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FAIRS Subject Report

Decree on Trade of Genetic Resources

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Report Highlights:

On August 20, 2008, the Government of China approved State Council Decree No. 533, which details the procedures for Chinese companies intending to import, export, or conduct joint research using "animal and poultry genetic resources." This rule will take effect on October 1, 2008.

Includes PSD Changes: No
Includes Trade Matrix: No
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Executive Summary:

On August 20, 2008, the Government of China, approved new State Council Decree No. 533, a piece of legislation detailing the procedures for Chinese companies intending to import, export, or jointly research "animal and poultry genetic resources" (as defined within the legislation). This decree details the roles of the Animal Husbandry and Veterinary Service Administration at both the provincial and State Council level. It also lists procedures that companies or institutions should go through and punishments for non-compliance.

This measure has not been submitted to the World Trade Organization. It will have some trade impact.

Begin Translation**State Council Decree
No. 533****The Measures for the Approval of Entry and Exit of Domestic Animal and Poultry Genetic Resources and the Cooperative Utilization with Foreign Entities**

The rules were passed in the State Council Executive meeting on August 20 and will take effect on October 1, 2008.

Premier Wen Jiabao
August 28, 2008

Article 1:

In order to strengthen the management of the entry and exit of animal and poultry genetic resources, increase cooperative utilization with foreign entities, protect and optimally utilize animal and poultry genetic resources, prevent the drain of genetic resources, and facilitate the sustainable development of animal husbandry, according to the Husbandry Law of People Republic of China (HLPRC), this legislation is established and promulgated.

Article 2:

When importing or exporting animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources in China (or referred to as being listed as "protected"), to or from foreign countries, all activities should comply with HLPRC and meet the regulations of this legislation.

Article 3:

The term "animal and poultry", in this legislation, means any animal or poultry listed in the publicized animal and poultry genetic resources specified in HLPRC Article 11.

The term "animal and poultry genetic resources" in this legislation means any animal or poultry and their derived ova (eggs), embryos, sperm (semen), and other genetic materials.

Article 4:

When introducing animal and poultry genetic resources from foreign countries, the conditions below should be complied with the following stipulations:

- 4.1 Purpose for introduction is clear, and the utilization is rational;
- 4.2 In concert with China's plan for the protection and utilization of animal and poultry genetic resources;
- 4.3 Be introduced from a non-epidemic area; and

4.4 Pose no risk to domestic animal and poultry genetic resources or the environment by complying with the regulations regarding the quarantine of animals and plants, entering or exiting the country, and of agricultural transgenic bio-safety.

Article 5:

Domestic entities planning to introduce animal and poultry genetic resources should apply to the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous region level or a city directly under central government and submit a contract signed by the exporter or a donation agreement signed by the donor.

When introducing animal and poultry genetic resources for breeding purposes, the documentation below is required:

- 5.1 License for breeding animals, poultry production, and trade;
- 5.2 Animal pedigree or poultry generation certification issued by the competent authority of the exporting country or region; and
- 5.3 When importing animal and poultry genetics that are introduced for the first time, submit the origin of the breeding animal and poultry genetic resources, distribution, breeding process, ecological attributes, production performance, the major genetic defects and special diseases in the genetic population.

Article 6:

When exporting animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources, the conditions below should be met:

- 6.1 Utilization purposes are clear;
- 6.2 In concert with China's plan for the protection and utilization of animal and poultry genetic resources;
- 6.3 Pose no risks to domestic animal and poultry production or product exports; and
- 6.4 Meet the rationality of the "national benefit sharing plan".

Article 7:

When exporting animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources of China, domestic entities should apply to the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous region level or city directly under the central government and the documentation below should be submitted:

- 7.1 A contract signed by the importers or a donation agreement signed by donation recipients; and
- 7.2 Definition of how activity will comply with the "national benefit sharing plan".

Article 8:

When utilizing animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources (thereby listed as "protected") in China, with cooperative foreign entities or individuals for joint research purpose, the following conditions should be met:

- 8.1 The research purpose, cooperation range, and period are clearly stated;
- 8.2 In concert with China's plan for the protection and utilization of animal and poultry genetic resources;
- 8.3 Clearly defined rights for cooperating parties regarding intellectual property;
- 8.4 Pose no risks to domestic animal and poultry genetics or the environment; and
- 8.5 Meet the rationality of the "national benefit sharing plan".

Domestic entities utilizing animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources in China, with cooperative foreign entities

or individuals for the purpose of joint research, should be legal entities classified as: Chinese educational institutions, research organizations or Chinese single-invested corporations.

Article 9:

Domestic entities planning to utilize animal and poultry genetic resources, which are listed as “protected” in China, with cooperative foreign entities or individuals for the purpose of joint research, should apply to the local Administration of Animal Husbandry and Veterinary Service of that province or autonomous region or city directly under the central government and the documentation below should be submitted:

9.1 The research project practicability report;

9.2 Joint research contract; and

9.3 Define how activities comply with the “national benefit sharing plan” and be signed by cooperative entities or individuals.

Article 10:

It is prohibited to export to foreign countries or utilize animal and poultry genetic resources that exist uniquely in China, which are newly indentified but not yet characterized by the National Animal and Poultry Genetic Resources Committee (NAPGRC), or those prohibited by the Animal Husbandry and Veterinary Service Administration of the State Council in China with cooperative foreign entities or individuals for the purpose of joint research.

Article 11:

Upon the receiving application documents for entry, exit, or joint research, the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous regions level or a city directly under central government should complete the evaluation process within 20 working days. The evaluation and documents should then be submitted to the Animal Husbandry and Veterinary Service Administration of the State Council for further review and approval.

Article 12:

Upon receiving the evaluation and documents submitted by the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous region level, or a city directly under the central government, the Animal Husbandry and Veterinary Service Administration of the State Council, should issue a permit for those complying with Article 4, 6, and 8 within 20 working days. If the application is declined the applicants should be notified in written form with explanations.

When exporting or cooperatively working with a foreign cooperator, with animal and poultry genetic resources listed as “protected” or importing animal and poultry genetics that are being introduced for the first time, the Animal Husbandry and Veterinary Service Administration of the State Council, upon receiving the evaluation and documents submitted by the local Administration of Animal Husbandry and Veterinary Service of at the provincial or autonomous region level, or city directly under the central government, should provide all the materials to National Animal and Poultry Genetic Resources Committee(NAPGRC) for evaluation and review within 3 working days. There is no time limit for the evaluation by the NAPGRC.

Article 13:

If a final decision is not reached within 20 working days, and after being approved by the section supervisor, the Animal Husbandry and Veterinary Service Administration of the State Council can extend the deadline another 10 working days, but it is required to notify the applicant of the reasons for the extension.

Article 14:

A permit for import or export is valid for 6 months, if an extension is required, the applicants should apply to the responsible agency within 10 working days before it expires, and the extension should not exceed 3 months.

Article 15:

When importing or exporting animal and poultry genetic resources, which are listed as "protected", the entities should go through the proper entry and exit quarantine procedures with the permit form. Customs will release the products after the Entry and Exit Quarantine Administration (CIQ) issues an "entry and exit goods custom clearance form". Within 10 working days, after the goods are released from customs, the entities should report the amount of animal and poultry genetic material imported or exported to the Animal Husbandry and Veterinary Service Administration of the State Council. For their documentation and for Environmental Protection Agency of the State Council, the Animal Husbandry and Veterinary Service Administration of the State Council should keep regular copies of the information.

Article 16:

During the joint research's cooperation period, if it is required to modify the research's purpose, scope, or cooperation period, or mend an IPR issue and/ or "research result mutual benefit agreement" and/or "national benefit sharing plan", the domestic entities should re-apply for approval according to the procedures described in this legislation.

Article 17:

The local Administration of Animal Husbandry and Veterinary service at the provincial or autonomous region level or city directly under the central government should follow up on imported animal and poultry genetic resources, organize experts to test and evaluate the production performance, monitor herd (flock) health, adaptability, and the relevant impacts on the environment and on local animal and poultry genetic resources. The Animal Husbandry and Veterinary Service Administration of the State Council should report the results of these findings.

If imported animal and poultry genetic resources pose a risk to the environment or local animal and poultry genetic resources, the Animal Husbandry and Veterinary Service Administration of the State Council should coordinate with relevant agencies to make the appropriate safety control measures.

Article 18:

Domestic entities who cooperate with foreign entities or individuals to utilize animal and poultry genetic resources, which are listed as "protected" in China, for the purpose of joint research, should report the status of the research to the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous region level or city directly under the central government, each year before December 31 for review and comments on the research. The local authority will then report to the Animal Husbandry and Veterinary Service Administration of the State Council for further documentation.

Article 19:

Those who have an interest-relationship with relevant entities (importers, exporters, domestic research entities, foreign research entities or individuals) should not be involved in or participate in the application evaluation, approval, testing, or evaluation of imported animal and poultry genetic resources.

Article 20:

China's domestic animal and poultry genetic resources information, including major animal and poultry genetic lines and specific geographical genetic resource data, documentation materials, or samples should not be exported or donated to foreign entities or individuals without the approval of the Animal Husbandry and Veterinary Service Administration of the State Council.

Article 21:

Government employees will be penalized for misconduct committed during approval or evaluation processes; once it is determined a crime has been committed and the offender will be punished by law.

Article 22:

Experts involved in the evaluation, review, and approval, according to this legislation, will be penalized for misconduct, for example: taking bribes, seeking personal interest, or providing false comments.

Article 23:

If entities hide information or provide false materials while importing, exporting, or utilizing animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources in China, from foreign countries, a warning will be issued by the local Administration of Animal Husbandry and Veterinary Service at the provincial or autonomous region level, or a city directly under the central government, and applications from this entity will be not be accepted for 3 consecutive years.

Article 24:

If entities use illegal means, such as bribery or falsifying documents, to obtain a permit while importing, exporting, or utilizing animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources in China, from foreign countries, the Animal Husbandry and Veterinary Service Administration of the State Council will revoke the permit, issue a fine ranging from RMB 10,000 to 50,000 *, and confiscate products and illegal income. Future applications from this entity will not be accepted for consecutive 10 years.

Article 25:

If, without approval, entities or individuals import or cooperatively utilize animal and poultry genetic resources listed as "protected" or newly identified but not yet characterized by NAPGRC in China with foreign cooperators the offenders will be punished by the Husbandry Law of PRC.

Article 26:

If, without approval, entities or individuals export animal and poultry genetic resources which are listed in the list as "protected", they will be punished by the Custom Law of PRC. Customs will transfer the detained products to the local Animal Husbandry and Veterinary Service Administration.

Article 27:

When exporting or utilizing animal and poultry genetic resources, which are found on the list of protected animal and poultry genetic resources in China, with the cooperative foreign entities or individuals for joint research purpose, should entities act against the regulations of national confidentiality, legal action will be taken based on the regulations in Confidentiality law of PRC.

* US\$1,461 to US\$7,305 (conversion rate = 6.84 on September 11, 2008)

Article 28 This rule will take effect on October 1, 2008.

End translation