduce categories that require less clinical evidence. Although a disclaimer must be enclosed in the health claim the fact that less clinical evidence are required in these categories makes it less expansive to get approval. Time to get all the scientific tests done and to go through the whole registration process also varies between the two countries. The Japanese process takes on average 18 months whereas the Chinese process takes about 13 months.

Another major difference is that in Japan the company is required to provide a reason for seeking approval as well as a description of how the product contributes to the

improvement of one's diet and the maintenance/enhancement of health of the entire population. It must be remembered that one of the key reasons that the Japanese government introduced the FOSHU system was to keep the aging population healthy through functional foods and to keep the health care costs down. This is still the case today with the Health Promotion Law introduced in 2003 championing 'Healthy Japan 21' that aims at promoting a healthy life style in Japan [10]. Improving the population health was not amongst the main reasons the Chinese government implemented its health food registration process; the key issue was to put into place a system that would control unsubstantiated health claims on food products.

One of the key differences that can be easily seen when comparing the two registration process diagrams (Figures 1 and 3) is that the Japanese system has more steps than the Chinese system. Indeed the Japanese registration process has seven major steps while the Chinese system has only five. There are three decision points in the Japanese system that can see a product rejected, whereas there are only two of them in the Chinese system. At any time in the evaluation processes the relevant authorities in each country may ask the applicant for additional information. Nonetheless, in China, the flowchart (Figure 3) shows four stages at which specific supplementary information may be requested whereas in Japan there are five of them. Another difference is that the SFDA may request to visit the company production sites if they see this as necessary whereas in Japan no such provision is made.

An interesting difference is the structure put into place by each country. China has developed the SFDA, a government regulation authority in charge of safety management of drug, food, health food, medical devices and cosmetics [22]. The MHLW is one of cabinet level ministries in the Japanese government. This government body regulates drugs, foods, medical devices, cosmetics as well as medical care, labour standards and social welfare [16]. Japan does not have a similar authority to regulate food and drugs exclusively. When the health food regulations were first enacted in 1996, the MOH was responsible for registering health food products. In October 2003, the MOH transferred the supervision and management responsibility of functional food to the SFDA [17]. The Chinese government's establishment of a single drug and health food regulatory authority was an important step towards foreign access because it eliminated the conflicting standards that prevailed among various provincial government agencies, centralized the Chinese healthcare regulatory system and made it more transparent. The SFDA now oversees all medications-both Western and TCM-as well as advertising [26]. It is not clear whether the Chinese government felt that there was a need for a separate regulatory authority or if it was the quest for international legitimacy that prompted the move. The SFDA follows US FDA's model. As Jane Qui [29] indicated: "*Chinese drug regulators have, in theory, adopted many of the rules that govern the US Food and Drug Administration (FDA), the largest and, arguably, most thorough drug regulator in the world.*"

Another difference is in some of the categories allowed under the current FOSHU system that the Chinese system does not have. The Japanese government wanted to deregulate the FOSHU system in order to increase participation in FOSHU. Health foods without health claims dominate the market as opposed to FOSHU products. New regulations were put into place allowing qualified health claims supported by a lower level of scientific evidence than required for ordinary FOSHU approval. Different levels of claims are allowed, from A to C, depending on the strength of the supporting data. The idea is interesting as in many ways it is similar to the current USA FDA approach [20]. In the US a major revision of the process for making product claims about diet and health for conventional foods and dietary supplements was initiated in 2002. It was based on the accumulated experience with product claims in labelling and advertising. The revision allows qualified heath claims on dietary supplements that would not have met the previous "significant scientific agreement" standards that were in place since the health claims for food were first introduced. In practice, this means that a claim can be made for a diet-disease relationship that had not reached scientific agreement as long as a disclaimer is included on the label stating that the data supporting the claim are not yet conclusive. An FDA guidance document described a process for systematically evaluating and ranking the scientific evidence for a qualified health claim [6, 30]. The ranking system uses an A,B,C or D grading system. A Grade A claim would meet 'significant scientific' agreement standards for a traditional (now called 'unqualified') health claim, and a B grade would be assigned to those petitions for which good scientific evidence exists supporting the claim but for which the evidence is not entirely conclusive. A C grade would apply to claims for which the evidence is limited and inconclusive; a D grade would be given to claims with little scientific support [6]. In both countries - USA and Japan – when only low levels of scientific evidence are available the product must include a disclaimer stating that effectiveness has not been proven [6, 16]. This suggests that Japan in its will to de-regulate and increase participation in the FOSHU system learned from the USA liberalisation of health claim regulations in 2002. However, Japan modified the ranking system slightly having only three levels while the USA has four levels. It is interesting that Japan, being one of the pioneer-innovators in functional food and nutraceutical registration processes, is now looking abroad for inspiration.

As of April 2005, Japan allowed disease-risk reduction claims. At present China

does not allow those types of claims. The disease-risk reduction claims are reflective of the Codex decision. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme [31]. The Codex defines *reduction of disease risk claims* as '*Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.'* [32]. The disease-risk claims are currently limited to two ingredients, calcium which helps reduce the risk of osteoporosis and folic acid which when taken by pregnant women may reduce the risk of neural tube defect, such spondyloschisis as (*spina bifida*) in babies, specifying the minimum and maximum limits of daily intake [13]. Only two disease-risk reduction claims are allowed, as only two claims may be manageable at this stage. Given that this is a recent change, it will be interesting to see if China will follow and allow disease-risk reduction claims in the near future.

Once a FOSHU product is approved it may carry the FOSHU symbol to distinguish it from other non-approved health food products. The symbol is attractive to consumers as it assures them that the product has passed the tests. China also had a symbol for its approved health food products but this requirement has since been removed.

CONCLUSIONS

A comparison of the nutraceutical registration processes in China and Japan reveals a number of similarities and differences. The most noticeable similarity is how the overall process takes place. The core steps in both processes start with the applicant certifying that the appropriate tests have been conducted before submitting an application. Once it has been submitted the authority decides whether to proceed with the application or not. If accepted the claims are analysed and an expert committee is put into place to evaluate the application. At any stage supplementary information may be requested from the applicant. The most noticeable difference is in the number of steps and the structure put into place by each country.

The regulations are changing rather quickly [34]. For instance a High-level International Forum on Food Safety was held in Beijing in November 2007. At the conclusion of the forum, the participants adopted the Beijing Declaration on Food Safety. It urges all countries to develop comprehensive programmes to improve consumer protection from production to consumption, from routine to emergency, and from domestic to international. Furthermore it urges all countries to actively participate in the International Food Safety Authorities Network and to share information on emerging food safety issues and experience about best practices. That suggests that the gaps between policies and registration processes of various countries might narrow down in the future.

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Table 5: Summary of the Similarities and Differences between the Chinese Health Food Regulations and the Japanese FOSHU regulation

Scientific Evidence	Application	Evaluation	Law and Categories	Labels and Claims	Cost and Time
Similarities					
Types of data	*Requirements*	*Initial acceptance*	*Legislation*	*Claims*	
Require safety, efficacy and active ingredient data, as well as testing methods for the active ingredient and product stability.	Manufacturing process, health claims, product packaging and labels, samples, applicant and manufacturer details, product formula, any other information that may support application.	There is an initial decision as to whether to accept the application and proceed further	Japan FOSHU regulation is under the Food Sanitation Law and China health food regulation is under the Food Hygiene Law	Allow function claims	
Clinical Trials	*Language*	*Quarterly Evaluations*	*Food Forms*		
Clinical trials must be done in Chinese or Japanese subjects in China or Japan.	All documents must be submitted in the national language (Chinese or Japanese)	Applications accepted at the end of each quarter in a year	Conventional and dosage forms allowed		
Other evidence		*External advice*			
Allow other information that may support the application e.g clinical studies conducted overseas		Documents and samples are sent to external centres where they evaluate the efficacy,safety and active ingredients and report back to the SFDA or MHLW.			
		Expert committe			
		Committee formed from experts around the country to evaluate application and scientific reports			
		Supplementary Material			
		May be requested at any stage of the evaluation process			
Differences					
Animal and Human tests	*Requirements*	*Stages*	*Categories*	*Claims*	*Cost*
In China, human clinical trials are not mandatory, it depends on the proposed claim. In Japan human clinical trials are compulsary.	China requires proof that product can be sold in country of origin, wheras Japan does not have this requirement. Japan requires how the product will benefit an individual's health and the entire populations health, whereas China does not have this requirement.	The FOSHU registration process has more stages than the Chinese health food registration process	Japan has for different FOSHU categories, which require different levels of scientific evidence, whereas China does not have such categories for health foods	Japan allows disease-risk reduction claims, China does not.	Japan: approx $1,500,000, China: approx $35,000
Conducting tests		*Checking production sites*		*Symbol*	*Time*
In China, testing has to be done by an authorised institute, wheras in Japan, testing can be done by the manufacturer. For Foshu approval, testing can be done by manufacturer.		SFDA may examine the overseas production sites of the product if they find it necessary, whereas in Japan they do not examine overseas sites		FOSHU products may have the FOSHU symbol on their label, China has no such symbol or logo	Japan: 18 months average, China: 13 months average
Validation		*Checking production sites*			
As well as the testing being done at an authorised testing institute, the SFDA send the samples for rechecks. In Japan the scientific evidence must be published in a Japanese scientific journal		SFDA may examine the overseas production sites of the product if they find it necessary, whereas in Japan they do not examine overseas sites			