

FIRST
EDITION
2015

GLOBAL AGRICULTURE LAW

A GLOBAL GUIDE FROM PRACTICAL LAW

Long-term demand for a range of agricultural (food) products will be increasing dramatically over the coming decades. This demand is mainly being driven by developing countries in Asia.

International merger and acquisition activities in the agri-food and biotech industry have surged worldwide. New technologies and growing methods are changing the conventional agricultural business models. In spite of the need for cross-border operations and investment, it has remained difficult for investors to navigate through domestic agricultural policies, laws and regulations.

This publication is unique in its field. It takes a foreign investor's stand-point and makes cross comparisons between countries and different practice areas relating to foreign investment in agriculture business.

General Editor: Jan VM Holthuis
HIL INTERNATIONAL LAWYERS & ADVISERS

ISBN 978-0-414-03719-9



9 780414 037199

FIRST
EDITION
2015

General Editor: Jan VM Holthuis
HIL INTERNATIONAL LAWYERS
& ADVISERS

A GLOBAL GUIDE FROM PRACTICAL LAW

GLOBAL AGRICULTURE LAW

FIRST
EDITION
2015

GLOBAL AGRICULTURE LAW

A GLOBAL GUIDE FROM PRACTICAL LAW

Preface

Jan VM Holthuis
HIL INTERNATIONAL LAWYERS
& ADVISERS

Foreword

Dr William S Niebur
VP/GM North ASIA
DUPONT PIONEER

Argentina

Pablo Viñals Blake &
Ignacio Sánchez Echagüe
MARVAL, O'FARRELL & MAIRAL

Australia

Andrew Hay, Peter McMahon,
Nick Thomas, Cameron Gascoyne,
Gary Berson, Richard Hoad,
Dr Michael Maxwell, Scott Girdler,
Cain Sibley & Yehudah New
CLAYTON UTZ

Belgium

Philippe de Jong
ALTIUS

Brazil

Alexei Bonamin,
Andreia de Andrade Gomes,
Darcy Teixeira Junior,
Elysangela de Oliveira Rabelo,
Luiz Renato Okumura, Vera Kanas &
Vladimir Miranda Abreu
TOZZINFREIRE ADVOGADOS

Chile

Matias Araya & Sebastián Norris
ARAYA & CÍA ABOGADOS

China

Jan VM Holthuis, Yi Tao,
Gerard van Swieten, Liu Shu &
Dan Wei
HIL INTERNATIONAL LAWYERS &
ADVISERS

Germany

Dr Philipp M Gregor
DR GREGOR RECHTSANWALT

Ghana

Cephas Motey,
Mame Esaama Orleans-Lindsay &
Victoria Kiki Quansah
LITHUR BREW & CO

Hungary

Ágnes Balassa & Réka Versics
BIHARY, BALASSA & PARTNERS
ATTORNEYS AT LAW

India

Nusrat Hassan
DH LAW ASSOCIATES

Italy

Ferdinando Albisinni
STUDIO LEGALE ALBISINNI

Japan

Takashi Hirano, Taketo Nasu &
Daisuke Beppu
BLAKEMORE & MITSUKI

The Netherlands

Jan VM Holthuis,
Marc van der Velden &
Behnam Sobhani
HIL INTERNATIONAL LAWYERS &
ADVISERS

Nigeria

Dr Oludayo G Amokaye
DAYO AMOKAYE & CO

Taiwan

Yulan Kuo & Hui-ming Huang
FORMOSA TRANSNATIONAL
ATTORNEYS AT LAW

Thailand

Prateep Naboriboon,
Siradapat Ratanakorn &
Chaiwat Keratisuthisathorn
TILLEKE & GIBBINS

Turkey

Zeynep Özkan Özeren &
İpek Güngörer
ÖZKAN LAW OFFICE

Ukraine

Anna Zorya & Kateryna Zviagina
ARZINGER LAW OFFICE

United Kingdom

Sian Edmunds, Kevin Kennedy,
William Neville & Alice Scott-Gatty
BURGES SALMON LLP

United States

Gretchen E Cleveland
EXACT SCIENCES CORPORATION

Vietnam

Kien Trung Trinh, Dung Thi Kim Vu &
Linh Duy Mai
TILLEKE & GIBBINS

Zimbabwe

Tatenda Mawere & Regis Chawatama
MAWERE & SIBANDA LEGAL
PRACTITIONERS

Global Agriculture Law

First edition 2015

**General Editor:
Jan VM Holthuis
HIL International Lawyers & Advisers**



THOMSON REUTERS

General Editor:
Jan VM Holthuis
HIL International Lawyers & Advisers

Commissioning Editor
Emily Kyriacou
emily.kyriacou@thomsonreuters.com

Commercial Director
Katie Burrington
katie.burrington@thomsonreuters.com

Publishing Editor
Dawn McGovern
dawn.mcgovern@thomsonreuters.com

Editor
Stuart Fellows
stuart.fellows@thomsonreuters.com

Editorial Publishing Co-ordinator
Nicola Pender
nicola.pender@thomsonreuters.com

Published in May 2015 by Thomson Reuters (Professional) UK Limited
Friars House, 160 Blackfriars Road, London, SE1 8EZ
(Registered in England & Wales, Company No 1679046.
Registered Office and address for service:
2nd floor, Aldgate House, 33 Aldgate High Street, London EC3N 1DL)

A CIP catalogue record for this book is available from the British Library.

ISBN:9780414037199

Thomson Reuters and the Thomson Reuters logo are trade marks of Thomson Reuters.

Crown copyright material is reproduced with the permission of the Controller of HMSO and the Queen's Printer for Scotland.

While all reasonable care has been taken to ensure the accuracy of the publication, the publishers cannot accept responsibility for any errors or omissions.

This publication is protected by international copyright law.

All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, or stored in any retrieval system of any nature without prior written permission, except for permitted fair dealing under the Copyright, Designs and Patents Act 1988, or in accordance with the terms of a licence issued by the Copyright Licensing Agency in respect of photocopying and/or reprographic reproduction. Application for permission for other use of copyright material including permission to reproduce extracts in other published works shall be made to the publishers. Full acknowledgement of author, publisher and source must be given.

© 2015 Thomson Reuters (Professional) UK Limited

Contents

Preface	Jan VM Holthuis HIL International Lawyers & Advisers	vii
Foreword	Dr William S Niebur VP/GM North ASIA DuPont Pioneer	ix
Argentina	Marval, O'Farrell & Mairal Pablo Viñals Blake & Ignacio Sánchez Echagüe	1
Australia	Clayton Utz Andrew Hay, Peter McMahon, Nick Thomas, Cameron Gascoyne, Gary Berson, Richard Hoad, Dr Michael Maxwell, Scott Girdler, Cain Sibley & Yehudah New	31
Belgium	Altius Philippe de Jong	63
Brazil	TozziniFreire Advogados Alexei Bonamin, Andreia de Andrade Gomes, Darcy Teixeira Junior, Elysangela de Oliveira Rabelo, Luiz Renato Okumura, Vera Kanas & Vladimir Miranda Abreu	89
Chile	Araya & Cía Abogados Matias Araya & Sebastián Norris	115
China	HIL International Lawyers & Advisers Jan VM Holthuis, Yi Tao, Gerard van Swieten, Liu Shu & Dan Wei	135
Germany	Dr Gregor Rechtsanwalt Dr Philipp M Gregor	161
Ghana	Lithur Brew & Co Cephas Motey, Mame Esaama Orleans-Lindsay & Victoria Kiki Quansah	177
Hungary	Bihary, Balassa & Partners Attorneys at Law Ágnes Balassa & Réka Versics	193
India	DH Law Associates Nusrat Hassan	215
Italy	Studio Legale Albisinni Ferdinando Albisinni	243
Japan	Blakemore & Mitsuki Takashi Hirano Taketo Nasu & Daisuke Beppu	263
The Netherlands	HIL International Lawyers & Advisers Jan VM Holthuis & Marc van der Velden & Behnam Sobhani	289
Nigeria	Dayo Amokaye & Co Dr Oludayo G Amokaye	311
Taiwan	Formosa Transnational Attorneys at Law Yulan Kuo & Hui-ming Huang	341
Thailand	Tilleke & Gibbins Prateep Naboriboon, Siradapat Ratanakorn & Chaiwat Keratisuthisathorn	365
Turkey	Özkan Law Office Zeynep Özkan Özeren & İpek Güngörer	393
Ukraine	Arzinger Law Office Anna Zorya & Kateryna Zviagina	415
United Kingdom	Burges Salmon LLP Sian Edmunds, Kevin Kennedy, William Neville & Alice Scott-Gatty	433
United States	Exact Sciences Corporation Gretchen E Cleveland	459
Vietnam	Tilleke & Gibbins Kien Trung Trinh, Dung Thi Kim Vu & Linh Duy Mai	481
Zimbabwe	Mawere & Sibanda Legal Practitioners Tatenda Mawere & Regis Chawatama	507
Executive summary		527
Contact details		563

Preface

Jan VM Holthuis HIL International Lawyers & Advisers

Being an international lawyer living in Beijing, it continues to impress me how comprehensively agriculture influences economy, society and people's health. Economies like India and China have an urgent need for modern agricultural technologies to secure sustainable production and safe food products while, in contrast, developed countries are in need of new (export) markets.

Long term demand for a range of agricultural (food) products will continue to increase dramatically over the coming decades. This demand is predominantly driven by developing countries in Asia. International merger and acquisition activities in the agriculture, food and biotech industry have surged worldwide. New technologies and breeding methods are changing the conventional agricultural business models. Agriculture related trade issues have become complex and can involve the national security of a country. This makes agriculture a global and strategic business affair.

Agriculture law covers a comprehensive and dynamic legal playing field in which national or regional laws interact with international obligations and standards as stated in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the UPOV Convention, the Cartagena Protocol on Biosafety and the Codex Alimentarius.

Agricultural law has become a distinct discipline in the legal landscape and deserves to be treated as such, next to the more established conventional legal practice areas like banking, M&A, real estate, intellectual property, employment, litigation and tax, to name a few.

This publication addresses different legal practice areas such as agricultural land ownership, agriculture related foreign investment issues, seed law, plant variety protection (including breeder's exemption and farmer's privilege), animal and plant gene rights, GM food trade, food safety standards and food product liability. The publication is not exhaustive. It does not advocate any particular agricultural policy or legal regime.

The purpose of these jurisdictional comparisons is to enable foreign investors, food producers, legal professionals and policy makers to make cross-border comparisons between countries on different agriculture practice areas.

This first edition has been a tremendous challenge to create. It covers key jurisdictions across Asia, Europe, Africa, and North and South America. At the time this first edition of the Agricultural Law Global Guide goes to print new candidate firms have already expressed interest in providing additional country contributions to be incorporated in a future edition and the online version.

My thanks go to all contributing lawyers and their respective firms for sharing their expertise, their time and their patience to comply with the stringent question format in order to bring about this unique publication. Great thanks are also due to Katie Burrington, Dawn McGovern, Emily Kyriacou, Nicola Pender and Stuart Fellows of the Thomson Reuters team, for their encouragement to start this particular publication project and for their ongoing professional support.

Finally, comments on the subject matter of this publication or suggestions to add certain chapters to a future edition or the online version will be gratefully received.

Jan V.M. Holthuis
General Editor
jholthuis@hil-law.com
Beijing, March 2015

Foreword

Dr William S Niebur VP/GM North ASIA DuPont Pioneer

Like in so many other industries, globalisation is impacting and changing agriculture. International markets present enormous growth opportunities in the coming decade in this industry for companies such as DuPont. While we see great potential for increasing global agricultural productivity, with technological innovation, international collaboration, and agricultural modernisation in developing countries in particular, navigating the different legal systems and markets to maximise the potential is not always obvious. In a major agricultural market like China, our AG and Nutrition business commits to the improvement of local agricultural productivity, professionalism and modernisation of local agriculture and food security for the entire country. Our commitment, nevertheless, presupposes an understanding and ability to work within China's legal and regulatory landscape. Starting with compliance with applicable laws and regulations, we conduct business and serve customers. The same discipline applies everywhere globally where we operate business as the DuPont company.

The Agricultural Law Global Guide provides an overview of agriculture laws and policies in key jurisdictions worldwide, and compares these countries on different aspects of agricultural law and practice areas. As such, I consider it a valuable guide for investors and businesses who would like to understand and navigate the agricultural laws and policies of these countries.

After working and living in China for the past five years, I am confident that China's agricultural and rural reforms will progress and improve. Today, the Chinese government considers the "rule of law" foundational to developing the rural China agriculture sector. Rural social, legal and environmental issues will be further regulated in the upcoming years. Regulators in other parts of the world will have to create the same momentum for change to ensure alignment across systems. I believe that the readers of this guide will find the information and perspectives helpful in operating in China under the conditions called the "new normal", as well as in other parts of Asia and the world.

Dr. William S. Niebur
VP/GM North ASIA
DuPont Pioneer

Vietnam

Tilleke & Gibbins

Kien Trung Trinh, Dung Thi Kim Vu & Linh Duy Mai

AGRICULTURAL POLICY

1. State whether and when your jurisdiction has joined the following:

- **The World Trade Organization.**
- **The Food and Agriculture Organization of the United Nations.**
- **The International Plant Protection Convention.**
- **The Office International des Epizooties, also known as the World Animal Health Organization.**

World Trade Organization (WTO)

Vietnam is a member of the WTO as of 11 January 2007.

Food and Agriculture Organization of the United Nations (FAO)

Vietnam is a member of the FAO as of 1975.

International Plant Protection Convention (IPPC)

Vietnam is a member of the IPPC as of 22 February 2005.

Office International des Epizooties (IOE)/World Animal Health Organization

Not applicable.

2. Describe the most recent national agricultural policy of your jurisdiction, in particular with respect to biotech crops and new crop growing technologies.

The Vietnamese government has issued several policies to encourage and support investment in and development of agriculture, at both the household and industrial level, the latest of which include:

- Decree No. 210/2013/ND-CP of the Government on incentive policies for enterprises (including foreign enterprises) investing in agriculture and rural areas.
- Decision No. 899/QĐ-TTg of the Prime Minister approving the project “Agricultural restructuring toward raising added value and sustainable development” in which special incentives were given to biotechnology and high technology in agricultural production, forestry and fisheries.

ACQUISITION OF AGRICULTURAL COMPANIES

3. Is the acquisition of domestic agricultural companies by foreign investors subject to special prior government approval(s)? Set out the approval procedures and the authorities involved.

There are no regulations classifying companies as agricultural companies. However, companies could be classified as such based on the lines of business (codes of business lines) indicated in their Business Registration Certificates or Investment Certificates.

The acquisition of agricultural companies does not require any special prior approvals from the governmental authorities.

4. Describe if specific legal forms (such as co-operatives) are regulated or used in the agricultural sector and whether they are open to foreign investment.

Foreign direct investment

Foreign investors carry out direct investment in Vietnam mainly through the following, in accordance with the applicable regulation of the Law on Investment and Law on Enterprises (*Article 21, Law on Investment*):

- Establishment of wholly foreign owned companies or joint ventures with local investors.
- Contribution of capital to purchase shares from Vietnamese enterprises or carry out the merger and acquisition of enterprises, and so on.

Co-operatives

The Law on Co-operatives provides for co-operatives and unions of co-operatives. A co-operative is defined as a collective economic organisation with co-owners and legal status, established voluntarily by at least seven members who co-operate with and assist one another in production, business, or job creation activities to meet their common needs on the basis of autonomy, self-responsibility, equality and democracy in management of the co-operative (*Article 3.1, Law on Co-operatives*).

There are several forms of support and preferential policies extended to co-operatives and unions of co-operatives operating in agriculture, forestry, fisheries or salt production, including (*Article 6.3, Law on Co-operatives*):

- Investment in infrastructure development.
- Land allocation and land lease.
- Preferential credit.
- Capital and breeding stock to recover from natural disasters and epidemics.
- Product processing.

Co-operatives and unions of co-operatives have the right to enter into joint ventures, associate, and co-operate with domestic and foreign organisations and individuals to achieve their operation objectives as well as to contribute capital to, purchase shares from, and establish businesses aiming at supporting their activities. Foreign individuals of more than 18 years of age residing in Vietnam are allowed to become members of co-operatives (*Article 4, Decree 193/2013/ND-CP*).

5. To what extent does competition (anti-trust) law apply to agriculture?

Competition law applies to all sectors of the economy, including agriculture. The Law on Competition prohibits the merger, consolidation, acquisition or joint venture between enterprises if the combined market share of the enterprises participating in economic concentration accounts for more than 50% of the relevant market, except for cases where:

- One or more of the parties is or is at risk of being dissolved or of becoming bankrupt.
- The economic concentration has the effect of improving exports or contribution to socio-economic development and/or to technical and technological progress.
- The enterprises, after implementing the economic concentration, are still small- or medium-sized enterprises as stipulated by the law.

ACQUISITION OF AGRICULTURAL LAND

Sale and transfer of usage rights and ownership

6. Set out the domestic laws that apply to the acquisition of:

- Usage rights to agricultural land.
- Ownership of agricultural land.

In Vietnam, the ownership of land, including agricultural land, belongs to the state. Individuals and organisations only have the right to use land, including agricultural land. In theory, any individual or organisation who has the right to use the land may:

- Exchange, assign, lease, sublease, bequeath, and donate land use rights.
- Mortgage, guarantee, and contribute capital using land use rights.

However, due to lack of clarity in the legislation on the enforcement of land users' rights as well as the weakness of the enforcement mechanism, these rights may not be enforced in practice.

Vietnam adopted a new Land Law in 2013, which took effect on 1 July 2014, replacing the 2003 Land Law. Consequently, there will be a number of decrees and circulars issued by the government and relevant ministries and agencies to implement the new Land Law. In addition to the Land Law, the main legislation governing the acquisition of land use rights is:

- Decree No. 44/2014/ND-CP.
- Decree No. 105/2009/ND-CP.
- Joint Circular No. 20/2011/TTLT-BTP-BTNMT.

7. Are there any legal restrictions on the acquisition of agricultural land (or usage rights) by a foreign (or foreign invested) party?

Foreign-invested companies can take land use rights transferred under the form of contributed capital from local land users (*Article 174.2(dd), 2013 Land Law*). Although there is no provision under the law stating clearly that direct sale of land use rights from local land users to foreign invested companies is prohibited, the law only allows foreign invested companies to acquire the land use right directly from the state.

The state may consider permitting foreign-invested enterprises that wish to use land for agriculture, forestry, aquaculture or salt farming to rent land for the purpose of carrying out investment projects (*Article 133.1, 2013 Land Law*).

Foreign-invested enterprises that have land use rights on the basis of annual rental payments are not allowed to transfer the land use rights to other entities and individuals. However, the following foreign-invested enterprises are allowed to transfer land use rights to other entities and individuals:

- Enterprises renting land from the state on the basis of lump-sum payments for an entire lease period.
- Enterprises allocated land on the basis of a land use levy to implement projects.

8. Are there any compulsory tendering or prior approval procedures required for a sale and purchase of agricultural land? Briefly describe these procedures and the approval authorities (if any).

There is no sale and purchase of agricultural land. Only the right to use agricultural land can be transferred from the state to individuals and organisations or between individuals and organisations. The 2013 Land Law does not contain any requirements on compulsory tendering or prior approval procedures for transfer of rights to use agricultural land. However, the law sets out some conditions for the transfer. If the state allocates or leases land to individuals and organisations, the allocation or lease will rely on:

- Annual district-level land use plans which are approved by competent state agencies.
- Land use demands as indicated in investment project documents or in applications for land allocation and land lease.

If rights to use agricultural land are transferred between individuals and organisations themselves, the general conditions are that the:

- Transferor must possess the certificate of land use rights.
- Land must be dispute-free.
- Land use rights must not be attached to ensure the enforcement of a judgment.
- Land use term must still be valid.

Households and individuals using agricultural land can only exchange their agricultural land use rights with other households and individuals in the same commune, ward or township to facilitate agricultural production (*Article 190, 2013 Land Law*).

There are also restrictions on the transfer of the right to use agricultural land in certain cases, such as (*Article 191, 2013 Land Law*):

- Economic organisations cannot acquire the rights to use paddy land from households or individuals, except in the case of change in land use purpose in accordance with the approved master plans and plans on land use.

- Households and individuals not directly engaged in agricultural production cannot receive the transfer or donation of paddy land use rights.
- Households and individuals cannot receive the transfer or donation of agricultural land use rights with regard to land located in areas of protective forests, strictly protected zones and ecological rehabilitation zones in special-use forests if they do not live in those protective forests or special-use forests.

Economic organisations, households and individuals can lease or receive the transfer or contribution as capital of agricultural land use rights to carry out investment projects in non-agricultural production and business when they fully meet the following conditions (*Articles 193 and 134, 2013 Land Law*):

- There is written approval from the competent authority.
- The use purpose for the land area is consistent with the approved master plans and plans on land.
- For land used exclusively for wet rice cultivation, the land receiver must pay an amount to the authority to compensate for the lost plot of agricultural land or increase the effectiveness of the paddy land.

The exchange, transfer, lease, sublease, inheritance, donation or mortgage of land use rights or contribution of land use rights as capital must be registered with the land registration agency and will take effect from the time of registration in the cadastral book (*Article 188, 2013 Land Law*).

9. Does the law and/or regulations prescribe minimum land purchase prices if the (local) government sells agricultural land?

There are no specific minimum prices for the purchasing of agricultural land use rights. Prices are determined on a case-by-case basis, according to certain principles, such as (*Article 112, 2013 Land Law*):

- The valuation must be based on the lawful land-use purpose at the time of valuation.
- The valuation must be based on the land-use term.
- The valuation must be in line with the:
 - popular market price of the transferred land types with the same usage purpose;
 - winning auction price in case of auctions of land use rights; or
 - income from the use of land.
- At a given time, adjacent land parcels with the same usage purpose, profitability and income from the use of land must have the same price.

Decree 44/2014/ND-CP further sets out methods for valuation of land including the method of direct comparison, method of elimination, method of income, method of surplus and method of land price adjustment coefficient.

10. Is there a maximum term applicable to the lease (or use) of agricultural land?

The maximum term applicable to the lease (or use) of agricultural land in most cases is 50 years. For large investment projects with slow recovery of capital, or projects in areas with difficult socio-economic conditions which require a longer than 50-year term, the term of land lease must not exceed 70 years (*Article 126, 2013 Land Law*).

11. In which circumstances can the government authorities expropriate agricultural land?

Under the 2013 Land Law, the governmental authorities may withdraw and expropriate agricultural land. Withdrawal of agricultural land can happen:

- For the purpose of national defence or security, or socio-economic development for the national or public interest.
- Due to violations of the land law.
- Due to termination of land use in accordance with law, voluntary return of land, or the risk of threatening human life.

The governmental authorities may expropriate agricultural land in cases of extreme necessity to perform national defence and security missions, or war or emergency circumstances, or to prevent and combat natural disasters.

Tax and financing

12. Which taxes apply with respect to the sale and transfer of land ownership (or usage rights)?

Only taxes on income (that is, personal income tax or corporate income tax) from the transfer of land use rights are applicable to the transfer.

13. Does your jurisdiction have special regulated agri/green-parks and is (foreign) investment in such parks incentivised? If so, what incentives apply in general?

Vietnam does not have special regulated agri/green-parks.

14. Briefly describe the procedures to mortgage/pledge agricultural land rights in order to acquire domestic financing.

A mortgage of land use rights must be registered with the land registration agency and will take effect from the time of registration in the cadastral book. The competent authority for registration of mortgage of land use rights is the provincial Department of Natural Resources and Environment where the mortgage is related to domestic organisations and foreign individuals or organisations, while the district-level Division of Natural Resources and Environment is authorised to register the mortgage for domestic individuals.

There is no specific provision regarding the mortgage of rights to use agricultural land. However, generally, an application dossier to register a mortgage of rights to use agricultural land must include the following documents:

- Request for mortgage registration.

- Lawfully notarised or certified contract on:
 - mortgage of land use rights;
 - contract on mortgage of land use rights together with land-attached assets; or
 - contract on mortgage of land use rights together with land-attached assets to be formed in the future.
- Certificate of land use rights and ownership of land-attached assets.
- Certified copy of the authorisation document, where the mortgage registration requester is an authorised person, except when the registration requester produces the original authorisation document, in which case only a copy is required for comparison.

CROP SEED BUSINESS

15. Which domestic laws and regulations regulate the crop seed industry and which domestic authorities/agencies supervise this sector?

Domestic laws and regulations regulating the crop seed industry

The main domestic laws and regulations governing the crop seed industry are:

- Decree No. 07-CP of 1996.
- The Ordinance on Plant Varieties.
- Decree No. 88/2010/ND-CP.
- The Ordinance on Plant Protection and Quarantine.
- Decree No. 187/2013/ND-CP.

Domestic authorities/agencies supervising this sector

National level. The Ministry of Agriculture and Rural Development (MARD) is responsible for exercising state management over plant seeds nationwide, including (*Article 20, Decree 7/1996*):

- Collecting and conserving gene funds.
- Researching, selecting and crossbreeding seeds.
- Experimenting, putting on trial production and recognising new seeds.
- Producing, trading, importing, exporting, assessing, examining, quarantining and controlling the quality of plant seeds.

Provincial level. Provincial Departments of Agriculture and Rural Development (DARD) are responsible for implementing and guiding the management of plant seeds through the state management system of MARD at the provincial level.

Import control

General. The procedure for import of plant varieties (that is, seeds, tubers, fruits, roots, trunks, branches, leaves, saplings, grafts, buds, flowers, tissues, cells, spores, spawns, weeds, algae and microalgae) can be separated into three categories (*Article 41, Ordinance on Plant Varieties; Appendices II and III, Decree 187/2013; Article 4, Clauses 1-3; Circular 88/2011*):

- Plant varieties permitted for production and trading on lists announced by the MARD: importation can be made without any import permit.

- Plant varieties not yet listed/permitted for production and trading: an import permit is required for importation (*see Question 16, Import of new plant species or varieties and crop growing technologies*).
- Plant varieties subject to specialised management by the MARD: the mechanism of pre-customs clearance registration and post-customs clearance inspection applies. After customs procedures are cleared, goods that fail to meet quarantine and food quality and safety requirements must be re-exported.

Hundreds of plant varieties have been announced by the MARD as permitted for production and trading in Vietnam, and additional varieties are regularly announced.

Plant quarantine. Plant varieties subject to quarantine as announced by the MARD must be quarantined before customs clearance. In general, an imported consignment subject to plant quarantine must meet the following requirements (*Article 7, Decree 187/2013; Ordinance on Plant Quarantine*):

- Has been granted a phytosanitary certificate issued by the competent authority of the exporting country.
- Is free from regulated pests or, if infested, complete treatments are made.
- For plant varieties subjected to Pest Risk Analysis, a phytosanitary import permit must be obtained from the Plant Protection Department, a department of the MARD.
- Imported wood packaging materials must undergo appropriate phytosanitary treatments.

Export control

As with import control, the export of plant varieties listed by the MARD as being permitted for production and trading can be exported without an export permit (*see above, Import control*). For export of plant varieties not yet listed/permitted for production and trading, an export permit is required (*Article 13, Circular 88/2011*).

In addition, there is a list of certain plant varieties which are banned from export, including a number of rice varieties and some industrial tree varieties. However, for scientific research or other special purposes, an exporter can obtain permission from the MARD to export these plant varieties (*Article 40, Ordinance on Plant Varieties*).

In 2010, Vietnam commenced its full implementation of IPPC regulations (that is, Decision No. 34 and Decision No. 48) and strictly follows WTO procedures. According to Vietnam's full implementation of IPPC regulations, all commodities must provide information on having undergone Pest Risk Analysis under current phytosanitary regulations before importation. The Plant Protection Department confirms that this information must be formally provided by National Plant Protection Organisations of the exporting countries (and therefore it is not the individual importer which must provide the information), accompanied by a formal request for technical market access submission.

In relation to import of plant varieties subjected to specialised management by the MARD (that is, quarantine, inspection of food safety,

inspection of quality or border-gate regulations), this import must be quarantined and/or meet food quality and safety requirements. Plant quarantine and food quality and safety control testing and inspection are based on or formulated on one or more of the following grounds (*Article 13, Law on Standards and Technical Regulations; Article 4.3, Ordinance on Plant Protection and Quarantine*):

- International, regional and foreign standards.
- Scientific and technological research results, and technical advances.
- Practical experience.
- Results of evaluation, assay, testing, checking and inspection.

16. State the approvals/licences that are required to engage in the following activities:

- **Import of new plant species or varieties and import of crop growing technologies.**
- **Set up of R&D centres and use of test plots of new crops.**
- **Crop seed production.**
- **Commercial crop production.**
- **Distribution of seeds or crops (wholesale/retail/e-commerce).**

Import of new plant species or varieties and crop growing technologies

New plant varieties. An import permit is required for import of plant varieties not on the lists of plant varieties permitted for production and trading in Vietnam (*see Question 15, Import control*). These plant varieties can be imported either for (*Article 14, Circular 88/2011*):

- Testing and trial production.
- Import for international co-operation, specimens for display at exhibitions or as gifts, or implementation of investment programmes and projects.

However, for import of new plant species or varieties that have already been included in the lists of plant varieties permitted for production and trading in Vietnam, no import permit is required (*see below, Set up of R&D centres and use of test plots of new crops*).

To apply for an import permit, an importer must obtain, among other things, the following documents (*Article 15, Circular 88/2011*):

- For import for trial production: decision on recognition of plant varieties for trial production issued by the Ministry of Agriculture and Rural Development (MARD).
- For first-time import of the entire quantity for testing and trial production: approval from the Department of Agriculture and Rural Development (DARD) of the province where the testing and trial production is to be conducted.
- For import for testing and trial production for the second time onward: report on results of import, testing and trial production of the previous imports without a technical declaration.
- For import of plant varieties for implementation of investment programmes and projects: written approval of investment programme or project acceptance by the provincial People's Committee.

Crop-growing technologies. There is no specific approval/import licence required for import of crop growing technologies into Vietnam, except import of the following (*Appendices II, Section III B, Items 3 and 8, Decree 187/2013*):

- Pesticides and materials for production of pesticides outside the list of those permitted for use in Vietnam or on the list of those subject to restricted use.
- Fertilisers outside the list permitted for production, trading and use in Vietnam.

Set up of R&D centres and use of test plots of new crops

The research, selection and creation of new plant varieties in the Vietnamese territory is permitted, and must comply with the provisions of the Ordinance on Plant Varieties, legislation on science and technology, and other relevant legal provisions (*Article 14, Ordinance on Plant Varieties*).

New plant varieties which are selected or created must have been assayed and recognised by the MARD before they can be added to the list of plant varieties permitted for production and trading (*Article 15, Ordinance on Plant Varieties*).

Assay of new plant varieties. Assay of new plant varieties covers the following areas:

- Assay of distinctiveness, uniformity and stability.
- Assay of the value of cultivation and use.

Creators of new plant varieties can choose to either have the new plant varieties assayed by assaying establishments accredited by the MARD or conduct assays by themselves in accordance with the MARD's regulations.

Recognition of new plant varieties. New plant varieties are recognised if they meet the following requirements:

- Have results of the assay from the assaying establishment (*see above*).
- Have trial production results, and have been approved for mass production by the DARD where the trial was conducted.
- Have appropriate names.
- Have assay results and trial production results already evaluated and proposed for recognition by the specialised scientific council set up by the MARD.

The MARD will consider and decide whether to recognise new plant varieties on the basis of the proposals of the specialised scientific council. New plant varieties may be proposed for exceptional recognition without having to go through trial production if their assay results show that they are particularly outstanding. New plant varieties, after being recognised, will be put on the list of plant varieties permitted for production and trading.

The recognition of maternal plants, initial plants, and seed orchards is effected through evaluation and selection organised by the provincial DARD (*Articles 18 and 19, Ordinance on Plant Varieties*).

Crop seed production

A licence is in theory required for production of plant seeds, and production activities must be in accordance with the licences granted and are subject

to inspection by the quality control agency of the MARD (*Article 14, Decree 7/1996 on Management of Plant Seeds*). However, the MARD has never issued any guidelines detailing the requirements and procedures for obtaining a licence. Therefore, in practice, crop seed production can be carried out without any specific licence. Nevertheless, only plant varieties listed and permitted for production are allowed to be produced. For the procedure for recognising new varieties, see above, *Set up of R&D centres and usage of test plots of new crops*.

Seed producers must bear responsibility for the quality of seeds through publicising the quality standards and that the quality of the seeds complies with the standards (*Article 42, Ordinance on Plant Varieties*). All acts of producing fake seeds, seeds of poor quality, mixed seeds, seeds with pest or disease germs, or seeds which have not been certified, are strictly forbidden (*Article 13, Decree 7/1996*).

Commercial crop production

It is prohibited to produce plant varieties which are not on the list permitted for production. Production of plant varieties which cause harm to production, human health, the environment or the ecosystem is strictly prohibited (*Article 9, Ordinance on Plant Varieties*).

To produce major plant varieties (varieties of plant species commonly planted in large quantities and of a high economic value, which must be strictly managed) for commercial purposes, producers must fully satisfy certain conditions, such as:

- Having a business registration or investment certificate for plant variety business.
- Location, being equipped with facilities, manpower, and so on, suitable for production of plant varieties.

To produce other plant varieties, plant producers must comply with the following regulations:

- Producing perennial industrial plants, fruit trees, or forest trees by the vegetative propagation method must propagate varieties from:
 - initial plants (that is, plants of a yield, quality, and resistance markedly higher than those of other plants of a variety grouping, which have been evaluated, selected and recognised for vegetative propagation); or
 - gardens of initial plants (that is, gardens vegetatively propagated from initial plants in service of variety production).
- Sowing and nursing forest trees must use seeds that have been evaluated, selected and recognised from:
 - maternal plants (that is, the best forest plants selected from natural forests, planted forests, variety forests or variety gardens for propagation);
 - variety gardens (that is, variety gardens planted according to a given plan with vegetative lines or nursed from seeds of the selected and recognised maternal plants); or
 - variety forests (that is, forests of variety plants propagated from

maternal plants and grown not according to a given plan or transformed from natural forests or planted forests already evaluated, selected and recognised).

- Producing short-term industrial plants, fruit trees, ornamental plants and other plants by the vegetative propagation method must follow the process promulgated by MARD (if any).

Distribution of seeds or crops

As with producing major plant varieties, in order to trade in major plant varieties, organisations and individuals must fully satisfy a number of statutory conditions (*see above, Commercial crop production*). However, there is no specific licence required for trading of major plant varieties or non-major plant varieties.

Traders in plant varieties are responsible for the quality of the plant varieties they trade in and must publicise the quality standards and that the quality of the plant varieties conforms with those standards (*Article 42, Ordinance on Plant Varieties*). All acts of trading fake seeds, seeds of poor quality, mixed seeds, seeds with pests or disease germs or seeds which have not been certified, are strictly forbidden (*Article 13, Decree 7/1996*).

17. Set out the domestic labelling requirements in the crop business sector.

All kinds of marketed seeds must be affixed with labels and have quality control certificates as required for each seed grade. Seeds sold on the market must be packaged in accordance with the packaging standard (*Article 13, Decree 7/1996*).

Packaging for plant varieties being traded must contain certain required information, such as:

- Name of the plant variety.
- Name and address of the responsible establishment.
- Quantification of the plant variety.
- Country of origin.

18. Are there any restrictions on foreign direct investment (FDI) in this sector?

There is no restriction on FDI in carrying out business in the crop seed industry. A FDI company can carry out businesses relating to crop seed industry in the same way as Vietnamese companies.

However, for operation of services incidental to agriculture, foreign investors can conduct business only through a business co-operation contract or joint venture with Vietnamese partners under which foreign capital contribution cannot exceed 51% of paid-up capital. These services are services provided on a fee or contract basis, mostly performed at the site where the agricultural production is done, for example:

- Services of providing agricultural machinery with drivers and crew.
- Harvesting and related services.
- Services of farm labour contractors.

- Animal boarding, care and breeding services.
- Services to promote propagation, growth and output of animals.
- Services to promote commercial hunting and trapping.
- Timber evaluation, firefighting, forest management including forest damage assessment services.
- Logging related services.
- Services related to fisheries and operational services of fish hatcheries or fish farms.

19. Summarise landmark or recent cases that have defined the law and practice in this sector.

According to recent reports, at present up to 80% of seeds consumed in Vietnam are imported from abroad, due to Vietnam's lack of science and technology in researching and breeding high yield/quality seeds. To improve this situation, the Vietnam Seed Trade Association and researchers have suggested that the government introduce policies to attract foreign companies to invest in seed research and development.

PLANT VARIETY RIGHTS (PVR)

20. Has your jurisdiction ratified the International Convention for the Protection of New Varieties of Plants 1961 (UPOV Convention) and its revisions in 1972, 1978 and 1991?

Vietnam ratified the International Union for the Protection of New Varieties of Plants, 1991 version, on 24 December 2006. Currently, Vietnam agrees to protect 90 species of plant variety. However, in accordance with the commitments to UPOV, as of 2016, Vietnam will extend the protection to all species if those species meet the requirements for protection.

21. Briefly describe the registration process for PVR in your jurisdiction.

Typically, the registration of PVR follows the following process:

- The applicant or the registered agency of the applicant files a PVR application with the New Plant Variety Protection Office (PVPO) under the Ministry of Agriculture and Rural Development (MARD). The applicant must enclose documents attesting to the priority right with the PVR application if claiming for priority right.
- The PVPO decides whether the application meets the formal requirements (this does not mean that the new variety recognition requirements have been satisfied (*see Question 16, Set up of R&D centres and use of test plots of new crops*)). If the application does not meet these requirements, the PVPO normally requires the applicant to provide supplementation and/or explanation. If the application dossier is sufficient, the PVPO will officially accept the application and request the applicant to provide samples of the plant variety to do technical tests.
- The PVPO publishes the application in a specialised magazine and proceeds with substantive examination. During the examination, the PVPO examines the novelty and proper denomination of the plant

variety as well as the results of technical tests of the plant variety. If the plant variety meets the criteria for protection, the PVPO will issue the patent and record it in the National Register of Plant Varieties.

At present, only 90 recognised species of plant variety enjoy protection in Vietnam. However, as of 2016, all plant varieties could be patented if they meet the criteria for protection (*see Question 22, Requirements for protection*).

22. Briefly describe the laws and procedures of your jurisdiction covering the protection of PVR in terms of:

- **Requirements for protection.**
- **Extent of the protection.**
- **Restrictions on the rights of the PVR holder.**
- **Farmer's privilege.**

Requirements for protection

Vietnam lays down almost the same requirements for protection of a plant variety as the ones in the UPOV. Plant varieties that are eligible for protection must be (*Article 158, IP Law*):

- Selected and bred or discovered and developed.
- In the list of protected plant species promulgated by the Ministry of Agriculture and Rural Development.
- Novel, distinct, uniform, and stable (*see below*).
- Designated by proper denominations.

In relation to the third bullet point:

- “Novelty” means commercial novelty. A plant variety is deemed novel if reproductive materials or harvested materials of that variety have not yet been sold or otherwise distributed for the purpose of exploitation in Vietnam in a certain number of years before the filing date of PVR applications.
- “Distinct” means it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of filing the application or on the priority date, as the case may be.
- “Uniform” means that it is sufficiently uniform in its relevant characteristics, subject to variation that may be expected from the particular features of its propagation.
- “Stable” means the variety’s relevant originally described characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each cycle.
- “Suitable” means it is distinguishable from those of other plant varieties of common knowledge within the same or similar species.

At present, there are only 90 species on the list of protected plant species. As of 2016, however, as required by the UPOV, Vietnam must protect all plant species. The list will no longer exist.

Extent of the protection

Rights of the variety owners can be extended to other plant varieties if the plant varieties originate mainly from the protected plant variety, unless the protected plant variety itself originates from another protected plant variety.

The variety owner's rights can be extended to cover plant varieties:

- That are not substantially distinct from the patented plant variety.
- The production of which requires the repeated use of the protected plant variety.

Under prevailing laws, the PVR applicant can enjoy provisional rights to the plant variety in question. The rights will arise from the date of publication of the application until the date of grant of the patent. Where no patent is granted for that plant variety, the protection registrant no longer has these provisional rights.

Restrictions on the rights of the PVR holder

If the breeder is also the variety owner, the owner cannot restrict another entity from using the protected variety to breed in the following situations:

- Breeding for personal and non-commercial purposes.
- Breeding for cross-breeding for scientific research purposes.
- Breeding to create new plant varieties distinct from the protected plant varieties.

The breeder/variety owner must also respect the farmer's privilege in using harvested materials of the protected plant variety for self-propagation and cultivation in the next season on the land area belonging to the farmer (*see below, Farmer's privilege*).

The right to a plant variety must not be applicable to acts related to materials of the protected plant variety which are sold on or otherwise brought onto the domestic or overseas market by the variety holder or its licensee, except for the following acts (*Article 190.2, IP Law*):

- Acts relating to further propagation of that plant variety.
- Acts relating to export of reproductive materials of that plant variety to countries where the genus or species of that plant variety is not protected, except where those materials are exported for consumption purposes.

Farmer's privilege

Farmers are entitled to use harvested materials of the protected plant variety to self-propagate and cultivate in the next season on the land area belonging to those farmers (*Article 190.1(d), IP Law*). However, the farmers are not permitted to trade or share the seeds with other farmers. In theory, the provision could cause prejudice to the rights of the variety owner. However, in Vietnam the cultivation land area of the local farmers is quite small. Therefore, in practice, the farmer's privilege would not cause much harm to the rights of the owner of the patented plant variety.

23. Which legal actions are available to owners of PVR in the event of PVR infringements?

Administrative action

Administrative actions are both cost-effective and time-efficient, and this is the most common route in Vietnam for most companies if their main priority is to stop the ongoing infringement.

Typically, to initiate the action, the variety owner must file a complaint with the competent authorities, such as the inspectorate in the field of agriculture and rural development. Other bodies such as the police, market control force, and so on, are also empowered to conduct administrative actions under the Law on Handling Administrative Violations 2012.

The authority examines the request and raids the infringer, where appropriate. If infringement is found, the competent authority imposes sanctions on the infringer. The most serious penalty in money is VND50 million, which may be imposed on infringers that are individuals, while the level applicable to organisations is VND100 million.

Civil action

The variety owner can take civil action to claim remedies available under law, such as:

- A compulsory cessation of the infringement.
- A public apology.
- Compensation for the infringement.

After the administrative action, the variety owner can also commence civil litigation to claim for damages based on the evidence collected in the administrative action.

Most IPR holders, including PVR holders, do not normally take civil action against the infringer due to the Vietnamese courts' lack of IP expertise. Therefore, in practice, the Vietnamese courts have dealt with few IP cases. To the best of the authors' knowledge, no suit on plant variety infringement has been filed with the local courts.

Criminal action

In theory, criminal sanctions can be used against the act of manufacturing and/or trading in fake goods, such as animal feeds, fertilisers, veterinary drugs, plant protection drugs, plant varieties, or animal breeds. However, as far as the authors are aware, no plant variety owner has ever sought a criminal charge against an infringer.

Border control measure

The plant variety owner can seek a customs seizure of infringing plant variety shipments at the borders of Vietnam under the border control measure.

Alternatives to legal action

The variety owner can opt for mediation or arbitration to settle the infringement. As a prerequisite to arbitration, the variety owner must obtain an agreement from the infringers to refer a dispute to arbitration. In practice this is not feasible.

Mediation is a more practical approach than arbitration. Typically, the variety owner will send a cease-and-desist letter, calling for a voluntary stop of the infringement as well as a compensation for damages (if necessary). The mediation will then follow the issue of that letter.

24. Summarise landmark or recent cases that have defined the law and practice in this sector.

On the whole, the protection of plant varieties is still in its infancy in Vietnam. So far, not many plant varieties have been registered, even though Vietnam is an agricultural country. To some extent, this is understandable because individuals and companies (including seed producers) in Vietnam have not attached much importance to IP. Therefore, seed producers have not generally attended to registering their varieties. Foreign seed producers also have not paid much attention to protection of their varieties in Vietnam. From 2004 to 2014, there have been only 491 PVR applications filed with the New Plant Variety Protection Office and 225 granted patents.

The authors are not aware of any enforcement cases relating to PVR since the introduction of the system for protection of plant varieties in Vietnam. With an increasing number of granted patents, enforcement actions will attract more attention from the variety holders in the foreseeable future.

GENETICALLY MODIFIED (GM) CROPS

25. Has your jurisdiction ratified the Cartagena Protocol on Biosafety 2002? What is the domestic policy with respect to GM crops?

Vietnam ratified the Cartagena Protocol on Biosafety 2002 on 21 January 2004 (<http://bch.cbd.int/about/countryprofile.shtml?country=vn>).

Generally, domestic policy with respect to GM crops is in line with the Cartagena Protocol. Vietnam is committed to implementing treaties on biodiversity to which it is a contracting party and expanding co-operation on biodiversity conservation and sustainable development with other countries, territories and foreign organisations and individuals (*Article 69.1, Law on Biodiversity*). In particular, Article 4.5 of the Law on Biodiversity provides general principles for the conservation and sustainable development of biodiversity that ensures management of risks caused to biodiversity by GM organisms and specimens of GM organisms.

In addition, organisations and individuals are only permitted to carry out research, experiments, production, trade in, use, importation, exportation, storage and transportation of GM organisms and their products that are included in the list established by the law, and must fully comply with all conditions and procedures required according to the provisions of the law (*Article 87.2, Law on Environmental Protection*).

26. Describe the domestic laws regulating genetic engineering. Which authority(ies) is(are) responsible for approving GM crops. Set out the permit requirements and prohibitions as well as sanctions in the event of infringement.

Regulations on approving GM crops are generally provided in:

- Decree No. 69/2010/ND-CP as amended by Decree 108/2011/ND-CP (Decree 69).
- Circular No. 08/2013/TT-BTNMT.

To be approved, the GM crops must be granted a biosafety certificate by the Ministry of Natural Resources and Environment (MONRE) certifying

that the GM organisms are safe for the environment and biodiversity and permitted to be released into the environment under specific conditions.

To be granted a biosafety certificate, GM organisms must satisfy the following conditions (*Article 22, Decree 69*):

- They were tested under Vietnam's specific conditions and the Ministry of Agriculture and Rural Development recognised their test results as satisfactory.
- The Biosafety Council concluded that they were safe for the environment and biodiversity.

The group of GM crops considered eligible for granting a biosafety certificate include (*Article 3, Circular 08/2013/TT-BTNMT*):

- GM crops carrying a single transformation event created as a result of transforming one or more genes encoding a desired trait by transgenic technology.
- GM crops carrying stacked transformation events created as a result of one of the two following processes:
 - simultaneously transforming genes encoding desired traits into traditional crops by using transgenic technology;
 - transforming genes or gene encoding a desired trait into a GM crop.

A number of acts are prohibited, including illegally importing or releasing GM organisms and genetic specimens of GM species (*Article 7, Law on Biodiversity*). Article 8.3 of Decree 69 provides some sanctions in case of infringement relating to management of risks of GM organisms to the environment, biodiversity and health of humans and domestic animals, namely, organisations and individuals that fail to comply with risk management measures will, depending on the severity of their violations, be administratively sanctioned, examined for penal liability or pay compensation under law. Decree No. 179/2013/ND-CP provides details on administrative sanctions against violation in this field.

27. Which safety evaluations are legally required before GM crop commercial market entry? How are GM crops regulated?

Regulations on safety evaluations before GM crop commercial market entry are generally provided in Decree 69 and Circular No. 02/2014/TT-BNNPTTN (Circular 02). Accordingly, the Ministry of Agriculture and Rural Development (MARD) is the authority that grants certificates of GM crops that are eligible for use as food and feed. Cases that require a certificate of GM crops eligible for use as food and feed, include (*Article 5, Circular 02*):

- GM crops carrying a single transformation event as a result of transformation of a gene encoding a desired trait by transgenic technology.
- GM crops carrying the stacked transformation event as a result of transformation of two or more genes encoding one or more desired traits by transgenic technology.

To qualify for a certificate, GM crops must satisfy one of the following conditions:

- Being permitted for use by at least five developed countries as food and feed without any risk in these countries.
- After reviewing the application dossier, the Council of Food and Feed Safety has concluded that the GM crops have no uncontrollable risks for human and animal health.
- The application is for a certificate of eligibility for use as feed, and the GM crops have been issued with a certificate of eligibility for use as food.
- Where the application is for the crops that have come into being as the result of traditional hybridisation from two or more single transformation events, and those single transformation events have been issued certificates of eligibility for use as food and feed.

The application dossier for the certificate of GM crops is submitted to the MARD. Within seven working days after receiving the application dossier, the MARD sends a written notice to the applicant informing the applicant of the receipt of a complete dossier or requiring further supplementation or explanation. If the application dossier is complete, the MARD will publish information and a summary of the report on risk assessment on its website to gather public opinions within 30 days. The MARD then sets up a Council to evaluate the dossier for issuing a certificate. If the application dossier is eligible for issue of a certificate, the MARD decides whether to issue a certificate within 30 days from the date of appraisal result of the Council. There is no term for the certificate; however, the certificate can be revoked for one of the grounds set out in Article 29.1 of Decree 69.

28. Describe the GM crop test plot regulations and requirements.

Article 14 of Decree 69 establishes step-by-step requirements for restricted tests to wide-area tests for GM organisms used for release, including culture, growing and purposeful release into the environment:

- Test zones must be a stipulated distance from conservation zones and densely populated areas.
- Restricted tests must be conducted under isolation conditions.
- Wide-area tests must be conducted in different eco-zones for which appropriate management and supervision measures are required, but not isolation conditions.

The Ministry of Agriculture and Rural Development is the competent authority to grant and revoke the certificate for an institution to be recognised as a GM organism-testing institution as well as the licence for testing.

29. Describe pre-market approval requirements (and approval timelines) to grow, produce and sell GM food or feed. Provide details on the competent approval authorities.

See *Questions 27* and *28*.

30. Set out the domestic product genetically modified organism (GMO) content labelling obligations (or the absence of them) and sanctions in the event of non-compliance or inaccurate content labelling.

Decree 69 and Decree No. 38/2012/ND-CP establish requirements on labelling of goods containing GM organisms or products from organisms. These provide that organisations and individuals that circulate on the market goods containing GM organisms or products exceeding 5% of the ingredients, must as well as complying with the law on goods labelling, show information related to GM organisms on the goods labels. A failure to meet these requirements may be subject to administrative sanctions, that is, a monetary fine from VND200,000 to VND80 million or other measure.

31. Summarise landmark or recent cases that have defined the law and practice in this sector.

As published in the website <http://antoansinhhoc.vn> (the official website identified by the Ministry of Natural Resources and Environment which officially publishes information on the list of GM organisms whose dossiers are submitted for approval), there are eight GM crops (corn) that are submitted for certificates. However, as indicated in the website, so far although the Ministry of Agriculture and Rural Development has recognised test results of almost all of the GM corn varieties, none of the GM corn has been granted a biosafety certificate or certificate of GM crops eligible for use as food and feed, only some of them are recognised temporarily for use in feed. Details can be found at <http://antoansinhhoc.vn/Noi-dung-don/Danh-muc-GMO/2452502>.

IMPORTING ANIMALS AND GENE PATENTS

32. Summarise the import/export control measures for animals and genetic resources.

Animals and animal products imported into Vietnam, including genetic resources (sperm, embryos, breeding eggs, larva and breeding genomes), must be quarantined if they are either (*Article 28, Ordinance on Veterinary Medicine; Article 35, Decree No. 33/2005/ND-CP (Decree 33); Article 3.1, Ordinance On Livestock Breeds*):

- In the list of animals and animal products that must be quarantined.
- Animals or animal products that do not exist in Vietnam.

When importing animals or animal products, prior to shipment, the concerned individuals and organisations must declare the importation with the competent animal quarantine agencies of Vietnam.

If the quarantine dossiers are valid, the animals are healthy, the animal products do not show signs of degeneration or carry no disease pathogens, animal quarantine agencies will give certification for goods owners to carry out customs procedures and take animals and/or animal products to isolated quarantine areas or establishments.

To-be-exported animals and animal products may be also quarantined, if quarantine is (*Article 27, Ordinance on Veterinary Medicine; Article 34, Decree 33*):

- Provided for in sale and purchase contracts or in international agreements.
- Requested by goods owners.

The current Vietnamese regulations in the field are not fully compliant with IOE's international sanitary standards for animals. A draft of the Law on Veterinary Medicine, which is intended to meet with IOE's standards, is being circulated for comment. It is hoped that the law will be passed by the National Assembly by the middle of 2015.

33. Does the law of your jurisdiction allow for patentability of livestock genes on the grounds of isolating and purifying them?

Plant varieties and animal breeds are excluded from patent protection in Vietnam (*Article 59.5, IP Law*). However, genes and GM animals/plants, if modified by humans, can be patentable (*Article 25.3.b(i); Circular No. 01/2007/TT-BKHHCN*). Therefore, isolated and purified livestock (genes, for example) and isolated gene sequences are patentable.

34. Which legal instruments are available to protect animal breeding know-how and a resulting animal nucleus?

The state protects traditional knowledge copyrights on genetic resources and encourages and supports organisations and individuals to register them (*Article 64, Law on Biodiversity*). Article 64 also provides that the Ministry of Science and Technology has the prime responsibility for, and co-ordinates with concerned ministries and ministerial-level agencies in, providing guidance procedures for registration. However, so far the Ministry has not issued a regulation on this issue.

35. Are there legal or practical restrictions on the introduction of new breeds/species, the breeding of certain animal species or certain breeding practices?

There are no general regulations or list on banned breeds. New livestock breeds are recognised only when they have their test results (*Article 18, Ordinance on Livestock Breeds*):

- Obtained from establishments for testing new livestock breeds.
- Assessed by a specialised scientific council, which is set up by the Ministry of Agriculture and Rural Development (MARD) and proposes the recognition of the new livestock breeds.

After the MARD's decision, the recognised new livestock breeds will be added to the list of livestock breeds permitted for manufacture and trading, including import and breeding. Organisations and individuals are only permitted to import livestock breeds on the list of livestock breeds permitted for manufacture and trading (*Article 23*). The import of sperm and embryos requires the MARD's permission. Organisations and individuals that import livestock breeds not yet on the list of livestock breeds permitted

for manufacture and trading for the purposes of research, assay, inspection or in other special cases must obtain permission from the MARD. Detailed regulations on research into, selection, creation, testing and recognition of new livestock breeds are also provided in the Ordinance on Livestock Breeds.

Restrictions in practice are not available because the authors have not been able to contact the Association on Animal Health (the association's website is not yet operational).

36. Summarise landmark or recent cases that have defined the law and practice in this sector.

On 23 July 2013, the Ministry of Agriculture and Rural Development issued Circular No. 36/2013/TT-BNNPTNT on the recognition of a new livestock breed for guinea pigs (*Cavia porcellus*) that would be added into the list of livestock breeds permitted for manufacture and trading. However, shortly after issuance of the Circular, the Ministry issued a notice notifying that the Circular should be cancelled due to technical mistakes and therefore this breed should not be added to the list.

AGRICULTURAL SAFETY AND PRODUCT LIABILITY

Standards

37. Summarise the system of food safety standard setting, the main regulator(s) and regulations. If industry input on the standards is possible, indicate how this is conducted.

In Vietnam, management of goods quality and food safety is mainly governed by the:

- Law on the Quality of Products and Goods.
- Law on Standards and Technical Regulations.
- Law on Food Safety.
- Law on Protection of Consumers' Rights.

The Law on Quality of Products and Goods states that the manufacturers and traders (including retailers) must take responsibility for the quality of goods that they manufacture or trade to ensure safety for humans, animals, plants, property and the environment.

The Law on Food Safety provides a general legal framework on the:

- Rights and obligations of organisations and individuals in assuring food safety.
- Conditions for assuring safety of:
 - foods and food production;
 - trading, import and export;
 - food advertisement and labelling;
 - food testing;
 - prevention, stopping and remedying of food safety incidents.

The Ministry of Health (MOH), the Ministry of Industry and Trade (MOIT), and the Ministry of Agriculture and Rural Development (MARD) are the major authorities responsible for food safety management. Under the Law on Quality of Products and Goods, the Ministry of Science and Technology

(MOST) will have overall responsibility for the management of the quality of goods.

Generally, product quality is controlled on the basis that the establishment in charge of the products (the local producer, importer, distributor or representative office in Vietnam of the manufacturer) must announce that it complies with the applicable technical regulations and standards (*Law on Standards and Technical Regulations*):

- Technical regulations mean regulations on the limits of technical characteristics and management requirements which products, goods, services, processes, the environment and other objects in socio-economic activities must comply with in order to:
 - ensure safety, hygiene and human health;
 - protect animals, plants and the environment;
 - safeguard national interests and security, consumer interests and other essential requirements.

They are issued by the competent state agency and are mandatory.

- Standards mean regulations on technical characteristics and management requirements used as standards for classifying and appraising products, goods, services, processes, the environment and other objects in socio-economic activities with a view to improving the quality and effectiveness of these objects. They are applied voluntarily by organisations and individuals.

All food products, additives, and processing aids sold and consumed in Vietnam must be declared to the authority, by the establishment in charge of the products, for Conformity with Technical Regulations, or Conformity with Food Safety Regulations (where there does not yet exist a national technical regulation).

The Vietnam National Codex Committee (VNCC) was re-founded on 1 January 2010 and is managed by the MOH. The leaders of the VNCC are leaders from the MOH, MOIT, MARD and MOST. The current legislation demonstrates that Vietnam has adopted the standards of the Codex Alimentarius:

- Food products for which Vietnam does not have food safety regulations must be declared for conformity with regulations of the international food standard committee (*Codex*).
- The authority will consider allowing the declaration for food additives, food processing enhancers or products containing food additives or food processing enhancers which are not in the list permitted to use in Vietnam but are in the list prescribed by the Codex or that are permitted to use in producing countries.

Liability

38. Set out the legal requirements to establish the liability of producers and suppliers for defective or contaminated food ingredients that cause damage, in relation to:

- Tort.

- Product liability.

Tort

There is no tort law; however, there are some general provisions on tort liability in the Civil Code requiring persons who intentionally or unintentionally infringe on the life, health, property rights or other legitimate interests of another party to pay compensatory damages (*Article 604*). Liability may be reduced to the extent that the victim is at fault in causing the damages (*Article 617*).

For the damages that would be recoverable, see *Question 40*.

Product liability

The Law on Food Safety provides general provisions concerning the liability of producers and suppliers for defective or contaminated foods, under which the producer must pay compensation for damages caused by unsafe foods which they have produced and the food trader must pay compensation for damages caused by unsafe foods which they have traded. However, this law does not provide specific provisions on how the producers or suppliers will pay compensation where they are jointly or severally liable.

The Law on Protection of Consumers' Rights promulgates more provisions on the liability for defective goods. Defective goods are defined as goods which:

- Fail to ensure safety for consumers.
- Endanger consumers' lives or health.
- Could cause loss and damage to consumers' assets.

This includes goods manufactured correctly in accordance with current technical standards or criteria in which the defect was undiscoverable at the time the goods were supplied to the consumer. The liable parties would be liable for quality and safety of products and for all actual damage that was directly caused by the defective goods, regardless of intent, even if unaware of, or not at fault in, causing the defect although they may be able to disclaim liability by proving the defect was undiscoverable by scientific or technical standards at the time the good was supplied to the consumer (*see Question 39*). The liable parties include the:

- Manufacturer.
- Importer.
- Holder of trade marks affixed to the goods.
- The retailer, if the establishments of the above three parties are unidentifiable.

39. Which defences are available to the producer and/or supplier to avoid liability? For instance, is market-entry prior government approval a legal defence against product liability and under which conditions?

Producers and/or suppliers can disclaim liability if they prove that the defect in goods was undiscoverable by scientific or technical standards at the time the trader supplied goods to the consumer (*Article 24, Law on Protection of Consumers' Rights*). For products which are not defective goods, the defendant has the burden of proving it was not at fault for causing loss and damage.

40. Which types of damage are generally compensated by civil courts in food safety liability cases? For instance loss of value, reparation costs, loss of revenue, and personal injury. Are punitive damages available?

Compensation for property damage, damages for personal injury or loss of life or other legitimate interests will be generally handled by civil courts in food safety liability cases (*Article 25, Civil Procedure Code; Article 604, Civil Code; Article 41, Law on Protection of Consumers' Rights*). Compensation for property damage can include:

- Actual losses to property, and the interests associated with the use or exploitation of this property.
- Reasonable expenses for preventing, mitigating or remedying the damage caused.

Damages for personal injury or loss of life can include:

- Reasonable medical, rehabilitation and caregiver expenses.
- Lost income incurred by the victim and his or her caregiver.
- Compensation for mental suffering, funeral expenses in the case of death and support allowances for the victim's legal dependants.

Punitive damages are not available under Vietnamese law.

41. Summarise landmark or recent cases that have defined the law and practice in this sector.

A recent landmark case relating to food safety in Vietnam is the recall in August 2013 of infant formula products made from three batches of whey protein concentrate contaminated with *Clostridium botulinum* produced by a New Zealand company. After the Embassy of New Zealand in Vietnam announced this information, the Vietnam Food Administration (VFA) under the Ministry of Health actively checked and verified the data and found that certain lots of milk powder products from two companies were potentially affected. The VFA requested the two companies to recall these lots from the market. These two companies rapidly recalled the potentially contaminated batches and sent samples to the National Institute of Food Control for testing. The testing revealed that the products did not violate the regulations and the companies were allowed to re-sell these batches in the market. Additionally, the VFA requested the inspection agencies to apply tight inspection for products containing whey protein imported from New Zealand. The VFA also checked with customs to look for data on whey protein concentrate that was imported from New Zealand since 2012. Information of recall procedures as

well as related information from other countries such as New Zealand, China, Malaysia, Singapore, and so on, was updated regularly on the website of the VFA.

ONLINE RESOURCES

Vietnam government portal

W <http://vanban.chinhphu.vn/portal/page/portal/chinhphu/hethongvanban>

Description. Official web portal of the Vietnamese government. The information is official but not always up-to-date. English translations are available for many documents, for reference only.

Ministry of Justice

W <http://vbpl.vn>

Description. National Database on Legal Normative Documents maintained by the Ministry of Justice. The information is official but not always up-to-date. English translations are available for many documents, for reference only.

Thu Vien Phap Luat

W <http://thuvienphapluat.vn/>

Description. Website maintained by Lawsoft Corporation, a Vietnamese company. Although unofficial, it tends to be more comprehensive and up-to-date than the official websites. Unofficial English translations are available for most documents, but require a subscription for access.

Contact details

GENERAL EDITOR

Jan VM Holthuis
HIL International Lawyers & Advisers
Room 2505B, ICC-Tower
No. 3000, North Zhongshan Road
200063 Shanghai
The People's Republic of China
T: +86 21 61730388
F: +86 21 61730386
E: jholthuis@hil-law.com
W: www.hil-law.com

ARGENTINA

Pablo Vinals Blake &
Ignacio Sánchez Echagüe
Marval, O'Farrell & Mairal
Leandro N. Alem 928
CABA C1001AAR
Argentina
T: +54 (11) 43100100
F: +54 (11) 43100200
E: pvb@marval.com
imse@marval.com
W: www.marval.com

AUSTRALIA

Andrew Hay
Clayton Utz
Level 28, Riparian Plaza,
71 Eagle Street,
Brisbane, QLD, 4000,
Australia
T: +61 7 3292 7299
F: +61 7 3221 9669
E: ahay@claytonutz.com
W: www.claytonutz.com

BELGIUM

Philippe de Jong
ALTIUS
Havenlaan 86C, B414
1000 Brussels
Belgium

T: +3224261414
F: +3224262030
E: Philippe.deJong@altius.com
W: www.altius.com

BRAZIL

Alexei Bonamin, Andreia de Andrade
Gomes, Darcy Teixeira Junior,
Elysangela de Oliveira Rabelo, Luiz
Renato Okumura, Vera Kanas,
Vladimir Miranda Abreu
TozziniFreire Advogados
Rua Borges Lagoa 1328
São Paulo, CEP 04038-904
Brazil
T: +55 11 5086 5179
F: +55 11 5086 5555
E: abonamin@tozzinifreire.com.br
T: +55 21 3535-2116
F: +55 21 3535-2121
E: angomes@tozzinifreire.com.br
T: +55 11 5086-5153
F: +55 11 5086-5555
E: dteixeira@tozzinifreire.com.br
T: +55 11 5086-5323
F: +55 11 5086-5555
E: erabelo@tozzinifreire.com.br
T: +55 11 5086-5174
F: +55 11 5086-5555
E: lokumura@tozzinifreire.com.br
T: +55 11 5086-5314
F: +55 11 5086-5555
E: vkanas@tozzinifreire.com.br
T: +55 11 5086-5219
F: +55 11 5086-5555
E: vabreu@tozzinifreire.com.br

CHILE

Matias Araya, Sebastián Norris.
Araya & Cía Abogados
Cruz del Sur 133 Of.902 Las Condes
Santiago 758-0151
Chile

T: +56 2 22082993
F: +56 2 22089802
E: matias@araya.cl
snorris@araya.cl
info@araya.cl
W: www.araya.cl

CHINA

Jan VM Holthuis, Yi Tao
HIL International Lawyers &
Advisers
Room 2505B, ICC-Tower
No. 3000, North Zhongshan Road
200063 Shanghai
The People's Republic of China
T: +86 21 61730388
F: +86 21 61730386
E: jholthuis@hil-law.com
ytao@hil-law.com
W: www.hil-law.com

GERMANY

Dr Philipp M Gregor
Dr Gregor Rechtsanwalt
Salzstraße 23
48143 Münster
Germany
T: +49 251 48254 0
F: +49 251 48254 10
E: gregor@dr-gregor.eu
W: www.dr-gregor.eu

GHANA

Cephas Motey, Mame Esaama
Orleans-Lindsay, Victoria Kiki
Quansah
LithurBrew & Company
No. 110B Off Kade Avenue
Kanda Estates, Accra
P. O. Box CT 3865, Accra
Ghana
T: +233 302 248105
F: +233 302 24815
E: cephasm@lithurbrewlaw.com
mameamao@lithurbrewlaw.com
kikiQ@lithurbrewlaw.com
W: www.lithurbrewlaw.com

HUNGARY

Ágnes Balassa, Réka Versics
Bihary, Balassa & Partners
Attorneys at Law
H-1026 Budapest
Pasaréti út 83.
Hungary
T: +36 1 391 44 91
F: +36 1 200 80 47
E: agnes.balassa@biharybalassa.hu
versics@biharybalassa.hu
W: www.biharybalassa.hu

INDIA

Nusrat Hassan
D.H. Law Associates
111, Free Press House
Free Press Journal Road
215, Nariman Point, Mumbai - 400 021
India
T: +91 22 6625 2222
F: +91 22 2285 5821
E: nusrat@dhlawassociates.com
W: www.dhlawassociates.com

ITALY

Ferdinando Albisinni
Studio Legale Albisinni
Via Ciro Menotti N.4
Rome 00195
Italy
T: +39 0632 16171
F: +39 0632 17034
E: f.albisinni@albisinni.it

JAPAN

Takashi Hirano, Taketo Nasu
Blakemore & Mitsuki
Nittochi Bldg, 4F
4-1, Kasumigaseki 1-chome
Chiyoda-ku, Tokyo
100-0013
Japan
T: +81 3 3503 5571
F: +81 3 3503 5577
E: hirano@blakemore.gr.jp
nasu@blakemore.gr.jp

W: www.blakemore.gr.jp

NIGERIA

Dr Oludayo G Amokaye
Dayo Amokaye & Co
West Wing, TBS, Suite 25-28B, 1st Flr
Tafawa Balewa Square
Nigeria
T: +23 4802 300 6055
F: +23 4818 096 7877
E: dayoamokayelaw1@gmail.com
dayoamokaye@yahoo.co.uk

TAIWAN

Yulan Kuo, Hui-ming Huang
Formosa Transnational Attorneys at Law
13th Floor, Lotus Building
136, Jen Ai Road, Sec.
3, Taipei 106
Taiwan, R.O.C.
T: +886 2 2755 7366
F: +886 2 2708 8435
E: yulan.kuo@taiwanlaw.com
hui-ming.huang@taiwanlaw.com
W: www.taiwanlaw.com

THAILAND

Prateep Naboriboon,
Siradapat Ratanakorn,
Chaiwat Keratisuthisathorn
Tilleke & Gibbins International Ltd.
Supalai Grand Tower, 26th Floor
1011 Rama 3 Road
Chongnonsi, Yannawa
Bangkok 10120
Thailand
T: +66 2653 5749
F: +66 2653 5678
E: prateep.n@tilleke.com

T: +66 2653 5622
F: +66 2653 5678
E: siradapat.r@tilleke.com

T: +66 2653 5507
F: +66 2653 5678
E: chaiwat.k@tilleke.com

W www.tilleke.com

THE NETHERLANDS

Jan VM Holthuis
HIL International Lawyers & Advisers
Room 2505B, ICC-Tower
No. 3000, North Zhongshan Road
200063 Shanghai
The People's Republic of China
T: +86 21 61730388
F: +86 21 61730386
E: jholthuis@hil-law.com
W: www.hil-law.com

Marc van der Velden
HIL International Lawyers & Advisers BV
Haaksbergweg 33
1101 BP Amsterdam
The Netherlands
T: +31 20 6513000
F: +31 20 6513001
E: mvandervelden@hil-law.com
W: www.hil-law.com

TURKEY

Zeynep Özkan Özeren
Özkan Law Office
Hüsrev Gerece Cad. Ömer Rüştü Paşa sok
No:12 Teşvikiye Beşiktaş 34 357
İstanbul
Turkey
T: +90 212 327 69 40
F: +90 212 327 69 43
E: zeynep@ozkan.av.tr
W: www.ozkan.av.tr

UNITED KINGDOM

Sian Edmunds, Kevin Kennedy,
William Neville and Alice Scott-Gatty
Burgess Salmon LLP
6 New Street Square
London EC4A 3BF
United Kingdom
T: +44 117 902 7187
F: +44 117 378 6575
E: sian.edmunds@burgess-salmon.com
T: +44 117 307 6934

F: +44 117 378 6638
E: kevin.kennedy@burges-salmon.com
T: +44 117 939 2202
F: +44 117 378 6489
E: william.neville@burges-salmon.com
T: +44 117 902 2729
F: +44 117 378 6749
E: alice.scott-gatty@burges-salmon.com
W: www.burges-salmon.com

UKRAINE

Anna Zorya
Arzinger Law Office
Eurasia Business Centre
75 Zhylyanska St., 5th Floor
01032 Kyiv
Ukraine
T: +38 044 390 55 33
F: +38 044 390 55 40
E: anna.zorya@arzinger.ua
W: www.arzinger.ua

UNITED STATES

Gretchen E. Cleveland
Exact Sciences Corporation
441 Charmany Drive
Madison, WI 53719
United States
T: +608 284 5700
E: gcleveland@exactsciences.com
W: www.exactsciences.com

VIETNAM

Kien Trung Trinh, Dung Thi Kim Vu,
Linh Duy Mai
Tilleke & Gibbins Consultants
Limited
HAREC Building, 4th Floor
4A Lang Ha Street, Ba Dinh District,
Hanoi, Vietnam
T: +84 3772 5567
F: +84 3772 5568
E: kien.tt@tilleke.com

T: +84 3772 5554
F: +84 3772 5568
E: kimdung.v@tilleke.com
T: +84 3772 5537
F: +84 3772 5568
E: duylinh.m@tilleke.com
W: www.tilleke.com

ZIMBABWE

Tatenda Mawere, Regis Chawatama
Mawere & Sibanda Legal
Practitioners
10th Floor, Chiedza House
Cnr 1st Street, Kwame Nkrumah
Avenue
Harare
Zimbabwe
T: +263 4 762 936/+263 4 750 627
F: +263 4 750 759
E: tmawere@maweresibanda.co.zw
E: rchawatama@maweresibanda.co.zw
W: www.maweresibanda.co.zw