Creation of the Animal Products Safety Division in the Ministry of Agriculture, Forestry and Fisheries of Japan

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Summary

The Animal Products Safety Division (APSD) of Japan was created in the Ministry of Agriculture, Forestry and Fisheries in October 2005 to strengthen the role of the Ministry in animal production food safety. The authors outline the background to the establishment of the APSD and its functions. The APSD is engaged in administration related to risk management during the production stage of terrestrial and aquatic animal products. The APSD endeavours to ensure that risk management measures are taken in accordance with the relevant laws, regulations and administrative notifications and that they are based on risk assessment and science. The APSD works in close collaboration with other national agencies, prefecture governments, foreign governments and international organisations.

Keywords

Animal production food safety, Aquatic animals, Feed safety, Japan, Traceability, Veterinary licensing, Veterinary medicinal products.

Creazione della Divisione per la Sicurezza dei Prodotti di Origine Animale all'interno del Ministero per le politiche agricole, forestali e ittiche del Giappone

Riassunto

In Giappone la Divisione per la sicurezza dei prodotti di origine animale (APSD) è stata creata all'interno del Ministero delle politiche agricole, forestali e ittiche nell'ottobre 2005 per rafforzare il ruolo del Ministero nell'ambito della sicurezza degli alimenti di origine animale . Gli autori delineano le basi dell'istituzione dell'APSD e i suoi compiti. L'APSD è impegnato nel controllo del rischio durante le fasi di produzione di prodotti animali terrestri e acquatici. L'APSD si adopera per garantire che le misure di controllo del rischio siano in conformità con leggi, regolamenti e notifiche amministrative, e siano basate sull'accertamento del rischio e sulle conoscenze scientifiche. L'APSD lavora in stretta collaborazione con altre agenzie nazionali, con governi di altre nazioni e con le organizzazioni internazionali.

Parole chiave

Animali acquatici, Farmaci d'uso veterinario, Giappone, Licenze veterinarie, Produzione animale e sicurezza degli alimenti, Sicurezza dei mangimi, Tracciabilità.

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Introduction

The detection of the first case of bovine spongiform encephalopathy (BSE) in 2001, the detection of agricultural chemical residues in imported vegetables in 2002 and the use of non-registered agricultural chemicals in domestic produce caused food safety concerns among Japanese consumers and led to the creation of the Food Safety Commission (FSC), a risk assessment agency, and organisational reform of the risk management agencies, including the Ministry of Agriculture, Forestry and Fisheries (MAFF). On 1 July 2003, the Food Safety and Consumer Affairs Bureau (FSCAB) was created as part of the MAFF to enhance its function in food safety and consumer protection. The objectives of the FSCAB are as follows:

- assurance of food safety from farm to table through risk management
- provision of information to consumers through fair labelling
- assurance of a stable supply of food through the prevention and control of animal diseases and plant pests
- enhancement of risk communication with consumers and other stake-holders
- promotion of nutritional education to achieve better eating habits.

On 1 October 2005, 15 months after the creation of the FSCAB, to enhance its food-chain approach and its function in animal production food safety, the Animal Health and Safety Division, which had previously been a part of the FSCAB, was reformed into two divisions: the Animal Health Division (AHD) and Animal Products Safety Division (APSD). The AHD is responsible for terrestrial animal disease prevention and control, including import and export quarantine. The APSD is responsible for the animal production food-feed safety, veterinary pharmaceutical affairs, cattle and beef traceability, aquatic animal diseases prevention and control as well as the licensing and supervision of veterinarians who play an important role in ensuring animal production food safety.

Assurance of safety and quality of feed

The safety and quality of feed is important to ensure the animal health and safety of animal products. Measures to guarantee the safety and quality of feed are taken in Japan in accordance with the Law on the Assurance of Safety and Improvement of Quality of Feed (Law No. 35, 1953) (Feed Safety Law). The law was enacted in 1954 and has been amended several times since then. Most recently, the law was amended in 2003 to enhance measures for feed safety, including measures for the prevention of spread of BSE, and to clarify the legal position of the Fertilizer and Feed Inspection Services (FFIS).

Measures taken under the Feed Safety Law

To ensure the safety of feedstuffs marketed in Japan, the following measures are taken in accordance with the Feed Safety Law (the Law applies to feeds and feed additives used in feed for cattle, sheep, goats, deer, pigs, chickens, quails, honey bees and 23 species of aquatic animals):

- establishment of standards and specifications for production, usage, storage and labelling of feed and feed additives (feed and feed additives that do not meet these standards and specifications are prohibited)
- prohibition of marketing of specified feeds which have not been tested by the FFIS or which are not produced by manufacturers registered by the Minister of Agriculture, Forestry and Fisheries
- prohibition of production, importation, marketing or use of feeds and feed additives containing hazardous substances or contaminated by micro-organisms
- appointment of a feed production manager at each plant that produces feeds containing antibiotics.

An Agricultural Production Materials Council is consulted when setting the standards and specifications of feeds and when designating the feed additives that are acceptable and the specified feeds that require quality tests before being marketed. By the end of 2006, maximum

residue limits (MRLs) had been established for 60 agricultural chemicals for feeds and grains used for manufacturing feeds (4). In addition, by the end of 2006, 153 feed additives had been designated (5). Risk assessments are being conducted by the FSC to evaluate the risk of antimicrobial resistance of important human pathogenic bacteria caused by the use of antimicrobial feed additives.

In addition to these measures based on the Feed Safety Law, administrative notifications setting maximum limits (MLs) for heavy metals and mycotoxins in feeds are issued.

To ensure that these measures are implemented in accordance with the Feed Safety Law, on-site inspections are conducted by officials of the FFIS and prefecture governments. The APSD works in close collaboration with these prefecture governments. Figure 1 shows the different organisations involved in ensuring feed safety and quality.

Feed regulations for the prevention of bovine spongiform encephalopathy

To prevent the spread of BSE, the use of meat-and-bone meal that originates from mammals, poultry and fish for the production of feeds for cattle and other ruminants is controlled. Meat-and-bone meal from pigs and poultry is only permitted for use in the production of feeds for pigs and poultry, provided that it is produced in a plant approved by the Minster of Agriculture, Forestry and Fisheries and must be a plant in which cross-contamination preventive measures are in place.

Genetically modified feeds

Genetically modified feeds are not allowed to be marketed unless their safety is confirmed in accordance with the Risk Assessment Guideline of Feeds Produced Using Genetically Modified Organisms (GMO). As of the end of 2006, 47 genetically modified varieties of feed crops and 4 feed additives manufactured using GMO were assessed and considered safe (Table I). Unintended contamination of feed by GMOs is only allowed provided that contamination is below one percent and the GMO is found to be safe after a risk assessment conducted by a foreign government that has an assessment system equivalent to that of Japan.

Table I
Number of genetically modified feed varieties assessed to be safe in Japan

Species	Number of genetically modified varieties
Rapeseed	15
Corn	13
Soybeans	4
Cotton	10
Sugar-beet	3
Alfalfa	2

Note: In addition to those listed above, 4 feed additives manufactured using genetically modified organisms have been assessed and are considered to be safe

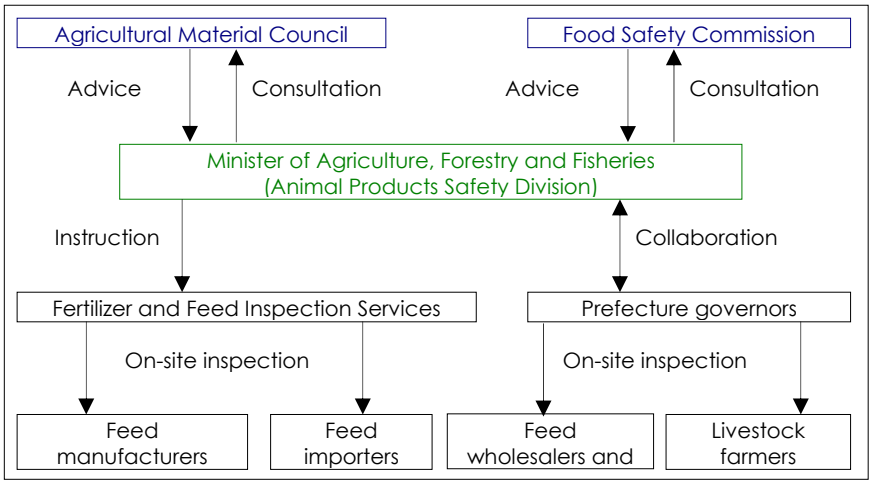

Figure 1
Organisations involved in feed safety assurance in Japan

Assurance of safety and quality of veterinary medicinal products

The Pharmaceutical Affairs Law (Law No. 145, 1960) has been enforced since 1960 to guarantee the quality, effectiveness and safety of medicinal products marketed in Japan. The pharmaceutical affairs for medicinal products for human use are under the jurisdiction of the Ministry of Health, Labour and Welfare. The pharmaceutical affairs for veterinary medicinal products fall under the jurisdiction of the MAFF.

The procedures for obtaining a licence to manufacture and market veterinary medicinal products, procedures for obtaining approval for medicinal products to be marketed and procedures for re-examination and re-evaluation of these products are stipulated in the Pharmaceutical Affairs Law and related regulations.

Approval of veterinary medicinal products to be marketed

A person who intends to manufacture (or import) and market veterinary medicinal products in Japan must obtain approval for each particular product to be manufactured (or imported) and marketed, and a license to manufacture and market them from the Minister of Agriculture, Forestry and Fisheries must be obtained. Approval of each medicinal product is made in consultation with the Pharmaceutical Affairs and Food Sanitation Council. The documents required in the application for approval include safety and clinical studies using the target species, which should be performed in compliance with good laboratory practice (GLP) and good clinical practice (GCP). To obtain a licence to manufacture (or import) and market the approved veterinary medicinal products, the company must be capable of observing good quality practice (GQP) and good vigilance practice (GVP).

A licence to manufacture and market veterinary medicinal products is issued and renewed every five years by the Minister of Agriculture, Forestry and Fisheries. Manufacturers of veterinary medicinal products must conform with the standards of structure, equipment and manufacturing practice (GMP) stipulated by the Minister of Agriculture, Forestry and Fisheries.

By the end of 2004, there were 3 352 veterinary medicinal products approved for manufacture (or importation) and marketing, and 330 establishments that were licensed to manufacture one or more of these approved veterinary medicinal products (1).

Wholesaling and retailing licence of veterinary medicinal products

A licence to wholesale and/or retail veterinary medicinal products is issued by the governor of the prefecture in which the wholesaling and/or retailing premise is located. By the end of 2004, there were 16 254 premises licensed to wholesale and/or retail veterinary medicinal products (1).

Measures taken to prevent veterinary medicinal products from remaining in foods

The approval procedure for veterinary medicinal products to be marketed includes an examination of their effectiveness and safety as well as their residue properties. Depending on their residue properties, a withdrawal period is established for veterinary medicinal products along with other instructions for use.

Furthermore, other measures are taken to prevent veterinary medicinal products from remaining in foods, as follows:

- prohibition of administration or prescription of some medicinal products without prior examination by a veterinarian
- prohibition of sale of some medicinal products to persons other than those who present a prescription or certificate issued by a veterinarian
- establishment of target animals, dosages, withdrawal periods and other usage instructions that should be observed by veterinarians and others who administer medicinal products
- promotion to encourage farmers to keep records of the medicinal products that they have used.

There are approximately 2 200 prefecture officials nationwide who are appointed by prefecture governors as pharmaceutical inspectors. The APSD works in close collaboration with them through prefecture governments to ensure that the Pharmaceutical Affairs Law is observed. Figure 2 shows the different organisations involved in ensuring proper manufacturing and marketing of veterinary medicinal products.

Risk assessments are currently being performed by the FSC to evaluate the risk of antimicrobial resistance of important human pathogenic bacteria being caused by the use of antimicrobial veterinary medicinal products for food-producing animals.

International cooperation

Japan is a member of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), which is a trilateral (European Union-Japan-United States) programme aimed at harmonising technical requirements for veterinary product registration. The Director of the APSD and an appointee from the National Veterinary Assay Laboratory, represent the regulatory authority of Japan on the VICH.

Cattle and beef traceability

Based on the Law for Special Measures Concerning the Management and Relay of Information for Individual Identification of Cattle (Law No. 72, 2003) (Cattle Traceability Law), cattle traceability has been established since December 2003 and beef traceability since December 2004. The objective of the law is to give consumers confidence in the safety of beef and to ensure proper implementation of measures to prevent the spread of BSE by identifying the cohort animals expeditiously. All cattle farmers are obliged to attach an ear-tag with a unique identification number, provided by the National Livestock Breeding Center (NLBC) to every bovine animal that existed on 1 December 2003. The NLBC has been entrusted by the Minister of Agriculture, Forestry and Fisheries to maintain a database for traceability. Cattle farmers were obliged to attach an ear-tag to calves born after 1 December 2003, showing an identification number with the following information provided to the NLBC:

- date of birth (or date of import)
- sex
- identification number of maternal parent (or name of the country of origin)
- breed.

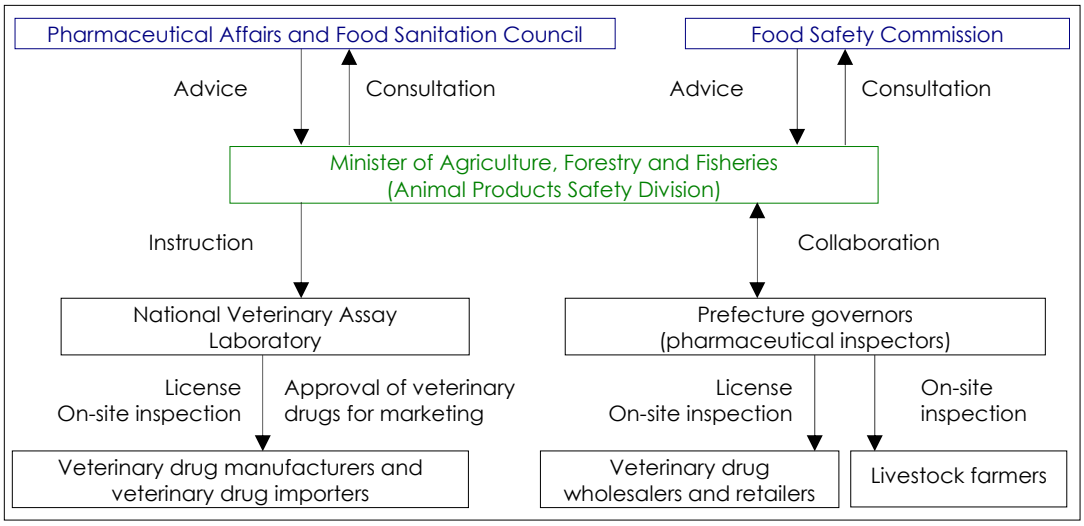

Figure 2
Organisations involved in the proper production and marketing of veterinary medicinal products in Japan

These details are relayed from the farmers to the people who own the cattle, or sell the beef produced from the cattle downstream by reporting the transaction along with the identification number to the NLBC (from birth to slaughter) or by keeping records (from slaughter to retailers or caterers). Through this cattle and beef traceability system, consumers can access (via the internet) the production history of the cattle from which the purchased beef originated, by imputing the identification number indicated on the beef packages sold by retailers or in restaurants.

Officials of the regional MAFF offices conduct on-site inspections of farmers, distributors and caterers (premises that cater Yakiniku [Korean barbecue], Sukiyaki, Shabushabu dishes and/or beef steaks), to ensure that the cattle are correctly identified and the information properly relayed to retailers and caterers. In addition, a meat sample is taken from every carcass and kept in a Japan Livestock Improvement Association (LIAJ) storage facility so that samples collected from retailers or caterers can be DNA tested to ensure that they originated from the cattle with the same identification number. The APSD works in close collaboration with the regional MAFF offices and LIAJ to ensure that the Cattle Traceability Law is observed. Figure 3 shows the different organisations involved in overseeing the efficient operation of the cattle and beef traceability system.

Since the enactment of the Cattle Traceability Law in December 2003, two farmers were put on trial and convicted for replacing an ear-tag with a false ID number and for reporting the false date of movement, respectively. Since December 2004, when beef traceability was put enforced, 12 distributors (3 retailers and 9 wholesalers) were found to be contravening the law (indicating an incorrect identification number) and received warnings from the Minister of Agriculture, Forestry and Fisheries.

Veterinary licensing and practice affairs

Veterinary licence and qualifications

Licensing of veterinarians and their qualifications are stipulated in the Veterinary Licensing Law (Law No. 186, 1949). Based on this law, the Minister of Agriculture, Forestry and Fisheries issues a veterinary licence to those who have passed the national qualification examination. The national veterinary qualification examination is held once a year by the Veterinary Affairs Council (VAC) in cooperation with the MAFF. Every year approximately 1 200 examinees, graduate from 16 veterinary schools, take the national qualification examination and approximately 1 000 qualify as veterinarians. Once qualified, the veterinarians have to observe the provisions stipulated in the Veterinary Licensing Law and the Veterinary Practice

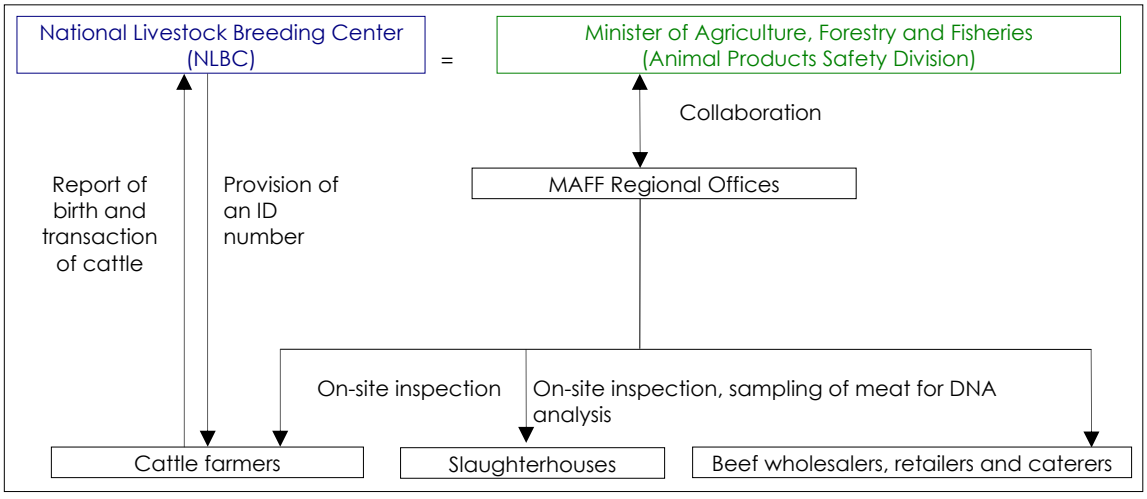

Figure 3
Organisations involved in cattle and beef traceability in Japan

Law (Law No. 46, 1992). The licences of veterinarians who contravene the law are revoked or suspended by the Minister of Agriculture, Forestry and Fisheries, in consultation with the VAC. Table II indicates the number of licensed veterinarians engaged in different occupations (1). Figure 4 shows the different organisations involved in providing a proper veterinary service.

Table II
Number of veterinarians engaged in different occupations, December 2006

Occupation	Number of veterinarians
Civil servant (national government)	465
Civil servant (local government)	8 647
Food animal practice	4 180
Companion animal practice	13 202
Other occupations	9 361
Total	35 855

Veterinary practice affairs

The standards concerning the structure and equipment of veterinary practice premises (veterinary hospitals and clinics) and restrictions on advertisements are prescribed by the Veterinary Practice Law. National and prefecture action plans for the provision of veterinary services are established in accordance with this law. Due to the increase in the number of small animal practice veterinarians and the increasing demands for quality veterinary service, there are three main issues that had to be solved recently and others that still need to be solved, as described below (2).

Post-graduate training of veterinarians engaged in small animal practice

The standard of veterinary practice premises that qualify to provide post-graduate training in small animal practices was established in January 2006. Veterinary practice premises that want to be designated as a post-graduate training centre must have experienced veterinarians who are capable of providing a training programme in cooperation with veterinary schools.

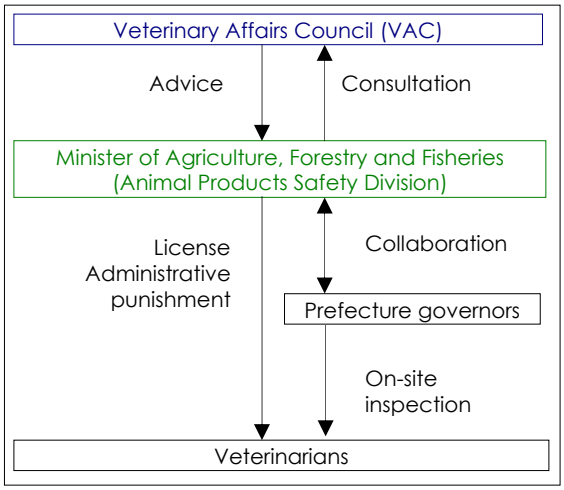

Figure 4
Organisations involved in guaranteeing the supply of proper veterinary service in Japan

Introduction of nuclear medicine in veterinary practice

The current enforcement regulations of the Veterinary Practice Law prescribe the structural standards of x-ray equipment to be used in veterinary practice premises. To guarantee quality veterinary service and to prevent radiation damage, an amendment of the regulations is required to include the standard of equipment for radiation diagnosis, e.g. technetium- 99-molybdenum (^{99m}Tc) for bone scanning in horses, fluoro-2-deoxi-D-glucose (^{18}F-FDG) for positron-emission tomography (PET) in dogs and cats.

Deregulation of advertisement of veterinary practice

Under the current provisions of the enforcement regulations of the Veterinary Practice Law, only the degree and field of specialisation can be advertised by a veterinary practice. An expansion of the items for which advertising is permitted is currently being considered.

Establishment of a qualification system for specialised veterinarians and animal health technicians (veterinary nurses) is another issue under consideration.

Aquatic animal disease prevention and control

Aquatic animal disease situation in Japan

Annual aquaculture production in Japan is 310 000 metric tons, representing approximately 271 billion yen (US$2.3 billion) in 2004. Koi herpes virus (KHV) disease, infectious haematopoietic necrosis *Oncorhynchus masou* virus disease, infectious pancreatic necrosis, epizootic ulcerative syndrome, bacterial kidney disease, red sea bream iridoviral disease and white spot disease are the diseases that cause the greatest economic losses in aquaculture, amounting to around 12 billion yen (US$102 million) annually, and representing 4% of total production. KHV was introduced into Japan in November 2003. In 2006, 1.8% of the carp farming operations were infected with KHV (3). Table III indicates the number of premises and prefectures with infected carp from 2003 through to 2006.

Table III
Number of Koi herpes virus-infected farms and waters

Year	Aquaculture farms	Natural waters*	Total
2003	12	84	96
2004	38	872	910
2005	30	280	310
2006	30	151	181

* including rivers, lakes and garden ponds

Domestic control measures against aquatic animal diseases

Domestic control measures are taken in accordance with the Sustainable Aquaculture Production Assurance Law (Law No. 51, 1999), which was enforced in May 1999. The law authorises the prefecture governors to apply movement control, destruction and disinfection in case of an outbreak of one of the specified diseases. Aquaculture farmers are obliged to report to the prefecture governor when they find an aquatic animal infected with a specified disease. A list of the specified diseases is shown in Table IV.

Table IV
List of specified aquatic animal diseases

Diseases	Host aquatic animals
Spring viraemia of carp	Carp, silver carp , bighead carp, grass carp, black carp and fish belonging to the genus *Carssius*
Koi-herpes virus disease	Carp
Viral haemorrhagic septicaemia	Eyed eggs and fry of fish belonging to the family *Salmonidae*
Epizootic haematopoietic necrosis	
Piscirichettsiosis	
Enteric redmouth disease	
Yellowhead disease	Juvenile shrimp
Infectious hypodermal and haemotopoietic necrosis	
Taura syndrome	
Tetrahedral baculovirosis	
Spherical baculovirosis	

Import control of aquatic animals

Import controls of aquatic animals to protect aquaculture in Japan were introduced with the amendment to the Fisheries Resources Protection Law (Law No. 313, 1951) in June 1996. This import control system is based on the standard of the OIE (World organisation for animal health/Office International des Épizooties). Since June 2006, carp, goldfish, eyed eggs and fry of salmonids and juvenile shrimps are subjected to import controls. A person who intends to import any of these aquatic animals must apply for an import permit to the Minister of Agriculture, Forestry and Fisheries. In April 2005, the Fishery Resources Protection Law was amended so that the range of aquatic animals subjected to import controls was expanded, and aquatic animals imported from a country which is not free from the target diseases are subject to quarantine after importation. Table IV lists the aquatic animals that are subject to import controls and the diseases that these aquatic animals must be certified to be free from when applying for an import permit. The APSD depends on information from the OIE in determining whether or not the imported animal should be subjected to quarantine.

Assurance of proper use of medicinal products for aquatic animals

Medicinal products for aquatic animals are subjected to regulations under the Pharmaceutical Affairs Law. Medicinal products for aquatic animals are only allowed to be manufactured and marketed after approval by the Minister of Agriculture, Forestry and Fisheries. To ensure the production of safe aquatic animal products, aquaculture farmers are not allowed to use medicinal products that have not been approved (formalin, malachite green and other medicinal products that are not approved have been prohibited since the amendment of the Pharmaceutical Affairs Law in July 2003). Farmers must observe the usage regulations, including target animals, dosage, administration methods and withdrawal periods (set for antimicrobial medicinal products and some vermicides). Furthermore, aquaculture farmers are required to keep records of the medicinal products used.

Risk management of contaminants in fish

Harvested fish are subject to a monitoring programme conducted by the MAFF for methyl-mercury, dioxins and dioxin-like compounds and other contaminants to ensure that residue levels are low enough to satisfy the tolerable intakes. In the 2005 financial year, 297 samples from 143 species of fish were subjected to monitoring tests for dioxin and dioxin-like compounds (6). The average content of dioxin and coplanar polychlorinated biphenyl (Co-PCB) was 0.69pgTEQ/g. This results in a daily intake of dioxin and dioxin-like compounds by Japanese people from fish and other sources of 1.22pgTEQ/kg body weight/day. This amount is below the tolerated daily intake of 4pgTEQ/kg body weight/day, set by the Ministry of Health, Labour and Welfare. Table V provides the results of the monitoring programme conducted during the 2005 financial year.

Shellfish are also monitored periodically for shellfish poisoning (contamination by biotoxins produced by marine algae) that is conducted by prefecture governments with support from the Fisheries Research Center. When shellfish poisoning is found as part of the monitoring activities, prefecture governments, in consultation with the APSD, ask the fish markets to voluntarily test their products for contamination with biotoxins. If their products are contaminated with biotoxins that exceed the regulatory levels, they are subjected to a voluntary marketing suspension.

International contribution

The APSD contributes to the standard-setting activities of the OIE, by providing information on KHV disease. Through the mediating efforts of the APSD, the Aquaculture Research Institute of the Fisheries Research Center was designated as the OIE reference laboratory for KHV disease in May 2006. The APSD also actively participates in Food and Agriculture Organization and World Health Organization Codex activities by providing information and setting risk management measures, e.g. for methyl mercury and dioxins and dioxin-like compounds.

Table V
Results of monitoring fish for dioxins and dioxin-like compounds during the 2005 financial year[a]

Aquatic species	Number of samples	Number of species	Average quantity of dioxins[b] and Co-PCB
Fin-fish	202	92	0.92 pgTEQ/g
Shellfish	30	14	0.15 pgTEQ/g
Crustaceans	27	18	0.22 pgTEQ/g
Other fish	38	19	0.20 pgTEQ/g
Total (average)	297	143	0.69pgTEQ/g

(a) 1 April 2005-31 March 2006

(b) dioxins include polychlorinated dibenzo-p-dioxins (PCDD) and polychlorinated dibenzofurans (PCDF)

Co-PCB coplanar polychlorinated biphenyls

pgTEQ picogram TEQ (toxicity equivalency quantity)

Conclusion

Although the APSD was established less than two years ago, it has made an outstanding contribution to ensure the safety of animal products during the production stages through risk management measures taken in accordance with the relevant laws, and has thus contributed to reinstilling consumer confidence in the safety of animal products marketed in Japan. As consumer interest in food safety in animal products increases, the role that the APSD plays in animal production food safety will become more important. The APSD will continue to ensure that risk management measures are taken based on science and risk assessment, and work in close collaboration with other national agencies, prefecture governments, foreign governments and international organisations.

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