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.
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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.
Preface

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
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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
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)
   The Netherlands is a party to the WTO (acceded on 1 January 1995). It had been a member of the WTO’s predecessor, the General Agreement on Tariffs and Trade, since 1 January 1948.

   Food and Agriculture Organisation of the United Nations (FAO)
   The Netherlands is a party to the FAO (acceded on 16 October 1945).

   International Plant Protection Convention (IPPC)
   The Netherlands is a party to the IPPC (acceded on 6 December 1951).

   Office International des Epizooties (IOE)/World Animal Health Organization
   The Netherlands is a party to the IOE (acceded on 25 January 1924).

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

   Dutch agricultural policy is primarily shaped by the EU’s Common Agricultural Policy (CAP). In general, Dutch agriculture policy is based on the following principles:
   • International competitiveness.
   • Sustainability (economic, social, and environmental).
   • Food quality and safety.
   • Animal welfare.
   • Preservation of biodiversity and natural landscapes, flora and fauna.
   • Preservation of historical man made landscapes and buildings, and livability of the countryside.

   An increasingly important part of agricultural policy is biotechnology and new crop growing technologies. Biotechnology applied to animals (for research or for practical applications) is in principle not allowed, unless a permit has been issued by the Ministry of Economic Affairs. Biotechnology
applied to plants is permitted, if a thorough risk assessment has been made which shows that the risks for humans, animals and the environment are minimal.

In recent years, many innovative plant breeding methods have been developed, but it is not always clear if they fall within the existing regulations on genetic modification. The Dutch government’s position is that this is determined at EU level.

**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.

The Dutch agricultural sector is world renowned and is a cornerstone of the Dutch economy, to which it contributes about 10% of its GDP. After the US, The Netherlands is the world’s second largest agricultural exporting country, with exports expected to top EUR80 billion in 2014. 12 out of 40 of the world’s largest agricultural and food companies have a major production base or research and development (R&D) centre in The Netherlands.

The acquisition of agricultural companies by foreign investors is not subject to special prior government approval. General approval rules apply equally to the acquisition of companies by foreign and domestic investors. This includes competition clearance (see Question 5).

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.

Although most farms are family owned or partnerships, the Dutch agricultural sector has a high percentage of co-operatives (*coöperaties*). In 2013, 68% of Dutch agricultural products were sold through co-operatives. In the last few decades, there has been strong consolidation between co-operatives, leading to only a few or even just one co-operative per sector. Several agricultural co-operatives operate internationally or are multinational, and belong to the world’s largest co-operatives.

A co-operative is a legal entity able to enter into agreements and own assets. Co-operatives have members rather than shareholders. The profits of the joint enterprise can be distributed to the members. The co-operative can be organised to limit or exclude the liability of the members for losses remaining after its dissolution.

Dutch co-operative law is flexible concerning internal governance and attracting equity from members or third parties. It has led to a large number of structures in the bye-laws of co-operatives to suit their strategic needs. This often includes a legal separation between the co-operative association and the co-operative firm. As the co-operative does not have a capital divided into shares it cannot be acquired as such. However its assets, and its individual member firms, are open to investment and can be acquired.
5. To what extent does competition (anti-trust) law apply to agriculture?
The agricultural sector must comply with provisions of European (and national) competition law. However, a specific competition regime has been in place for the agricultural sector since 1962 due to its special characteristics and products, and to ensure a fair standard of living for farmers.

Under EU Regulation 1803/2013, in effect as of 1 January 2014, producers’ organisations (POs) are recognised as playing an important role in strengthening the position of farmers in the agricultural production chain. Through producers’ organisations, farmers can combine their production efforts and co-operate in joint sales and other conducive activities. Essentially, all producers of agricultural products under the Regulation can pool their sales in order to negotiate higher prices. Normally, such joint sales would often violate competition rules, but for the agricultural sector an exemption is made for recognised producers’ organisations.

To be recognised, a producers’ organisation in:
- The dairy sector requires at least 150 members.
- The fruit and vegetables sector requires at least ten members with combined sales of at least EUR25 million.
- Other sectors requires at least 115 members.

Joint sales must be sold exclusively by the PO.

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.

Usage rights
Most agricultural land usage rights in The Netherlands are acquired by a specific agricultural lease (pacht) regulated by Book 7 of the Dutch Civil Code, and a distinction is made between establishing the lease and transferring the lease. Establishing the lease requires approval of the lease contract by the Agricultural Tenancies Authority (Grondkamer). The lessee can transfer the lease to direct family members (that is, spouse or (grand) children) without the consent of the lessor upon application to the agricultural tenancies division of the district court (Pachtkamer).

Ownership
Transfer of ownership of agricultural land is not specifically regulated under Dutch law. The general provisions on immovable property apply.

7. Are there any legal restrictions on the acquisition of agricultural land (or usage rights) by a foreign (or foreign invested) party?
In The Netherlands there are no restrictions on the acquisition of agricultural land (or usage rights) by a foreign party. However, an agricultural land purchaser must take into account provisions on zoning, land use and supervision.
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 are no compulsory tendering or prior approval procedures required for a sale and purchase of agricultural land.

9. Does the law and/or regulations prescribe minimum land purchase prices if the (local) government sells agricultural land?
Municipal authorities adopt land development policies. Each municipality can set its own prices but the prices should be in line with market standards.

10. Is there a maximum term applicable to the lease (or use) of agricultural land?
An agricultural lease agreement must in principle be concluded for a definite period of time, being 12 years for farms and homesteads and six years for separate land or buildings (Article 7:325(1), Civil Code).
This basic rule intends to offer the lessee a degree of protection, as the certainty of an agreement for a predetermined amount of time will allow the lessee to plan his/her business accordingly. Lease agreements for longer terms are allowed, but only if a clear termination date is included in the agreement (Article 7:325(2), Civil Code).

11. In which circumstances can the government authorities expropriate agricultural land?
The circumstances under which government authorities can expropriate (agricultural) land are regulated in the Expropriation Act (Onteigeningswet). Expropriation is only allowed if it serves the public interest and meets certain conditions. Additionally, the financial position of the landowner cannot be adversely affected as a result of the expropriation.

Tax and financing
12. Which taxes apply with respect to the sale and transfer of land ownership (or usage rights)?
Income tax
An agricultural enterprise can be run as an unincorporated personal enterprise or as a company. The determination of taxable income (for the unincorporated personal enterprise) or of taxable profit (for the company’s enterprise) is the same. The rate of taxation differs:
- An individual is subject to progressively increasing income tax with a maximum of 52% (but after various allowances and exemptions).
- A company is subject to corporate income tax at a rate of 25%.
Agricultural land is considered to be an asset that does not lose its value; it can therefore not be depreciated for tax purposes. If the land used in an agricultural enterprise is sold, there is an exemption for the gains realised (landbouwvrijstelling). No tax on the gain of the seller is due if the gain relates to an increase in value between the moment of purchase and the moment of sale, provided the agricultural use of the land is continued by the buyer.
Gains from land sales are taxed if they relate to an increase in the land value due to:

- The owner having taken measures such as levelling the land or installing drainage systems.
- A change in zoning.
- Agricultural land being converted into residential land.

A seller of agricultural land can defer the taxation of the gain under the reinvestment reserve facility (herinvesteringsreserve). This facility ensures that no tax is due on the gain, provided that the gain is re-invested in a similar asset within three years.

Lessees that buy the land from their lessors sometimes pay a price that is lower than the market value. This benefit (pachtersvoordeel) is taxed when the lessee later sells the land.

**Property transfer tax**

Property transfer tax of 6% of the sale price is payable by the buyer on the sale and transfer of immovable property other than residential property.

However, exemptions are available. In particular for agriculture, the sale and transfer of agricultural land is exempted from transfer tax if the land will continue to be used for agricultural purposes for a period of ten years following the transfer. If this period of ten years is not completed, the buyer will be liable for the property transfer tax.

In addition, there are exemptions:

- In cases of land exchange or land use projects, such as where agricultural areas are re-arranged between existing owners to increase the efficiency of land use.
- When an enterprise has to be moved due to government policy and the government purchases land for this reason.

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?**

The Netherlands does not have a policy to encourage foreign investment in agri/green-parks.

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

Mortgaging agricultural land/rights is no different from mortgaging other immovable property in The Netherlands. The mortgage is created by a notary (through a mortgage deed signed by the mortgagee and the mortgagor), who then registers the mortgage in the public land register.
CROP SEED BUSINESS
15. Which domestic laws and regulations regulate the crop seed industry and which domestic authorities/agencies supervise this sector?

Laws and regulations
The following domestic laws and regulations regulate the crop and seed industry:

- Pesticides and Biocides Act (Wet Gewasbeschermingsmiddelen en biociden).
- Plant Diseases Act 1951 (Plantenziektenwet).

The phytosanitary import and export requirements are directly based on the EU plant health regime, most notably the Plant Health Directive (Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community). Dutch implementing legislation includes the:

- Regulation on Import, Export and Transfer of Plants (Regeling invoer, uitvoer en verkeer van planten).

Regulatory authorities
This sector is regulated at national level by the:

- Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit) (NVWA). This partly operates under the Ministry of Health, Welfare and Sport (with regard to food and product safety issues) and the Ministry of Economic Affairs and the Directorate-General for Agriculture and Rural Development (with regard to phytosanitary issues, veterinary inspections and certification, and also partly food safety issues).
- Plant Protection Service section of the NVWA (Plantenziektenkundige Dienst).
- Board for the Authorisation of Pesticides and Biocides (College voor de toelating van gewasbeschermingsmiddelen en biociden).
- Dutch General Inspection Service for Agricultural Seed and Seed Potatoes (Nederlandse Algemene Keuringsdienst voor zaaizaad en pootgoed van landbouwgewassen) (NAK), which operates under the Ministry of Economic Affairs.
- Netherlands Inspection Service for Horticulture (Stichting Nederlandse Algemene Kwaliteitsdienst Tuinbouw) (NAK Tuinbouw), which operates under the Ministry of Economic Affairs.
- Flower Bulbs Inspection Service (Stichting Bloembollenkeuringsdienst) (BKD), which operates under the Ministry of Economic Affairs.

Import/export control measures
Imports. The national phytosanitary import requirements of The Netherlands are directly based on the plant health regime of the EU. The EU Plant Health Directive lists harmful organisms which are:

- Banned outright from introduction into the EU common market (Part A).
Banned from introduction into protected zones (as defined in the Directive) (Part B).

Importer are regularly inspected by the Plant Protection Service. Inspections should take place at a location approved by the Plant Protection Service, usually the place of delivery. The inspection criteria apply to both exit and entry inspections.

Additionally, certification and inspection is mandatory for some products. A phytosanitary certificate declares that the crop seeds are healthy and free of disease(s) and is issued by the authorisation body in the country of origin. In some cases, as part of the import requirements, the certificate should contain an additional declaration. The contents of the additional declaration depend on the origin and product.

Further, the Plant Health Directive requires the varieties to have a “plant passport”, in order to sell the crop seeds in the EU. A plant passport for agricultural (field) crops can be requested at the NAK. The plant passport for horticulture crops (fruit, vegetables, and ornamental varieties) is issued by the NAK Tuinbouw. A plant passport proves that the plant varieties comply with all relevant phytosanitary requirements applicable in the EU, and will be issued if the plant varieties:

- Comply with all the special requirements in Annex IV, Part A, Section II of the Plant Health Directive.

Exports. A separate phytosanitary export regime applies to crop seeds. The exact requirements depend on the country of destination and are listed in the Country Overview on the NVWA website.

If the country of destination requires an import licence, the NVWA can be requested to grant an instruction for import permit (instructie voor invoervergunning). The NVWA then assesses whether the applicant complies with the deviating norm requested by the country of destination.

Exit inspections are conducted on all plant varieties for which inspection is required (as determined in the Country Overview). A shipment that is to be inspected must be:

- Completely free of organisms specified in the Register of Quarantine Organisms (based on the Plant Health Directive).
- Completely free of organisms specified in the country information listed in the Country Overview.
- Compliant with all basic standards specified in the Overview Basic Standards (based on the Plant Health Directive).
- Practically free of other organisms that are not specified further.

However, not all crop seeds are subject to inspections and the certificate requirement. This depends on the product and the country of origin. Trade of crop seeds within the EU is exempt from border control if the seeds have a plant passport.
International Plant Protection Convention (IPPC) compliance
Since The Netherlands is a WTO member, restrictions on the import of plant materials need to be based on international standards or justified on a scientific basis under the WTO Agreement on Sanitary and Phytosanitary measures (see www.wto.org/english/tratop_e/sps_e/sps_e.htm). The international phytosanitary (plant health) standards are developed by the Secretariat of the International Plant Protection Convention (IPPC) (see www.ippc.int/standards).

The IPPC office has stated that in principle that The Netherlands implements the IPPC and its standards. For certain standards there are aspects that are not applicable, not workable in specific situations, or are still being implemented.

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
Import of plant varieties can only take place through an authorised importer registered with the NVWA Product Safety Authority.

Set up of research and development (R&D) centres and use of test plots of new crops
The Netherlands plant health regime does not have specific licence/permit requirements for laboratories.

Crop seed production
The Netherlands plant health regime does not have specific licence/permit requirements for crop seed producers, aside from the requirements for import and export (see Question 15) and trade/distribution of crop seeds (see below, Distribution of seeds or crops).

Commercial crop production
The Netherlands plant health regime does not have specific licence/permit requirements for commercial crop producers, aside from the requirements for import and export (see Question 15) and trade/distribution of crop seeds (see below, Distribution of seeds or crops).

Distribution of seeds or crops
Seed trade is subject to quality and variety control in accordance with EU regulations. The compliance framework consists mainly of:
- Plant variety recognition.
- Quality control.
• Phytosanitary control through the issue of the EU plant passport (see Question 15).

See also Question 20.

E-commerce is subject to the Electronic Commerce Directive (Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market), which has been implemented into Dutch law.

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

The plant passport (see Question 15) is an official label containing required information, and may also have an accompanying document. The following minimum information must be stated on the plant passport:

• Title of plant passport.
• EU-code of the relevant member state.
• Name or code of the inspection service that issued the plant passport.
• Registration number of the producer, distributor or importer.
• Individual tracking number for the consignment.
• Botanic name of the plants in the consignment.
• Number of plants in the consignment.

In addition, the European labelling requirements to market seeds and young plants apply. Different labelling requirements apply, depending on the type of seeds (for example, basic or certified seed). The official label (for basic seed) must include:

• “EC rules and standards”.
• Certification authority and member state, or their initials.
• Month and year of sealing, or month and year of the last official sampling for the purposes of certification.
• Lot reference number.
• Species stated at least in roman characters, under its botanical name (which can be in abridged form without the authors’ name) or common name, or both.
• Variety, stated at least in roman characters.
• Category.
• Country of production.
• Declared net or gross weight, or declared number of seeds.
• Where weight is indicated, and granulated pesticides, pelleting substances or other solid additives are used, the nature of the additive and also the approximate ratio between the weight of clusters or pure seeds and total weight.
• In case of varieties which are hybrids or inbred lines, specific rules also apply.
• Where at least germination has been re-tested, the words “re-tested” can be stated.

The minimum dimensions of the label are 110mm x 67 mm.
18. Are there any restrictions on foreign direct investment (FDI) in this sector?
There are no specific additional restrictions on FDI in this sector.

19. Summarise landmark or recent cases that have defined the law and practice in this sector.
In *Association Kokopelli v Graines Baumaux SAS* (*Case C-59/11*), the European Court of Justice (ECJ) reconfirmed that, in principle, only seeds of registered varieties can be traded in the EU. Seeds of “old varieties” (that is, varieties not or no longer listed in the official catalogues) can only be traded in certain circumstances.

**PLANT VARIETY RIGHTS (PVR)**

The Netherlands became a member of the UPOV Convention on 10 August 1968 and is party to the latest Act of 1991. The UPOV 1991 Act has been implemented in national law through the Seeds and Planting Materials Act 2005 (*Zaaizaad- en plantgoedwet 2005*) and further implementing decrees.

Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights establishes a system of EU PVR for its member states.

A clear distinction is made between:
- Granting a PVR.
- The right to place propagation material on the market (trading).

**PVR**
The Community PVR system exists in parallel with national systems. If a national PVR (*kwekersrecht*) is granted for a new variety, it is added to The Netherlands Register of Varieties (*Nederlands Rassenregister*).

Once the national right has been obtained, the applicant can apply for a Community PVR with the Community Plant Variety Office (CPVO) in Angers, France. If a Community PVR is granted and registered in the EU Common Catalogue, the national PVR will become “dormant” for the period the Community PVR is in force.

**Trading of new plant variety propagating material**
Trading of new plant varieties (agriculture crops, forestry, fruit and vegetables) may require prior admission to the National Plant Variety Register (*Nationale rassenverkeerslijst*). Registration on this list may be subject to a Value for Culture and Use (*Cultuur- en Gebruikswaarde Onderzoek*) test. This test is required for most agriculture crops, but not for fruit and vegetables.

Once a variety has been admitted to the National Plant Variety Register, the Dutch Plant Varieties Board will notify the EU and other member states and the propagation material can be freely traded in the EU. Horticulture plant varieties can be traded without registration in the National Plant Variety Register.
21. Briefly describe the registration process for PVR in your jurisdiction.
An application for a Dutch PVR should be filed at the Plant Varieties Board. The most important details to provide include:
- The (proposed) name of the plant variety.
- Characteristics of the plant variety.
- A detailed description of the distinctive characteristics.
   Additionally, the Plant Varieties Board can request the applicant to provide it with plant materials for testing and verification.
   The name of a plant variety is important, as propagating material of a registered plant variety can only be brought into the market under this name. For example:
- The proposed name will only be accepted by the Plant Varieties Board if it is suitable to identify the plant variety. In particular, it must be sufficiently different from names of other (existing) plant varieties registered in any of the UPOV member countries, and must not be confusingly similar to existing trade marks or trade names.
- The proposed plant variety name cannot have been registered as a trade mark.
- The applicant must waive its existing rights to the name for the same or similar goods in any of the UPOV member states.
For qualifying plant varieties bred or discovered and developed outside The Netherlands, a Dutch PVR will only be granted to a non-Dutch national (natural person or legal entity) if either:
- The non-Dutch national originates from a UPOV member state.
- The plant variety is eligible for protection in both the country where it has been bred and in The Netherlands.
   A priority right of one year is granted for applicants who have already applied for a PVR in one of the other UPOV member states.
   A successful application for a PVR in The Netherlands results in the registration and recording of the grant in The Netherlands Register of Varieties. The regular term of protection of a Dutch PVR is 25 years.

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
A PVR can be obtained for plant varieties that are all of the following:
- Novel.
- Distinct.
- Uniform.
- Stable.
   The Plant Variety Board’s experts establish whether these requirements are met through a preliminary examination, which can include testing.
**Novelty.** This is generally established if, at the time of the application, no propagation material or harvested material of the variety has been sold or otherwise made available to third parties, with or without the breeder’s permission, with the aim to exploit the variety. For sale or availability in The Netherlands, there is a grace period of one year before the application. In case of sale or availability outside The Netherlands, the grace period is four years (for trees or vines) or six years (for other varieties). Making a variety available to others solely for testing does not exclude novelty.

**Distinct.** A plant variety is distinct if it is clearly distinguishable from any other plant variety known at the time of the application. A plant variety can distinguish itself from other plant varieties in economic, functional or purely morphological respects. Differences in morphology may be in the height of the plant, thickness of the stem, shape, length or width of the leaf, diameter of the flower, and so on.

**Uniformity.** This means that the plants belonging to a variety do not differ from each other in respect of the distinctive characteristics, except where these differences are inherent to propagation of the particular plant variety.

**Stability.** This means that the plant variety after each (subsequent) propagation shows the same distinctive characteristics.

**Extent of the protection and restrictions on the rights of the holder**

A Dutch PVR gives its holder the exclusive right to:

- Produce, or further propagate, propagation material of the protected variety.
- Treat such propagation material for the benefit of propagation.
- Place such propagation material on the market.
- Export or import such propagation material.
- Keep such propagation material in stock for one of the above purposes.
- Have the above acts performed on its behalf.

Propagation material is defined under the applicable statute as not only including plants or plant parts that are destined for but also de facto used for the cultivation or propagation of crops, such as consumption material of potatoes, grain and pulses.

The following acts do not infringe the rights of the PVR right holder:

- Private acts that are not committed in a commercial capacity.
- Acts in the interest of scientific research.
- Acts that are considered a farmer’s privilege (see below, Farmer’s privilege).
- Acts carried out for the breeding of other varieties (breeder’s exemption).

**Farmer’s privilege**

A farmer’s privilege is the right of a grower to use harvested materials within the premises of their company for propagation purposes. This privilege only applies to crops in sectors in which the use of own seeds and seed materials is customary (for example, grain and potato crops). In this respect, the grower must:

- Inform the PVR holder of the details of his company and the use of the seeds and seed materials.
• Pay a reasonable licence fee for the use of the harvested materials. In general, 60% of the licence fee that is due in trade for use of that variety is considered reasonable.

A breeder’s exemption allows a third party to use the protected variety to breed a new variety, without paying a royalty fee. This breeder’s exemption is not an infringement of the rights of the PVR holder.

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

A holder of a Dutch PVR can enforce its exclusive rights (see Question 22) against any person who is infringing the PVR, or any person assisting the infringing acts by offering services used to infringe the PVR.

The holder can also enforce its rights against harvested materials of a variety, plants and plant materials acquired by use of propagation material without permission, unless the PVR holder could have reasonably enforced his rights at an earlier stage in relation to the propagation material. This right extends to products directly derived from the harvested materials.

The holder also has an action against varieties derived from its protected plant variety, except when the protected plant variety is in fact a derivation. A variety (for example, B) is considered to be derived from another variety (for example, A) if any one of the following applies:

- B is mainly derived from A, or from another variety derived from A.
- Based on the test of distinctiveness, B is clearly distinct from A.
- B is similar to A in terms of essential characteristics arising from the genotype or combination of genotypes of A, except for derivations resulting from acts of derivation.

The exclusive rights of the PVR holder extend to a variety:

- Derived from the protected variety that is not clearly distinct from the protected variety.
- For which, each time it is bred, the protected variety is required.

If an applicant is not resident or does not have a registered office in the EU, he must obtain domicile in The Netherlands (for example, at the address of a legal representative).

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

The Hague Court of Appeal has ruled that, under Articles 57 and 1(g) of the Seeds and Planting Materials Act 2005, that no person can offer, sell, supply, transfer, and export propagation material of a protected plant variety, except the PVR holder and those acting with the holder’s permission (*Europe Fruit Trade v Plant Research International*, 31 August 2010).

**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?**

Although not banned, commercial cultivation of GM crops does not take place in The Netherlands. The genetic modification of plants is generally supported by the Dutch government, as it enables more efficient creation of improved plant varieties. However, it is only permitted if careful scientific research shows that the possible risks to humans, animals, and the environment are negligible.

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.

Domestic laws regulating GM crops implement EU GM Organisms (GMO) legislation, most notably EU Directives:

- 2002/55/EC on the marketing of vegetable seed.

Dutch implementing legislation includes the:

- GMO (Environmental Management) Decree (Besluit genetisch gemodificeerde organismen Milieubeheer).
- GMO Regulation (Regeling genetisch gemodificeerde organismen).

A permit is required for the following activities involving GM crops:

- Experiments in containment (contained use): these include experiments in a laboratory or greenhouse.
- Experiments involving deliberate release into the environment, for instance field tests of GM crops.
- Cultivation, production, import or export of new GM crops (market authorisations).

Applications for a permit are handled by the GMO Bureau (Bureau Genetisch Gemodificeerde Organismen), a department of the Ministry of Infrastructure and Environment (MIE). Applications for market authorisations take longest, as these are reviewed by the GMO Bureau, the European Commission, and all other EU member states.

The applicant must conduct an environment risk analysis before applying for any of these permits, focusing on the risks of the proposed use for humans and the environment. This risk analysis must include:

- Possible undesired side effects.
• The risk that these side effects will occur.
• Measures proposed to decrease this risk.

MIE will check the risk analysis and will only grant a permit if the identified risks are negligible. MIE is advised by the Committee on Genetic Modification (Commissie Genetische Modificatie) (Cogem).

Applications for large-scale contained use or deliberate release permits are partially public, as decisions are only made after a special administrative law preparatory procedure has been completed.

Applications for market authorisations at MIE follow European procedures. The European Commission ultimately determines whether a GM crop can be introduced into the European market. After receipt and a first review of the application, MIE will therefore forward it to the European Commission. The application will then be sent to all other EU member states for consultation. The European Food Safety Authority (EFSA) conducts the risk assessment of a particular GMO crop. For The Netherlands, additional risk assessments are done by Cogem and RIKILT, part of the University of Wageningen.

The Human Environment Inspectorate (Inspectie voor de Leefomgeving) continuously monitors permit holders. If new facts occur that could have important consequences for the risks involved with the permitted use of GM crops, MIE can order the permit holder to temporarily or permanently cease certain activities, or change the permit requirements.

Currently no GM crops are cultivated in The Netherlands. However, if in future a farmer wishes to grow GM crops that have been granted (EU) market authorisation, he should report to the National Service for the Implementation of Regulations (Dienst Regelingen) of the Ministry of Economic Affairs for registration in the national GM crop registry.

27. Which safety evaluations are legally required before GM crop commercial market entry? How are GM crops regulated?
See Question 26.

28. Describe the GM crop test plot regulations and requirements.
See Question 26.

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 Question 26.

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.

The permit holder for contained use (see Question 26) must label all GM crops and products derived from them that it makes available to others. This label must be clearly visible and must indicate that the crops or products are GM.
Based on the European regulations, food products in general that are GM or contain (above 0.9%) GM ingredients must be clearly labelled.

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

The ECJ has ruled that pollen derived from GM corn falls outside the meaning of GMO, as it has lost its ability to reproduce and cannot transfer the genetic material it contains (Bablok and others v Freistaat Bayern, Case C-442/09). However, even where the pollen cannot transfer the genetic material, honey or other food supplements containing the pollen are foodstuffs containing ingredients produced from GMOs, and accordingly require EU authorisation (see Question 26) before being put on the market.

The EU legislature overturned this ruling in Directive 2014/63, clarifying that honey is a single ingredient product and pollen is not an ingredient.

GENE RIGHTS

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

Imports

Import control measures for animals and products of animal origin from outside the EU require:

- Document control, identity checks, and material and physical checks.
- A health certificate, from the country of origin by the competent authority, to accompany all animal imports.
- A declaration to the external border inspection post (BIP).

For pure bred animals and hybrid pigs from outside the EU brought into The Netherlands, the animals must:

- Be accompanied by a pedigree and zoo technical certificate.
- Have been entered or registered in a herd book in the country of origin.
- Be accompanied by evidence that they are going to be entered or registered in an EU herd book.

Importing genetic resources into The Netherlands requires a health certificate. Several countries are authorised to export genetic resources of bovine, porcine, ovine and caprine species into the EU. A health certificate must also accompany imports of semen, ova, and embryos.

Exports

The export of animals is allowed if, among others, it complies with requirements relating to identification of animals, animal health condition, certification, and transportation.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) lays down the lists of species that are protected and cannot be imported or exported. The Netherlands is party to CITES. In addition, the Animal and Plant Species (Flora and Fauna Act) Designation Regulations (Besluit aanwijzing dier-en plantensoorten Flora en fauna wet) provides a list of protected animal species that cannot be imported or exported. The Netherlands Food and Consumer Product Safety Authority
(NVWA) has established a list with temporary measures against countries where the risk of zoonotic transmission of pathogens exists. Importing these animals is restricted accordingly.

**World Animal Health Organisation (IOE) compliance**
Since The Netherlands is a WTO member, restrictions on the import of animals and genetic resources need to be based on international standards, or justified on a scientific basis under the WTO Agreement on Sanitary and Phytosanitary Measures. The international sanitary standards for animals are developed by the IOE (www.oie.int/). For animals these are in particular the Terrestrial Animal Health Code and The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

There is currently no information available on The Netherlands’ adoption of IOE standards.

33. **Does the law of your jurisdiction allow for patentability of livestock genes on the grounds of isolating and purifying them?**
Article 2A(2) of the Dutch Patent Act 1995 (Rijksoctrooiwet 1995) only allows the patentability of biological material on the ground of isolating and purifying it if a technical process is involved.

Patent protection of biological material with specific characteristics extends to any biological material derived from it through propagation or multiplication in an identical or divergent form with those same characteristics.

The following are not patentable:

- Inventions the commercial exploitation of which is contrary to public policy or public morality.
- Whole plant or animal varieties.
- Essential biological processes.

34. **Which legal instruments are available to protect animal breeding know-how and a resulting animal nucleus?**
Microbial or other technical processes used to derive biological materials, or products resulting from them, are patentable.

Inventions concerning plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Currently there is no exclusive right to protect general know-how or business secrets.

35. **Are there legal or practical restrictions on the introduction of new breeds/species, the breeding of certain animal species or certain breeding practices?**
The Ministry of Economic Affairs has the authority to prohibit certain animal species or breeding practices. Currently such restrictions only relate to the Pit bull terrier dog.

A permit is required to both:
• Adjust the genetic material of an animal beyond the natural barrier of propagation and recombination.
• Apply biotechnological processes on an animal or embryo. Breeding techniques can only be applied as long as the animal will not unnecessarily suffer pain, injury, stress or any other discomfort. Breeding practices like cloning and electro-ejaculation are prohibited in The Netherlands. Embryo transplantation methods are prohibited for sheep.

36. Summarise landmark or recent cases that have defined the law and practice in this sector.
The ECJ has ruled that patent protection for a DNA sequence is limited to where the genetic information is currently performing the functions described in the patent (Case C-428/08 Monsanto Technology LLC v Cefetra BV and Argentina). This is the case for the protection of both the genetic information and the materials in which it is contained.

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.
Legislation
The most important EU legislation in the area of food safety is Regulation (EC) 178/2002 on the general principles and requirements of food law and establishing the European Food Safety Authority (General Food Law). The General Food Law is the foundation of European food safety law.

One of the basic principles of the General Food Law is the responsibility for food safety placed on the “food and feed operators” (including agricultural companies), as they are in the best position in the production chain to ensure compliance with all relevant safety regulations.

In addition to the General Food Law, there is a large and diverse body of European legislation on various topics. Some legislation prescribes general rules for all products (horizontal legislation). The scope of other legislation is limited to specific products or product groups (vertical legislation).

Likewise, Dutch food safety laws are a tapestry of acts of parliament, local regulations, ministerial orders, and regulations by semi-public trade organisations. The basis is the Commodities Act (Warenwet), which acts as a framework law.

Regulatory authorities
Compliance and enforcement of product quality/food safety regulations in all parts of the production chain (for example, imposing fines) is largely the responsibility of the Netherlands Food and Consumer Product Safety Authority (NVWA).
Food and Agriculture Organisation (FAO) compliance
As The Netherlands is a WTO member, restrictions on the import of food need to be based on international standards or justified on a scientific basis under the WTO Agreement on Sanitary and Phytosanitary measures. The international standards for food safety are set out in the Codex Alimentarius of the FAO (www.codexalimentarius.org/about-codex/en/) (Codex Standards) and they apply in The Netherlands. The delegate’s office was not able to provide precise figures on the adoption of Codex Standards in the EU, or an overview of the implementation of Codex Standards into EU legislation.

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.


The basic principle of the product liability law is that a producer bears strict liability (risicoaansprakelijkheid) for a defective product, as the producer is able to take measures to prevent or minimise the chances of a product being defective and causing damage. For liability to arise, the consumer must prove:
• The existence of damage.
• The damage was caused by the product.
• The product is defective.

If the consumer succeeds, the producer’s liability is established. This liability is mandatory and cannot be contractually excluded by the producer. The term producer refers to the important links in the production chain. These include:
• Producers of end products.
• Producers of raw materials or components.
• All others that present themselves as producers.

Without prejudice to the liability of the producer, any person that imports a product into the EU for sale, hire, lease, or any form of distribution is equated with the producer, and bears the same strict liability as the producer.

If the original producer cannot be identified, liability passes to the supplier of the defective product. However, this liability can be avoided if the supplier within a reasonable period of time reveals the identity of the producer (which should be possible if traceability requirements have been met). There is no product liability for the supplier based on negligence.

As with product liability, in a tort action a consumer must prove that damage has been suffered, which was caused by an unlawful action (the defective product) of the producer.
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?**

The major defences regarding the Product Liability Directive (including liability for agricultural products) include:

- The producer did not put the product into circulation on the market.
- The defect which caused the damage did not exist at the time when the product was put into circulation on the market.
- The producer did not manufacture the product for sale or distribution for an economic purpose, or the producer did not manufacture or distribute the product in his professional practice or business.
- The defect is due to compliance with mandatory regulations of the authorities.
- The defect could not have been discovered at the time when the producer put the product into circulation, due to the state of scientific and technical knowledge at that time.
- In the case of a producer of an ingredient or component, the defect is attributable to the design of the product in which the component or ingredient has been fitted, or the instructions given by the manufacturer of the product.

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?**

Damage that is eligible for compensation under the Product Liability Directive is limited to:

- Death and bodily harm (for instance medical costs).
- Damage to personal items for daily use.

Any other damage must be claimed through tort actions, or actions based on breach of contract.

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

European and Dutch case law has further detailed the major defences for producers/suppliers (see Question 39).

The ECJ has noted that the Product Liability Directive does not define putting “into circulation”. The ECJ has stated that a product must be considered as having been put into circulation when it leaves the production process operated by the producer, and enters a marketing process in the form in which it is offered to the public to be used or consumed (Judgment of 9 January 2006, Case C-127/04).

The Supreme Court of the Netherlands (HR 24 December 1993, NJ 1994, 214 Leebeek/ Vrumona) has ruled that if a party can prove that a product was used in a normal manner, but an unexpected event causing damage still occurred, the product is assumed to be defective. The Supreme Court states that to avoid liability, the producer must prove all of the following:
The defect was not present before the marketing of the product.
The defect could not have been discovered earlier.
The product was not used for the purpose for which it was intended.

The ECJ has ruled that Article 7(c) of the Product Liability Directive is to be interpreted so that the exemption from liability, where an activity has no economic or business purpose, does not extend to defective products manufactured and used for specific medical services financed entirely from public funds for which the patient is not required to pay any consideration (Veedfald, Case C-203/99).

According to the Dutch Supreme Court, having a trade permit from the appropriate authorities cannot absolve a producer from civil liability (HR 30 June 1989, NJ 1990, 652 Halcion).

The ECJ has ruled that invoking the state of scientific knowledge defence in the Product Liability Directive should be considered an objective test, based on the state of scientific and technical knowledge available at that time, and not reliant on the producer's own experience in his field (judgment of 29 May 1997, Case 300/95).

A fabric producer has argued among other things that a producer of semi-finished goods is not liable for the end product. However, the Dutch Supreme Court has ruled that a producer is generally required to take measures to ensure that products put in circulation will not cause damage, and that there is no inherent difference between producers of semi-finished products and producers of end products with regard to their liability to consumers (HR 22 October 199, NJ 2000, 159 Koolhaas c.s./Rockwool Lapinus).

ONLINE RESOURCES
ECJ case law
W http://curia.europa.eu/juris/recherche.jsf
Description. ECJ case law is the official EU website to publish cases of the European Court of Justice.
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