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Voluntary Public

Date: 5/21/2012

GAIN Report Number: CH12035

China - Peoples Republic of

Post: Beijing

Requirements on the Application Materials for Import Feed and Feed Additives

Report Categories:

FAIRS Subject Report

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Report Highlights:

On May 2, 2012, China's Ministry of Agriculture (MOA) published a notice on soliciting comments on application materials for administrative approval for feed and feed additives. The notice is attached with requirements for application materials for seven different application situations. MOA said these requirements are based on the Administrative Measures for Feed and Feed Additives which was enforced on May 1, 2012. This report contains an UNOFFICIAL translation for one of the seven applications-Requirements on the Application Materials for Import Feed and Feed Additives (other six application materials are relevant to domestic feed and feed additive manufacturing and are in the process of translation). MOA requested all comments on these requirements be submitted before June 2, 2012.

Executive Summary:

On May 2, 2012, China's Ministry of Agriculture (MOA) published a notice on soliciting comments on application materials for administrative approval for feed and feed additives. The notice is attached with requirements for application materials for seven different application situations. MOA said these requirements are based on the Administrative Measures for Feed and Feed Additives which was enforced on May 1, 2012. This report contains an UNOFFICIAL translation for one of the seven applications-Requirements on the Application Materials for Import Feed and Feed Additives (other six application materials are relevant to domestic feed and feed additive manufacturing and are in the process of translation). MOA requested all comments on these requirements be submitted before June 2, 2012.

General Information:

BEGIN TRANSLATION

Ministry of Agriculture Notice on Soliciting Comments on Application Materials for Administrative Approval for Feed and Feed Additives

Published by: Department of Animal Husbandry, Ministry of Agriculture

Date: May 2, 2012

Key words: Feed , Feed Additives, Comments

The Administrative Measures for Feed and Feed Additives (the Measures) were amended and approved by State Council's No.177 conference, and enforced on May 1, 2012. Based on the Measures, the Ministry of Agriculture drafted requirements for seven application materials (for comments), and published hereby for comments from the public. All comments from all relevant organizations and industry shall submit comments before Jun2 2, 2012 to:

Contact: Feed Industry Division of National Animal Husbandry Center (China Feed Industry Association)

Tel: 010-5919-4582 or 59194591 (Fax)

Address: No.404 of Building 20, Maizidian Street, Chaoyang District, Beijing; 100125

Email: cfiaslc@163.com

May 2, 2012

Appendixes: 1-Requirements on the Application Materials of the Import Feed and Feedstuff Additives;

Appendix 1 :

Requirements on the Application Materials of the Import Feed and Feedstuff Additives (Draft for Comments)

I. Application Scope

The feed and feedstuff additives manufactured by foreign corporations which are sold and used for the first time inside People's Republic of China. The feed and feedstuff additives manufactured in Hong Kong Special Administrative Region (SAR), Macao SAR and Taiwan province shall be applied for registration in reference to the Requirements.

The feed referred to in "Regulations on Managing the Feed and Feedstuff Additives" means feed for animals that has been processed and manufactured through industrial procedures, including single feed, feed premixed with additives, concentrated feed, compound feed and fine fodder supplemented feed.

The feedstuff additives referred in "Regulations on Managing the Feed and Feedstuff Additives" means the small or tiny quantity of materials added during processing, manufacturing and using the feed, including the nourishing feedstuff additives and the general feedstuff additives.

The import feed and feedstuff additives shall follow the principles of safety and effectiveness and shall comply with relevant laws and regulations in the origin or in China as well as the requirements of relevant technical standards.

Any feed or feedstuff additive that has not been approved to be used or produced, or has been prohibited to be used or produced shall not be registered.

II. Requirements on the Format of the Application Materials

(1) The application materials shall include the "The Application Form for Registration of the Import Feed and Feedstuff additives" (See Table 1, hereinafter referred to as the "Application Form") and the application materials (for details, please refer to the "List of Application Materials for the Import Feed and Feed Stuff Additives", hereinafter referred to as "List of Application Materials"). If the product to be registered is feed or feedstuff additives not yet allowed to be used in People's Republic of China, or such product belongs to the special case as stipulated in the "Measures for Registration Management of the Import Feed and Feed Stuff Additives", the registration can only be made with approval of the National Feed Evaluation Committee.

(2) The application materials shall be in the bilingual text of Chinese, English and other foreign

languages, with other foreign language version after the English version, and after the Chinese version. If the producing country is not an English-speaking country, the registration materials in the language of the producing country shall also be attached and such registration materials shall be translated into both Chinese and English. The translated documents shall be notarized by the notary organ inside China. All the application materials shall be in duplicate, with one original and one copy.

(3) The original registration materials in foreign languages shall be issued on the paper with the letterhead of the manufacturing facility, signed by the director or stamped with the common seal. The translated materials shall be issued on the paper with the letterhead of the representative agency and stamped with the common seal.

(4) The registration materials in Chinese shall be printed on A4 paper (in Size 3 minus Song Ti), the contents shall be complete and no obliteration.

(5) The application materials shall not include any information irrelevant to the declared product.

(6) The first page of the application materials shall be the catalog and the application materials shall be bound in a book according to the order prescribed in the “List of Application Materials” marked by page numbers. The application materials include 13 items in total, among which obvious identification shall be marked; and each item of the application materials shall be indicated with name and the serial number in the catalog; Official certification or the notarized certificates shall not be split or bound freely.

(7) The application materials of the non-first-time declaration shall be provided with the copies of the Notice of Disapproval of Application or the Notice of Non-acceptance of Application; the additional materials may be otherwise bound in a book and the reasons for re-application shall be placed in the first page.

III. Filling out the “Application Form”

The “Application Form” shall be filled out in both Chinese and English. The principal of the representative agency shall sign and stamp with the common seal at the place for signature.

(1) Common Name: the true attributes of the feed and feedstuff additives shall be reflected, and the words that can indicate the major raw materials or describe the purposes of the products.

(2) Trade Name: the name in foreign language sold or used in the original country, and the Chinese name to be used when selling and using the product in China. The Chinese name shall be simple, easy to understand, and in line with the expression habit in Chinese. The trade name shall not be represented entirely by letters of foreign languages, symbols, Chinese spellings or numbers. The trade name shall

not misguide or deceive consumers.

(3) Product Classification: it shall comply with the product classification approved in the producing country, and the requirements in the “General Terminology of Feed Industry” of China (GB/T 10647).

(4) Appearance: the color, odor, shape (powder, particle, crystal, and massive) and state (solid state, liquid state) shall be described.

(5) Guarantee Period of the Product: several months or (years or days) shall be described.

(6) Carrier Name and Content: it must be filled out for the products containing any carrier. If no, it shall be filled out with “None”.

(7) Quality Standards of the Product: it shall include the content of effective ingredients, the limits of sanitation index of the product, which shall be in line with the quality standards of the product as set forth in the application materials.

(8) Scope of Applications: it shall indicate the feeding objects and feeding periods of the products.

(9) Methods for Usage and the Dosage: it shall indicate the methods for usage and the dosage of the products. In case of the feed premixed with additives, concentrated feed and fine fodder supplemented feed, it shall indicate relevantly matched recommended formulas and the cautions; if required by max limits, such maximum limit requirements shall be marked.

(10) Manufactory and Address: the name and address of the facility of manufacture of the product, which cannot be substituted by the name and address of the head office and the dealer. Physical address, rather than P.O. Box, number is required. As for fish meal, if it is processed on a processing ship, the name and number of the processing ship are required.

(11) Applicant Company and Address: shall be identical to the name and address of the manufacturing facility in general, while the name and address of the head office are also allowed. As for fish meal, if it is processed on a processing ship, the name and address of the head office shall be provided and the product shall be marked as “Made at Sea”.

(12) Agent: the name, post code, correspondence address, contact person, telephone and fax of the company or individual deputized to apply for the import application registration.

IV. Content of Application Materials

(1) Qualification Certificates of the Representative Agency

1. If the application for import registration is entrusted to its representative office resident in China by a foreign enterprise, the copy of the “Registration Certificate of Representative offices of Foreign

Enterprises Resident in China shall be provided and shall be stamped with the common seal of the enterprise.

2. If the application for import registration is entrusted to other representative agency by a foreign enterprise, the copies of the Business License of Enterprise Legal Person and the Organization Registration Code Certificate of the representative agency shall be provided and shall be stamped with the common seal of the enterprise.

(2) Letter of authorization

1. The letter of authorization that a foreign manufacturer has authorized a representative agency inside China to go through the import registration procedures for the product, which shall jointly signed by the foreign manufacturer and the representative agency inside China and shall be notarized by the notary organ of the producing country. A letter of authorization shall include the names and addresses of the entrusting unit and the entrusted unit and the name of the products to be registered.

2. The letter of authorization shall acknowledge that the representative agency shall be liable for the authenticity of the application materials and the accuracy of the translated materials that have been offered by the foreign manufacturer; the representative agency shall bear the corresponding legal responsibility according to the provisions in Article 28 in “Measures for Registration Management of the Import Feed and Feed Stuff Additives” issued by the Ministry of Agriculture.

3. In terms of the products of manufacturing consignment, an Agreement on Manufacturing Consignment jointly signed the manufacturer and the applicant enterprise shall be provided and shall be notarized by the notary organ of the producing country.

Certificate of approval to manufacture and sell the product in the producing country, and registration materials in other countries

The documentary evidence certifying that the registered product and its main components are permitted to be manufactured and used as feed and feedstuff additives in the producing country. As for the product generated from microorganisms and their fermented products, the documentary evidence for the Stockpiling and Management of the Bacteria Culture issued by the authoritative organization of the producing country, including the generic name, specific name and strain number of the fungus shall be provided.

The documentary evidence issued by the official authority of the producing country to permit manufacture of these products in pursuant to local laws and regulations.

The certificate of free sale issued by the official authority of the producing country, displaying the product name, as well as the name and address of the manufacturing facility, proving that there are no restrictions limiting the manufacture, sales and utilization in the producing country.

If the product has acquired the import license in other countries, relevant documentary evidence or the copy of the registration license shall be provided.

The official documentary evidence shall be confirmed by an Embassy or Consulate of the People's Republic of China in the producing country. In case that the official documentary evidence is issued in non-English language, the translations both in Chinese and English issued by the official translating organization of the producing country shall be offered and the original and the translation shall be jointly notarized.

) The physical and chemical properties of the product

The physical and chemical properties therein shall include the sensory properties (color, order and state of existence, etc.) and physical and chemical parameters (e.g., the boiling point, melting point, specific gravity, refractive index, the solubility in common menstruum, and the stability towards the light or heat, etc.)

(5) Origin and components of the product

Origin of the Product: The animal and vegetal origin of the product or all the primary materials used for the chemical composition shall be described. As for the micro-organic fungus, the generic name, specific name and strain number shall be provided. Furthermore, the name and origin of the fungus and the component of the culture medium shall be provided for the zymolytic product.

Components: the components or effective ingredients of the material. The material name shall be as detailed as possible, and the chemical constitutional formula shall be provided for those materials with chemical constitutions.

Transgenic Products: shall go through the formalities according to relevant regulations of the State.

(6) The manufacturing method

The manufacturing process flow chart and type matter of the product. The process chart shall display the critical steps in the manufacturing process. The type matter shall describe the technical conditions and methods in the process and the technical parameters of the key steps, and briefly illustrate the materials and equipment used in the production, as well as each step of the manufacturing process.

(7) The quality standard, method of inspection and quality inspection report

The quality standard: the quality standard of the product shall be consistent with the quality specification and method of inspections approved and recognized by the relevant administrative authorities of the producing country. The quality standard shall include the content of each kind of effective ingredient, as well as a description of each kind of harmful substance in the product.

Method of inspection: for those adopting international standards such as the International Standardization Organization / International Electrotechnical Committee (ISO/IEC), Association of Official Agricultural Chemists (AOAC), etc., the standard code shall be noted; for those adopting other methods of inspection, the detailed operational process for the inspection shall be provided.

Quality inspection report: the quality inspection report for samples of three different batch numbers shall be provided for each product, and two samples for each batch number are required; as for animal feedstuff and its product, the quality inspection report issued by a third party inspection authority officially recognized by the producing country shall be provided; in terms of the high risk products such as Dioxin, the quality inspection report issued by a third party inspection authority officially recognized by the producing country shall be provided.

) Pattern of the label used in origin, the pattern of label in Chinese and trademark

Pattern of the label used in origin: the original label shall be the sample or photo of the label of the product used in the producing country.

The pattern of label in Chinese: the Chinese label shall comply with the “Label for the Feed” standard (GB 10648).

Trademark: the product, with a registered trademark in China, shall be provided with the pattern of the trademark.

) Purpose of applicability, range of applicability and method of application

The range of animals suited to apply the product; the functional purposes; the quantity to be added in different animal feeds, as well as the items to be noted when using the product shall be described in detail. If required by max limits, such maximum limit requirements shall be provided.

Packing specifications, packing materials, conditions for storage, storage life and matters needing attention

Packing specifications: the packing materials and unit net weight of the product shall be described. If necessary, the actual cutting sample of the original packing bag of the product may be required.

Notes in storage: the place, conditions and methods of the storage shall be included.

Storage life: the production date and storage life of the product shall be clearly marked.

1) The situation of promotion and application

The situation of promotion and application of the product in the producing country and other countries shall be provided.

(12) Main references

Literature references on the development, research and manufacture of the product shall be provided.

(13) The following application materials shall be offered for the products of technical evaluation

The appraisal report of the chemical constitution of the effective ingredients or the classification and determination report of the animal, plant and microorganism

The effective ingredients shall be chemically defined: instruments and method of inspections employed in the experiment shall be described and determined, e.g., the spectrum charts of the infrared and ultraviolet spectrum, the mass spectrum or the nuclear magnetic resonance, and the characteristic reaction of the chemical functional group, etc., attached by the normative and real test report issued by a third party.

The effective ingredients shall be divided in to the animal, plant, microorganism and their products: classification and determination shall be made. The classification and determination shall be made to the genus and species level, and to the subspecies or individual plant level when necessary. The classification and determination of the animal and plant shall be carried out by relevant authorities, while the determination of the microorganism shall be carried out by the organization specified by the Ministry of Agriculture, with normative and real survey report provided.

2. Test report of feeding effect, residue degradation dynamics, toxicology and safety evaluation report

The test report of feeding effect, residue degradation dynamics, toxicology and safety evaluation report shall be issued by the inspection organizations recognized by the Ministry of Agriculture. When applying for the registration of the import feedstuff additives, the analytic and evaluation report on the possible impact on human health by the residues of such feedstuff additive in the product from the fed animals shall be offered. The test programs shall be examined by the Ministry of Agriculture. The expenses from the test shall be borne by the applicant.

If the safety evaluation test is necessary to be added outside of China, the test organization to conduct the evaluation shall be recognized by the Ministry of Agriculture. The test programs shall be examined

by the Ministry of Agriculture. The expenses from the test shall be borne by the applicant.

3. Stability test report, environmental impact statement and measures for pollution prevention.

If required by max limits, the inspection methods for the effective components in the feedstuff products shall be offered.

Requirement for sample for re-checking and quality inspection

Upon receiving the Notification of Acceptance, the applicant shall submit the sample of the applied product and the Notification of Acceptance to the inspection organization specified by Ministry of Agriculture for rechecking and inspecting of the quality of the product within 15 working days. Three samples of different batch numbers and two samples for each batch number shall be provided for each product for rechecking and quality inspection. Each batch number of the solid sample shall be no less than 5 times of the required inspecting amount. The packing materials of the sample shall be equal to those in the application materials, the package shall be complete. The inspection expenses shall be borne by the applicant. If necessary, the applicant shall provide the standard product or the chemical reference substance as required by the inspection organization.

Table 1

Application Form for registration of Import Feed or Feed Additives

Trade Name:	Common Name:
Product Classification:	Appearance:
Life Shelf:	Name and content of Carrier:
Application animals:	Usage and Dosage:
Ingredient Guaranteed	Hygiene Index and limit:
Certificate of Analysis	
Manufactory:	
Applicant Company:	
Agent:	Signature (Seal)

Table 2**List of Application Materials for the Import Feed and Feed Stuff Additives**

S.N.	Application Materials	Product requires no assessment	Product requires assessment
1	Application Form for registration of Import Feed or Feed Additives	√	√
2	Qualification certificate of agent	√	√
3	Letter of authorization	√	√
4	Certificate of approval to manufacture and sell the product in the producing country, and registration materials in other countries	√	√
5	The physical and chemical properties of the product	√	√
6	Origin and components of the product	√	√
7	The manufacturing method	√	√
8	The quality standard, method of inspection and quality inspection report	√	√
9	Pattern of the label used in origin, the pattern of label in Chinese and trademark	√	√
10	Purpose of applicability, range of applicability and method of application	√	√
11	Packing specifications, packing materials, conditions for storage, storage life and matters needing attention	√	√

12	The appraisal report of the chemical constitution of the effective ingredients or the classification and determination report of the animal, plant and microorganism		√
13	Test report of feeding effect, residue degradation dynamics, toxicology and safety evaluation report		√
14	Stability test report, environmental impact statement and measures for pollution prevention		√
15	Situation of promotion and application		√
16	Main references		√

Note : “√”denotes the required application materials.

Requirements for Re-Registration of Imported Feed and Feedstuff Additives

I. Scope of the Re-registration

When the imported feed and feedstuff additives are to be sold and used inside China after the expiration of the import registration license, the registrant shall apply for re-registration six months before the import registration license has expired.

II. Requirements on the Format of the Application Materials

The material needed is identical to the requirements on format of the application materials in Section 2 in the “Requirements on the Registration Materials of the Import Feed and Feedstuff Additives”.

III. Filling out the Requirements for Re-Registration of Imported Feed and Feedstuff Additives (hereinafter referred to as the “Application Form”) shall be in the bilingual text of Chinese and English

(1) The common name of the product

(2) The and trade name of the product

The Number of Former License and the Date Issued: shall be filled out in accordance to the import registration license.

Manufactory and address: the name and address of the manufacturing facility of the product, which cannot be substituted by the name and address of the head office and the dealer. As for fish meal, if it is processed on a processing ship, the name and number of the processing ship are required.

Applicant Company: shall be identical to the name and address of the manufacturing facility in general,

while the name and address of the head office are also allowed. As for the fish meal, if it is processed on a processing ship, the name and address of the head office shall be provided and the product shall be marked as “Made at Sea”.

Sales Agent inside China: name of the company, post code, correspondence address of the company, name of the business entity, contact person, telephone and fax.

Supplementary Material: tick “√” in front of the respective items changed.

Agent: the name, post code, correspondence address, contact person, telephone and fax of the company or individual deputized to apply for the import application registration.

Signature: shall be signed by the principal of the agent and stamped with the common seal of the agent.

IV. Content of Application Materials

(1) Import registration license: The original Import Registration License or its copy.

Qualification certificate of agent: The material needed is identical to the requirements on format of the application materials in Article 1, Section 4 in the “Requirements on the Registration Materials of the Import Feed and Feedstuff Additives”.

(3) Letter of authorization: The material needed is identical to the requirements on format of the application materials in Article 2, Section 4 in the “Requirements on the Registration Materials of the Import Feed and Feedstuff Additives”.

(4) The latest approval documents issued by the producing country:

Mainly include:

The documentary evidence certifying that the registered product and its main components are permitted to be manufactured and used as feed and feedstuff additives in the producing country. As for the product generated from microorganisms and their metabolites, the generic name, specific name and strain number of the fungus shall be provided.

The documentary evidence issued by the official authority of the producing country to permit manufacture of these products in pursuant to local laws and regulations.

The certificate of free sale issued by the official authority of the producing country, displaying the product name, as well as the name and address of the manufacturing facility, proving that there are no restrictions limiting the manufacture, sales and utilization in the producing country.

4. If the product has acquired the import license in other countries, relevant documentary evidence or the copy of the registration license shall be provided.

The official documentary evidence shall be confirmed by an Embassy or Consulate of the People's

Republic of China in the producing country

(5) The quality standard, method of inspection, quality inspection report

The quality standard: the quality standard of the product shall be consistent with the quality specification and method of inspections approved and recognized by the relevant administrative authorities of the producing country. The quality standard shall include the content of each kind of effective ingredient, as well as a description of each kind of harmful substance in the product.

Method of inspection: for those adopting international standards such as the International Standardization Organization / International Electro Technical Committee (ISO/IEC), Association of Official Agricultural Chemists (AOAC), etc., the standard code shall be noted; for those adopting other methods of inspection, the detailed operational process for the inspection shall be provided.

Quality inspection report: the quality inspection report for samples of three different batch numbers shall be provided for each product, and two samples for each batch number are required; as for animal feedstuff and its product, the quality inspection report issued by a third party inspection authority officially recognized by the producing country shall be provided; in terms of the high risk products such as Dioxin, the quality inspection report issued by a third party inspection authority officially recognized by the producing country shall be provided.

) Pattern of the label used in origin, the pattern of label in Chinese and trademark

Pattern of the label used in origin: the original label shall be the sample or photo of the label of the product used in the producing country.

The pattern of label in Chinese: the Chinese label shall comply with the “Label for the Feed” standard (GB 10648).

Trademark: the product, with a registered trademark in China, shall be provided with the pattern of the trademark.

) Product outline:

It shall include the information on the origin of the product, compositions, physical and chemical properties, range of applicability, usage and dosage, packing specifications, matters needing attention and storage life.

) Requirements on the materials with changed items

If the Chinese or English trade name of the product and the name of the applicant or manufacturing facility have been altered, relevant materials shall be provided in accordance to the “Requirements on the re-registration materials of the import feed and feedstuff additives”.

The product that has not gone through the Re-Registration within specified time limit and the change of the address of manufacturing facility, the product standard, the manufacturing technique or the range of applicability, the registration procedures shall be re-registered according to the “Requirement on the registration materials of the import feed and feedstuff additives”.

V. Requirement on Samples for Re-checking and Quality Inspection.

The requirements on samples are identical to requirements in Section 5 in the “Requirements on the Registration Material of the Import Feed and Feedstuff Additives”.

Application Form for Re-registration of Import Feed or Feed Additives

Products Name:	Common Name:
The Number of Former License and the Date Issued:	
Manufactory:	
Applicant Company:	
Sales agent inside China:	
Supplementary Material: <input type="checkbox"/> Trade name of the products in Chinese and English: <input type="checkbox"/> Name of Applicant Company: <input type="checkbox"/> Name of Manufactory:	

Agent:	Signature: <div style="text-align: center;">(Seal)</div> <div style="text-align: center;">Date :</div>
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Requirements for Altering Existing Registration Materials of Imported Feed and Feedstuff Additives

I. Registration Scope

If the any of the following contents has been changed during the effective period of the import registration license of the imported feed and feedstuff additives, alteration of the registration shall is required:

- (1) Trade name of the product in Chinese and foreign languages;
- (2) Name of the applicant company;
- (3) Name of the manufacturing facility.

II. Requirements on the format of the registration material.

It is identical to requirements on format of the application materials in Section 2 in the “Requirements on the Registration Materials of the Import Feed and Feedstuff Additives”.

III. Filling out the “Application form” in the bilingual text of Chinese and English

- (1) Trade name
- (2) Common name

The Number of the Former License and the Date Issued: shall be filled out in accordance to the former import registration license.

Altered Content: the trade name of the product in Chinese or English, the name of the applicant and manufacturing facility shall be included.

- (5) Former Name: the respective name in the original import registration license.
- (6) Present Name: name after the change.

(7) Manufactory: the detailed address of the manufacturing facility of the product.

Agent: the name, post code, correspondence address, contact person, telephone and fax of the company or individual deputized to apply for the import application registration.

Signature: shall be signed by the principal of the agent and stamped with the common seal of the agent.

IV. Content of Application Materials

The former import registration license:

The original of the former import registration license.

(2) Explanation for the alteration:

Reasons provided by the manufacturing facility for altering the relevant content.

(3) Documentary evidence of the producing country:

The documents issued by the official authorities of the producing country to permit the alteration of relevant content. The documentary evidence shall be confirmed in the Chinese consulate in the producing country. If the copy of the documentary evidence has been provided, it shall be notarized by the third party.

(4) Letter of authorization:

The material needed is identical to the requirements on format of the application materials in Article 1, Section 4 in the “Requirements on the Registration Materials of the Import Feed and Feedstuff Additives”.

Application Form for Alter Registration of Import Feed or Feed Additives

Products Name:	Common Name:

The Number of Former License and the Date Issued”	
Alter Content:	
Former Name:	
Present Name:	
Manufactory:	
Applicant or Agent:	Signature
	(Seal)



END TRANSLATION

