Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

About this Guide

This survey covers a series of questions on transgenics, pesticides, plaguicides, rodenticides and insecticides.

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Columbia

Prepared by Lex Mundi member firm **Brigard & Urrutia**

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes. Permission from the Colombian government is required for planting, commercializing, importing and exporting GMOs and Live Modified Organisms.

If the product is meant for agricultural or veterinary purposes, permission from the Colombian Agriculture Institute (the "ICA") is required. On the other hand, if the product is for human consumption, the competent authority is the National Institute of Food and Drug Monitoring (the "INVIMA").

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Yes. The distributors must be legally constituted in Colombia in order to import or sell GMOs.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

In Colombia there are technical committees specialized in biosafety that are responsible for GMOs regulations: i) The Technical Committee for GMOs used for human health and food; and ii) The Technical Committee for GMOs used for agriculture, livestock animals, fishing, agribusiness and/or forestry.

The technical committees are integrated by, among others, the Ministry of Agriculture and Rural Development, the Ministry of Health, the Ministry of Environment and Sustainable Development, and a representative from the ICA.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Only performance and safety studies carried out locally are accepted. Additionally, national authorities may require *in-situ* evaluations in order to verify that storage conditions and handling capabilities meet applicable requirements.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

Yes. Permission granted by local authorities provides for the consumption of GMOs by human beings. Nevertheless, packages containing food derived from GMOs have to include labels informing this circumstance.

2. Peticides, insecticides and rodenticides

2.1 Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?

Yes. Once local presence has been established, an application before the Ministry of Agriculture and Rural Development has to be filed. After the Ministry of Agriculture and Rural Development has classified the relevant products, examined the studies submitted and assessed the impact the products may have, a subsequent application will then have to be filed before the ICA –if the product is meant for agricultural or veterinary purposes– or before the INVIMA –if it is for domestic purposes–.

2.2 Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?

Yes. The distributors must be legally constituted in Colombia in order to import and sold pesticides, insecticides, rodenticides and/or their consumables.

2.3 Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?

There are several authorities involved in the determination of the environmental health and safety of pesticides, insecticides and rodenticides, each assessing different aspects, such as:

The Ministry of Agriculture and Rural Development: through the ICA authorizes:

- the imports and exports of pesticides, insecticides and rodenticides;
- the quality of the products and their performance on the crops where they were used.

The Ministry of Health: through the INVIMA determines the impact that pesticides, insecticides and rodenticides may have on human health.

The Ministry of Environment and Sustainable Development: focuses on the impact of pesticides, insecticides and rodenticides on the environment.

2.4 Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?

Only performance and/or environmental safety studies carried out locally are accepted. Additionally, national authorities may require *in-situ* evaluations in order to for verify that storage conditions and handling capabilities meet applicable requirements.

3. Herbicides

3.1 Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?

Yes. A prescription by an agronomist, who is a qualified professional, is required only for determined products that are highly risky and/or are manufactured with inputs controlled by the Colombian National Directorate of Narcotic Drugs.

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Cyprus

Prepared by Lex Mundi member firm **Dr. K. Chrysostomides & Co LLC**

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

No GMOs can be planted, commercialized, imported or exported without permission from the competent authorities. Such permission may be subject to specific conditions which must be complied with by the Applicant, otherwise the permission may be revoked. Only EU authorised GMOs can be planted, imported and commercialized.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

There is no statutory provision requiring local presence for the registered distributor of GMOs sought to be imported and sold in Cyprus.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The competent Authorities involved in the determination of the regulations involving GMOs are (a) the Department for the Environment of the Ministry of Agriculture, Natural Resources and Environment and (b) The Department of Agriculture of the Ministry of Agriculture, Natural Resources and Environment (c) the Ministry of Health (relating to food products) and more specifically the General Laboratory and the Health Services, the Institute of Agricultural Research. A Scientific Committee has been set up by Law, consisting of the aforementioned departments. This Scientific Committee is a member of the Department of Labour Inspection; the Federation of Ecological and Environmental Associations; and the Committee on Bioethics.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Each person applying for permission to import GMOs is obliged by law to present an evaluation of the environmental risks. Such evaluation must be conducted by an organization or individual, whose evaluations have already been accepted by a member state of the European Union. If the product has been EU authorised no further action is required. However there are further special provisions that need to be followed as, for example, the distance between plantations that included GMOs with plantation with non - GMO products.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

All products that have been imported need to be EU Authorised. Permission is granted for food containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable and there is no need to label it for containing GMOs. Specific regulations apply to such products, in line with EU legislation. If food contains a proportion higher than 0.9% then it can still be granted permission but what needs to be done is to be labeled as a product consisting GMOs.

In addition, the relevant competent authorities conduct regular inspections and audit controls of growers, manufacturers and importers to make sure that the above percentages are accurate.

2. Peticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Foreign companies do not need to obtain any governmental permission in order to be able to carry out such activities. The products, however, do need to be registered (with the exception of products intended solely for re-export to 3rd countries, in which case there is only a requirement to notify the authorities accordingly).

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

The Applicant for registration of such products must have a permanent seat in the EU. If the Applicant does not reside in Cyprus or another EU member state, the application needs to be signed by an agent or distributor in Cyprus or another EU member state, who undertakes the Registrant's obligations.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The environmental health and safety of pesticides, insecticides, rodenticides is assured through the registration procedure – this means that a registered product is considered safe for the environment and health if it is used according to its registration terms (label instructions).

The competent authority involved in the registration of the products is the Plant Protection Products and Biocide Board (members of this Board are officers of the Department of Agriculture, the State General Laboratory, the Pharmaceutical Services, the Department of Labour Inspection, the Council of Agronomists).

The competent authority involved in the official controls for the correct use of these products (according to label instructions), is the Department of Agriculture.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

The authorisation of these products is granted in Cyprus after the mutual recognition of the results of the evaluation of studies, carried out in other southern member states. If these studies are in accordance with the provisions of Regulation (EC) no 1107/2009, then they are accepted and evaluated accordingly by that member state.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No prescription by a qualified professional is required in the herbicides commercialization.

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Ireland

Prepared by Lex Mundi member firm Arthur Cox

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes. The contained use or deliberate release of GMOs requires notification and/or consent from the Environmental Protection Agency ("EPA") under laws implementing Directive 2001/18/EC.

As for genetically modified plant varieties/seeds, authorisation from the EPA is required under laws implementing Directive 98/95/EC.

The export of GMOs requires consent from the authority of the import country prior to the export.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Yes, within the European Community.

When marketing a GMO product, part of the information to be provided is the full name and address of the person established in the Community who is responsible for seeking the necessary authorisation, whether importer, manufacturer or distributor.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The EPA is responsible for contained use, deliberate release and transboundary movement.
The Food Safety Authority of Ireland ("FSAI") is responsible for monitoring GMO foods.
The Irish Medicines Board is responsible for GMOs in medicinal and veterinary products.
The Department of Enterprise, Trade and Employment is responsible for biological agents at work and the transport of certain GMOs.
The Department of Agriculture, Food and the Marine ("DAFM") is responsible for marketing of GMO plant varieties.

The Department of Health is responsible for food safety aspects of GMOs and products derived from them.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Studies from the country of origin may be relied upon. A person who submits a notification for consent pursuant to Directive 2001/18/EC, implemented by SI 500/2003, to market a GMO shall carry out an environmental risk assessment pursuant to the legislation. Part of this assessment is an analysis of the cumulative long-term effects relevant to the release and the placing on the market. Cumulative long-term effects means the accumulated impact of consents on human health and the environment.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

To market a GMO food and make it available for consumption, the applicant will undergo a procedure outlined in EC Regulation 1829/2003. The application is sent to the FSAI. The FSAI informs the European Food Safety Authority (the "Authority"). The application includes a technical dossier and monitoring plan. The Authority will then form a reasoned opinion on whether or not to authorise the food.

GMO foods must also comply with labelling and traceability requirements.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Yes. At present, the consent of the Pesticide Control Service ("PCS") of the DAFM is required for the placing on the market of any biocide or plant protection product under laws implementing Directive 98/8/EC and Regulation EC (No 1107/2009). Biocides include pest control products. Plant protection products include substances used to influence the life process of plants, other than as a nutrient.

Exporters (and importers) of biocides shall provide annual returns to the PCS. Exporters of pesticides shall also notify the PCS.

The Biocidal Product Regulation (EC Regulation 528/2012) will take effect on 1 September 2013 and provides that biocidal products which contain only approved active substances will have access to the EU market through a single authorisation by a Member State so there is no need for mutual recognition. The authorisation holder must notify each Member State prior to placing the biocidal product on its market. The PCS will remain the competent authority for the obtaining of an authorisation in this jurisdiction.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Yes, within the European Community.

An applicant for authorisation of a plant protection product shall be established in a Member State.

An applicant for authorisation or registration of a biocidal product shall have a business premises in a Member State.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The PCS is responsible for both plant protection products and biocidal products.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

Studies from the country of origin may be relied upon. For biocides, a risk assessment of the active substances present is required, as per Directive 98/8/EC. Where a quantitative risk assessment cannot be made a qualitative assessment is produced.

Plant protection products require tests to be conducted for the purposes of compiling the necessary dossiers to be submitted as part of the authorisation procedure, as per Regulation EC (No. 1107/2009).

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No. There is no specific prescription required by a qualified professional in the commercialisation of herbicides.

Herbicides are plant protection products. The same authorisation process as pesticides applies.

Chemists, toxicologists, eco-toxicologists etc. are employed by the PCS as part of the commercialisation and authorisation process.

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Jamaica

Prepared by Lex Mundi member firm Myers, Fletcher & Gordon

1. GMOs

1.1 Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?

Yes. Approval must be obtained from the Ministry of Agriculture and under the Natural Resources Conservation and Plant Quarantine Acts.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Yes, within the European Community.

When marketing a GMO product, part of the information to be provided is the full name and address of the person established in the Community who is responsible for seeking the necessary authorisation, whether importer, manufacturer or distributor.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

Please see response to question one

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Local studies must be performed.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

The import permissions relate to importation for growth or importation for sale.

2. **Peticides, insecticides and rodenticides**

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Yes. The Pesticides Act prohibits any person from manufacturing, importing, advertising or selling any pesticides unless the pesticide is registered with the Pesticides Control

Authority. A licence is required for the manufacture and importation, whereas sellers and their premises must be registered.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Yes, local presence is required. The Pesticides Control Authority also requires that the distributor be a Jamaican company or a Jamaican national.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The Pesticides Control Authority established under the Pesticides Control Act.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

No local studies or environmental safety assessments are required. However, the Pesticides Control Authority reserves the right to request any additional information when assessing an application to register a pesticide.

3. **Herbicides**

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No. A prescription by a qualified professional is not required for herbicides commercialization.

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Mexico

Prepared by Lex Mundi member firm Basham, Ringe y Correa, S.C.

1. GMOs

1.1 Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?

A permission to liberate plant, import, export, commercialize and/or distribute Genetically Modified or Engineered Products/Organisms (GMO's) in Mexico is required.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Only entities domiciliated in the Mexican territory can file an application to obtain a special permission in relation to any activities associated to GMO's. This means that local presence is a mandatory condition to be considered as a duly registered company for any activity regarding such products.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

a) Environment and Natural Resources Ministry ("SEMARNAT").
b) Food and Agriculture Ministry ("SAGARPA").
c) Health Ministry ("Secretaría de Salud").
d) Inter-Ministries Commission for Biosecurity of Genetically Modified Organisms ("CIBIOGEM").
e) Federal Commission Against Health Risks ("COFEPRIS")
f) National Registry for Biosecurity of Genetically Modified Organisms (RNBGMO's).
g) National Service of Agroalimentary Safety ("SENASICA").

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Local performance and/or environmental safety studies are required to obtain an authorization regarding any activity with GMO's; however safety studies carried out in the country of origin where it has already been certified are accepted.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

A special permission for GMO's consumption by human beings can be obtained. For this purposes, there are special rules that apply to these types of products regarding labelling, packaging, and identification. The rules are included in the Law for Biosecurity of Genetically Modified Organisms, and in the applicable Mexican Official Standards.

2. **Pesticides, insecticides and rodenticides**

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

A special permission needs to be obtained before the competent authorities, in order to import, export, commercialize and/or distribute pesticides, insecticides, rodenticides and/or their consumables.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Only entities domiciled in the Mexican territory with specific manufacturing or warehousing facilities can file a petition to obtain an authorization regarding any activity related to pesticides, insecticides, rodenticides and/or their consumables. This means, local presence is a necessary condition to be considered as a duly registered company for any activity regarding such products.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

a) Food and Agriculture Ministry ("SAGARPA").
b) Health Ministry. (Secretaría de Salud").
c) Environment and Natural Resources Ministry. ("SEMARNAT").
d) Federal Commission Against Health Risks ("COFEPRIS").
e) Inter-Ministries Commission for the Control of Plaguicides, Fertilizers, and Dangerous and/or Toxic Substances ("CICOPLAFEST")
f) Registry for Plaguicides, Fertilizers, and Dangerous and/or Toxic Substances

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

Local performance and/or environmental safety studies are required to obtain an authorization to market pesticides, plaguicides, rodenticides and/or insecticides are required; however these safety studies can be carried out in the country of origin.

3. **Herbicides**

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No. However, there are special rules that apply to this type of products regarding labelling, packaging, identification, and ingredients that can be used for its production.

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Netherlands

Prepared by Lex Mundi member firm **Houthoff Buruma**

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes, all “releases” of GMOs require prior authorisation. The authorising body and extent of authorisation depends on the purpose and territory of the release:

Releases into the environment for marketing (including importation) require authorisation from a territorial competent authority (TCA - see question 3) under Part C of Directive 2001/18/EC (the Directive)

Releases into the environment for purposes other than marketing require authorisation from a TCA under Part B of the Directive

Exports of GMOs require prior authorisation from the first country of import

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

The obligations in EC Regulation 1946/2003 fall on the exporter. The local presence requirements are that there must be a person established in the EC who is responsible for placing the GMO on the market, whether it be the manufacturer, importer or distributor.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The Bureau Genetic Modified Organisms (Bureau GGO) authorises
GMO releases (Territorial Competent Authority).
European Food Safety Authority (EFSA) regulates releases for marketing of GMOs for consumption.
Ministry of Infrastructure and Environment (I&M) reviews the assessment of risks to humans and the environment.
The Ministry of Health, Welfare and Sport (VWS) reviews the evaluation of food safety.
Ministry of Economic Affairs, Agriculture and Innovation (EL&I) reviews the safety of animal feeds.
The Netherlands Commission on Genetic (COGEM) advises the Government on environmental risks associated with European licence applications for GMOs.

The RIKILT Institute of Food Safety carries out a quick scan of the risks.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Applications for consent to release GMOs must include an environmental risk assessment and data from any previous release by the applicant.

Authorizations to market a GMO from the Netherlands are valid throughout the EU. A TCA may prohibit a previously authorized release in the EU only on the basis of new evidence found after that consent; which affects the environmental risk assessment on which the consent was based, or where the existing information is reassessed in light of additional scientific information.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

The authorisations detailed above do not authorize release of GMOs for consumption. Such consents are assessed and authorised by EFSA in accordance with EC Regulation 1829/2003 following application to the FSA. Consents are valid throughout the EU for 10 years.

To be authorised, the GMO must not:
Present a risk to health,
Mislead consumers,
Be of less nutritional value than the food(s) it is intended to replace.
Food products containing GMOs must also comply with additional labelling and traceability requirements.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is as independent administrative body responsible for the authorisation of pesticides, insecticides and rodenticides.

Authorisation is regulated by the Plant Protection Products and Biocidal Products Act (Wgb) which is an implementation of directive 91/414/EEG and the Biocides Directive 98/8/EG. From the 1th of September 2013 onwards Directive 98/8/EG will be replaced by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. The new Biocidal Products Regulation (BPR), when implemented, will have direct effect in the Dutch legislation. Wherever the new BPR is of importance, it will be referred to in this note.

Plant protection products (insecticides, herbicides and fungicides) are not to be placed on the market without first having been authorised by the Ctgb. A plant protection product may only be authorized if its active substance(s) have been approved as basic substance(s) under article 23 of Regulation (EG) 1107/2009.

Regarding biocides the law regulates the authorization for products containing an existing EU authorised active substance, included in Annex I of Directive 91/414/EEC ('the Directive') or products containing new active substances marketed in EEA since 26/07/93.

Under the new BPR this authorisation mechanism is maintained. The approval of active substances takes place at Union level and the authorisation of the biocidal products at Member State level. Authorisation can be extended by mutual recognition. The new BPR allows authorisation at Union level. If approved, the biocidal product may be placed on the market in the entire Union. There will be no obligation to obtain a national authorisation followed by mutual recognition

The importation, exportation, transportation and production of pesticides which have not been authorized is allowed in the Netherlands if the they are intended for another EU member state where they are allowed.

The importation, exportation and transportation of biocides which have not been authorized is allowed in the Netherlands if the they are intended for another EU member state where they are allowed.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

For professional use of pesticides and biocides a valid proof of competence is required. When selling these pesticides and/or biocides a distributor must make sure that a sufficient amount of his personnel is in possession of such a proof of competence.

A valid proof of competence (or license) for the professional use of pesticides is granted by *'Bureau Erkenning'*. A valid proof of competence for the professional use of biocides is granted by *'Stichting Examen en Certificeringsinstituut Plaagdierpreventie'* and *'Stichting Certificeringsinstituut Plaagdierbeheersing, Mileu en Volksgezondheid'*

A valid proof of competence is not required if the pesticide or biocide has been classified by the Ctgb for non-professional, private use.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is as independent administrative body responsible for the authorisation of pesticides, insecticides and rodenticides.

Netherlands Food and Consumer Product Safety Authority (NVWA) monitors and enforces the rules concerning pesticides, together with the Inspectorate for Environment and Transport (ILT), Inspectorate SZW and the Regional Water Authorities.

Inspectorate for Environment and Transport (ILT) monitors and enforces the rules concerning biocides, together with the Netherlands Food and Consumer Product Safety Authority (NVWA), Inspectorate SZW and the Regional Water Authorities.

European Food Safety Authority (EFSA) evaluates the scientific risk assessment and reports to the European Commission.

The European Chemicals Agency (ECHA) will be responsible for the assessment of applications for the Union authorisation of biocidal products (under the new BPR)

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

A manufacturer wishing to place a pesticide on the market in the Netherlands must apply for authorisation to the Ctgb while submitting data about effectiveness, physical-chemical properties of the product and the possible risks for humans, animals and environment. The Ctgb then assesses whether the dossier is complete and whether the submitted studies meet the quality criteria. It is not required to redo previous studies. If the pesticides contains a new substance application authorization will take place at EEA level.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

Herbicides are subject to the rules concerning pesticides. Hence no proof of competence is required if the herbicide has been classified as for non-professional, private use. If it is classified as for professional use a proof of competence is required, which is granted by the *'Bureau Erkenning'*.

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Lex Mundi World Ready

Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

Pakistan

Prepared by Lex Mundi member firm RIAALAW

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

According to rule 11 of the Pakistan Biosafety Rules, 2005 ("PBR") a license is required from the Pakistan Environmental Protection Agency ("EPA") for importing, exporting, selling, purchasing or trading living microorganisms, substances or cells or any product thereof, for any purpose. Rule 21 of the PBR states that genetically engineered microorganisms, cells or products thereof cannot be imported, sold or used except with the prior approval of the National Biosafety Committee.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

None.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

None. The Environmental Protection Agency (section 6 of the Pakistan Environmental Protection Act of 1997), the Institutional Biosafety Committee (rule 9 of the PBR), the National Biosafety Committee (rule 5 of the PBR) and the Technical Advisory Committee (rule 7 of the PBR).

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

There is no requirement that laboratory tests and field trials for the GMO sought to be planted, commercialized, imported or exported be conducted locally.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

There is no restriction on the commercialization of genetically modified products for human consumption once license under rule 11 of the PBR with respect to the same has

been secured. Further, there are no specific rules governing the consumption of GMO's by human beings.

2. Pesticides, insecticides and rodenticides

2.1 Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?

Any person intending to import, manufacture, formulate, sell, offer for sale, hold in stock for sale or in any manner advertise any brand of pesticide is required by section 4 of the Agricultural Pesticides Ordinance of 1971 ("APO") to register the same with the Government. According to the Import Policy Order 2009, active ingredients for formulation/manufacturing of pesticides are importable by industrial users only. Moreover, insecticides, rodenticides, fungicides, herbicides, anti-sprouting products, disinfectants and similar products, excluding plants growth regulators, put up in forms or packing for retail sale or as preparation, or articles (for example sulphur, treated bands, wicks and candles and fly-papers) are importable in accordance with the provisions of the APO, as amended from time to time, and the rules made there under, and those drugs which are registered under the Drugs Act, 1976, and the rules made there under.

There are no restrictions on the export of pesticides or their consumables.

2.2 Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?

Yes, according to sub-section 5 (3) of the APO a local agent or representative is required where a person not domiciled in Pakistan seeks to effectuate the registration of a pesticide, as defined in the APO.

2.3 Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?

Environmental Protection Agency (rule 4 (3) of the Agricultural Pesticides Rules 1973), National Food Security and Research Division (section 5 of the APO, Rule 3 (3) of the Rules of Business 1973 and para 22 B of Schedule II there under), Department of Plant Protection (Rule 4 (4) of the Rules of Business of 1973 and para 58 C of Schedule III there under) and Agricultural Pesticides Technical Advisory Committee (section 12 of the APO).

2.4 Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?

Local performance of environmental safety tests is not required to be conducted by the persons registering a pesticide, and results of tests conducted outside Pakistan may be submitted. However, the Federal Government will conduct tests locally on the sample of the pesticide provided with the application for its registration when processing such application for registration.

3. **Herbicides**

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

None.

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Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

Paraguay

Prepared by Lex Mundi member firm Peroni Sosa Tellechea Burt & Narvaja

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes, it is required to file for permission and authorization from the local authorities in order to plant, commercialize, import or export products that have been genetically modified or engineered.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Yes, local presence is required. Foreign companies may establish a Branch in Paraguay or may distribute its products through a third company legally established in Paraguay; in any case, it is required to be duly registered.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The government authorities involved in such determination are:
Ministry of Agriculture (Ministerio de Agricultura y Ganaderia –MAG)
National Service of Quality and Sanity of Vegetals and Seeds (Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas – SENAVE)
National Institution of Alimentation and Nutrition (Instituto Nacional de Alimentación y Nutrición – INAN)
Secretary of Environment (Secretaria del Medioambiente – SEAM)
Agricultural Biosecurity Comittee (Comisión de Bioseguridad Agropecuaria y Forestal – COMBIO)

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Any activity executed in Paraguay which could generate an impact on the environment, as well those related to GMOs, require environmental permits established by law. Such permits are Environmental Licenses issued by the Secretary of Environment (SEAM) after an EIA (Environmental Impact Assessment) has been performed and dully approved.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

The Government must authorize for the consumption of GMOs by human beings. The National Institution of Alimentation and Nutrition (INAN) is the authority that establishes the requirements and guides in order to obtain the sanitary registry of products that will be consumed by human beings.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Foreign companies may not commercialize, import or export products without being a duly registered company in Paraguay. (Please see answer to question 2.).

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Yes, local presence is required. The company that will import and sell the products must be dully registered at local Public Registries.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The governmental authorities involved in such determination are:
Ministry of Agriculture (Ministerio de Agricultura y Ganaderia –MAG)
Secretary of Environment (Secretaria del Medioambiente – SEAM)
National Service of Quality and Sanity of Vegetals and Seeds (Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas – SENAVE)

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

Local studies and permits are required in order to obtain said authorizations. The National Service of Quality and Sanity of Vegetals and Seeds (Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas – SENAVE) and ultimately, the Secretary of Environment (SEAM) are responsible of such authorizations.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

YES, a “Certificate of Free Commercialization” is required. Such certificate is issued by the Agrochemical Department from the National Service of Quality and Sanity of Vegetals and Seeds (Servicio Nacional de Calidad y Sanidad Vegetal y de Semillas – SENAVE).

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Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

Philippines

Prepared by Lex Mundi member firm Romulo Mabanta Buenaventura Sayoc & De los Angeles]

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Yes, a license is required to allow an entity to import, export, commercialize or propagate genetically modified or engineered products.

The Bureau of Plant Industry (BPI) is the government regulatory agency tasked to regulate GMO activities. Said agency issues four kinds of permits for all genetically engineered crops.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

No. Local presence is not required. Anyone is allowed to import GMOs provided the said commodities are already approved by the required agencies in the Philippines as listed in the BPI approval registry.

Should the product not be in the BPI approval registry, the importer has to provide a declaration signed by an accredited laboratory or company from the country of origin. The BPI shall then determine if further tests should be conducted in the Philippines.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The Bureau of Plant Industry, under the Department of Agriculture (DA), is the lead and single entry point of GMO applications and the agency responsible for conducting environmental risk assessments. The BPI is also in charge of issuing all the abovementioned permits, through its Biotech Core Team (BCT) and the Scientific and Technical Review Panel (STRP)

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Accredited studies carried out in the country of origin are required to be submitted with the application for registration of a GMO product currently not in the BPI registry.
In addition to such requirement, greenhouse/laboratory experiments as well as limited or multi location field trials have to be conducted locally, depending on the sufficiency of

data provided by the importer/exporter/distributor of the specific GMO product, as well as the credibility of the studies.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

Yes. After the required satisfactory risk assessment processes of specific GMOs by the Scientific and Technical Review Panel members, and respective regulatory agencies under the Department of Agriculture as mentioned above, the BPI shall then issue a biosafety permit for direct use as food and feed or for processing.

There are no specific rules for the consumption of GMOs.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Yes, All commercial applicators of pesticides shall apply for a license, in a form to be supplied by the FPA, and shall obtain a commercial applicator's license. The following are the different types of licenses available for pesticide companies and other handlers: Pesticide Manufacturer/Fomulator License, Pesticide Repacker License, Pesticide Importer/Trader/Indentor License, Pesticide Distributor License, License for Pesticide Supplier's Local Representative, Pesticide Dealer's License.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Foreign-owned corporations desiring to sell pesticides and other agricultural chemicals may apply and become a licensed dealer of pesticides. However, such foreign corporations should be registered with the Securities and Exchange Commission and licensed to do business in the country. A foreign company, or a company not licensed to do business in the country may also distribute pesticides in the Philippines through a local subsidiary.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The Fertilizer and Pesticide Authority (FPA) is the government agency exercising control over pesticides.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

In the application for registration of pesticides, the FPA accepts studies carried out in the country of origin of the products. However, it has the discretion to conduct its own independent local testing especially in cases where in the pesticide's country of origin has a different climate from the Philippines.

Should the applicant decide to avail of local testing, it must choose from a list of accredited researchers from the FPA.
Furthermore, applications for commodity pesticides and some proprietary compounds may be satisfied by citing appropriate reviews of the relevant data in developed countries

or providing results of international reviews by organizations such as the World Health Organization or Food and Agriculture Organization.

3. **Herbicides**

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No, it is not required.

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Lex Mundi World Ready

Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

Spain

Prepared by Lex Mundi member firm Uría Menéndez

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

Under Spanish GMO regulations, the deliberate release and the commercialisation of GMOs (which would comprise the planting, the commercialisation, the import and export, as applicable) are subject to prior authorisation. For food and feed containing GMOs, EU law establishes a single authorisation procedure valid throughout the EU. Exports to third countries are also generally subject to the importer's consent.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Placing of GMOs on the market must be made under the responsibility of a person established in the EU, whether it be the manufacturer, the importer or the distributor. Also, the applicant for an authorisation of GMOs to be used as food or feed, the authorisation-holder, or his representative shall be established in the EU. Certain entities or products are subject to specific prior registration or authorisation obligations (e.g. food, feed or biocides operators).

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

Generally, GMO related matters are the responsibility of central government bodies ascribed to the Ministry of the Agriculture, Food and Environment (currently being the Inter-ministerial Council for Genetically Modified Organisms and the National Commission for Biosecurity). Where applicable, these bodies include representatives from other Ministries such as Health, Interior, Education, Finance, Science and Technology, scientific institutions, or the autonomous regions. Autonomous regions also exercise certain powers, among others, regarding surveillance, control, inspection and penalty proceedings.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

Studies performed in the country of origin of the product would not per se be considered sufficient. The risk assessment must be carried out on a case-by-case basis, so that the information required may vary depending on the nature of the GMOs, their intended uses,

whether any other GMOs have already been released in such environment, and, generally, the prevailing conditions in the receiving territory. This is without prejudice to existing GMO mutual recognition mechanisms.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

Food and feed containing GMOs must be authorised under a specific authorisation procedure before the Member State's authorities although the authorisation will be granted by the EU authorities. The authorisation granted will be valid throughout the EU. These products are subject to specific traceability obligations, labelling requirements (except for those foods containing GMOs in proportions no higher than 0.9 per cent, provided that this presence is adventitious or technically unavoidable) and, finally, to applicable EU and Spanish regulations regarding food products generally.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Both biocides (for use in non-agricultural sectors) and plant protection products must be authorised and registered in Spain prior to their commercialisation or use (certain low-risk biocides are subject only to prior notification and registration). Authorisations granted by another EU Member State should be automatically recognised in Spain, unless authorisation conditions are not equivalent. However, a recognition application must be submitted and the relevant product must be registered with the pertinent registry in Spain. Exports of certain hazardous chemicals and pesticides are subject to the importer's prior consent.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Applicants of authorisations for placing plant protection products or biocides on the market must have a permanent address within the EU (but not necessarily in Spain). However, in practice, not having a local address or representation office in Spain may raise practical issues when interacting whit the Spanish authorities.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

Generally, the Ministry of Health, Social Services and Equality is responsible for all matters related to biocides, and the Ministry of Agriculture, Food and Environment for matters related to plant protection products. In any case, the competent bodies will be assisted as necessary by representatives of other Ministries or of the autonomous regions. The autonomous regions are responsible for the registration of the premises located in their respective territory, and, generally, surveillance, inspection, control and penalty proceedings.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

Studies performed in the country of origin are not per se considered sufficient. As regards plant protection products, it is expressly foreseen that, where the product is authorised in another EU Member State, there is no need to carry out new studies if the plant health,

agricultural and environmental conditions are equivalent. In principle, although no express provision exists, a similar conclusion would apply to biocides. This is without prejudice to applicable mutual recognition procedures.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

Prescription by a qualified professional is not required. However, distributors, sellers and other market operators of herbicides must have the proper university degree, or employ someone who has such qualification, in order to commercialize herbicides. On the other hand, any personnel who handles herbicides or applies herbicides treatment must be in possession of a particular license ("carnet de aplicador"), with different levels depending on the nature of the herbicide concerned.

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Lex Mundi World Ready

Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

USA, Delaware

Prepared by Lex Mundi member firm Richards, Layton & Finger

1. GMOs

1.1 Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?

Delaware does not expressly require its permission to plant, commercialize, import or export GMOs. Such products are subject, however, to Title 3 of the Delaware Code and its regulations, which govern agricultural products and livestock being imported, exported or otherwise used in the state. Additionally, Delaware's Pure Food and Drugs Act does not permit the manufacture, sell or trade of food or drugs that are adulterated, misbranded, poisonous or deleterious. 16 Del. C. § 3302.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

Any person who solicits or receives on consignment, purchases for resale, or negotiates the purchase or sale of any fruits or vegetables must obtain a license from the Delaware Department of Agriculture. 3 Del. C. § 2502. Livestock dealers, other than state-federal approved livestock markets, must also obtain a license from the Department for the buying, selling or transporting of any cattle, sheep, swine, goats, horses, mules, other equines, poultry or cultured aquatic stock. Id. § 7603.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

The Delaware Department of Agriculture, the Delaware Department of Health and Social Services and the Delaware Department of Natural Resources and Environmental Control each have regulatory authority over agricultural products and livestock.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

There is no specific permit program to plant, commercialize, import or export genetically modified or engineered products in Delaware.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

There is no specific permit program to plant, commercialize, import or export genetically modified or engineered products in Delaware.

2. Peticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

Every pesticide that is distributed within Delaware or delivered for transportation or transported in intrastate commerce or between points within the state must be registered with the Delaware Department of Agriculture, subject to certain limited exemptions. See 3 Del. C. §§ 1203 & 1204(b); 601 Del. Admin. C. § 4.1. Additionally, no person may sell, transport or ship any plant pest or biological control agent without a U.S. Department of Agriculture permit or its Delaware equivalent. Id. § 1107(a).

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

Delaware requires any person engaged in the business of applying pesticides to the property of another to be licensed by the Delaware Department of Agriculture. 3 Del. C. § 1206(a). Such person must be certified as, or employ, a certified applicator at all times. Id. Nonresidents of Delaware may apply for a license. Id. § 1213.
No person may sell a ""restricted use pesticide"" or a ""state restricted use pesticide"" unless issued a dealer permit by the Department. 3 Del. C. § 1214.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

Services and the Delaware Department of Natural Resources and Environmental Control have regulatory authority over pesticides, insecticides and rodenticides

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

Delaware does not require local performance and/or environmental safety studies to register a pesticide, plaguicide, rodenticide or insecticide or to obtain a dealer permit. See 3 Del. C. §§ 1204 and 1214.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

A prescription by a qualified professional for herbicide commercialization is not required under Delaware's pesticides laws and regulations. See 3 Del. C. § 1201 et seq.; 601 Del. Admin. C. § 1.0 et seq.

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Lex Mundi World Ready

Requirements to Sell, Manufacture or Commercialize Transgenics, Insecticides, Pesticides, Herbicides and Rodenticides

USA, Kansas

Prepared by Lex Mundi member firm Foulston Siefkin LLP

1. GMOs

1.1 **Is permission required from the government in order to plant, commercialize, import or export products that have been genetically modified or engineered ("GMOs")?**

There are currently no requirements under Kansas statutes or regulations specifically related to planting, commercializing, importing or exporting products that have been genetically modified or engineered. There are general laws and regulations applicable to foods, drugs, and cosmetics manufactured, transported, or sold in Kansas; the sale and labelling of agricultural seeds; the importation of animals that may be used in the preparation of meat or meat products; and the commercial importation.

1.2 **Is local presence required in order to be considered a duly registered distributor where the GMO is going to be imported and sold?**

There are no special local presence rules for GMOs.

1.3 **Which governmental authorities are involved in the determination of the regulations involving GMOs (for example, food and agriculture, environmental, health, safety)?**

Not applicable.

1.4 **Are local performance and/or environmental safety studies required to obtain the permit to plant, commercialize, import or export GMOs, or are studies carried out in the country of origin of the GMO where it has already been certified, valid or accepted?**

No. There are no specific performance or environmental safety studies required.

1.5 **Does the permission granted by the Government authorize the consumption of GMOs by human beings? Are there specific rules for the consumption of GMOs?**

Not applicable.

2. Pesticides, insecticides and rodenticides

2.1 **Is governmental permission required for foreign companies to commercialize, import or export pesticides, insecticides, rodenticides and/or their consumables?**

The wholesale or retail sale in Kansas, delivery for transportation in Kansas, and transportation in intrastate commerce or between points within Kansas through any point

outside Kansas of agricultural chemicals (which includes pesticides, insecticides, rodenticides, herbicides, and their consumables) requires compliance with labeling laws and annual product registration. Poisonous insecticides, fungicides and rodenticides sold in Kansas must be distinctly colored.

2.2 **Is local presence required in order to be a registered or authorized distributor where the pesticides, insecticides, rodenticides and/or their consumables are going to be imported and sold?**

No.

2.3 **Which governmental authorities are involved in the determination of the environmental health and safety of pesticides, insecticides, rodenticides?**

The Kansas Department of Agriculture.

2.4 **Are local performance and/or environmental safety studies required to obtain the authorization to market pesticides, plaguicides, rodenticides, insecticides, or are studies carried out in the country of origin of the products, valid or accepted?**

No. There are no specific performance or environmental safety studies required.

3. Herbicides

3.1 **Is a prescription by a qualified professional required in the herbicides commercialization? If the answer is "YES", what is the professional that grants such prescription?**

No. A pesticide business license is required in order to sell or perform any service for the control of a pest on the property of another. No individual may use any restricted pesticide in Kansas without a commercial applicator's certificate unless they are working under a commercial applicator, are a certified private applicator, are a veterinarian or physician, are qualified laboratory personnel at a recognized pesticide research facility, or are federal employees using pesticides as a part of their employment by a federal agency which has its own certification program which is the full equivalent of the Kansas requirements.

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