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Legislative and Institutional Framework for the Food Safety Control of Live Animals in China

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Report 6.03.08

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In 2002, both China and the EU suffered from a trade dispute over animal products. The aim of the report is to document this framework, in order to make a constructive contribution towards bridging the gap of understanding and accessibility of the countries' procedures in particular and of their trade relations in general. This report illustrates how the Chinese legal and institutional system differs from that in the EU. Laws, administrative documents and regulations are all part of the Chinese legal system and have an equally binding force. The Ministry of Agriculture (MoA) and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) are the two most important institutions monitoring food safety in China.

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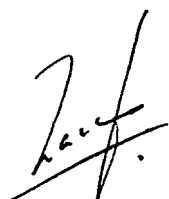
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Preface

'Legislative and Institutional Framework for the Food Safety Control of Live Animals in China' is the name of a joint research project carried out by the Agricultural Economics Research Institute (LEI) and the Institute of Food Safety (RIKILT) of Wageningen University and Research Centre. The project was financed by the International Cooperation Programme of the Dutch Ministry of Agriculture, Nature Management and Fisheries.

We should like to express our gratitude to the Rural Development Institute of the Chinese Academy of Social Sciences, and in particular to Prof. Liu Yuman and Dr Chen Jinsong, for their cooperation and support.

A handwritten signature in black ink, appearing to be 'L.C. Zachariasse', written in a cursive style.

Prof. Dr. L.C. Zachariasse
Director General LEI B.V.

Summary

China and the EU Member States have important trade relationships as regards agrofood products of animal origin. Such an international relations involves trade and food safety issues. These issues can sometimes be of a delicate nature and lead to disputes. This was the case in 2002 when the EU imposed a ban on Chinese animal products that were alleged to contain a high level of chloramphenicol. Soon afterwards a consignment of Chinese rabbit meat was confiscated and destroyed by the Dutch authorities, which provoked the Chinese authorities to impose a ban on Dutch pork casings. A trade dispute had been born.

This research project was launched in order to play a modest but constructive role in bridging the gap of understanding between the two countries. The objective was to document China's legislative and institutional framework for food safety control with regard to live animals. The project was executed by studying EU legislation and the mission report of Food and Veterinary Office (FVO) of the European Commission, preparing a questionnaire and interviewing competent authorities at both governmental and local levels in China.

The results of these efforts are provided in this report. The Chinese legal and institutional system differs from that of the EU in some important respects. As regards legislation, the main difference is that not only laws but also administrative documents and regulations are part of the Chinese legal system and have an equally binding force. On the institutional side, both the Ministry of Agriculture (MoA) and the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) have their own national network, but cooperate when and where necessary, even though this is not easy and sometimes complex.

While the dispute has been going on, the Chinese authorities have made great efforts to catch up on alleged failings as reported by the FVO mission. For example, a list of forbidden drugs has been issued and is available on the Internet, and a technical evaluation of veterinary drugs has been performed in line with the system used by the European Agency for the Evaluation of Medicinal Products (EMA). Furthermore, the management and licensing of veterinary drug manufacturers and dispensers have been tightened. Even though the dispute continues, bans are gradually being lifted on, for instance, aquacultural products.

Two important features were noted by the researchers during their field trip to China: the wide use of the Internet to disseminate information, and the 'name and shame' policy used for offenders.

We think it is very important for authorities in both the EU and China to open up so as to ensure healthy trade relations in the future. While the EU is puzzled about the Chinese legislation system, the Chinese government is wondering how to follow the cue of EU legislation - bearing in mind that China has to deal with two de-facto EU standards, namely, one at the Community level and one at the level of individual Member States.

1. Introduction

1.1 Problem statement

China and the EU countries have an important trade relationship as regards products of animal origin. For the Netherlands alone, the export of these products to China in 2001 amounted to € 23 million. China recently joined the WTO as a full member. This means that not only trade regulations but also Sanitary and Phytosanitary Agreements must be adhered to. It is a huge task to implement all these new regulations in such an enormous country.

In 2001, EU veterinary inspectors came across contaminated animal-derived foodstuffs from Southeast Asia, including China. It appears that meat and fish products (as well as honey) were contaminated with residues of prohibited veterinary drugs or other substances. Many of these products had entered the EU through one of its main ports of entry, Rotterdam. As time progressed, the inspectors became more suspicious and the situation resulted in January 2002 in an EU import ban on all Chinese animal products. This decision was based on the report of a mission by the Food and Veterinary Office (FVO) of the European Commission to assess the residue control of foodstuffs of animal origin in China. Soon afterwards, a large quantity of rabbit meat from China was intercepted in Rotterdam harbour and destroyed by the Dutch authorities. The meat contained a high level of the antibiotic chloramphenicol, which is forbidden in the EU. The seizure and destruction of this cargo was in accordance with EU legislation. However, the move angered the Chinese authorities. In April 2002, China slapped a ban on the import of salted pork intestine casings from the Netherlands. This product was also contaminated with a residue of chloramphenicol. A ban on animal products from both sides followed.

According to the FVO mission report, China lacks a legal basis for the residue control of and related control programmes for live animals and animal feed. In response, the Chinese authorities repeatedly clarified the differences between the Chinese legal system and EU legislative operations. Both sides blamed one another for not being familiar with each other's rules, regulations and procedures.

In an effort to start discussions with respect to international trade and food safety issues, a workshop on agrofood safety was held in Beijing in October 2002. It was jointly organised by the Department of International Cooperation of the Ministry of Agriculture of the People's Republic of China (PRC), the World Bank and The Netherlands Trust Fund for Food Safety Capacity Building. The objectives of this workshop were to discuss relevant agrofood safety issues with governments, public organisations and manufacturers. Experiences were exchanged in order to promote the development of an effective agrofood safety system in China, to enhance the capacity of the agrofood trade and to strengthen international coordination and cooperation between China and international agrofood safety organisations and other relevant institutions.

The main conclusions of the workshop were that actions need to be coordinated

under the flag of a common strategy. Rules and regulations must be clarified and harmonized, and governments should take the necessary actions at all costs. One conclusion stands out: if nothing is done, the costs to all concerned will be even higher.

As of December 2002, the present situation had improved and restrictions are gradually being lifted. The EC has proposed to allow the resumption of imports of all fishery products from China, with the exception of aquacultural products, eels and shrimps. However, restrictions remain in place on a range of other products, notably poultry meat, rabbit meat and honey. The situation regarding these remaining restrictions will be kept under review in the light of information and guarantees provided by the competent authorities in China and on the basis of the test results carried out by EU Member States. As of early 2004, the Chinese side had not lift their ban on animal products from the Netherlands.

1.2 Objectives

The objective of this research project was to document the legislative and institutional framework for the food safety control of live animals in China, in order to make a contribution towards bridging the gap of understanding and accessibility of the countries' procedures in particular and of trade relations in general.

1.3 Materials and methods

The project was started by studying FVO reports in order to gain an insight into the situation and an understanding of the background issues. EU legislation was studied on the prohibited use of veterinary drugs, on rules for monitoring and sampling plans, and on procedures for establishing a maximum residue limit for veterinary medicinal products. Interviews were held with Friesland Cobeco Dairy Foods, since the company's milk powder was on China's list of banned Dutch products. In addition, newspaper articles were consulted, as were World Bank project managers in China. The next step was to design a questionnaire pertaining to residue legislation and institutional framework at central government and local levels in China. This questionnaire was sent to Dr Chen Jinsong and Prof. Liu Yuman of the Chinese Academy of Social Sciences in order to carry out some preliminary work. These colleagues arranged appointments with the competent authorities involved in China.

The research was followed by a field mission to Beijing, where an intensive round of interviews was held with the Chinese authorities on both government and local levels (see Appendix 2) and with the Dutch Agricultural Counsellor. The programme also included a visit to a broiler slaughterhouse and a de-boning plant outside the city.

The results of the literature inventory and the interviews are presented in this report.

2. Legislative framework for food safety

2.1 Legislation in China in general

In the People's Republic of China, the People's Congress (PC) is responsible for formulating the laws and regulations. The PC system operates at national, provincial, city, county and township levels. Only PCs at national and provincial levels are relevant to this project. The National People's Congress (NPC) is at the top of the legislative framework in China and formulates laws. The Provincial People's Congress (PPC) formulates bylaws based on the laws formulated by the NPC. The highest level of Chinese law is the Constitutional Law, below which there are four other levels:

- Level 1: *Formal Laws*: These general laws include criminal laws, labelling laws, patent laws, etc. The NPC of the PRC passes these laws and their revisions. The laws which have a strong impact on society have to be passed by the National Congress Assembly, which is convened every March or April. Less influential laws can be discussed and passed by the Standing Committee of the NPC, which meets every two months.
- Level 2: *Regulations*: There are two categories of regulations: one at the state council level and one at the provincial level. These regulations have an operational status and are used to explain how to implement the laws. However, state council regulations are valid nationwide, whereas provincial regulations are valid only in the relevant province. It may be argued that a regulation is a kind of temporary law, as law-making is a very complicated and time-consuming affair.
- Level 3: *Administrative regulations*: These regulations usually deal with new, emerging issues to be converted into laws later on (e.g. GM food labelling management methods). The state council and all its ministries can issue management methods at the national level.
Administrative regulations, concerning local matters, can be issued at the provincial level. An administrative regulation (measure) is in a sense a temporary regulation, introduced if there is not yet a law or regulation pertaining to a particular issue.
- Level 4: *Administrative documents*: To facilitate their routine work, administrative institutes issue certain documents, often called 'announcements'. These announcements may be instructions for registration, inspection, monitoring, etc. Most administrative documents are formulated at provincial or lower levels.

Laws and regulations are broad concept laws at all four levels. They have a judicial status and judicial powers in the PRC, and can be enforced.

2.2 Law enforcement system

There are two channels for law enforcement in China: through the law courts and through the administrative law enforcement system. There are four levels of law court in China: Supreme Court, High Court, Middle Court and Basic Court (national, provincial, city and county levels, respectively). Normal cases appeal to a basic court whilst special cases – such as those concerning intellectual property rights – appeal to a Middle Court or a higher one. Substantial cases (> 50 million RMB) appeal to a High Court.

The administrative law enforcement has entrusted several administrative organisations to enforce relevant laws issued by the government. The vertical organisations include the State Administration for Industry and Commerce, the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ), and Customs. Horizontal organisations including Intellectual Property Right (IPR) Bureau the Copyright Bureau and Public Security Bureau.

Three types of cases can be distinguished: civil, administrative and criminal. Most civil cases appeal directly to courts or administrative organisations. Administrative cases first appeal to relevant administrative organisations. If prosecutors do not agree with the decision of the administrative organisations, they appeal to a law court. Criminal cases appeal directly to law courts.

2.3 Legislation related to food safety

In the People's Republic of China, the general laws regarding food safety cover a wide spectrum. The Water Pollution Prevention Law was issued by the NPC in the mid-1980s. This was followed by the Environmental Protection Law (1993), Products Quality Law (1993), Consumer Rights Protection Law and Air Pollution Prevention Law (2000). In the same period specific laws regarding food safety were formulated by the NPC. These laws included the Standardisation Law (1988), Animal Disease Prevention Law (1997), Fisheries Law (1986, revised 2000), Food Hygiene Law (1995), Inspection Laws on Entry-Exit Products (1989, revised 2002), Quarantine Inspection Law on Entry-Exit Animal and Plants (1991), Feed and Feed Additives Law (revised 2001), Medicine and Drugs Management Law (2001), and the Agricultural Products Quality and Safety Law (in preparation).

Several laws have been revised or are in the process of being updated in order to take into account recent developments, such as WTO assessments and issues related to food safety (contaminations). In addition, the Chinese government is giving high priority to sustainable agricultural production. Finally, the government is continuing regulate the agricultural input markets pesticides, seeds, feed, fertilizers and veterinary drugs. In order to help enforce these laws, the relevant ministries – such as the MoA – have adopted various administrative measures. Under the leadership of the MoA's Department of Policy and Regulation, all provinces and 800 counties have formed law enforcement teams with trained staff and mandatory means.

Several regulations regarding food safety have been formulated at a central level. These are the Implementation Regulation of Quarantine Inspection Law on Entry-Exit Plants and Animals. Other regulations at the state level are Management Regulations on

Hog Slaughtering, Breeders' Livestock and Poultry, Pesticides, Veterinary Drugs, Feed and Feed Additives and GMO Biosafety. Regulations recently (2002) formulated at a ministry level (MoA) are Management Measures on Pollution-free Agricultural Products, and a Catalogue of Veterinary Drugs and Other Chemicals Prohibited for Application to Animals for Human Consumption. In addition, the agricultural product standardisation concerning food safety at national and local levels is being revised.

These food standards are formulated by the central government (state standards), by ministries (professional standards) and by provincial governments (local standards). The first two standards apply nationwide, while local standards apply only within individual provinces.

Food Hygiene Standards are an example of standards at the state level. These standards, which mainly concern processed food products, were formulated by the Ministry of Health (MoH) and are implemented on a compulsory basis.

Standards at ministry levels are: Pollution-free Agricultural Products Standards (MoA), Green Food Standards (MoA) and Organic Food Standards (State Environmental Protection Administration; SEPA).

The Pollution-Free Agricultural Product Standards are compulsory and are a direct result of public health concerns. The standards are based on and formulated according to four aspects:

1. environmental quality standards, including the quality of air, water and soil;
2. production technology standards, including quality controls of production inputs;
3. product standards, including primary and processed product standards;
4. packaging, labelling, storage and transportation standards.

The Standards were first initiated in 2000 and came into effect in 2001.

Green Food Standards are voluntary standards and are supervised by the Green Food Development Centre (GFDC) under the MoA. Green Food Standards are divided into two grades (A & AA). The A-grade standard allows the limited use of agrochemicals on certain crop varieties and for limited periods of time. However, no residues may remain in/on these products. The AA-grade standard does not allow any agrochemicals to be used during any part of the production process. High environmental standards concerning air, water and soil must also be adhered to. These requirements mean that AA-grade products are in fact organic products. Green Food Standards were developed in the 1980s.

The Organic Food Development Centre (OFDC) formulates Organic Food Standards, which are voluntary standards. The OFDC certifies organic food by issuing Organic Certification Standards. The Standards are based on Organic Production and Processing Standards from the International Federation of Organic Agricultural Movement (IFOAM), EU regulations on organic agriculture (EEC no. 2092/91) and the standards of other countries, such as Germany, Sweden, the UK and the USA. The Standards are the fundamental requirements for organic production, processing and trading. They were first established in 1991.

In 2003, OFDC is planning to scrap the AA grade and use the Organic Standards instead, meaning that there will be three food-quality schemes in China: pollution-free food, green food and organic food. The first is to be a compulsory standard in China, while the other two are to be recommended.

2.4 Legislation related to residues of veterinary drugs in live animals and animal products

The first law in the People's Republic of China concerning animal residues was the Animal Disease Prevention Law, which deals with both feed management and veterinary drug management regulations.

Regarding legislation on the specific subject of residues of veterinarian drugs and certain other substances, the first version of the Management Regulation on Veterinary Drugs was passed in 1987 by the State Council. The Regulation was completely revised in 2001. New items in the regulation are:

- regulations on drug manufacturing and marketing
- new drug management regulation
- biological drug management regulation
- biological product methods
- import-export drug management.

In October 2002, the MoA issued the Management Measure on Veterinary Drug Labelling and Descriptions Decree, which lays down the information to be provided on labels, such as the name of the active substance, withdrawal time, shelf-life, batch code number, etc.

Veterinary drugs in China are divided into two grades. The first includes three categories for a national level only:

- Category 1: completely new drugs
- Category 2: domestically approved, but not included in pharmacopoeia
- Category 3: approved drugs which have been included in domestic and international pharmacopoeia.

The second grade is at a provincial level where category 4 and category 5 veterinary drugs are issued. Drug category 4 refers to syringes for injections and category 5 includes drugs the active ingredients of which have been approved, but which have a deviating formula. It should be stressed that all drugs approved at a provincial level must have their medical ingredients filed with the national Veterinary Pharmacopoeia or must be a new veterinary drug already approved by the MoA.

3. Institutional framework for the food safety control of live animals

3.1 General

The institutional framework includes the State Council/central government, provincial government, city government, county government and township government (Figure 1). The State Council is at the top of the institutional framework and is responsible for administrative regulations at a central level. Directly below the Council is the provincial government, which makes administrative regulations at a local level. Only these two institutions are important for our research purposes.

The State Council assigns specific responsibilities to different ministries. Each ministry is divided into several departments, and within each department there are various divisions. These divisions carry out the actual administrative work on specific issues. The MoA is divided into fifteen departments, of which the Bureau of Animal Husbandry and Veterinary is the most relevant. Three divisions of this department are involved in food safety related to live animals: the Veterinary Division, the Veterinary Drugs Management Division and the Feed Quality Control Division.

At a ministry (national) level, apart from ministries, ten institutions are actively involved in the control of the food safety of live animals and animal products. Two of the institutions relevant to this research are the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the China Institute of Veterinary Drug Control (IVDC).

At a provincial (local) level, the competent authorities (bureaux) are responsible for working out ministerial regulations. An example of such a bureau is the Beijing Agricultural Bureau. The Animal Husbandry & Health Office, which operates from such a bureau, deals with administrative documents, all of which have a legal binding force.

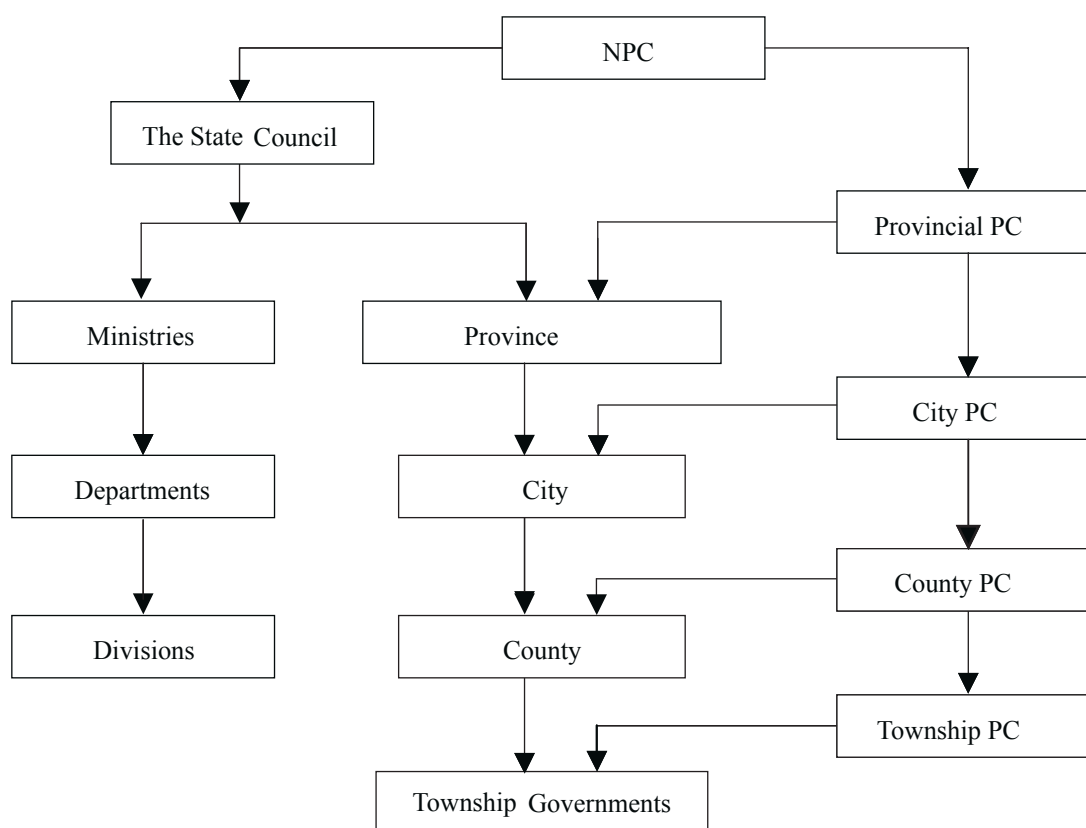


Figure 1: The administrative framework in China

3.2 Governmental institutions

MoA

The MoA is a governmental organisation, which represents the State Council for establishing a framework for food quality and food safety issues. Because of its direct involvement with food safety issues, the MoA as a governmental institution has an important role to play in the sphere of food safety controls.

The MoA is responsible for drafting and enforcing laws, regulations and policies associated with the food safety control of live animals and of products of animal origin. Two other departments within the MoA are relevant to this study, namely the Department of Agricultural Regulations and Policies (DARP) and the Department of Market and Economic Information (DMEI). DARP plays a leading role in law enforcement. For example, in 2001 DARP mobilized 1.5 million inspectors to inspect 40,000 agro-input markets, 620,000 retail stores and 40,000 agro-input production enterprises. It is interesting to note in this respect that the focus of these inspections was on prohibited, out-of-date or poor-quality products. When malpractice was observed or an offence committed, the government discussed the issue publicly in a newspaper or on TV or the Internet (the 'name and shame' approach). For instance, in Hainan Province, all illegal products and their

producers were listed on the Internet. In addition, the MoA publicized a nationwide telephone number, so that anyone could immediately report faulty products to the proper authority. This hotline is said to be very busy.

The MoA and its subsidiary agents are responsible for checking for residues of veterinary drugs in live animals and in food of animal origin. The MoA is also responsible for monitoring/testing residues of veterinary drugs in animal products in the country as well as drawing up and amending laws and regulations concerning these residues. The MoA is furthermore responsible for establishing technical standards (e.g. the Maximum Residue Level) and standards for testing methods, the residue surveillance plan, and its annual surveillance programme. The MoA also organises, harmonizes and supervises residue monitoring work. The National Residues' Monitoring Expert Committee was established by the MoA.

The General Administration for Quality Supervision, Inspection and Quarantine

The General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) is a ministry level bureau responsible for entry-exit animal and plant quarantine, certification, accreditation and standardisation. There are fifteen departments/bureaux within the AQSIQ. The most relevant departments/bureaux for this study are the Department for Supervision on Animal and Plant Quarantine, the Import and Export Safety Bureau, the Department of Supervision, the Department of Standardisation, and the State Committee of Superintendents and Administration of Certification Approval. AQSIQ has 35 operational desks scattered all over China; All local desks are under the direct control of Beijing headquarters.

One of AQSIQ's duties was to advise the MoA; now, however its task is to comply with WTO agreements. This means that AQSIQ is destined to become a flexible organisation with respect to WTO rules. The institution is also the main supplier of food safety documents to EU missions on an annual basis. The AQSIQ works closely together with the Ministry of public Health on all public health issues related to food safety and with the MoA on the national residue programme.

The AQSIQ plays an important role as regards residues in imported and exported foods of animal origin, as it is responsible for monitoring the residues. This entails establishing performance criteria for testing methods and standard methods for the determination of residues and toxic substances in import and export products of animal origin. Together with the MoA, it has established an annual, national residue monitoring programme for animals and related products. It also inspects and administers imported and exported animals and animal products.

The China Institute of Veterinary Drug Control

The China Institute of Veterinary Drug Control (IVDC) is an important professional institute directly affiliated to the Bureau of Animal Husbandry and Veterinary of the MoA. Its main responsibilities are derived from the Management Regulation of Veterinary Drugs, issued by the State Council. The IVDC received the accreditation certificate in 1999, awarded by the then National Quality and Technology Surveillance Bureau of China, and

later merged with AQSIQ. Since then, the IVDC, as a legal institute, has been able to publicize impartial test data on the quality of veterinary drugs. The IVDC has eighteen departments, including the Division of Veterinary Drug Inspection, the Department of Safety Assessment on Veterinary Drugs, and the Office of Veterinary Pharmacopoeia. In addition, other offices – such as the Office of the National Expert Committee of Veterinary Drug Residues in Food (CVDR) and the Office of the Working Committee of GMP of Veterinary Drugs of the MoA (VD GMP) – are located within the Institute. Some of the main IVDC tasks relevant to this study are:

- inspecting, supervising, testing and the final arbitration of veterinary drug quality;
- setting and revising the national and professional standards for veterinary drugs;
- drafting, reviewing, verifying and revising the standards for new and imported veterinary drugs;
- establishing and revising the way surveillance tests and tests of veterinary drug residues in animal-derived food are carried out;
- providing guidance to the provincial Institute of Veterinary Drug Control and to manufacturing enterprises;
- carrying out research on test methods, quality standards, standard/reference substances, safety and efficacy of veterinary drugs;
- disseminating information about veterinary drugs.

Sampling tests are a key tool for the supervision and inspection of veterinary drugs. A large number of samples from manufacturers, distributors and users all over the country are tested each year. Information about the quality of veterinary drugs is obtained and the circulation of fake and adulterated products is reduced. From 1996 to 2001, a total of 27,657 lots of veterinary drug samples were checked in IVDC. In addition, the surveillance test of veterinary drug residues has resulted in the adoption of analytical methods for veterinary drug residues in food derived from animals. In the period 1999-2002, 626 lots of samples were tested and 11 analytical method standards were adopted. The safety assessments of veterinary drugs resulted in an investigation of the toxicity of veterinary drugs on animals and the influence on human food, as well as in the establishment of the acceptable daily intake (ADI) and the maximum residue level (MRL). Since 1986, more than 10 types of veterinary drugs have been evaluated for a safety rating.

3.3 Beijing Municipality

The Beijing Animal Husbandry and Health Office (which is affiliated to the Beijing Bureau of Agriculture) is responsible for monitoring and inspecting the residue control of live animals in Beijing. Attached to this office are two operational institutions: the Animal Husbandry and Veterinary Station, and the Veterinary Drug Inspection Institute. The Station is responsible for issuing permits related to drug production and marketing (precondition); the Institute is in charge of drug monitoring and testing.

The Beijing Municipality announced its Meat Product Safety Programme in 2000, much earlier than the MoA. Based on the Animal Husbandry Food Action Plan announced by the MoA in 2002, Beijing city started its Safe Meat Action by promoting the whole

chain of management from breeding, production, processing, slaughtering, transportation and marketing. In July 2002, the Beijing Municipality issued Quarantine and Inspection Methods for the Entry of Animals and Animal Products from other province. Although such regulations are administrative documents, they must be adhered to.

Regarding the standards for pollution-free products, Beijing adopted a series of production procedures for individual animal species, such as chicken, duck and cow. They adopted the highest level between national and professional standards, although they admit that they do not completely follow the MoA standards (professional level). Taking aquacultural products as an example, the MoA standard changes almost every year, as does the list of banned drugs. At the production site, each farm has its own procedure guidelines, such as a drug-use registration form (name, reason for use, withdrawal time, etc.). All these actions require the signature of a veterinarian.

Two institutions are involved in the safety of animal products. The Veterinary Sanitary and Inspection Institute is in charge of taking samples, while the Veterinary Drug Monitoring Institute is responsible for testing and analysis. Every year the MoA allocates a sampling quota to Beijing city (880 lots in 2002). In addition, the office carries out intensive inspections twice a year, and each lasts a month. Their own sampling is based on past experiences (e.g. bad management, large production quantities). The inspection also covers the required certification for pollution-free production bases sampling.

The sample quantity is 250 grams for animal feed and for meat, 50 grams for urine and for fat, 60 grams for drinking water, etc. In 2002, 430 animal products were sampled, in addition to the MoA quota. In the same year, 300 veterinary drugs were sampled. Apart from the Agricultural Bureau, the Public Health Bureau also samples and inspects, but does so in the markets. All counties and district levels in Beijing perform samplings and inspections, except the municipal level. Their focus is mainly on small enterprises and family businesses. If a test result is positive, several actions are taken:

- The products/drugs are destroyed or burnt.
- If the test concerned live animals, enterprises must stop marketing their animals for 30 days. After proper rechecking, the office allows the enterprise to resume marketing its animals.
- If the enterprise is not qualified, it must be temporarily closed. All staff members must study the laws and regulations again.
- If a series of incidents occur, the enterprise is 'named and shamed' in the press.
- If exporting enterprises are involved, the AQSIQ will not grant export permission. The enterprises have to report their plans for improvement to the AQSIQ. After two checks by the AQSIQ, they can start exporting again.

All laws and regulations are available on the Internet. The media is used to publicize new laws, as well as administrative meetings. Information about regulations and banned drugs are hung on the walls of animal farms, and include the name of the responsible vet. One senior veterinary is responsible for 10 farmers. It is his/her duty to deliver the regulations in time to each worker on the farm. If an incident occurs, the relevant information has to be passed on to every administration level. These cases are normally dealt with by the local authority.

The MoA has special documents for GMP (Good Manufacture Practice). All drug

manufactures must comply with GMP. By June 2003, companies which do not have GMP-certificate will no longer be licensed to produce new veterinarian drugs. By 2005, only GMP-certified drug enterprises will be operating legally in China. Out of a total of 96 drug manufactories in Beijing, one enterprise has already obtained a GMP certificate whilst 6 others are in the appraisal process. So far, there are 40 GMP drug manufacturers in China. Every year, the Beijing Agricultural Bureau organises GMP training courses for drug enterprises. Food processing enterprises are promoting HACCP. Before 2000, they focused on ISO 9000, but have now switched to HACCP. So far, two poultry enterprises have been approved. The government will award them for obtaining the certification.

Beijing Huadu Broiler Corporation

This company, which was founded in 1982, is the first large-scale poultry enterprise in the PRC to operate an integrated production chain. The chain comprises a grandparent, parent broiler breeding, broiler raising, fodder production, broiler slaughtering and processing. The products are sold not only in domestic markets in 20 provinces but also internationally (Japan, Middle East, Southeast Asia).

The breeding system is equipped with a biological safety system, including a veterinarian monitoring system and a rigid epidemic prevention system. The chicken feed factory produces specialized AA-broiler feed from corn and beans; it does not contain any animal protein. An integrated production system is used for the broiler slaughtering and de-boning. A modern assembly line is run to slaughter, clean and de-bone over 8,000 broilers per hour. A three-step inspection takes place, involving modern scientific technology regarding the condition of isolated aseptic manipulating, with rigid hygiene and temperature controls, thus ensuring a pollution-free and deterioration-free processing course. All products pass a metal detection instrument before packaging.

Overall quality management systems have been established to realize quality objectives, such as veterinarian monitoring centres, hygiene examination centres and chicken feed material test centres. ISO 9002 quality management and HACCP food safety management are in operation and are certified for the production, processing and marketing of chicken products. In 2001, Huadu was awarded the Beijing Eaten Agricultural Products Safety Qualification (a food safety licence). Since 2001 the enterprise has been developing the ISO 9000-2000 management system.

The management focuses on food safety issues, because of government requirements, customers' wishes, competition angles and/or its own knowledge exploration to work safely and efficiently.

For more information, visit www.hdb.com.cn

4. Monitoring plan for certain substances and residues in live animals and products of animal origin

In 1999, the Chinese government drew up annual monitoring plans for certain residues in animals and animal-related products. The purpose was not only to ensure the product safety for domestic markets, but also to promote the export of Chinese animal products. Since then, the Chinese government has designed annual monitoring plans under this framework by taking into account the previous year's monitoring results and recommendations from exporting markets. To provide an overview of the monitoring plan, below we present a translated version of it.

4.1 Outline

Policy makers the People's RC recognizes that residues and certain substances in animal products and other foods may be hazardous to the consumer and affect the quality of animal products, and that the improper use of certain veterinary medicines can seriously affect human health.

Special regulations concerning hygiene, import and export commodity inspection, epidemic prevention, the use and control of veterinary medicines, and the registration administration of factories of food for export are promulgated in the PRC. However, more detailed and clear special stipulations on certain key points under the existing laws are necessary regarding the production of animals and animal products intended for export. The enforcement of monitoring by the governmental authorities is an essential measure in this control system.

The PRC has established maximum residue limits (MRLs) for pesticides, veterinary drugs and other hazardous chemicals in animal-derived foods. The Chinese government prohibits the use of hormonal substances such as diethylstilboesterol or steroid substances (anabolic or adrenoceptor agonists) from 1 January 1999.

The monitoring system covers the manufacture, distribution, sale and use of veterinary medicines and the field of animal raising and animal product manufacturing. This monitoring for unauthorized substances and their residues is carried out entirely and systematically by the supervision and inspection bodies of the competent authorities of the PRC. However, to further ensure the effective performance of this monitoring system so as to effectively control and inspect residues throughout the country, special stipulations must be established to harmonize the cooperation of competent authorities such as inspection and quarantine authorities, husbandry and veterinary authorities.

To ensure that uniform controls shall be effectively and swiftly performed, all monitoring rules and measures should be presented in one document. This is the reason behind this plan for a monitoring system. This plan mainly embraces:

- laws and special rules concerning residue monitoring, the prohibition and authorisation of substances under monitoring, detailed rules of distribution and sale

- of substances under monitoring;
- the organisation of competent authorities and authorities concerned in the monitoring system;
- laboratory testing network and its testing ability;
- self-control measures by the processing plants and official control measures;
- rules for official sampling;
- substances to be tested, method of analysis, number of samplings and the reason for them, sampling criteria, and frequency and number of samplings to be taken by officials;
- measures to be taken concerning contaminated animals or animal products.

The system of control in the PRC is such that the production of animals and animal products for the domestic market is clearly separated from that for the export market. Controls exist to ensure that only animals reared on farms and processed in establishments of export standard are allowed to be exported.

The following residues surveillance plan is based on the actual situation in the PRC and, with reference to EC Directives 96/22/EC and 96/23/EC, applies to the production of animals and animal products for export.

4.2 Scope and definition

These monitoring measures are promulgated in order to control every group of residues,

Definitions

- Foods of animal origin (animal-derived food): all kinds of products of animal origin for human consumption including egg, milk and honey.
- Poultry: farmed birds including chicken, duck, turkey, goose, pigeon, etc.
- Farmed animals: farmed animals such as cattle, swine, sheep, goat, farmed solipeds and camels, and finned fishes.
- Farmed and wild animals: rabbit, farmed and wild game, including pheasant and guinea fowl.
- Veterinary medicine: substances for therapeutic use, disease diagnosis and deliberate adjustment of physiological function, whose function, purpose, usage and dose are regulated.
- Therapeutic treatment: after diagnosis by veterinarians, hormonal substances can be used, according to the rules governing the usage and administration of veterinary drugs, on individual farmed animals for the purpose of treating reproduction problems, such as the termination of unwanted pregnancy. Beta agonists may be used for therapeutic purposes on horses not intended for human consumption, for cows at the time of calving and for diseases of the respiratory system.
- Animal treatment: after veterinary examination, the application of substances authorized for use by rules governing the use and administration of veterinary drugs to individual farmed animals for the synchronisation of oestrus, preparation of the insemination implantation donor and recipient; to farmed aquatic animals to change

- the sex of a group under the guidance and supervision of veterinarians.
- Illegal treatment: the use of unauthorized substances or products, or of authorized substances or products for forbidden purposes or under unauthorized conditions.
- Unauthorized substances or products: hormonal growth promoters and beta agonists used to promote growth. Substances or products which may not be used on animals according to rules governing the use and administration of veterinary drugs and the legislation of importing countries.
- Residue: residue of any substance having medicated action and its ester and metabolites, and the residue of any other substance which, when remaining in a product of animal origin, proves to be hazardous to human health.
- Competent authority: institutions authorized by the State Council of the PRC.
- Official sample: samples taken for the purpose of testing for illegal substances or residues by testing agencies appointed by competent authorities, and which are labelled with specification, number, sampling methods, sex of animals and the origin of animal or animal products
- Approved laboratory: laboratory approved by competent authorities for the purposes of testing for residues in official samples.
- Batch of animals: a group of animals of the same age and species, reared on the same farm during the same period and under the same conditions
- Beta agonist: a beta-adrenoceptor agonist.

4.3 Legislation

4.3.1 Relevant laws and regulations

- Product Quality Law of PRC
- Law on Food Hygiene of PRC
- Epidemic Prevention Law of PRC
- Law of PRC on the Import and Export Commodity Inspection
- Provisions on the Administration of Veterinary Drugs
- Provisions on the Administration of Animal Feed.

4.3.2 Relevant rules

- Rules on Authorizing Certain Veterinary Drugs to be Used as Feed Additives and their Uses.
- List of Additives Allowed to be Used in Animal Feed.
- Maximum Residue Limit in Food of Animal Origin.
- Administration Stipulation for the Sanitation Registration of Food Manufacturers for Export.
- Administration Provisions for Licensing Laboratories for Import and Export Commodity Inspection.
- Administrative Provisions for Spot Inspection of Import and Export Commodities.
- Sanitary Registration Standards for Export-Oriented Processing Plants of Livestock

- and Poultry Meat and their Products.
- Sanitary Registration Standards for Export-Oriented Processing Plants of Aquatic Products.
- Administrative Provisions on the Registration of Export-oriented Eel Farms.

The formulation and implementation of the PRC Residue Monitoring Plan follow the relevant domestic legislation, while taking into account the requirements of importing countries. The enforcement of the plan is guaranteed by administrative orders.

4.4 Institutions responsible for administration and organisation

The MoA and its subsidiary agents are responsible for the surveillance over residues in animals and in food of animal origin. The General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and its subsidiary organisation is responsible for the surveillance over residues in imported and exported foods of animal origin. The annual reports are published before 1 July of the ensuing year.

An expert coordination group between the MoA and AQSIQ has been established to formulate the national residue surveillance programme and annual plan, to exchange relevant information, and to prepare and draft the annual report on the results of residue monitoring.

The MoA has established the National Residues Monitoring Expert Committee, and invited experts from other competent authorities to serve on it.

4.4.1 National Residue Monitoring Expert Committee

The National Residue Monitoring Expert Committee is to formulate the National Residue Monitoring Plan. The Committee is to assess the efficiency and effect of the monitoring plan and to make necessary amendments according to: (1) the use of veterinary medicines and information about environmental protection, and (2) the statistics from local residue monitoring organisations and the information of selling and using of pesticides and veterinary medicines.

The Committee is also responsible to have dialogues with relevant international professional organisations, and to formulate and review the annual Residue Monitoring Plan.

4.4.2 Ministry of Agriculture

The MoA is responsible for the surveillance over the residues of veterinary medicines in animal products in the country, drawing up and amending the laws and regulations on the residues of veterinary medicines, promulgating technical standards (e.g. MRL and standards for testing methods, etc.), promulgating the residue surveillance plan and its annual surveillance programme, and the administration of organising, harmonizing and supervising the residue monitoring work.

4.4.3 General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ)

AQSIQ is responsible for controlling and measuring residues in imported animal products and those intended for export; establishing performance criteria for testing methods and standard methods for determination of residues and toxic substances in import and export products of animal origin; formulating a residue surveillance programme for import and export animals and products of animal origin as part of the national surveillance plan; and conducting the inspection and administration of imported and exported animals and animal products.

4.4.4 Local residue-monitoring organisations

Local agricultural and animal husbandry authorities:

1. The provincial, municipal and autonomous regional Bureau of Animal Husbandry is responsible for coordinating local residue monitoring and control.
2. The provincial institute for the supervision of veterinary pharmaceuticals and animal disease control departments is responsible for:
 - performing the task of residue detection in animals and animal products for domestic consumption;
 - inspecting and supervising the local animal drug and medicated feed manufacturing facilities;
 - conducting residue surveillance and inspection on local animal farms;
 - collecting samples from animal farms and slaughterhouses for the domestic market.

Local Control of the Inspection and Quarantine System (Local CIQs):

Local CIQs are approved by AQSIQ to carry out residue monitoring and control. These tasks comprise:

- taking official samples from slaughterhouses oriented towards export;
- implementing residue inspection on animal products for export;
- inspecting and supervising imported animal products;
- inspecting animal products for export and supervising export-oriented slaughterhouses;
- conducting comparative testing on residues in products of animal origin;
- investigating the usage of veterinary medicines in local slaughterhouses for export, and providing the data of residue monitoring and other relevant information to AQSIQ.

4.4.5 Analysing ability of laboratories

This embraces laboratories of the MoA system and AQSIQ, as well as academic laboratories accredited by MoA and AQSIQ.

Laboratories have drawn up systematic regulations according to ISO/IEC 25-1990 and have standardized administration. They will take part in regular tests at the international level and organise cooperative and comparison experiments between themselves.

Only after taking examinations and obtaining qualification certificates according to

the administration requirements of laboratories shall the inspectors make their inspections. All the approved laboratories are equipped with sufficient precision instruments and the necessary facilities for their inspection work.

4.5 Co-responsibility of enterprises

Any enterprise (natural or legal person) that operates animal product production facilities and/or an animal farm must follow the state's relevant administration regulations. All export-oriented enterprises must operate according to the requirements of the importing countries.

Producers of animal products must take all necessary measures to ensure that they accept for slaughter only those animals which have observed the withdrawal periods for any medicines administered to them. By means of inspection or examination they must ensure that residues in the animals or materials are below the prescribed limits. Animals and animal products must be free from unauthorized substances.

All export operators (natural or legal persons) must ensure that any animals or animal products which are exported:

- have observed the withdrawal periods for any medicines used;
- do not contain any residues of authorized substances above the MRL;
- do not contain any illegal or unauthorized substances;
- do not contain residues of any substances which may be harmful to human health.

Farming conditions and the use of any veterinary medicines must be supervised by veterinarians approved by the MoA. The veterinarians shall write down the date of using the medicine, the name of the medicine, the identification and status of the animal treated, and the date the medicine was withdrawn.

Processors of animal products must establish independent quality control sections and laboratories equipped with the relevant inspection instruments, equipment and testing reagents, establish relevant monitoring systems and take corrective measures in case of violation. The processors must maintain records on medicine usage, vaccination and technical supervision. Quality control records must be kept for each point.

Producers of animal-derived products for export should be supervised and checked by inspection and quarantine authorities. These producers have the responsibility to supply relevant information to competent authorities.

The CIQ inspectors should strengthen the control over the health markings and labels for the products processed by the plants in their charge.

Feed mills should apply to and obtain approval from competent authorities for their feed additives, medicated additives and the formulation of nutrition contents, and record in detail the origin of feed additives and added drugs.

The drugs used by livestock farms should be approved according to the relevant regulations. Livestock farmers must record drug usage, at least indicating the name of the drug, style of use, dosage and withdrawal time. The animals treated and their status must also be identified. Prescriptions issued by a veterinarian should be kept for five years. Farmers must ensure that their animals are not sold within the withdrawal times. The

slaughterhouse should carefully examine and check the drug usage card and quarantine certificate.

4.6 Official control measures

4.6.1 Scope and content

Local authorities shall make checks to implement the annual plan as regards the following aspects:

- the production, handling, storage, transport, distribution and sale of substances in Group A (anabolic and/or unauthorized substances);
- at any point in the production and distribution of feed;
- the production of animals and products of animal origin;
- the detection for the presence of unauthorized drugs before slaughter, detaining the suspected animals for confirmation and immediately submitting notification of any positive results.

The checks provided for in paragraph 4.6.1 must be conducted particularly in order to detect the use or presence of banned substances or products administered to animals for the purposes of fattening or illegal treatment.

Where fraud is suspected, and in the case of positive results from any of the checks referred to in paragraph 4.6.1, positive tissues and animals will be dealt with in accordance with the relevant regulations.

The checks must be carried out by competent authorities without prior notice. The owner, the person empowered to dispose of the animals, or their representative shall be obliged to facilitate pre-slaughter inspection operations, and in particular to assist the official veterinarian or the authorized staff with any action judged necessary. Authorities shall take appropriate measures where abuse is suspected:

1. Where illegal treatment is suspected, they must ask the owner or person in charge of the animals or the veterinarian in charge of the farm to provide documentation justifying the treatment.
2. Where this inquiry confirms the illegal use of prohibited substances/products, or where there are grounds for suspecting such use, the following measures should be taken:
 - spot check for residues of banned substances;
 - if necessary, spot check on animal feed and drinking water;
 - if necessary, spot check on the water of farms for aquacultural products;
 - check on the production, handling, storage, transport, distribution and sale of any drugs which may be authorized for domestic production but may not be administered to animals intended for export;
 - checks on the source of any prohibited substances and products.
3. Where the maximum residue levels laid down by domestic regulations or the importing country have been exceeded, carry out any measures or investigations that may

be deemed appropriate in relation to finding the reason for the presence of the residue in question.

4.6.2 Reference laboratories

The MoA has established reference laboratories in the Veterinary Drug Monitoring and Supervision Institute and in the University of Agriculture of PRC, and AQSIQ has established such laboratories in the China Import and Export Commodity Inspection Technology Institute. Each laboratory, and others to be established, will specialize in detecting the residues of a particular group or groups of substances.

Responsibilities of reference laboratories:

- To coordinate the work of the other national laboratories responsible for residue analysis, in particular by coordinating the standards and methods of analysis for each residue or residue group concerned.
- To assist the competent authorities in organising the plan for monitoring residues;
- To periodically organise comparative tests for each residue or residue group assigned to them.
- To ensure that national laboratories observe the established limits.
- To disseminate information about residue control supplied by other countries.
- To ensure that their staff is able to take part in further training courses organised by international organisation so as to maintain its continued professional development.

Local competent authorities shall establish approved routine laboratories for the implementation of the national residue control plan.

4.6.3 Review and classification of substances

- Chemical pesticides
- Veterinary drugs
- Environmental contaminants
- Residues monitoring priorities.

There are many residual substances in a group and, considering the actual situation in China (i.e. the production, sale and use of a substance), the competent authorities shall assess the degree of the danger posed by certain residues, and make a priority list of residual substances to be monitored. With regards to exporting products, they will respect the requirements laid down in the legislation of the importing countries.

Method of classifying compounds

The potential hazardous effect on human health of each compound to which animals are exposed shall be evaluated by the following criteria:

- the use of relevant compounds;
- exact dosage or approximate dosage;
- whether there is abuse and its potential to produce hazardous residues;

- the absorption, distribution, metabolism, and excretion in animal, plant and the environment, including the biological effects and consistence of the metabolized residues;
- the chemical characteristics and toxicity of residues.

For the purposes of domestic production, based upon the criteria mentioned above compounds can be classified into four categories, viz. A, B, C and D. The letters A, B, C and D represent the degradation sequence of the potential residue occurrence at the time of slaughtering (A, B and C represent the maximum/minimum potency of a compound, while D represents 'not listed yet'). As regards importing countries, they will respect the requirements of those countries' legislation.

4.6.4 Sampling strategy

The residue control plan is aimed at surveying and establishing the reasons for the presence of hazardous residues in foods of animal origin at farms, slaughterhouses, dairies, honey farms, fish farms, fish-processing plants and egg-collecting and egg-packing stations.

The official sampling strategy for domestic production in China will be worked out and enacted by reference to the general international sampling levels and frequency. Official samples for export testing are to be taken in accordance with the legislation of the importing country, for example, EC Directive 96/23/EC and EC Decision 98/179/EC.

4.6.5 Testing methods

Performance criteria for testing methods will be established. Any methods fulfilling the requirements of the criteria may be used in testing.

- Official method of AOAC
 - could be applied directly;
 - after retesting by three analyst (in two or three laboratories), it could be extended to apply to other analysis, tissues, species and products;
 - it could also be extended to apply to other relevant analysis with the same matrix as that in the earlier studies.
- The Methods for Detecting the Presence of Residues of the Ministry of Agriculture, PRC.
- The AQSIQ Methods for Detecting the Presence of Residues in Products of Animal Origin for Export.
- Where appropriate, the regulatory method and performance standards approved by the relevant importing country.
- The analytical methods published in the Federal Register and collected in the Federal Code of Regulations, USA, FDA-approved methods, and FSIS methods.

4.6.6 Standard substances

The internationally recognized reference materials will be accepted.

4.6.7 Official samples

Official samples must be taken in accordance with the rules on sampling strategy and sampling level and frequency in order to be examined in approved laboratories.

Whenever authorisation is granted to market a veterinary drug intended for administration to a species of animal, the meat or product of which is intended for human consumption, the MoA shall concurrently issue the routine analysis method for the detection of residues. If challenged on the basis of a contradictory analysis, those results must be confirmed by the reference laboratory designated for the substance or residue in question.

4.6.8 Measures to be taken in the event of infringement

If upon examination official samples have positive results, there has been illegal treatment. The competent authorities (such as the MoA and AQSIQ) shall take necessary measures to obtain:

- all the information required to identify the animal and farm of origin or departure;
- full details of the examination and its results. If the controls carried out in a province demonstrate the need for an investigation or other form of action in one or more provinces, or by another appropriate authority (system), the MoA and AQSIQ shall coordinate the appropriate measures taken in another province where an investigation or other action proves necessary.

The appropriate authority shall carry out:

- an investigation on the farm of origin or departure, as appropriate, to determine the reasons for the presence of residues;
- in the case of illegal treatment, an investigation of the source/sources of the substances/products concerned at the stage of manufacture, handling, storage, transport, administration, distribution or sale, as appropriate;
- any other further investigation which the authority considers necessary.

In respect of export establishments

- a. Where the investigation concerns an establishment authorized to export, the authority shall immediately sample other animals or animal products from the same establishment. They will identify animals from which samples have been taken and immediately notify the animal husbandry authority concerned. No animals should in any circumstances leave the farm until the results of the checks are available. If there is confirmation of a case of illegal treatment, the flock where animal or animals are found to be positive shall immediately be put under official control and the export production and processing permits of the enterprise shall immediately be suspended. AQSIQ will make all efforts to identify and recall any other animals or animal products which may be affected.
- b. Where it has been established that authorized drugs have been abused or withdrawal times have not been observed, the enterprise concerned shall be required to take appropriate and preventive measures to correct its practice. The farm shall be

subjected to more stringent checks for the residues in question. The export permit may be withdrawn if an enterprise repeatedly violates the regulations or laws.

In respect of domestic production

- c. If there is any evidence showing that the residues of substances or products exceed the maximum limit, the competent authority shall investigate the farm of origin to establish the cause of the failure, and take all necessary measures to safeguard public health, which may include prohibiting animals from leaving the farm and/or establishment concerned for a set period. Where illegal treatment is established, authorities shall ensure that the livestock under investigation is immediately placed under official control; all the animals concerned should bear an official mark or identification, as a first step, and an official sample must be taken from a statistically representative sample.
- d. In the event of repeated infringements of maximum residue limits, intensified checks on the animals and products from the farm and/or establishment in question must be carried out by the MoA and other government departments concerned for a period at least six months, and the products and animal carcasses must be impounded pending the result of analyses of the samples. Any result showing that the maximum residue limit has been exceeded must lead to the carcasses or products concerned being declared unfit for human consumption
- e. Where the investigation confirms that suspicion was justified, products are found positive or illegal treatment of the products, the cost of analysis shall be borne by the producer or person having charge of the animal.

Measures taken when an enterprise violates the regulations

Where unauthorized substances or products or substances listed in Group A or Group B (1) and (2) of Appendix I to this document are discovered in the possession of non-authorized persons, those unauthorized substances or products must be placed under official control until appropriate measures are taken by the competent authorities, without prejudice to the possible imposition of penalties on the offenders.

Where any prohibited drugs are found to be used in any animal farms, the animals on the farm in question may not leave the farm of origin or be handed over to any other person except under official control. The competent authorities shall take appropriate precautionary measures in accordance with the nature of the substance or substances identified.

If the authorities suspect or have evidence that the animals concerned have been subjected to an authorized treatment but that the withdrawal periods have not been complied with, they may postpone slaughter of the animals until they are satisfied that the quantity of residues does not exceed the permitted levels, specifically for beta agonists used for authorized therapeutic purposes not less than 28 days.

Any failure to cooperate with the competent authorities and any obstruction during inspection and sampling as required for the implementation of the national plan for monitoring residues and during the investigations and checks provided for in this regulation, shall result in the appropriate criminal and/or administrative penalty being imposed by the competent national authorities.

Proper government administrative penal measures shall be taken against persons who possess or supply substances or products which are not allowed by the regulations, or persons who administer the substance or products to animals.

Issued by:

European Affairs Department, Ministry of Foreign Trade and Economic Cooperation, PRC

Bureau of Animal Husbandry and Veterinary Affairs, Ministry of Agriculture, PRC

Department of Certification Supervision, the General Administration for Quality, Supervision, Inspection and Quarantine, 1999.

5. Action taken in 2002 regarding monitoring, legislation and institutional issues

5.1 2002 Monitoring Plan

The 2002 Residue Monitoring Plan for live animals and products of animal origin issued by the MoA and AQSIQ focused on:

- increasing the number of monitoring samples and species in regions where positive results were detected in 2001;
- adopting good recommendations from importing countries and regions, especially from the EU;
- prioritizing the testing of banned drugs and adding new MRLs for importing countries;
- promoting residue monitoring work in the western part of China.

Major changes in this plan included increased drug inspections for certain animal species. For cows, for example, eight drugs were added to the testing list. Substantial numbers of drugs were added to the list for horses, pigs, sheep, rabbits, poultry and aquacultural products. Testing for chloramphenicol residues was added for shrimps, bees, sausage casings and milk. Details are to be found in Appendix 1 (Monitoring for Certain Substances and Residues in Live Animals and Products of Animal Origin).

The 2002 sampling plan provided for the sampling of 27,621 lots. Most of the quotas were allocated to the major animal husbandry regions and exporting provinces/cities. The number of samplings to be carried out in western and central parts of China was also increased. Because of space constraints, the detailed sampling plan has been omitted. Those who are interested in this plan should contact the authors.

In 2002, 71 laboratories participated in the residue test; of these, 8 are reference labs and 63 are approved labs. The list of reference labs is given in the section below.

5.2 Banned drugs and other compounds for animal food (including therapeutic category or use)

Therapeutic category:	Name:
Bronchodilator	Clenbuterol, salbutamol,
Repartitioning agent	Cimaterol
Antineoplastic	Diethylstilbestrol
Animal growth promoter	Zeranol
Anabolic	Trenbolone
Progestagen	Mengestrol acetate
Antibacterial	Chloramphenicol
Antibacterial	Dapsone
Antimicrobial	furazolidone, furaltadone, nifurstyrenate sodium
Growth promoter	Sodium nitrophenolate, Nitrovin
Sedative, hypnotic	Methaqualone
Insecticide	Lindane
Insecticide	Camahechlor
Insecticide	Carbofuran
Insecticide	Chlordimeform
Acaricide	Amitraz
Parasiticide	Antimony potassium tartrate
Antiprotozoal	Tryparsamide
Dye with fungicidal activity	Malachite green
Insecticide, wood preservative	Pentachlorophenol sodium
Cathartic	Calomel
Fire guiliding	Mercurous nitrate
Antibacterial	Mercurous acetate
Oestrogen	Methyltestosterone
Androgen	Testosterone propionate
Anabolic	Nandrolone phenylpropionate
Oestrogen	Estradiol benzoate
Antiemetic	Chlorpromazine
Anxiolytic	Diazepam
Antiprotozoal	Metronidazole, dimetronidazole

The above list was issued by the MoA in April 2002

5.3 New/amended laws and regulations in 2002

Title	Effective from	Issued by
1. Registration Rules for Foreign Food Exporting Enterprises	14 March 2002	AQSIQ
2. Hygiene Registration Rules for Food Exporting Enterprises	19 April 2002	AQSIQ

3. Administrative Measures related to the Inspection and Quarantine of Entry-Exit Meat Products	22 August 2002	AQSIQ
4. Administrative Measures related to the Inspection and Quarantine of Entry-Exit Aquacultural products	6 November 2002	AQSIQ
5. Administrative Measures related to the Quarantine of Entry Plants and Animals	1 September 2002	AQSIQ
6. Administrative Measures related to Veterinary Drugs Labelling and Description	31 October 2002	MoA
7. Water Law of PRC	1 October 2002	State Council
8. Rural Land Tenure Laws of PRC	1 March 2003	State Council
9. Administrative Measures related to the Labelling of Live Animal Vaccines	1 July 2002	MoA
10. Administrative Measures related to Animal Quarantine	1 July 2002	MoA
11. Administrative Measures related to Pollution-Free Products	29 April 2002	MoA and AQSIQ
12. Quality Control Rules concerning Veterinary Drug Production (GMP)	19 March 2002	MoA
13. Administrative Measures related to the Labelling of GM Products	20 March 2002	MoA
14. Administrative Measures related to the Safety of Entry of GM Products	20 March 2002	MoA
15. Administrative Measures related to Agricultural Biosafety Assessment	20 March 2002	MoA
16. Agricultural Law (amended)	1 March 2003	NPC
17. Grassland Law (amended)	1 March 2003	NPC

It should be noted that in addition to formal laws, all the above-mentioned regulations and administrative measures have to be adhered to by law throughout the country. It is obvious that the majority of the 2002 regulations are related to the safety control of animal products. This is a direct result of the current Sino-EU trade dispute over animal products.

Besides enacting new laws and regulations, the Chinese government has been working hard to upgrade its legal and regulatory systems. In order to comply with WTO rules, China has amended over 2,300 laws and regulations and has abolished a further 830. The amended laws and regulations for the agricultural sector include:

- Fishery Law
- Administrative Measures on Feed and Feed Additives
- Animal Feed Law
- Product Quality Law
- Administrative Measures related to Veterinary Drugs
- Administrative Measures related to Biological Products.

6. Conclusions and recommendations

The Chinese legal system differs from that of the EU. The Chinese legal system consists of laws, administrative regulations, local laws and regulations at a ministerial level, and local regulations. Therefore, all administrative documents and regulations at a ministerial level are part of the Chinese legal system and all are equally binding (source: comments by the Ministry of Agriculture on the EU mission in 2001).

A General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and the Ministry of Agriculture (MoA) are the two major institutions involved in drafting and implementing food safety laws and regulations. The MoA is responsible for monitoring and testing food safety issues at a national level, whilst AQSIQ focuses on the safety control of entry-exit products. Both the MoA and AQSIQ have their own national networks, which makes their cooperation a necessary, though sometimes complex issue.

Since the incident in Europe in which Chinese products were found to have too high a residue of veterinary drugs and the subsequent ban on the import of Chinese animal products in March 2002, the PRC has taken great efforts to set things right. First, a list of forbidden drugs was issued and released on the Internet. Next, a technical evaluation of veterinary drugs was performed, similar to the system used by the European Agency for the Evaluation of Medicinal Products (EMEA). Drug manufacturing management was tightened such that now both the manufacturer and the product require a licence. In the future, veterinary drugs will be available only on prescription. Also a system focused on prohibited drugs has been established by the MoA: both factories and storage facilities will be inspected for the presence of these drugs. Any prohibited drugs found will be destroyed. These inspections can also be executed at the farm level.

With regard to the lack of MRLs mentioned in the EU report, the Chinese website stated that MRLs have been in existence in the PRC since 1994, were revised in 1997 and 1999, and are due for revision again in 2003. We were also able to download the 1999 version of MRLs from the Internet.

As a result of the wide range of measures taken by the Chinese authorities, the EC has lifted restrictions four times since they were imposed on 30 January 2002, viz. on 14 June, 11 July, 28 September and 19 November for a number of fishery products (crayfish and surimi), gelatines and sausage casings.

Despite the gradual reopening of the market, Chinese traders of poultry and rabbit meats, honey and certain fishery products are still subject to the initial ban. Equally important, the Chinese authorities still ban animal products from the Netherlands and cosmetics from the EU, and require extra quarantine measures for wood packaging (pallets). In an effort to ease tensions between the political powers on both sides, the EU and the Chinese authorities have been working towards implementing a mechanism to prevent trade disruption. On 30 October 2002, an agreement to establish an information and consultation procedure was signed during a ceremony in Brussels. The agreement is intended to avert future trade disputes and to clarify misinterpretations of legislation, and

covers technical regulations on industrial products as well as cooperation mechanisms.

Despite the hot issues concerning the trade business, we noted two important features during our field trip to China: the widespread use of the Internet and the 'name and shame' policy. Given that China is the second largest Internet user in the world, it makes sense that the Internet is the most efficient way to disseminate information. Our research benefited substantially from the websites of the MoA and AQSIQ, which furnished almost all laws, regulations, rules, announces, etc. The 'name and shame' policy seems to be common practice in China; these blacklists appear frequently on TV and the Internet as well as in newspapers.

We think it is very important for both the EU and China to open up to ensure healthy trade relations in the future. Whilst the EU is puzzled about the Chinese legislation system, the Chinese government is wondering how to follow the cue of EU legislation, bearing in mind that China has to deal with two de-facto standards of EU legislation, namely at a community level and an individual Member State level.

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Appendix 1 Monitoring for Certain Substances and Residues in Live Animals and Products of Animal Origin (2002)

附录 1 中华人民共和国 2002 年度动物及动物源食品监控的残留物质及动物种类表
(2002 年 1 月—12 月)

动物种类 Species		牛 Cattle	马 Horse	羊 Sheep	猪 Pig	禽 Poultry	兔 Rabbit	水产品 Aquatic products	蜂蜜 Honey	肠衣 Intestine s	虾 Shrimp
兽药 Veterinary drugs	A1、二苯乙烯类 Stibenes	△	△	△	△	△	△	△ □			
	己烯雌酚 DES										
	*A1、乙二烯雌酚 Dienoestrol	△	△	△	△	△	△	△			
	*A1、己烷雌酚 Hexoestrol	△	△	△	△	△	△	△			
A2、甲状腺拮抗剂 Thyrostats	甲巯咪唑 Tapazole		△			△	△				
A3、类固醇类 Steroids	1 9 - 去甲睾酮 19-Nortestosterone	△	△			△	△	△			
	氢化泼尼松 (强地松龙) prednisolone	△	△			△	△	△			
A4、二羟基甲酸内酯 Resorcylic acid lactones	玉米赤酶醇 Zeranol	△	△			△	△				
A5、β -受体激动剂 Beta agonists	克伦特罗 Clenbuterol	△	△		△ □	△	△				
	沙丁胺醇 Salbutamol	△	△		△	△	△				
A6 1、氟霉素 Chloramphenicol	氟霉素 Chloramphenicol	□	△	□	△	△ □	△	△ □	△ □	△	△
2、硝基咪唑类 Nitromidazoles	二甲硝基咪唑 Dimetridazole		△		□	△ □	△				
	甲硝达唑 Metronidazole		△		□	△ □	△				
	洛硝达唑 Ronidazole		△			△	△				
3、硝基呋喃类 Nitrofurans	呋喃唑酮 Furazolidone		△			△ □	△	□			

磺胺类									
2	磺胺-5-甲氧嘧啶	Sulfamethoxydiazine	△				△	△	△
3	磺胺二甲嘧啶	Sulfadimidine	△ □			□	△ □	△ □	△
4	磺胺喹恶啉	Sulfaquinoxaline	△ □			□	△ □	△ □	△
5	磺胺二甲氧嘧啶	Sulfadimoxinum	□			□	□		△
6	磺胺间甲氧嘧啶	Sulfamonomethoxine	□			□	□	□	△
7	磺胺甲氧嘧啶	Sulfamethoxypyridazine	□			□	□	□	△
8	磺胺甲恶唑	Sulfamethoxazole	□			□	□	□	△

动物种类 Species		牛 Cattle	马 Horse	羊 Sheep	猪 Pig	禽 Poultry	兔 Rabbit	水产品 Aquatic products	蜂蜜 Honey	肠衣 Intestines	虾 Shrimp
兽药 Veterinary drugs	1 六六六 (BHC)	△	△			△	△	△	△	△	△
	2 滴滴涕 (DDT)	△	△			△	△	△	△	△	△
	3 六氯苯(Hexachlorobenzene)	△	△			△	△	△	△	△	△
	4 多氯联苯 PCBs					△		△			△
B3b、有机磷 (OPPs)	皮蝇磷 Fenchlorphos	△	△						△		
	毒死蜱 Chlorpyrifos	△	△						△		
	敌百虫 Trichlorfon	△	△						△		
	蝇毒磷 Coumaphos	△	△						△		
B3c、化学元素 Chemical elements	马拉硫磷 Malathion	△	△						△		
	铅 Lead	△	△		△	△	△	△	△	△	△
	镉 Cadmium	△	△		△	△	△	△	△	△	△
	砷 Arsenic	△	△		△	△	△	△	△	△	△
B3d、真菌毒素 Mycotoxins	汞 Mercury	△	△		△	△	△	△	△	△	△
	黄曲霉毒素 B1、B2、G1、G2 [Afla = CORRECT?] Toxin B1、B2、G1、G2=		△			△		△	△		
	孔雀石绿 Malachite green							△			
	二硫化硫 Sulphur dioxide							△			
B3e、染料类 Dyes	甲醛 Formaldehyde							△			
添加剂											

Appendix 2: National Veterinary Reference Laboratories

National Avian Influenza Reference Laboratory
Harbin Veterinary Research Institute
China Academy of Agricultural Sciences (CAAS)
427 Maduan Street, Nangang District, Harbin 150001, Heilongjiang Province
Tel: [0451-2725786 ext.280
Contact: Dr Chen Hualan

National Diagnosis Centre of Exotic Animal Diseases
National Bovine Spongiform Encephalopathy Reference Laboratory
National Newcastle Disease Reference Laboratory
Animal Quarantine Institute of Ministry of Agriculture
369 Nanjing Road, Qingdao 266032, Shandong Province
Tel: 0532 - 5621 552 / 7839 779
Contact: Dr Wang Zhiliang

National Classical Swine Fever Reference Laboratory
China Institute of Veterinary Drug Control
8 Zhongguanchun South Street, Beijing 100081
Tel: [010-62158844 ext.3320
Contact: Dr Ning Yibao

National Foot and Mouth Disease Reference Laboratory
Lanzhou Veterinary Research Institute, CAAS
11 Yanchangpu xujiaping, Lanzhou 730046
Tel: 0931 - 8342 710
Contact: Dr Liu Xiangtao

National Rinderpest Reference Laboratory
China Institute of Veterinary Drug Control
8 Zhongguanchun South Street, Beijing 100081
Tel: [010-62158844 ext. 3223
Contact: Dr Wang Leyuan, Li Huijiao

National Contagious Bovine Pleuropneumonia Reference Laboratory
Harbin Veterinary Research Institute, CAAS
427 Maduan Street, Nangang District, Harbin150001, Heilongjiang Province
Tel: 0451 - 2725 786
Contact: Dr Xin Jiuqing

National Diagnosis Laboratory of Exotic Animal Diseases
Tropical and Subtropical Animal Virology Laboratory, Ministry of Agriculture
Jindian, Kunming 650224, Yunnan Province
Tel: [0871-5019110 or 5010721

Contact: Dr Zhang Fuqiang

National Bovine Spongiform Encephalopathy Test Laboratory
China Agricultural University

2 Yuanmingyuanxilu, Haidian District, Beijing 100094

Tel: 010 - 6289 2980

Contact: Dr Zhao Deming