

联合国 Fo 粮食及 Or 农业组织

Food and Agriculture Or Organization of the Un United Nations

Organisation des Nations Unies pour l'alimentation et l'agriculture

s Продовольственная и n сельскохозяйственная организация Объединенных Наций

Organización de las вация Naciones Unidas para la Alimentación y la Agricultura منظمة الأغذية والزراعة للأمم المتحدة E

# TECHNICAL CONSULTATION ON LOW LEVELS OF GENETICALLY MODIFIED (GM) CROPS IN INTERNATIONAL FOOD AND FEED TRADE

Rome, Italy, 20 - 21 March 2014

The results of the FAO survey on low levels of genetically modified (GM) crops in international food and feed trade

This document is printed in limited numbers to minimize the environmental impact of FAO's processes and contribute to climate neutrality. Delegates and observers are kindly requested to bring their copies to meetings and to avoid asking for additional copies. Most FAO meeting documents are available on the Internet at www.fao.org

## The results of the FAO survey on low levels of genetically modified (GM) crops in international food and feed trade

## Table of Contents

| Acknowledgement  |
|--|
| Note   |
| Working definitions  |
| 1. Survey response rate  |
| 1.1. Total survey response rate  |
| 1.2. Regional response rate  |
| 1.3. List of responding countries  |
| 2. GM Crop Production  |
| 3. Export/import of agricultural commodities (both non-GM and GM)7                     |
| 3.1. Export situation  |
| 3.2. Import situation  |
| 4. Regulations on GM crops 10  |
| 4.1. Regulations in place10  |
| 4.2. Labelling regulations11   |
| 4.3. Policies and risk assessments 12  |
| 5. LLP and detection & quantification 15   |
| 6. LLP and AP incidents  |
| Annex 1. Individual responses from each countries regarding information on regulations |

## Acknowledgement

This document is a simple compilation of the results of the FAO international survey conducted between February and June 2013. The development of the document was coordinated by Masami Takeuchi and Renata Clarke, in the Food Safety and Quality Unit of FAO. FAO would like to express the greatest appreciation to the countries that responded to the survey for their time and efforts. Data input and qualitative data categorization were conducted by two FAO interns namely Mehad Omer and Jing Peng. Technical contributions from many other FAO colleagues, experts and government officials are also gratefully appreciated.

## Note

The country-specific information and data provided in the paper are based on the responses submitted through the FAO survey. As the survey responses have been submitted by the national authorities, FAO considers that they are official responses. However, owing to the differences in methods, frequency and precision of monitoring applied to LLP/AP incidents, the data may not perfectly correspond to the actual events monitored elsewhere.

## **Working definitions**

In this survey, some technical terms and acronyms are applied that are based on the terms generally used in various Codex documents (http://www.codexalimentarius.org/). They differ among countries, and translations in various languages may increase the confusion associated with the terminology. The following working definitions have been adopted for the purpose of this survey. Readers should note that these are not official FAO definitions but terms that have been used in this paper in an attempt to minimize possible misunderstanding.

**GM Crops:** A genetically modified (GM) crop refers to a recombinant-deoxyribonucleic acid (r-DNA) plant. An r-DNA plant is a plant in which the genetic material has been changed through *in vitro* nucleic acid techniques, including r-DNA injection and direct injection of nucleic acid into cells or organelles.

**Low Level Presence (LLP):** LLP refers to the detection of low levels of GM crops that have been approved in at least one country on the basis of a food safety assessment according to the relevant Codex guidelines. Readers should note that low level presence (LLP) is not specifically defined by Codex, however in the context of the Codex guidelines it is referred to as LLP.

Adventitious Presence (AP): AP refers to detection of the unintentional presence of GM crops that have not been approved in any countries on the basis of a food safety assessment according to the relevant Codex guidelines.

## 1. Survey response rate

## 1.1. Total survey response rate

Table 1. Total survey response rate

|                               | Number |
|-------------------------------|--------|
| Countries that the survey was | 193*   |
| sent                          |        |
| Responses received            | 75*    |
| Response rate (%)             | 38.86% |

\* includes European Union

## 1.2. Regional response rate

## Table 2. Regional response rate

| Region            | Number of FAO | Number of   | Regional      | Regional      |
|-------------------|---------------|-------------|---------------|---------------|
|                   | Members       | respondents | distributions | response rate |
|                   |               |             | (share)       | (%)           |
| Africa            | 48            | 14          | 18.67         | 29.17         |
| Asia              | 23            | 10          | 13.33         | 43.48         |
| Europe            | 54*           | 26*         | 34.67         | 48.15         |
| Latin America and | 33            | 16          | 21.33         | 48.48         |
| Caribbean         |               |             |               |               |
| Near East         | 17            | 4           | 5.33          | 23.53         |
| North America     | 2             | 2           | 2.67          | 100.00        |
| Pacific (Oceania) | 16            | 3           | 4.00          | 18.75         |
| Total             | 193           | 75          | 100           | -             |

Figure 1. Regional distributions (share)

\* includes European Union



Figure 2. Regional response rate



## Regional response rate, %

#### 1.3. List of responding countries

Argentina Australia Austria Bahamas Bangladesh Barbados Bolivia Botswana Brazil Bulgaria Cambodia Canada Cape Verde Colombia Congo Costa Rica Croatia Cuba Cyprus **Czech Republic** Denmark **Dominican Republic DRC Congo** Ecuador El Salvador

Estonia **European Union** Finland France Gambia Germany Grenada Honduras Hungary Iran Ireland Italy Jamaica Japan Laos Latvia Lithuania Luxemburg Madagascar Malaysia Mali Moldova Mongolia Morocco Mozambique

Myanmar Namibia Netherlands New Zealand Niger Norway Pakistan Philippines Poland Qatar Samoa Seychelles Slovakia Slovenia Somalia Spain Sudan Sweden Syria Thailand Togo Trinidad and Tobago Turkey Uruguay United States of America

## **2. GM Crop Production**

#### Q1. Does your country produce GM crops?

| Table 3. On crop producing countries             |              |              |  |  |  |
|--|--------------|--------------|--|--|--|
| Response option                                  | Response (%) | Yes and No % |  |  |  |
| Yes - Research only (field trials)               | 18.92        | 40.54        |  |  |  |
| Yes – Both research and<br>commercial production | 21.62        |              |  |  |  |
| No   | 59.46        | 59.46        |  |  |  |
| Total  | 100          | 100          |  |  |  |

Table 3. GM crop producing countries

## Q2. How many GM crops (the number of GM events) does your country produce (both research and commercial production)?

Table 4. Existing GM events

| Response option | Response (%) |
|-----------------|--------------|
| Less than 20    | 52.70        |
| 21-50           | 5.41         |
| 51-80           | 5.41         |
| Over 80         | 2.70         |
| Not applicable  | 17.57        |
| No response     | 16.22        |
| Total           | 100          |

### Q3. In your country, how many GM crops (the number of GM events) are currently in pipeline?

| Response option | Response (%) |  |  |  |
|-----------------|--------------|--|--|--|
| Less than 20    | 52.70        |  |  |  |
| 21-50           | 4.05         |  |  |  |
| 51-80           | 5.41         |  |  |  |
| Over 80         | 0.00         |  |  |  |
| Others*         | 1.35         |  |  |  |
| Not applicable  | 18.92        |  |  |  |
| No response     | 17.57        |  |  |  |
| Total           | 100          |  |  |  |
|                 |              |  |  |  |

Table 5. GM events in pipeline

\*Others: Ireland: as per EU

## Q4. How many GM crops (the number of GM events) are authorized to be commercialized in your country?

Table 6. Commercialized GM events

| Response option | Response (%) |
|-----------------|--------------|
| Less than 20    | 40.54        |
| 21-50           | 10.81        |
| 51-80           | 4.05         |
| Over 80         | 4.05         |
| Others*         | 6.76         |
| Not applicable  | 20.27        |
| No response     | 13.51        |
| Total           | 100          |

\*Others:

- Finland, Hungary (None apart from those approved in EU)
- Ireland (As per EU)
- Mali (Any food product authorized in the exporting country)
- Slovenia (All authorized in European Union)

## 3. Export/import of agricultural commodities (both non-GM and GM)

## 3.1. Export situation

Q5. Please fill out the table below for your country's export situation of some selected agricultural commodities.

### 3.1.1. Does your country export any GM crops of this commodity?

| Commodity        | Yes (%) | No (%) | Not        | No       | No          | Total (%) |
|------------------|---------|--------|------------|----------|-------------|-----------|
|                  |         |        | applicable | response | information |           |
|                  |         |        | (%)        | (%)      | (%)         |           |
| Maize            | 5.41    | 74.32  | 1.35       | 16.22    | 2.70        | 100       |
| Soy              | 8.11    | 71.62  | 1.35       | 16.22    | 2.70        | 100       |
| Sorghum          | 0.00    | 79.73  | 1.35       | 17.57    | 1.35        | 100       |
| Wheat            | 0.00    | 79.73  | 1.35       | 17.57    | 1.35        | 100       |
| Rice             | 0.00    | 79.73  | 1.35       | 16.22    | 2.70        | 100       |
| Rapeseed         | 2.70    | 75.68  | 1.35       | 18.92    | 1.35        | 100       |
| Other (specify)* | 5.41    | 48.65  | 1.35       | 43.24    | 1.35        | 100       |

#### Table 7. Export situations of GM commodities

\*Specified crops: Cotton (Argentina, Australia, USA), Cotton lint (Colombia, "Algodón fibra"), Alfalfa (USA).

| Commodity   | Proportion of GM<br>Crops in Total<br>Exports of this<br>Commodity, %   | Major Trading Partners  |
|-------------|---|---|
| Maize       | 90  | N. Africa, S. America, Asia   |
| Soy         | 99  | Asia, Middle East, EU   |
| Cotton      | 95  | S.E. Asia   |
| Rapeseed    | 23  | Pakistan, Japan, UAE, Bangladesh  |
| Cotton      | 100   | China, Japan, Republic of Korea,<br>USA   |
| Soy         | 99  | Peru, Colombia, Ecuador, Brazil   |
| Soy         | -   | China, EU, S. Korea, Japan  |
| Maize       | Ca. 85  | USA, Spain, Egypt, Iceland, Hong<br>Kong  |
| Soy         | Ca. 50  | China, Japan, USA, Netherlands,<br>Belgium, Egypt, Malaysia.  |
| Rapeseed    | Ca. 95  | China, Japan, Mexico, USA   |
| Cotton lint | 70  | -   |
| Maize       | 70-80   | Several African countries (90%),<br>especially Senegal and Tunisia  |
| Soy         | 100   | China (77%), Holland (9%), Egypt<br>(3%)  |
| Maize       | -   | Japan, Mexico, China, South<br>Korea, Venezuela   |
| Soy         | -   | China, Mexico, Japan, Indonesia,<br>Germany   |
| Cotton      | -   | China, Turkey, Mexico, Vietnam,<br>Indonesia  |
|             |   |   |
|             | Commodity<br>Maize<br>Soy<br>Cotton<br>Rapeseed<br>Cotton<br>Soy<br>Soy<br>Maize<br>Soy<br>Rapeseed<br>Cotton lint<br>Maize<br>Soy<br>Maize<br>Soy<br>Maize | CommodityCrops in Total<br>Exports of this<br>Commodity, %Maize90Soy99Cotton95Rapeseed23Cotton100Soy99Soy-MaizeCa. 85SoyCa. 50RapeseedCa. 95Cotton lint70Maize70-80Soy100Maize-Soy100Maize-Soy100Maize-Soy100Maize-Soy- |

Table 8. Proportion of GM crops in total export by country and commodity

\_\_\_\_\_

## 3.2. Import situation

Q6. Please fill out the table below for your country's import situation of some selected agricultural commodities.

3.2.1. Does your country import any GM crops of this commodity?

| Commodity        | Yes (%) | No (%) | Not        | No       | No          | Total (%) |
|------------------|---------|--------|------------|----------|-------------|-----------|
|                  |         |        | applicable | response | information |           |
|                  |         |        | (%)        | (%)      | (%)         |           |
| Maize            | 27.03   | 43.24  | 0.00       | 21.62    | 8.11        | 100       |
| Soy              | 39.19   | 31.08  | 0.00       | 22.97    | 6.76        | 100       |
| Sorghum          | 2.70    | 55.41  | 0.00       | 33.78    | 8.11        | 100       |
| Wheat            | 4.05    | 56.76  | 0.00       | 31.08    | 8.11        | 100       |
| Rice             | 5.41    | 55.41  | 0.00       | 31.08    | 8.11        | 100       |
| Rapeseed         | 12.16   | 45.95  | 1.35       | 32.43    | 8.11        | 100       |
| Other (specify)* | 4.05    | 24.32  | 0.00       | 63.51    | 8.11        | 100       |

## Table 9. Import situations of GM commodities

\*Specified crops: Cotton (Argentina, Japan), Cottonseed (Australia)

## Table 10. Proportion of GM crops in total import by country and commodity

| Reporting Country  | Commodity             | Proportion of GM<br>Crops in Total<br>Imports of this<br>Commodity | Major Trading Partners                  |
|--------------------|-----------------------|--|---|
| Argentina          | Cotton                | 100  | Brazil                                  |
| Australia          | Rapeseed              | 56   | Canada, USA                             |
| Australia          | Cotton seed           | 100  | USA                                     |
| Austria            | Soy                   | 81.4   | USA, Brazil                             |
| Bolivia            | Maize                 | 99   | Argentina, Brazil                       |
| DUIIVIa            | Soy                   | 99   | Argentina                               |
| Brazil             | Maize                 | -  | Argentina, Paraguay                     |
| DI dZII            | Soy                   | -  | Argentina, Paraguay                     |
| Bulgaria           | Soybean Meal          | 90   | Brazil, Argentina                       |
|                    | Maize                 | 95-100   | USA                                     |
| Canada             | Soy                   | 95-100   | USA.                                    |
| Canada             | Sorghum               | -  | USA                                     |
|                    | Rapeseed              | 95-100   | USA                                     |
| Colombia           | Maize & Soy           | -  | -                                       |
| Croatia            | Soy                   | 15   | Brazil, Argentina                       |
|                    | Maize                 | 70   | USA, Brazil, Argentina                  |
| Cuba               | Soy                   | 90   | Brazil, Argentina                       |
| Cuba               | Wheat                 | -  | USA                                     |
|                    | Rice                  | -  | -                                       |
| Cyprus             | Soy                   | 99   | Brazil, Argentina, Spain                |
| Dominican Republic | Maize, Soy & Wheat    | -  | -                                       |
| Finland            | Soy                   | 15   | -                                       |
| France             | Maize, Soy & Rapeseed | -  | -                                       |
| Honduras           | Maize & Rice          | -  | USA                                     |
|                    | Maize                 | -  | Brazil, Argentina, Ukraine              |
| Iran               | Soy                   | -  | Brazil, Argentina, Ukraine              |
|                    | Rapeseed              | -  | Canada                                  |
|                    | Maize                 | 37   | USA, Brazil, Canada                     |
| Ireland            | Soy                   | 94   | Argentina, USA, Brazil                  |
|                    | Rapeseed              | 20   | Canada, USA                             |
| Italy              | Maize & Soy (feed)    | -  | USA, Argentina, Brazil                  |
|                    | Maize & Soy           | -  | USA, Brazil                             |
| Japan              | Rapeseed              | -  | Canada, Australia                       |
|                    | Cotton                | -  | Australia, USA                          |
| Latvia             | Soybean Meal          | 89   | Argentina, USA                          |
| Lithuania          | Soy                   | 74   | China, Russia, Israel, S. Korea, India, |

|             |             |                                       | Argentina, Ukraine   |
|-------------|-------------|---------------------------------------|--|
| -           |             |                                       | USA, Cambodia, India, Pakistan,  |
|             | Rice        | 24                                    | Vietnam, Thailand, South Korea,  |
|             | THEE        |                                       | Canada   |
|             |             |                                       | Through transit, main producer   |
| Luxembourg  | Soy         | 80                                    | countries including USA, Brazil,   |
| -           |             |                                       | Argentina, India.  |
| Malavaia    | Maize       | -                                     | South Africa, USA  |
| Malaysia    | Soy         | -                                     | USA  |
|             | Maize       | -                                     | -  |
| Netherlands | Soy         | 75 (soybean);<br>90-100 (crushed soy) | USA, Paraguay, Uruguay, Brazil   |
|             | Rapeseed    | -                                     | -  |
|             | Maize       | 90                                    | USA, Argentina   |
| Philippines | Soy         | 90                                    | Argentina, USA   |
| -           | Rapeseed    | -                                     | -  |
|             | Maize       | -                                     | N. Zealand   |
| -           | Soy         | -                                     | Australia  |
| Samaa       | Sorghum     | -                                     | USA  |
| Samoa       | Wheat       | -                                     | China  |
|             | Rice        | -                                     | Europe   |
|             | Rapeseed    | -                                     | American Samoa   |
| Slovenia    | Soy         | 80                                    | Brazil, Argentina  |
| Sudan       | Maize       | -                                     | -  |
| Suuan       | Soy         | -                                     | -  |
| Thailand    | Maize & Soy | -                                     | USA, S. Africa   |
| Trinidad    | Maize & Soy | -                                     | -  |
| Turkey      | Maize       | 5                                     | France, Spain, Slovakia, Hungary,<br>Romania, Bulgaria, Ukraine, Moldova,<br>Russia, Bosnia and Herzegovina,<br>Serbia, Ethiopia, USA, Brazil, Argentina |
|             | Soy         | 100                                   | Spain, Germany, Ukraine, Moldova,<br>Russia, USA, Brazil, Paraguay,<br>Argentina, China  |
|             |             |                                       |  |
| Uruguay     | Maize       | 90-100                                | Mainly Argentina, Paraguay, Brazil   |

## 4. Regulations on GM crops

## 4.1. Regulations in place

## Q7. Does your country have any food safety, feed safety or environmental regulations on GM crops?

| Response option                 | Response (%) | Yes and No % |
|---------------------------------|--------------|--------------|
| Yes                             | 77.03        | 77.03        |
| No – but we plan to have one in | 14.86        | 21.62        |
| the future                      |              |              |
| No – we don't have one          | 6.76         |              |
| No response                     | 1.35         | 1.35         |
| Total                           | 100          | 100          |

Table 11. The existence of the national food/feed/environmental regulations on GM crops

## **Q8.** Please provide the following information for each regulation:

| Response           | Response (%) |  |
|--------------------|--------------|--|
| Responses provided | 81.33        |  |
| Not applicable     | 17.33        |  |
| No information     | 1.33         |  |
| Total              | 100          |  |

Table 12. Information on regulations\*

\*Includes EU; see Annex 1 for individual responses

## 4.2. Labelling regulations

## Q9. If your country has a specific labelling requirement for GM crops, please briefly describe key features of the requirement. Please select all that apply.

| Table 13 | Lahelling | requirements | (multinle re | snonses) |
|----------|-----------|--------------|--------------|----------|
|          | LUDCHING  | requirements | inducipic ic | Sponses/ |

| Response option  | Response (%) | Note  |
|--|--------------|---|
| Mandatory  | 10.81        | -   |
| Voluntary  | 5.41         | -   |
| Mandatory and voluntary  | 2.70         | -   |
| Subject to threshold   | 1.35         | Niger: No further explanation was provided  |
| Mandatory + positive and<br>negative labelling and subject to<br>threshold level | 2.70         | Turkey: 0.9 %   |
| Voluntary + positive labelling   | 2.70         | -   |
| Mandatory + positive labelling +<br>subject to threshold level                   | 1.35         | Brazil: 1%  |
| Mandatory + positive labelling   | 37.84        | -   |
| Mandatory + positive and<br>negative labelling                                   | 1.35         | Mongolia: No further explanation was provided   |
| Mandatory + subject to<br>threshold level  | 2.70         | Thailand: labelling is required<br>by weight, if each ingredient<br>constitutes 5 percent or more<br>of the final product and 5<br>percent or more of that<br>ingredient is derived from<br>GMO ingredients.<br>Syria: < 1% |
| Positive labelling + subject to<br>threshold level                               | 1.35         | Sudan: No further explanation was provided  |
| Mandatory + Other  | 1.35         | Malaysia: Future possibility  |
| Other  | 1.35         | Rely on certifications of<br>imported products  |
| Not applicable   | 8.11         | -   |
| No response  | 17.57        | -   |
| No information   | 1.35         | -   |
| Total  | 100          |   |

## 4.3. Policies and risk assessments

## Q10. Does your country have a "zero-tolerance<sup>1</sup>" policy for unauthorized GM crops?

| Response option | Response (%) |
|-----------------|--------------|
| Yes             | 72.97        |
| No              | 20.27        |
| No response     | 6.76         |
| Total           | 100          |

## Q11. How does your country conduct food safety assessment of GM crops?

| Table 15. Food safety assessment of GM | crops (multiple responses) |
|--|----------------------------|
|--|----------------------------|

| Response (%) | Note   |
|--------------|--|
| 12.16        | -  |
|              |  |
|              |  |
| 6.76         | Note that the respondents                                  |
|              | who selected this option do                                |
|              | not necessarily mean that they                             |
|              | do not follow international                                |
|              | guidelines. The domestic<br>guidelines can be well in line |
|              | with the international                                     |
|              | guidelines.  |
| 31.08        | OCDE and ILSI have been                                    |
|              | mentioned.   |
|              | Note that the respondents                                  |
|              | who selected this option do                                |
|              | not necessarily mean that they                             |
|              | do not follow international                                |
|              | guidelines. The other                                      |
|              | guidelines can be well in line                             |
|              | with the international                                     |
|              | guidelines.  |
| 24.32        | -  |
| 10.10        |  |
| 12.16        | -  |
|              |  |
|              |  |
| 3 70         |  |
| 2.70         | -  |
|              |  |
|              |  |
|              |  |
|              |  |
|              |  |

<sup>&</sup>lt;sup>1</sup> Zero tolerance policy: any imported food or feed material cannot contain even trace amounts of GMO substances that have not been authorized in the importing country.

| etc)   |      |   |
|--|------|---|
| According to the international<br>guidelines (Codex principles and<br>guidelines) + according to the<br>other guidelines (regional,<br>private, trade-partner countries' | 1.35 | - |
| etc)   |      |   |
| Not applicable   | 1.35 | - |
| No response  | 6.76 | - |
| No information   | 1.35 | - |
| Total  | 100  |   |

## Q12. How does your country conduct feed safety assessment of GM crops?

| Response option  | Response (%) | Note   |
|--|--------------|--|
| According to the international guidelines (OECD)   | 9.46         | -  |
| According to the domestic guidelines   | 9.46         | Note that the respondents<br>who selected this option do<br>not necessarily mean that they<br>do not follow international<br>guidelines. The domestic<br>guidelines can be well in line<br>with the international<br>guidelines. |
| According to the other<br>guidelines (regional, private,<br>trade-partner countries' etc)  | 32.43        | Note that the respondents<br>who selected this option do<br>not necessarily mean that they<br>do not follow international<br>guidelines. The other<br>guidelines can be well in line<br>with the international<br>guidelines.    |
| We do not conduct feed safety assessment of GM crops   | 29.73        | -  |
| According to the international<br>guidelines (OECD) + according to<br>the domestic guidelines  | 6.76         | -  |
| According to the international<br>guidelines (OECD) + according to<br>the domestic guidelines +<br>according to the other guidelines<br>(regional, private, trade-partner<br>countries' etc) | 2.70         | -  |
| According to the domestic<br>guidelines+ according to the<br>other guidelines (regional,<br>private, trade-partner countries'<br>etc)  | 2.70         | -  |
| No response  | 5.41         | -  |

Table 16. Feed safety assessment of GM crops (multiple responses)

| No information | 1.35 | - |
|----------------|------|---|
| Total          | 100  |   |

## Q13. How does your country conduct environment safety assessment of GM crops?

## Table 17. Environmental risk assessment of GM crops (multiple responses)

| Response option                    | Response (%) | Note                           |
|------------------------------------|--------------|--------------------------------|
| According to international         | 10.81        | -                              |
| guidelines (IPPC, OECD,            |              |                                |
| Cartagena Protocol)                |              |                                |
| According to the domestic          | 9.46         | Note that the respondents      |
| guidelines                         | 5110         | who selected this option do    |
| Succines                           |              | not necessarily mean that they |
|                                    |              | do not follow international    |
|                                    |              | guidelines. The domestic       |
|                                    |              | guidelines can be well in line |
|                                    |              | with the international         |
|                                    |              | guidelines.                    |
| According to the other             | 31.08        | Note that the respondents      |
| guidelines (regional, private,     | 51.00        | who selected this option do    |
| trade-partner countries' etc)      |              | not necessarily mean that they |
| the particle countries city        |              | do not follow international    |
|                                    |              | guidelines. The other          |
|                                    |              | guidelines can be well in line |
|                                    |              | with the international         |
|                                    |              | guidelines.                    |
| We do not conduct environment      | 21.62        | -                              |
| safety risk assessment of GM       |              |                                |
| crops                              |              |                                |
| According to international         | 14.86        | _                              |
| guidelines (IPPC, OECD,            |              |                                |
| Cartagena Protocol) + according    |              |                                |
| to the domestic guidelines         |              |                                |
| According to international         | 2.70         | -                              |
| guidelines (IPPC, OECD,            |              |                                |
| Cartagena Protocol) + according    |              |                                |
| to the other guidelines (regional, |              |                                |
| private, trade-partner countries'  |              |                                |
| etc)                               |              |                                |
| According to international         | 1.35         | -                              |
| guidelines (IPPC, OECD,            |              |                                |
| Cartagena Protocol) + according    |              |                                |
| to the domestic guidelines +       |              |                                |
| according to the other guidelines  |              |                                |
| (regional, private, trade-partner  |              |                                |
| countries' etc)                    |              |                                |
| Not applicable                     | 1.25         | -                              |
|                                    | 1.35         |                                |
| No response                        | 5.41         | -                              |
| No response<br>No information      |              |                                |

## Q14. What is the authorization policy for the imported GM crops in your country?

| Response option   | Response (%) |
|---|--------------|
| Authorization (including various risk assessments according to the  | 25.68        |
| international guidelines) process is done domestically, then permit |              |
| the crops to be sold in the country                                 |              |
| Authorization (including various risk assessment according to the   | 5.41         |
| international guidelines) process depends on the one done by the    |              |
| country of origin, then permit the crops to be sold in the country  |              |
| Do not permit any GM crops to enter the country                     | 17.57        |
| Other *   | 36.49        |
| Authorization requires both exporting country's risk assessment and | 1.35         |
| domestic risk assessment  |              |
| No response   | 13.51        |
| Total   | 100          |

Table 18. Authorization policy for imports (multiple responses)

\*Specified authorization mechanisms: Bolivia: Regional (EU) Regulation is carried out from production to trade, when there is a food deficit GM-product like maize is allowed (Bolivia)

## 5. LLP and detection & quantification

## Q15. Does your country require testing for imported agricultural commodities for detection of low level or adventitious presence of GMOs? Please select all that apply.

| Response option   | Response (%) | Note   |
|---|--------------|--|
| Yes, testing in the exporting country                           | 33.78        | -  |
| Yes, testing in the importing country                           | 12.16        | -  |
| (domestic laboratories)   |              |  |
| Other   | 5.41         | Brazil: GMO controls in general.   |
|   |              | Canada: Not generally required for   |
|   |              | imported commodities, but can be   |
|   |              | required on a case-by-case basis.  |
|   |              | Uruguay: no requirement for analysis of raw materials but officially takes |
|   |              | control  |
|   |              | USA: Risk-based approach for the   |
|   |              | examination of imports   |
| No  | 28.38        | -  |
| Yes, requires testing in both exporting and importing countries | 9.46         | -  |
| Yes, testing in the exporting country                           | 1.35         | New Zealand: For living modified   |
| and other (specify)   |              | organisms approval is required under                                       |
|   |              | the Hazardous Substances and New   |
|   |              | Organisms Act 1996. For processed  |
|   |              | foods the authorisation process is   |
|   |              | carried out under the joint Australia                                      |
|   |              | New Zealand Food Standards system.   |
| Yes, requires testing in both exporting                         | 2.70         | Norway: Samples of food, feed, and   |
| and importing countries as well as                              |              | seeds are analysed for the presence of                                     |

Table 19. Testing requirement for detection of LLP/AP of GM crops

| other (specify) |      | genetic material in connection with an<br>annual surveillance program<br>Togo: Ongoing research |
|-----------------|------|---|
| No response     | 6.76 | -   |
| Total           | 100  |   |

## Q16. Does your country have a threshold level for LLP/AP?

| Table 20. | Threshold    | level |
|-----------|--------------|-------|
| 10010 201 | 1111 6011010 | 10101 |

| Response option | Response (%) | Note   |
|-----------------|--------------|--|
| Yes             | 33.78        | -  |
| No              | 54.05        | -  |
| Yes and No      | 1.35         | Japan:<br>Yes-Feed safety (Use of<br>unauthorized GM crop as feed<br>is, in principle, prohibited. If<br>the LLP crop of concern has<br>already been approved as a<br>safe GM feed in a country<br>whose GMO safety assessment<br>system is equivalent to or<br>better than that of Japan, the<br>presence of that LLP crop in<br>feed consignments up to 1%<br>will be tolerated.<br>No: Environment (LLP<br>situations are managed in<br>some different ways<br>depending on the GMO's<br>approved status in exporting<br>country, characteristics or<br>intended use in Japan |
| Not applicable  | 1.35         | -  |
| No response     | 9.46         | -  |
| Total           | 100          |  |

## Q17. Does your country's domestic (reference) laboratory have technical capacity to detect or quantify GMOs according to the Codex guidelines (CAC/GL 74-2010)?

| Response option                 | Response (%) | Yes and No %             |  |  |  |
|---------------------------------|--------------|--------------------------|--|--|--|
| Yes                             | 47.30        | 47.3 (Yes, fully)        |  |  |  |
| Partially                       | 9.46         | 48.64 (No and not fully) |  |  |  |
| Yes and partially               | 2.70         |                          |  |  |  |
| Partially and capacity is being | 1.35         |                          |  |  |  |
| developed                       |              |                          |  |  |  |
| No, but capacity is being       | 10.81        |                          |  |  |  |
| developed                       |              |                          |  |  |  |
| No                              | 24.32        |                          |  |  |  |
| No response                     | 4.05         | 4.05                     |  |  |  |

Table 21. Capacity for detection and quantification of LLP/AP

| Total | 100 | 100 |
|-------|-----|-----|
|       |     |     |

## Q18. What kind of detection methods does your country use?

## Table 22. Detection methods

| Response option   | Response (%) | Note   |
|---|--------------|--|
| Quick methods (presence or                                  | 12.16        |  |
| absence)  |              |  |
| Detection and quantification                                | 39.19        | Japan: Detect specific DNA<br>sequences by qualitative PCR<br>method and if 1 % threshold<br>level for feed is applied,<br>quantify the LLP crop by<br>quantitative PCR<br>New Zealand: We don't use<br>Quantification PCR methods as<br>they cannot report below 0.1%<br>GM content<br>Norway: Screening and event-<br>specific methods |
| Other   | 2.70         | Cambodia: we have no idea<br>Gambia: Samples are sent to<br>reference laboratories in<br>neighbouring countries<br>Mali: Eliza, PCR<br>Samoa : Use Scientific Research<br>of Samoa (SROS)<br>USA: We would use whatever<br>methods deemed most<br>appropriate to the situation<br>presented  |
| We don't conduct<br>detection/quantification testing        | 22.97        | -  |
| Both quick methods as well as detection and quantification  | 12.16        | Myanmar: Simple PCR  |
| Detection and quantification, as well as other              | 1.35         | Croatia: PCR detection   |
| All (quick methods, detection and quantification and other) | 2.70         | Czech Republic: sequencing,<br>when applicable (unapproved<br>GMO)<br>Germany: DNA-based<br>sequencing and event-specific<br>methods (PCR)   |
| Not applicable  | 1.35         | -  |
| No response   | 4.05         | -  |
| No information  | 1.35         | -  |
| Total   | 100          |  |

## 6. LLP and AP incidents

Q19. Has your country faced situations of LLP or AP in imports in the last 10 years?

| Response option | Response (%) |
|-----------------|--------------|
| Yes             | 35.14        |
| No              | 50.00        |
| Being evaluated | 1.35         |
| Not applicable  | 1.35         |
| No response     | 9.46         |
| No information  | 2.70         |
| Total           | 100          |

Table 23. LLP/AP incidents in the last 10 years

Table 24. LLP/AP incidents

| Total                        | 198 |
|------------------------------|-----|
| 2002 – 2009 (8 years)        | 60  |
| 2009 – 2013 (latest 5 years) | 138 |

Figure 3. Number of LLP/AP incidents by country of origin



Figure 4. LLP/AP incidents by commodity



Figure 5. Number of LLP/AP incidents and trend (2002–2012)



## Q20. If yes, please provide the details below:

## Table 25. LLP/AP incidents reported by countries

| Reporting | Year | Commodity    | Amount (tonne;    | Imported from | How situation was     | How situation was man                           |
|-----------|------|--------------|-------------------|---------------|-----------------------|---|
| country   |      |              | unless stated)    |               | discovered            | aged  |
| Argentina | 2008 | Canola       | 100               | Canada        | Farmer complaint      | Converted to biofuel                            |
| Brazil    | 2009 | Flax         | ND                | Canada        | Detection at the port | Consignment rejected                            |
|           | 2012 | Maize        | ND                | United States | Detection at the port | Consignment rejected                            |
| Bulgaria  | 2007 | Unauthorize  | Two lots, of 2.7  | Brazil        | Rejected by the       | Notification reference "2007.CBB" was issued by |
|           |      | d GM soy     | and 6.2 tons      |               | Bulgarian authorities | Bulgaria via RASFF                              |
|           |      | protein      |                   |               |                       |   |
| Canada    | 2005 | Corn (Bt10)  | 86 acres worth of | United States | Proponent informed    | Proponent destroyed crop                        |
|           |      |              | the event         |               | the government        |   |
|           | 2006 | Rice         | None in Canada,   | United States | Proponent informed    | Proponent removed crop from commercial seed     |
|           |      | (LLRice601)  | trace amount in   |               | the government        | production                                      |
|           |      |              | the United States |               |                       |   |
|           |      |              | of America        |               |                       |   |
| Croatia   |      | Food         | -                 | -             | Official control      | Consignment held for testing                    |
|           |      | supplements  |                   |               | (inspection and       |   |
|           |      |              |                   |               | sampling)             |   |
|           |      | Soy          | -                 | -             | Official control      | Consignment held while information was sought   |
|           |      | -            |                   |               | (inspection and       | and then released (under 0.9%)                  |
|           |      |              |                   |               | sampling)             |   |
|           |      | Feed         | -                 | -             | Official control      | If it unauthorized GMO it would be destroyed or |
|           |      |              |                   |               | (inspection and       | returned to country of origin                   |
|           |      |              |                   |               | sampling)             |   |
| Cuba      | 2002 | Rice         |                   | United States | Review                |   |
| Cyprus    | 2007 | Rice protein | 100               | China via the | Control on the market | Returned to the dispatcher                      |
|           |      |              |                   | Netherlands   |                       |   |
|           | 2007 | Pet food     | 19.5              | United States | Control on the market | Returned to the dispatcher                      |

|         | 2007 | Pet food                | 2.16           | United States/<br>Greece  | Control on the market  | Returned to the dispatcher                         |
|---------|------|-------------------------|----------------|---|--|--|
|         | 2009 | Pet food                | 19.7           | United States   | Sampling   | Seized, destroyed                                  |
|         | 2009 | Pet food                | 19.6           | United States   | Sampling   | Seized, destroyed                                  |
|         | 2010 | Maize                   | 0.74           | Italy   | After laboratory testing   | Consignment was sent back to the country of origin |
| Denmark | 2009 | Linseed<br>(feed use)   | 1.5            | Presumably<br>originating from<br>Canada (bought<br>via supplier in<br>Germany) | A sample of linseeds<br>showing a low level of<br>Flax CDC Triffid<br>(FP967) was identified<br>in the official control<br>of feed | Affected batches were destroyed                    |
|         | 2009 | Linseed<br>(food use)   | Different lots | Canada via<br>other EU<br>Member States   | Via the EU rapid alert system  | Affected batches were withdrawn from the market    |
| France  | 2004 | Maize GA21              | -              | United States   | RASFF of member  | Market withdrawal                                  |
|         | 2005 | Maize Bt10              | -              | United States   | Information from US authorities  | EU emergency measures                              |
|         | 2006 | Rice LL601              | -              | United States   | Information from US<br>Authorities   | EU emergency measures                              |
|         | 2006 | Rice LL62               | -              | United States   | Official control   | Market withdrawal                                  |
|         | 2006 | Rice Bt63               | -              | China   | Greenpeace   | EU emergency measures                              |
|         | 2009 | Lin FP967               | -              | Canada  | RASFF of member  | Market withdrawal                                  |
|         | 2009 | Maize<br>MON88017       | -              | United States   | RASFF of member  | Blocked, pending EU approval                       |
|         | 2009 | Maize<br>MIR604         | -              | United States   | RASFF of member  | Blocked, pending EU approval                       |
|         | 2012 | Rice Kefeng6<br>and KMD | -              | China   | Official control   | Market withdrawal and consumer recall              |
|         | 2012 | Rice OGM                | -              | Pakistan/ India   | Operator auto control  | Market withdrawal and consumer recall              |
|         | 2012 | Рарауа                  | -              | Thailand  | Official control   | Market withdrawal and consumer recall              |

| Germany      | 2003 | Rice (24),    | -                  | China (41),       |                      | Recall, withdrawal, destruction |
|--------------|------|---------------|--------------------|-------------------|----------------------|---------------------------------|
| (numbers of  | to   | Rice noodles  |                    | United States     |                      |                                 |
| incidents in | 2013 | and crackers  |                    | (24), Colombia    |                      |                                 |
| parentheses) |      | (30), Linseed |                    | (2), Canada (36), |                      |                                 |
|              |      | (45), Maize   |                    | Thailand (3),     |                      |                                 |
|              |      | and maize     |                    | Pakistan (2),     |                      |                                 |
|              |      | flour (2),    |                    | India (1),        |                      |                                 |
|              |      | Papaya (16),  |                    | Philippines (1),  |                      |                                 |
|              |      | Pet food (4)  |                    | Germany (7),      |                      |                                 |
|              |      |               |                    | Italy (3),        |                      |                                 |
|              |      |               |                    | Belgium (3)       |                      |                                 |
| Hungary      | 2007 | Maize seed    | 0.21               | -                 | -                    | Fined                           |
|              | 2010 | Maize seed    | 21                 | Argentina         | Check sampling       | Fined                           |
|              | 2011 | Maize and     | 376                | Canada, United    | Check sampling       | Destroyed                       |
|              |      | soybean       |                    | States,           |                      |                                 |
|              |      | seed          |                    | Romania,          |                      |                                 |
|              |      |               |                    | Croatia, France,  |                      |                                 |
|              |      |               |                    | Chile             |                      |                                 |
|              | 2012 | Maize seed    | ≥134               | United States,    | Check sampling       | Destroyed                       |
|              |      |               |                    | Romania, Chile,   |                      |                                 |
|              |      |               |                    | France, South     |                      |                                 |
|              |      |               |                    | Africa, Serbia,   |                      |                                 |
|              |      |               |                    | the Netherlands   |                      |                                 |
| Iran         | 2005 | Maize and     | Millions of tonnes | Argentina and     | Research by graduate | Not managed                     |
|              | to   | soy           |                    | Brazil            | students and random  |                                 |
|              | 2012 |               |                    |                   | check by public      |                                 |
|              |      |               |                    |                   | research institutes  |                                 |

| Ireland | 2007 | Maize<br>(Herculex-<br>RW) -Feed | 12 000 | United States | Laboratory tests  | Product was stored until EU authorization of<br>Herculex was approved and then released.<br>There is ongoing disruption to trade due to<br>asychronous authorizations between EU and<br>third countries. The current "tolerance" of<br>< 0.1% under Reg 619/2011 is inadequate to<br>facilitate trade between third countries and the<br>EU. Trade problems are likely to increase in<br>future, as more GM events enter the pipeline,<br>giving rise to more frequent incidents of<br>asynchronous authorizations and rejection of<br>consignments |
|---------|------|----------------------------------|--------|---------------|---|---|
| Italy   | 2007 | Maize in pet<br>food             | -      | United States | Official control at import                                      | Consignment redispatched  |
|         | 2009 | Maize in<br>dried pet<br>food    | -      | United States | Official control at import                                      | Consignment rejected  |
|         | 2010 | Maize for popcorn                | 25     | Argentina     | Official control at<br>import                                   | Consignment redispatched  |
|         | 2013 | Maize grains<br>(popcorn)        | 2.5    | Argentina     | Market control  | Withdrawal from the market  |
| Japan   | 2005 | Maize (Bt10)                     | 42000  | United States | (Detected in Japan)<br>Notification by the<br>exporting country | After the notification, consignments already<br>imported into Japan were tested and those<br>found positive were shipped back.<br>After the above phase, import became<br>acceptable only when consignments for Japan<br>were tested and certified to be free of Bt10.<br>Without such certification, consignments were<br>tested in Japan, and if Bt10 was detected, those<br>consignments were rejected   |
|         |      |                                  |        |               |   |   |

| 2006 | Rice<br>(powder,<br>noodle) | 138 | China         | Testing at the time of importation       | Consignment rejected  |
|------|-----------------------------|-----|---------------|--|---|
| 2007 | Rice<br>(powder,<br>noodle) | 362 | China         | Testing at the time of importation       | Consignment rejected  |
| 2008 | Rice<br>(powder,<br>noodle) | 69  | China         | Testing at the time of importation       | Consignment rejected  |
| 2008 | Maize<br>(DAS59132)         | N/A | United States | Notification by the<br>exporting country | After the notification, consignments already<br>imported into Japan were tested and found to<br>be free of DAS59132. After the above phase,<br>import became acceptable only when<br>consignments for Japan were tested and<br>certified to be free of DAS59132. Without such<br>certification, consignments were tested in Japan,<br>and if DAS59132 was detected, those<br>consignments were rejected |
| 2009 | Rice<br>(powder,<br>noodle) | 26  | China         | Testing at the time of importation       | Consignment rejected  |

|   |      | Flax (FP967)                     | N/A  | Canada  | Notification by the<br>industry involved                                   | After the notification, consignments already<br>imported into Japan were tested and found to<br>be free of or < 1% FP967. If FP967 was detected<br>at < 1%, the consignment could be used as feed<br>but only for processing under appropriate<br>measures to limit the contact with the<br>environment.<br>After the above phase, import became<br>acceptable only when consignments for Japan<br>were tested and certified as under the<br>threshold. Without such certification,<br>consignments are tested in Japan, and if FP967 is<br>detected: at < 1%, the consignment can be<br>imported but only for processing under<br>appropriate measures to limit the contact with<br>the environment; at > 1%, the consignment will<br>be rejected |
|---|------|----------------------------------|------|---------|--|--|
| 2 |      | Flax seed<br>(fresh,<br>roasted) | 31   | Canada  | Testing at the time of<br>importation                                      | Consignment rejected   |
| 2 |      | Flax seed<br>(roasted)           | 5.6  | Canada  | Testing at the time of importation   | Consignment rejected   |
| 2 | 2011 | Рарауа                           | N/A  | Taiwan  | By testing conducted<br>in response to<br>information from a<br>researcher | Recalled unplanted seeds from their distributors<br>Destroyed all plants germinated from the seeds<br>of concern   |
| 2 | 2011 | Flax seed<br>(granola)           | 0.04 | Canada  | Testing at the time of importation   | Consignment rejected   |
| 2 |      | Rice<br>(powder,<br>noodle)      | 1.1  | China   | Testing at the time of importation   | Consignment rejected   |
| 2 | 2011 | Rice noodle                      | 14   | Vietnam | Testing at the time of importation   | Consignment rejected   |

|            | 2012 | Rice noodle  | 3.6     | Vietnam            | Testing at the time of importation   | Consignment rejected  |
|------------|------|--|---------|--------------------|--|---|
| Latvia     | 2011 | Soybean<br>meal  | 5451.5  | Argentina          | Manufacturing<br>enterprise attested<br>GMO certificate<br>Monsanto Roundup<br>40-3-2  | Consignment was released for free circulation in EU                           |
|            | 2012 | Hipro<br>soybean<br>meal and<br>soybean<br>expeller<br>(feed<br>materials) | 5700    | United States      | Manufacturing<br>enterprise attested<br>GMO certificate<br>Monsanto Roundup<br>40-3-2<br>(1 from all<br>consignments was<br>selected for sampling<br>and tested for quality<br>and quantity of<br>Monsanto 40-3-2) | Consignment was released for free circulation                                 |
|            | 2012 | Soybean<br>meal  | 7615.23 | Argentina          | Manufacturing<br>enterprise attested<br>GMO certificate<br>Monsanto Roundup<br>40-3-2  | Consignment was released for free circulation in EU                           |
| Luxembourg | 2009 | Linseed  | 55      | Germany/<br>Canada | EU RAFF  | After confirming the AP by testing, the linseed was withdrawn from the market |
| Madagascar | 2007 | Maize  | -       | France             | Environmental impact study   | Demolition  |

| Namibia     | 2013 | Maize   | Not disclosed | South Africa  | The enterprise trust<br>sent samples of maize<br>for testing in South<br>Africa and found that<br>these products<br>contained genetically<br>modified maize | The Namibian Agronomic Board (NAB) has<br>reprimanded those responsible for producing<br>and marketing maize products that a consumer<br>lobby alleged contain so-called genetically<br>modified maize                                      |
|-------------|------|---|---------------|---------------|---|---|
| Netherlands | 2005 | Bt10 maize in feed  | -             | United States | Announcement by company   | Consignments held for testing and later released<br>on basis of negative results; EU emergency<br>measure put in place (19 April 2005)  |
|             | 2006 | Chinese rice<br>(Bt63) in<br>food                                     | -             | China         | Greenpeace/ Friends<br>of the Earth   | EU emergency measure (9 April 2008)   |
|             | 2006 | LLRICE601 in<br>food  | -             | United States | Announcement by company   | Blocking of US rice consignments by Dutch<br>companies until negative test results were<br>obtained, risk assessment by Dutch Food safety<br>authority (NVWA-front office); EU emergency<br>measure (23 August 2006)                        |
|             | 2007 | Maize in<br>maize gluten,<br>brewers<br>grain<br>Herculex RW<br>59122 | -             | United States | Greenpeace  | Consignments traced and held for testing by<br>Dutch food safety authority, tests negative, no<br>need for further measures.<br>Action plan put in place by US company for<br>voluntary testing of consignments to EU and<br>certification  |
|             | 2009 | FP967<br>linseed (CDC<br>Triffid) in<br>food                          | -             | Canada        | Detection by third<br>country authorities   | Consignments traced and held for testing by<br>Dutch food safety authority, recalls performed,<br>risk assessment done by the Netherlands Food<br>and Consumer Product Safety Authority-front<br>office, action plan by Canadian government |
| New Zealand | 2001 | Maize seed  | -             | United States | In-house testing of<br>growing crop by<br>company   | Crops 'held' while information was sought and then released   |

|             | 2002 | Maize seed                                      | 1400 seeds | United States                      | In-house testing of<br>finished crop by<br>company                        | Seed testing; field management   |
|-------------|------|---|------------|------------------------------------|---|--|
|             | 2003 | Sweetcorn<br>product                            | -          | United States                      | Testing of sweet corn<br>product in Japan                                 | Residual seed tested   |
|             | 2004 | Maize   | -          | United States                      | Re-testing seed<br>consignments from<br>earlier season                    | Stored grain used for feed rather than food  |
|             | 2006 | Sweetcorn<br>seed                               | 1.8        | United States                      | Ministry of Primary<br>Industry's quality<br>system                       | Retesting arranged by seed supplier. Unplanted seed and young plants destroyed.  |
| Norway      | 2008 | JiangXi rice<br>vermicelli                      | -          | China                              | Compulsory testing by<br>authorities according<br>to national legislation | Consignment held for testing and rejected after testing  |
|             | 2010 | Rice Mix  | -          | United States<br>(origin Thailand) | Testing according to<br>national surveillance<br>programme                | The product was not allowed to sell and the finding was notified in the European RASFF-system  |
|             | 2012 | Dongguan<br>Rice<br>Vermicelli                  | 7.9        | China                              | Compulsory testing by<br>authorities according<br>to national legislation | Consignment held for testing and rejected after testing, notified in the European RASFF-system   |
|             | 2012 | Oriental rice<br>cracker mix                    | 6.2        | China                              | Compulsory testing by<br>authorities according<br>to national legislation | Consignment held for testing and rejected after testing, notified in the European RASFF system   |
| Philippines | 2006 | Liberty Link<br>rice<br>LL601 (for<br>food use) | -          | -                                  | Report of alleged<br>presence in the local<br>market by<br>Greenpeace     | All commercial rice alleged to contain LL601 was<br>recalled by the National Food Authority; Further<br>shipments from the source were required for<br>testing (negative) by Philippine authorities<br>(Department of Agriculture-Bureau of Plant<br>Industry) |
|             | 2008 | TC 1508 (for propagation)                       | -          | -                                  | Declaration by technology developer                                       | Whole shipment was quarantined and destroyed   |
| Poland      | 2011 | RR oilseed<br>rape                              | -          | -                                  | -   | Withdrawn from the market  |

| ſ | Spain | 2009 | Maize, soy | - | United States | - | Border rejection |
|---|-------|------|------------|---|---------------|---|------------------|
|   |       |      | cake       |   |               |   |                  |

## Q21. What is the importance of the factors below in contributing to the trade risks posed by LLP/ AP in your country?

Table 26. Factors in contributing to the trade risks\*

| Factor   |       |       | Score (%) |       |       | NA   | NR    | NI   | Total |
|--|-------|-------|-----------|-------|-------|------|-------|------|-------|
| FdClOf   | 1     | 2     | 3         | 4     | 5     | NA   | INK   | INI  | Total |
| Different policies on GMOs exist between trading partners  | 4.05  | 4.05  | 13.51     | 12.16 | 41.89 | 1.35 | 21.62 | 1.35 | 100   |
| Different timing (and duration of the process) for approval of GM crops  | 2.70  | 4.05  | 21.62     | 12.16 | 35.14 | 1.35 | 21.62 | 1.35 | 100   |
| Approvals not consistently sought from many countries that are importers of the commodity                      | 9.46  | 8.11  | 20.27     | 14.86 | 21.62 | 1.35 | 22.97 | 1.35 | 100   |
| Lack of trust in the other countries' food safety assessment procedures and results; or their approval process | 16.22 | 8.11  | 20.27     | 10.81 | 16.22 | 1.35 | 25.68 | 1.35 | 100   |
| Unintentional movement/development of unauthorized GM crops/ seed  | 8.11  | 9.46  | 9.46      | 8.11  | 39.19 | 1.35 | 21.62 | 1.35 | 100   |
| Inadequate separation between the commercialized and the field trial production areas                          | 16.22 | 12.16 | 9.46      | 12.16 | 24.32 | 1.35 | 22.97 | 1.35 | 100   |
| Inadequate separation between GM crops and non-GM crops (during milling, storage, transport, etc)              | 10.81 | 9.46  | 10.81     | 12.16 | 29.73 | 1.35 | 24.32 | 1.35 | 100   |
| Difficulty in accessing information on food safety assessments carried out in other countries                  | 16.22 | 12.16 | 16.22     | 12.16 | 16.22 | 0.00 | 25.68 | 1.35 | 100   |
| Difficulty in accessing information on feed safety assessments carried out in other countries                  | 13.51 | 13.51 | 17.57     | 10.81 | 17.57 | 0.00 | 25.68 | 1.35 | 100   |
| Difficulty in accessing information on environmental safety assessments carried out in other countries         | 13.51 | 20.27 | 9.46      | 12.16 | 17.57 | 0.00 | 25.68 | 1.35 | 100   |

\*This table excludes European Union. NA: not applicable; NR: no response; NI: no information.

# Annex 1. Individual responses from each countries regarding information on regulations<sup>2</sup>

### Argentina

| In what year did the regulation go into effect?                 | 1991  |
|---|---|
| What is the scope/ objective of the regulation?                 | Planting, processing ,feed, food and seed production                              |
| Is a safety/ risk assessment required?                          | Yes   |
| Is there a labelling requirement?                               | No  |
| Is there a LLP test requirement?                                | No  |
| Is there a traceability requirement?                            | No  |
| Is a socio-economic assessment required?                        | Regulation requires an assessment of impacts in production and commercialization. |
| Which authority is responsible for implementing the regulation? | Ministry of Agriculture, Livestock and Fisheries                                  |

## Australia

For food safety

| In what year did the regulation go into effect?                                  | 1999   |
|--|--|
| What is the scope/ objective of the regulation?                                  | Food standard  |
| Is a safety/ risk assessment required?   | Yes  |
| Is there a labelling requirement?  | Yes  |
| Is there a LLP test requirement?   | No   |
| Is there a traceability requirement?   | No   |
| Is a socio-economic assessment required?   | No   |
| Which authority is responsible for implementing the regulation?                  | Food Standards Australia New Zealand   |
| For environmental regulation (includes feed safety)                              |  |
| In what year did the regulation go into effect?                                  | The <i>Gene Technology Act 2000</i> came into effect on 21<br>June 2001. Prior to this there was a voluntary scheme<br>under the Genetic Manipulation Advisory Committee.  |
| What is the scope/ objective of the regulation?                                  | The object of the Gene Technology Act 2000 "is to<br>protect the health and safety of people, and the<br>environment, by identifying risks posed by or as a<br>result of gene technology, and by managing those<br>risks through regulating certain dealings with<br>genetically modified organisms (GMOs)".                           |
| Is a safety/ risk assessment required?   | Yes  |
| Is there a labelling requirement?  | No, mandatory labelling for commercial GM crops is<br>not prescribed under the <i>Gene Technology Act 2000</i> .<br>Labelling may be imposed as a licence condition to<br>manage a risk identified for human health and safety<br>and the environment. For field trials there are<br>labelling requirements for transport and storage. |
| Is there a LLP test requirement?   | No. Australia has an unintended presence strategy<br>based on cooperation between government and<br>industry<br>http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/<br>Content/mon-unintended-1.  |
| Is there a traceability requirement?<br>Is a socio-economic assessment required? | No, but licence conditions are imposed which require<br>a method for the reliable detection of the presence of<br>the GMOs and the introduced genetic material in a<br>recipient organism.   |
| ······································   | -  |

<sup>2</sup> In original language.

| Which authority is responsible for implementing the | Office of the Gene Technology Regulator |
|---|---|
| regulation?   |   |

## Austria (EU)

#### Bahamas (Not applicable)

#### Bangladesh

| In what year did the regulation go into effect?     | 2012  |
|---|---|
| What is the scope/ objective of the regulation?     | To regulate release of GMO product into environment |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | Yes   |
| Is there a LLP test requirement?                    | No  |
| Is there a traceability requirement?                | No  |
| Is a socio-economic assessment required?            | No  |
| Which authority is responsible for implementing the | Department of Environment, Ministry Of Environment  |
| regulation?   | &Forest   |

#### Barbados (Not applicable, biosafety framework act passed in 2012 but no regulations)

#### Bolivia

| ¿En qué año fue aplicada la regulación?             | 2011   |
|---|--|
| ¿Cuál es el fin/objetivo de la regulación?          | Proteger la biodiversidad, el impacto ambiental y la |
|   | salud humana   |
| ¿Se requiere de una evaluación de seguridad/riesgo? | No   |
| ¿Existe algún requisito de etiquetado?              | No   |
| ¿Existe algún requisito de análisis de LLP?         | No   |
| ¿Existe algún requisito de rastreabilidad?          | No   |
| ¿Se requiere la evaluación socio-económica?         | No   |
| ¿Cuál es la autoridad competente responsable de la  | Ministerio de Medio Ambiente y Aguas                 |
| regulación?   |  |

#### Botswana (Not applicable)

#### Brazil

| 1995 and then revised in 2005                         |
|---|
| Safety norms and inspection mechanisms for the        |
| construction, culture, production, manipulation,      |
| transportation, transfer, import, export, storage,    |
| research, commercialization, consumption, release     |
| into the environment and disposal of genetically      |
| modified organisms (GMOs) and their derivatives       |
| Yes   |
| Yes   |
| No  |
| No  |
| Not as an obligation, but is a possibility            |
| National Biosafety Council, National Biosafety        |
| Technical Commission, Ministry of Agriculture,        |
| Livestock and Food Supply, Ministry of Health,        |
| Ministry of Environment and Ministry of Fisheries and |
| Aquaculture   |
|   |

### Bulgaria (EU)

Cambodia (No information)

#### Canada

| Canada<br>Food Safety:  |  |
|---|--|
| In what year did the regulation go into effect?   | November 1999  |
| What is the scope/ objective of the regulation?   | Under the Food and Drugs Act, Health Canada has<br>established a stringent process for evaluating the<br>safety of foods derived through genetic modification<br>(often referred to as biotechnology-derived foods or<br>novel foods).   |
| Is a safety/ risk assessment required?  | Yes, as per guidelines attached in q.11  |
| Is there a labelling requirement?   | Special labelling is required for all foods, including<br>genetically modified foods, where safety concerns<br>such as allergenicity and compositional or nutritional<br>changes are identified. In this situation, labelling is<br>required to alert consumers or susceptible groups in<br>the population. For voluntary labelling, see below Q.9   |
| Is there a LLP test requirement?  | No   |
| Is there a traceability requirement?  | No   |
| Is a socio-economic assessment required?  | No   |
| Which authority is responsible for implementing the                                       | Food and Drugs Act. Division 28 of part B of the Food  |
| regulation?   | and Drugs Regulations.   |
| Feed Safety Regulations:<br>In what year did the regulation go into effect?               | Although the Novel Feeds regulations were<br>promulgated in 1996, the CFIA had authority to<br>conduct pre-market assessment under the current<br>1983 <i>Feeds Regulations</i> . The rational being that<br>Canada regulates biotech based on a product<br>(novelty) rather than a process used to create a<br>product.   |
| What is the scope/ objective of the regulation?<br>Is a safety/ risk assessment required? | <ul> <li>The manufacture, sale and import of livestock feeds are regulated in Canada under the <i>Feeds Act</i> and <i>Regulations</i>. All feeds must be safe, to livestock; to humans (by the potential transfer of residues into human food, i.e., meat, milk and eggs, and via worker/bystander exposure); and to the environment.</li> <li>Feeds must also be shown to be effective for their intended purpose. Approved feed ingredients are listed and defined in Schedules IV and V of the <i>Feeds Regulations</i>, with appropriate guarantees, standards, and label requirements. All imported feeds must meet the same standards as domestic feeds. Similarly, the regulatory framework for contaminants is applied to all feeds, including novel feeds.</li> <li>Yes. All feeds must be safe, to livestock; to humans (by the potential transfer of residues into human food, i.e., meat, milk and eggs, and via worker/bystander exposure); and to the environment.</li> </ul> |
| Is there a labelling requirement?   | intended purpose.<br>Not GM specific. Yes, regarding general feed labelling<br>requirements (e.g. proximates etc.)   |
| Is there a LLP test requirement?  | No   |
| Is there a traceability requirement?  | No   |
| Is a socio-economic assessment required?  | No   |
| Which authority is responsible for implementing the regulation?                           | The Canadian Food Inspection Agency under the<br>Feeds Act and Regulations   |

| · · · · · · · · · · · · · · · · · · ·               |   |
|---|---|
| In what year did the regulation go into effect?     | 1996  |
| What is the scope/ objective of the regulation?     | Environmental release of seed to ensure that            |
|   | environmental safety of PNTs is assessed prior to their |
|   | release into environment to maintain Canada's high      |
|   | standards for the protection of human health and the    |
|   | environment.  |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | No  |
| Is there a LLP test requirement?                    | Case by case following risk analysis                    |
| Is there a traceability requirement?                | Not for PNTs authorized for unconfined release          |
| Is a socio-economic assessment required?            | Not in assessment of individual products; the socio-    |
|   | economic considerations were taken into account in      |
|   | development of the regulations.                         |
| Which authority is responsible for implementing the | Canadian Food Inspection Agency under the Seeds Act     |
| regulation?   | and Seeds Regulations                                   |

## Environmental release of Plants with Novel Traits (PNTs) (including many GM crops):

Cape Verde (Not applicable, but Decreto Lei\_24/2009 was mentioned)

| Colombia |     |      |
|----------|-----|------|
| : En     | auó | ວຄິດ |

| ¿En qué año fue aplicada la regulación?             | 1998 (Acuerdo 003 y Resolución ICA 3492), 2002 (Ley   |
|---|---|
|   | 740 de 2002), 2005 (Decreto 4525)   |
| ¿Cuál es el fin/objetivo de la regulación?          | <ul> <li>Acuerdo 003: Por el cual se crea el Consejo Técnico<br/>Nacional (CTN) para la introducción, producción,<br/>liberación y comercialización de Organismos<br/>Modificados Genéticamente (OMG) de uso agrícola.</li> <li>Resolución ICA 3492: Por la cual se reglamenta y se<br/>establece el procedimiento para la introducción,<br/>producción, liberación y comercialización de<br/>Organismos Modificados Genéticamente (OMG) y se<br/>distan otras disposiciones</li> <li>Ley 740 de 2002: Por medio de la cual se aprueba el<br/>"Protocolo de Cartagena sobre Seguridad de la<br/>Biotecnología del Convenio sobre la Diversidad</li> <li>Biológica", hecho en Montreal, el veintinueve (29) de<br/>enero de dos mil (2000).</li> <li>Decreto 4525 de 2005: Por el cual se reglamenta la</li> </ul> |
|   | Ley 740 de 2002   |
| ¿Se requiere de una evaluación de seguridad/riesgo? | Si  |
| ¿Existe algún requisito de etiquetado?              | Se deben rotular o etiquetar todos los envases o<br>empaques de alimentos derivados de OGM para<br>consumo humano que no sean sustancialmente<br>equivalentes con su homólogo convencional y cuando<br>se encuentren en cualquiera de las siguientes<br>condiciones:  |
|   | <ul> <li>Los valores de la composición nutricional existente<br/>en el alimento que contiene el OGM o que empleo<br/>materias primas que son OGM, no son<br/>sustancialmente equivalentes en comparación con<br/>el homologo convencional o el producto alimenticio<br/>que se encuentra en el mercado.</li> <li>La forma de almacenamiento, preparación o<br/>cocción del alimento que contiene el OGM o la<br/>utilización de materias primas que son OGM, difiere<br/>a causa de éste, en comparación con el homologo</li> </ul>   |

|   | <ul> <li>convencional o el producto alimenticio equivalente existente en el mercado.</li> <li>La presencia de un alérgeno introducido como resultado de la modificación genética en un alimento que contiene el OGM o que empleó materias primas que son OGM y que los consumidores no esperan que se presente.</li> <li>La presencia de una diferencia en las propiedades organolépticas de un alimento, como consecuencia de la modificación genética en comparación a su homologo convencional.</li> </ul>  |
|---|--|
|   | Para la semilla se tiene establecido que cuando se<br>trate de materiales OGM, deberá tener impreso y<br>claramente visible en el empaque la siguiente frase<br>"Organismo Genéticamente Modificado"   |
| ¿Existe algún requisito de análisis de LLP?                       | No, se está trabajando en ello   |
| ¿Existe algún requisito de rastreabilidad?                        | No   |
| ¿Se requiere la evaluación socio-económica?                       | No   |
| ¿Cuál es la autoridad competente responsable de la<br>regulación? | Ministerio de Agricultura y Desarrollo Rural, a través<br>del Instituto Colombiano Agropecuario -ICA- será<br>competente para la autorización de Organismos Vivos<br>Modificados -OVM-, exclusivamente para uso agrícola,<br>pecuario, pesquero, plantaciones forestales<br>comerciales y agro industriales,<br>El Ministerio de Ambiente, Vivienda y Desarrollo<br>Territorial será competente para la autorización de<br>Organismos Vivos Modificados -OVM- exclusivamente<br>para uso ambiental.<br>El Ministerio de la Protección Social directamente o a<br>través de la autoridad que delegue, será competente<br>para la autorización de Organismos Vivos Modificados<br>–OVM para uso exclusivo en salud o alimentación<br>humana. |

**Congo** (Not applicable, but one remark is provided on the ongoing development of multi-sectoral coordination inter-agency mechanism to deal with the issue)

| Costa Rica  |  |
|---|--|
| ¿En qué año fue aplicada la regulación?             | 1996, 2006   |
| ¿Cuál es el fin/objetivo de la regulación?          | Proteger el ambiente, la salud humana y animal       |
| ¿Se requiere de una evaluación de seguridad/riesgo? | SI   |
| ¿Existe algún requisito de etiquetado?              | NO   |
| ¿Existe algún requisito de análisis de LLP?         | NO   |
| ¿Existe algún requisito de rastreabilidad?          | SI   |
| ¿Se requiere la evaluación socio-económica?         | NO   |
| ¿Cuál es la autoridad competente responsable de la  | Ministerio de Agricultura y Ganadería, Ministerio de |
| regulación?   | Salud, Ministerio de Ambiente y Energía, Ministerio  |
|   | de Ciencia y Tecnología.                             |

#### Croatia (EU)

| In what year did the regulation go into effect? | 2008   |
|---|--|
| What is the scope/ objective of the regulation? | provide the basis for ensuring a high level of<br>protection of human life, animal health and welfare,<br>environment, provide objectives of facilitating<br>accurate labelling, monitoring the effects on |

|   | environment, on health and traceability                |
|---|--|
| Is a safety/ risk assessment required?              | Yes  |
| Is there a labelling requirement?                   | yes  |
| Is there a LLP test requirement?                    | yes  |
| Is there a traceability requirement?                | yes  |
| Is a socio-economic assessment required?            | yes  |
| Which authority is responsible for implementing the | Ministry of Healthy, Ministry of Environmental and     |
| regulation?   | nature protection, Ministry of sciences, education and |
|   | sport, Ministry of Agriculture                         |

#### Cuba

| ¿En qué año fue aplicada la regulación?                        | 2005   |
|--|--|
| ¿Cuál es el fin/objetivo de la regulación?                     | Garantizar la inocuidad de los alimentos   |
| ¿Se requiere de una evaluación de seguridad/riesgo?            | Si   |
| ¿Existe algún requisito de etiquetado?                         | No   |
| ¿Existe algún requisito de análisis de LLP?                    | No   |
| ¿Existe algún requisito de rastreabilidad?                     | No   |
| ¿Se requiere la evaluación socio-económica?                    | No   |
| ¿Cuál es la autoridad competente responsable de la regulación? | Instituto de Nutrición e Higiene de los Alimentos,<br>Centro Nacional de Seguridad Biológica, Centro<br>Nacional de Toxicología. |

## Cyprus (EU)

| Food |  |
|------|--|
|------|--|

| 2012  |
|---|
| Prevent LLP and AP presence of GMO's in             |
| conventional maize seed lots (0% threshold)         |
| NO  |
| NO  |
| YES   |
| YES   |
| NO  |
| Department of Agriculture, Ministry of Agriculture, |
| Natural Resources and Environment                   |
|   |
| 2006  |
| Traceability and Labelling of GM Feed               |
| NO  |
| YES   |
| YES   |
| YES   |
| NO  |
| Department of Agriculture, Ministry of Agriculture, |
| Natural Resources and Environment                   |
|   |

## Czech Republic (EU)

Food and feed – EU

Environment (Czech Act No. 78/2004 Coll. On the use of genetically modified organisms and genetic products

| Is a safety/ risk assessment required?          | Environmental risk assessment is required  |
|---|--|
|   | products consisting of or containing GMOs  |
|   | except authorisation of GM food and feed,<br>environmental risk assessment of all GMOs and |
| What is the scope/ objective of the regulation? | Contained use and deliberate release of all GMOs,  |
| In what year did the regulation go into effect? | 2004   |
| Is there a labelling requirement?                               | Yes  |
|---|--|
| Is there a LLP test requirement?                                | There is zero tolerance for unauthorised GMOs  |
| Is there a traceability requirement?                            | Documentation on the use of GMOs is required   |
| Is a socio-economic assessment required?                        | No   |
| Which authority is responsible for implementing the regulation? | Ministry of the Environment of the Czech Republic<br>(for food and feed safety, Ministry of the Agriculture<br>of the Cech Republic) |

### Denmark (EU)

## Dominican Republic (Not applicable)

## DRC Congo (Not applicable)

#### Ecuador

| ¿En qué año fue aplicada la regulación?             | 2008   |
|---|--|
| ¿Cuál es el fin/objetivo de la regulación?          | Constitución de la República; Declara al Ecuador libre |
|   | de semillas y cultivos transgénicos                    |
| ¿Se requiere de una evaluación de seguridad/riesgo? | La normativa vigente no contempla la evaluación de     |
|   | riesgo   |
| ¿Existe algún requisito de etiquetado?              | Si hay marco legal pero todavía no se implementa       |
| ¿Existe algún requisito de análisis de LLP?         | No   |
| ¿Existe algún requisito de rastreabilidad?          | No   |
| ¿Se requiere la evaluación socio-económica?         | No se aplica todavía                                   |
| ¿Cuál es la autoridad competente responsable de la  | Ministerio del Ambiente                                |
| regulación?   |  |

#### **El Salvador**

| ¿En qué año fue aplicada la regulación?             | 2007   |
|---|--|
| ¿Cuál es el fin/objetivo de la regulación?          | Manejo Seguro de los OGM                           |
| ¿Se requiere de una evaluación de seguridad/riesgo? | Si   |
| ¿Existe algún requisito de etiquetado?              | Si   |
| ¿Existe algún requisito de análisis de LLP?         | No   |
| ¿Existe algún requisito de rastreabilidad?          | No   |
| ¿Se requiere la evaluación socio-económica?         | Solamente para análisis de riesgo                  |
| ¿Cuál es la autoridad competente responsable de la  | Ministerio de Medio Ambiente y Recursos Naturales, |
| regulación?   | Ministerio de Salud Publica y Asistencia Social,   |
|   | Ministerio de Agricultura y Ganaderia.             |

### Estonia (EU)

### **European Union**

Food and Feed Safety (EU Regulation 1829/2003)

| In what year did the regulation go into effect? | 2003  |
|---|---|
| What is the scope/ objective of the regulation? | Provide the basis for ensuring a high level of<br>protection of human life and health, animal health<br>and welfare, environment and consumer interests in<br>relation to genetically modified food and feed, whilst<br>ensuring the effective functioning of the internal<br>market<br>Lay down Community procedures for the<br>authorisation and supervision of genetically modified<br>food and feed<br>Lay down provisions for the labelling of genetically<br>modified food and feed |
| Is a safety/ risk assessment required?          | Guidance document of the scientific panel of GMOs   |

|   | for risk assessment of GM plant and derived food and feed  |
|---|--|
| Is there a labelling requirement?                               | Yes  |
| Is there a LLP test requirement?                                | There is zero tolerance for unauthorised GMOs in<br>food and seeds.<br>Commission Regulation (EU) No 619/2011 of 24 June<br>2011 laying down the methods of sampling and<br>analysis for the official control of feed as regards<br>presence of genetically modified material for which<br>an authorisation procedure is pending or the<br>authorisation of which has expired (LLP=0.1%) |
| Is there a traceability requirement?                            | The traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds, is ensured by Directive 2001/18/EC and regulation (EC) No 1830/2003.  |
| Is a socio-economic assessment required?                        | No   |
| Which authority is responsible for implementing the regulation? | National authorities   |

#### Finland (EU)

| ( - )   |   |
|---|---|
| In what year did the regulation go into effect?     | 1995  |
| What is the scope/ objective of the regulation?     | Implementation of EC legislation;. contained use of |
|   | GMO's and field trials with GMO's                   |
| Is a safety/ risk assessment required?              | yes for field trials                                |
| Is there a labelling requirement?                   | no  |
| Is there a LLP test requirement?                    | no  |
| Is there a traceability requirement?                | no  |
| Is a socio-economic assessment required?            | no  |
| Which authority is responsible for implementing the | Board for Gene technology                           |
| regulation?   |   |

## France (EU)

#### Gambia

| In what year did the regulation go into effect?     | 1994 – National Environmental Management Agency   |
|---|---|
| What is the scope/ objective of the regulation?     | Environmental Impact Assessment Issues            |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | Yes   |
| Is there a LLP test requirement?                    | Yes   |
| Is there a traceability requirement?                | Yes   |
| Is a socio-economic assessment required?            | No  |
| Which authority is responsible for implementing the | Ministry of Health, National Nutrition Agency and |
| regulation?   | Ministry of Agriculture                           |

## Germany (EU)

## Grenada (Not applicable)

#### Honduras

| ¿En qué año fue aplicada la regulación?             | 1998                                   |
|---|--|
| ¿Cuál es el fin/objetivo de la regulación?          | Regular el uso y manejo de cultivos GM |
| ¿Se requiere de una evaluación de seguridad/riesgo? | Si.                                    |
| ¿Existe algún requisito de etiquetado?              | No.                                    |
| ¿Existe algún requisito de análisis de LLP?         | No.                                    |
| ¿Existe algún requisito de rastreabilidad?          | No.                                    |

| ¿Se requiere la evaluación socio-económica?        | No.   |
|--|---|
| ¿Cuál es la autoridad competente responsable de la | La Secretaría de Agricultura y Ganadería a través del |
| regulación?  | Departamento de Certificación de semillas del         |
|  | SENASA.   |

| Hungary (EU)  |  |
|---|--|
| In what year did the regulation go into effect?                 | 1998: Hungarian Act on gene technological activities<br>(Act No. XXVII of 1998), later harmonised with the<br>current EU legislations. and also several national<br>implementing regulations |
| What is the scope/ objective of the regulation?                 | authorisation system and procedure of GM field<br>trials/GM foods/GM feeds/GM seeds  |
| Is a safety/ risk assessment required?                          | yes  |
| Is there a labelling requirement?                               | yes  |
| Is there a LLP test requirement?                                | yes  |
| Is there a traceability requirement?                            | yes  |
| Is a socio-economic assessment required?                        | not yet  |
| Which authority is responsible for implementing the regulation? | several authorities  |

#### Iran

| In what year did the regulation go into effect?                 | 2009   |
|---|--|
| What is the scope/ objective of the regulation?                 | Production, release, transmission, export, import, purchase, selling and use of LMOs |
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | The law has left it for regulation. If approved it will be for transportation only   |
| Is there a LLP test requirement?                                | No   |
| Is there a traceability requirement?                            | No   |
| Is a socio-economic assessment required?                        | No   |
| Which authority is responsible for implementing the regulation? | National Biosafety Committee   |

#### Ireland (EU)

| In what year did the regulation go into effect?     | Directive 2001/18; Reg 1829/2003; Reg 1830/2003     |
|---|---|
| What is the scope/ objective of the regulation?     | Cultivation, Food & Feed                            |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | Positive labelling                                  |
| Is there a LLP test requirement?                    |   |
| Is there a traceability requirement?                | Yes, Reg. 1830.2003                                 |
| Is a socio-economic assessment required?            | No  |
| Which authority is responsible for implementing the | Dept Agriculture, Food & Marine, Environmental      |
| regulation?   | Protection Agency, Food Safety Authority of Ireland |

Italy (EU)

### Jamaica

| In what year did the regulation go into effect?     | 2004   |
|---|--|
| What is the scope/ objective of the regulation?     | Prohibit the import of GMO's unless licensed |
| Is a safety/ risk assessment required?              | Yes  |
| Is there a labelling requirement?                   | No   |
| Is there a LLP test requirement?                    |  |
| Is there a traceability requirement?                |  |
| Is a socio-economic assessment required?            |  |
| Which authority is responsible for implementing the | The Natural Resources Conservation Authority |

| regulation? |  |
|-------------|--|

# Japan

## Food

| 1000  |   |
|---|---|
| In what year did the regulation go into effect?                 | 2001  |
| What is the scope/ objective of the regulation?                 | Genetically modified foods and food products made   |
|   | from such foods   |
| Is a safety/ risk assessment required?                          | Yes, it is.   |
| Is there a labelling requirement?                               | Yes, there is. The Labelling rules on GM farm products<br>and their processed food were provided based on the<br>JAS Law and Food Sanitation Act and labelling became<br>requirement in April 2001. |
| Is there a LLP test requirement?                                | No test specialized particularly for LLP.   |
| Is there a traceability requirement?                            | No, it is not.  |
| Is a socio-economic assessment required?                        | No, it is not.  |
| Which authority is responsible for implementing the regulation? | Ministry of Health, Labour and Welfare is.  |
| Franking property and Food                                      |   |

**Environment and Feed** 

|   | Environment  | Feed   |
|---|--|--|
| In what year did the regulation go into effect?                 | 2003   | 2003<br>(GM feed safety assessment<br>procedure was developed in 1996<br>has been used since. It was put<br>into law in 2003.) |
| What is the scope/ objective of the regulation?                 | To prevent adverse effects on the biological diversity | To prevent adverse effects on the<br>animal health and to ensure animal<br>products safety                                     |
| Is a safety/ risk assessment required?                          | Yes  | Yes  |
| Is there a labelling requirement?                               | No   | No   |
| Is there a LLP test requirement?                                | No   | No   |
| Is there a traceability requirement?                            | No   | No   |
| Is a socio-economic assessment required?                        | No   | No   |
| Which authority is responsible for implementing the regulation? | Ministry of Agriculture, Forestry and Fisheries        | Ministry of Agriculture, Forestry<br>and Fisheries   |

#### Laos

| In what year did the regulation go into effect?     | Not applicable                           |
|---|--|
| What is the scope/ objective of the regulation?     | Regulate to research, transport, import. |
| Is a safety/ risk assessment required?              | Yes                                      |
| Is there a labelling requirement?                   | Yes                                      |
| Is there a LLP test requirement?                    | Yes                                      |
| Is there a traceability requirement?                | Yes                                      |
| Is a socio-economic assessment required?            | Yes                                      |
| Which authority is responsible for implementing the | Ministry of Science and Technology       |
| regulation?   |  |

## Latvia (EU)

### Lithuania (EU)

| In what year did the regulation go into effect? | "Law on Environmental Protection" entered into force |
|---|--|
|   | on 21 January 1992.                                  |
|   | "Law on Genetically Modified Organisms" entered      |

|   | into force on 31 December 2002. Lithuania has<br>transposed the requirements laid down in the<br>Directive 2001/18/EC of 12 March 2001 on the<br>deliberate release into the environment of GMOs.<br>Rules on Co-Existence of Genetically Modified Crops<br>with Conventional and Organic Crops approved by the<br>Order of Minister of Agriculture and Minister of<br>Environment No 3D-504/D1-608, 16-11-2007.  |
|---|---|
| What is the scope/ objective of the regulation? | The Law on Environmental Protection shall regulate<br>public relations in the field of environmental<br>protection, establish the principal rights and duties of<br>legal and natural persons in preserving the<br>biodiversity, ecological systems and landscape<br>characteristic of the Republic of Lithuania, ensuring a<br>healthy and clean environment, rational utilisation of<br>natural resources in the Republic of Lithuania, the<br>territorial waters, continental shelf and economic<br>zone thereof.<br>The purpose of Law on GMOs is to establish the<br>spheres of activities involving genetically modified<br>organisms and genetically modified products, their<br>state management and regulation, also the rights,<br>duties and responsibility of the users of the said<br>organisms and products.<br>The Law does not establish compulsory safety<br>requirements for the carriage of genetically modified<br>organisms and genetically modified products across<br>the territory of the Republic of Lithuania in transit,<br>also by rail, road, inland waterway, sea or air.<br>Lithuania has put in place a comprehensive system of<br>risk assessment and risk management dealing with<br>releases into the environment or placing on the<br>market of GMOs ("Order on Regulation of Risk<br>Assessment on GMOs"; "Regulation on GMOs<br>Deliberate Release into the Environment, Placing on<br>the Market", and etc.).<br>Rules on Co-Existence of Genetically Modified Crops<br>with Conventional and Organic Crops approved by the<br>Order of Minister of Agriculture and Minister of<br>Environment No 3D-504/D1-608, 16-11-2007.<br>Published in Official Journal "Valstybės žinios" No 121-<br>4978 (2007); 58-2848 (2010). These rules establish<br>GM crop cultivation, maintenance, harvesting, storage<br>and transportation requirements in order to avoid the<br>presence of GMOs in conventional and organic crops,<br>and provides the liability for latter contamination by<br>GMOs. |
|   |   |
| Is a safety/ risk assessment required?          | Yes   |
| Is there a labelling requirement?               | No, but in all cases it must comply with EU rules of  |
|   | GMO labeling.   |
| Is there a LLP test requirement?                | GMO labeling.<br>No   |

| Is a socio-economic assessment required?            | No   |
|---|--|
| Which authority is responsible for implementing the | The Ministry of Agriculture of the Republic of   |
| regulation?   | Lithuania and the Ministry of Environment of the |
|   | Republic of Lithuania                            |

## Luxembourg (EU)

#### Madagascar

| En quelle année la réglementation est-elle entrée en vigueur?             | 2011                                       |
|---|--|
| Quel(le) est la portée / objectif de la réglementation?                   | Interdiction des OGM                       |
| Une évaluation de la sécurité / des risques est-elle nécessaire?          | Oui  |
| Y a-t-il une obligation d'étiquetage?                                     | Oui  |
| Y a-t-il une obligation d'essais de la PFQ?                               |  |
| Y a-t-il une obligation de traçabilité?                                   |  |
| Une évaluation socio-économique est-elle exigée?                          |  |
| Quelle autorité est responsable de la mise en œuvre de la réglementation? | Ministère de l'Environnement et des Forêts |

### Malaysia

| ivial a ysia  |  |
|---|--|
| In what year did the regulation go into effect?                 | 2010   |
| What is the scope/ objective of the regulation?                 | To regulate the release, importation, exportation and<br>contained use of LMO/GMO, and the release of<br>products of such organisms, with the objectives of<br>protecting human, plant and animal health, the<br>environment and biological diversity. |
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | Yes  |
| Is there a LLP test requirement?                                | No   |
| Is there a traceability requirement?                            | No   |
| Is a socio-economic assessment required?                        | Yes  |
| Which authority is responsible for implementing the regulation? | Department of Biosafety, NRE   |

#### Mali

| IVIAII   |   |
|--|---|
| En quelle année la réglementation est-elle entrée en vigueur?    | 2008  |
| Quel(le) est la portée / objectif de la réglementation?          | L'importation/exportation, transit, utilisation<br>confinée, la libération ou la mise sur le marché de<br>tout OGM, |
| Une évaluation de la sécurité / des risques est-elle nécessaire? | Oui   |
| Y a-t-il une obligation d'étiquetage?                            | Oui   |
| Y a-t-il une obligation d'essais de la PFQ?                      | Oui   |
| Y a-t-il une obligation de traçabilité?                          | Oui   |
| Une évaluation socio-économique est-elle exigée?                 | Oui   |
| Quelle autorité est responsable de la mise en œuvre              | Agence de Développement Durable pour  |
| de la réglementation?  | l'Environnement (Ministère en charge de   |
|  | l'Environnement).   |

| Moldova   |  |
|---|--|
| In what year did the regulation go into effect? | 2001   |
| What is the scope/ objective of the regulation? | The law regulates the activities related to testing, |
|   | production, utilization, and marketing GMOs through  |

|   | modern biotechnologies.  |
|---|--|
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | Yes  |
| Is there a LLP test requirement?                                | Yes  |
| Is there a traceability requirement?                            | Yes  |
| Is a socio-economic assessment required?                        | Yes  |
| Which authority is responsible for implementing the regulation? | National Committee which is composed of<br>representatives of relevant state institutions and<br>whose composition and functioning is adopted by<br>Government of Moldova. |

#### Mongolia

| In what year did the regulation go into effect?                 | 2007•06•28   |
|---|--|
| What is the scope/ objective of the regulation?                 | The purpose of the Law is to regulate the relations in<br>respect of producing, handling and use of living<br>modified organisms, its trans-boudary movement<br>through the state border protection of bio-safety<br>within the state territory. |
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | Yes  |
| Is there a LLP test requirement?                                | Yes  |
| Is there a traceability requirement?                            | Yes  |
| Is a socio-economic assessment required?                        | Yes  |
| Which authority is responsible for implementing the regulation? | General agency for specialized inspection, MoIA,<br>MoEGD, National Biosafety Committee.   |

#### Morocco

| En quelle année la réglementation est-elle entrée en vigueur? | 1999  |
|---|---|
| Quel(le) est la portée / objectif de la réglementation?       | Interdiction de commercialisation de produits OGM |
| Une évaluation de la sécurité / des risques est-elle          | -   |
| nécessaire?   |   |
| Y a-t-il une obligation d'étiquetage?                         | -   |
| Y a-t-il une obligation d'essais de la PFQ?                   | -   |
| Y a-t-il une obligation de traçabilité?                       | -   |
| Une évaluation socio-économique est-elle exigée?              | -   |
| Quelle autorité est responsable de la mise en œuvre           | ONSSA   |
| de la réglementation?   |   |

## Mozambique

| In what year did the regulation go into effect?                 | National biosafety framework by Decree nr. 6/2007 of 25 <sup>th</sup> April.                    |
|---|---|
| What is the scope/ objective of the regulation?                 | According to the technical requirement set by the national scientific                           |
| Is a safety/ risk assessment required?                          | At all stages of decision-making activities related to GMOs and their coming                    |
| Is there a labelling requirement?                               | No, its voluntary   |
| Is there a LLP test requirement?                                | Yes   |
| Is there a traceability requirement?                            | Yes   |
| Is a socio-economic assessment required?                        | In all stages of making decisions on activities related with GMOs and their products            |
| Which authority is responsible for implementing the regulation? | GIIBS composed of representatives from seven ministries and academic and research institutions. |

## Myanmar (Not applicable)

| Namibia   |   |
|---|---|
| In what year did the regulation go into effect?                 | Biosafety Act (Act 6 of 2006)   |
| What is the scope/ objective of the regulation?                 | To provide for measures to regulate activities<br>involving the research, development, production,<br>marketing, transport, application and other uses of<br>genetically modified organisms and specified products<br>derived from genetically modified organisms; to<br>establish a Biosafety Council and define its powers,<br>functions and duties; and to make provision for<br>incidental matters. |
| Is a safety/ risk assessment required?                          | Yes   |
| Is there a labelling requirement?                               | Yes   |
| Is there a LLP test requirement?                                | Yes   |
| Is there a traceability requirement?                            | Yes   |
| Is a socio-economic assessment required?                        | Yes   |
| Which authority is responsible for implementing the regulation? | <ol> <li>Ministry of Agriculture, water and Forestry</li> <li>Ministry of Education</li> </ol>  |

## Netherlands (EU)

## New Zealand

| In what year did the regulation go into effect? | Living modified organisms(LMOs) are regulated under<br>the Hazardous Substances and New Organisms(HSNO)<br>Act 1996;<br>Animal Feed( including GMO animal feed) is covered<br>under the Agricultural Compounds and Veterinary<br>Medicines(ACVM) Act 1997 and is regulated under<br>the ACVM( exemptions and prohibited substances)<br>regulations 2011<br>For food the relevant regulations came into effect in<br>1998 |
|---|--|
| What is the scope/ objective of the regulation? | The Scope and objectives of the HSNO Act 1996 are<br>set out in the legislation:<br><u>http://legislation.govt.nz/act/public/1996/0030/latest</u><br>/DLM381222.html<br>Details of the scope and objectives of NZ regulations<br>covering relating to animal feeds can be accessed<br>from the following:  |
|   | http://www.legislation.govt.nz/act/public/1997/0087<br>/latest/DLM414577.html<br>http://www.legislation.govt.nz/regulation/public/201<br>1/0327/latest/DLM3982848.html?search=ts_regulatio<br>n_Agricultural++Compounds_resel&p=1&sr=1   |
|   | With regard to food, The Australia New Zealand Food<br>Standards Code regulates the use of GM food and<br>ingredients in NZ(refer standard 1.5.2) The joint<br>standard on the sale of GM food between Australia<br>and New Zealand came into effect when the food<br>code was adopted in 2000 and phased in over a 2 year<br>period. Code is given legal effect in New Zealand with                                     |

|   | joint standards issued under the Food Act 1981.   |
|---|---|
|   | Section 18(1) of the Food Standards Australia New<br>Zealand Act 1991 sets out the objectives of the<br>Authority in developing or reviewing food regulatory<br>measures and variations of food regulatory measures:<br>(1) The objectives (in descending priority order) of<br>the Authority in developing or reviewing food<br>regulatory measures and variations of food regulatory<br>measures are:<br>(a) the protection of public health and<br>safety; and<br>(b) the provision of adequate information<br>relating to food to enable consumers to make<br>informed choices; and |
|   | <ul> <li>(c) the prevention of misleading or<br/>deceptive conduct.</li> </ul>  |
| Is a safety/ risk assessment required?                          | Yes   |
| Is there a labelling requirement?                               | Yes   |
| Is there a LLP test requirement?                                | Yes   |
| Is there a traceability requirement?                            | No  |
| Is a socio-economic assessment required?                        | Yes   |
| Which authority is responsible for implementing the regulation? | Environmental Protection Authority for approving GM crops for field tests/release; Ministry for Primary Industries for regulating LLP in imported commodities   |
|   | (seed for sowing) and monitoring compliance with food composition and labelling requirements  |

## Niger (Not applicable)

#### Norway

| Norway  |   |
|---|---|
| In what year did the regulation go into effect? | <ul> <li>The Gene Technology Act regulates living GMOs and<br/>entered into force 1 September 1993. This act is an<br/>implementation of EU Directive 2001/18/EC with<br/>some national adaptations.</li> <li>The Norwegian Food Act regulates processed GM<br/>food and feed products and entered into force 1<br/>January 2004.</li> </ul>  |
| What is the scope/ objective of the regulation? | <ul> <li>The Gene Technology Act: To ensure that the production and use of genetically modified organisms is done in an ethical and socially responsible manner, and in accordance with the principle of sustainable development without health and environmental hazards.</li> <li>The Norwegian Food Act: To ensure safe and wholesome food, to promote health, quality and consumer concerns along the whole production chain, to provide for sustainable production, to promote sound plant and animal health, and to take into account the interests of operators throughout the production chain including market access abroad.</li> </ul> |
| Is a safety/ risk assessment required?          | Yes   |
| Is there a labelling requirement?               | Yes   |
| Is there a LLP test requirement?                | No  |
| Is there a traceability requirement?            | No (for GM products, authorization may include traceability requirements)   |

| Is a socio-economic assessment required?                        | Yes (only for living GMOs; no requirements for GM products)  |
|---|--|
| Which authority is responsible for implementing the regulation? | <ul> <li>Regulations concerning living GMOs are the<br/>responsibility of the Ministry of the Environment.</li> <li>The responsibility of regulations concerning GM<br/>products is shared between the Ministry of Health<br/>and Care Services, the Ministry of Agriculture and<br/>Food, and the Ministry of Fisheries and Coastal<br/>Affairs.</li> </ul> |

## Pakistan

| Fakistali   |  |
|---|--|
| In what year did the regulation go into effect?                 | April, 2005  |
| What is the scope/ objective of the regulation?                 | <ul> <li>a- Prevention of unintentional negligence<br/>leading to misuse and irresponsibility by<br/>laboratory workers/researchers as well<br/>as the end users.</li> </ul>   |
|   | <ul> <li>b- Regulation of manufacturing, import and<br/>storage of recombinant gene<br/>technological products research whether<br/>conducted in laboratory</li> <li>c- Regulation of field trials and commercial<br/>release of GM plants, animals,<br/>import/export and purchase of GMOs</li> </ul> |
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | No   |
| Is there a LLP test requirement?                                | No   |
| Is there a traceability requirement?                            | No   |
| Is a socio-economic assessment required?                        | No   |
| Which authority is responsible for implementing the regulation? | National Biosafety Centre (NBC)  |

## Philippines

| Finippines  |   |
|---|---|
| In what year did the regulation go into effect?     | 1990; 2002  |
| What is the scope/ objective of the regulation?     | 1990-contained use/experiments and field tests;       |
|   | 2002- field tests and commercial propagation          |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | For events for contained use, field tests and         |
|   | commercial propagation, the events have to be clearly |
|   | identified.   |
|   | For GM commodities for FFP, they should be            |
|   | identified as "may contain" in the shipment           |
| Is there a LLP test requirement?                    | No, although we have been working on regulations for  |
|   | FFP in food and feed since 2009                       |
| Is there a traceability requirement?                | Yes, through a declaration of GM content              |
| Is a socio-economic assessment required?            | Socio-economic considerations is exercised by         |
|   | competent authorities as part of their mandates but   |
|   | there are no formal guidelines                        |
| Which authority is responsible for implementing the | At the moment, the regulations are for GM crops only  |
| regulation?   | National Committee on Biosafety of the Philippines –  |
|   | guidelines for common concerns such as risk           |
|   | assessment  |
|   | Department of Science and Technology – contained      |
|   | use and confined tests                                |
|   | Department of Agriculture – field tests and           |
|   | propagation   |

## Poland (EU)

Qatar (Not applicable)

### Samoa

| In what year did the regulation go into effect?     | 2004 Samoa National Bio-safety Framework (SNBF),       |
|---|--|
|   | 2005 Bio-security Act.                                 |
|   | (2011 Draft Food Bill) Food Act – not yet enacted      |
| What is the scope/ objective of the regulation?     | SNBF – Awareness of GMO Impact abd sate transfer,      |
|   | handling and use of GMO resulting from modern          |
|   | biotechnology. For the Bio-security Act – mainly the   |
|   | disallowing of GMO importation and manufacturing in    |
|   | the Country.   |
| Is a safety/ risk assessment required?              | Yes  |
| Is there a labelling requirement?                   | Not sure of this but would consider the above legal    |
|   | framework as label.                                    |
|   | Draft regulation on food labelling under development   |
|   | by Ministry of Health                                  |
| Is there a LLP test requirement?                    | No   |
| Is there a traceability requirement?                | No.  |
|   | Food Bill has provisions for recall of food considered |
|   | not safe or suitable, or mislabelled or incorrectly    |
|   | identified   |
| Is a socio-economic assessment required?            | Within the context of the risk analysis                |
| Which authority is responsible for implementing the | Ministry of Agriculture and Fisheries for the Bio-     |
| regulation?   | security and Ministry of Natural Resource and          |
|   | Environment (MNRE) for SNBF.                           |
|   | Ministry of Health for the Food Act and Regulations    |

## Seyechelles (Not applicable)

## Slovakia (EU)

Slovenia (EU)

### Somalia

| In what year did the regulation go into effect?     | Not in place                       |
|---|------------------------------------|
| What is the scope/ objective of the regulation?     |                                    |
| Is a safety/ risk assessment required?              |                                    |
| Is there a labelling requirement?                   | yes                                |
| Is there a LLP test requirement?                    |                                    |
| Is there a traceability requirement?                |                                    |
| Is a socio-economic assessment required?            |                                    |
| Which authority is responsible for implementing the | MoH and Min. of Agri and livestock |
| regulation?   |                                    |

## Spain (EU)

#### Sudan

| In what year did the regulation go into effect? | 2010  |
|---|---|
| What is the scope/ objective of the regulation? | <ul> <li>Promoting the application of Biotechnology<br/>as a tool in the sustainable development of<br/>the country to benefit the people of the<br/>Sudan</li> </ul> |

|   | <ul> <li>To protect the environment and economics, and regulate the import and export system.</li> <li>To gain the advantages of the Biotechnology without incurring any harm to biological diversity or to human health.</li> </ul> |
|---|--|
| Is a safety/ risk assessment required?              | Yes  |
| Is there a labelling requirement?                   | Yes  |
| Is there a LLP test requirement?                    | No   |
| Is there a traceability requirement?                | Yes  |
| Is a socio-economic assessment required?            | Yes  |
| Which authority is responsible for implementing the | All Ministries and National Authorities which work on  |
| regulation?   | the field of food production& food safety, But mainly  |
|   | The National Council of Bio safety And The Sudanese  |
|   | Standard & Metrology Organisation.   |

## Sweden (EU)

#### Syria

| In what year did the regulation go into effect? | 14 October 2013   |  |
|---|---|--|
| What is the scope/ objective of the regulation? | Objectives:   |  |
|   | <ul> <li>Ensure a safe level for human health, animal and plant and the environment and to introduce controls for import, export, transfer and production, handling and use of living modified organisms (LMOs) and their products.</li> <li>Contribute to the development of a regulatory framework for research and development in the field of genetic engineering</li> </ul>  |  |
|   | Scope: This law applies to:   |  |
|   | <ul> <li>A. LMOs, including plants, animals and micro-<br/>ortanisms intended for research and<br/>experiments or for agricultural or industrial<br/>production in place of containment.</li> <li>B. LMOs intended for release into<br/>environmental and agricultural systems</li> <li>C. Non-living products of living genetically<br/>modified organisms either locally produced<br/>or imported and intended for industrial<br/>production or for human or animal<br/>consumption of raw or processed.</li> </ul> |  |
|   | The following are excluded from the application of the provisions of this law:  |  |
|   | <ul> <li>a. Living modified organisms and their products<br/>for pharmaceutical and therapeutic purposes<br/>or for the production of medical and<br/>pharmaceutical materials in containment for</li> </ul>  |  |

|   | <ul> <li>the purpose of human or veterinary use<br/>which are subject to the regulations and the<br/>Ministries of Health and Agriculture and<br/>Agarian Reform.</li> <li>b. Materials or products that contain<br/>genetically modified ingredients below the<br/>level determined by the executive<br/>instructions.</li> </ul>   |
|---|--|
| Is a safety/ risk assessment required?                          | Yes  |
| Is there a labelling requirement?                               | Yes  |
| Is there a LLP test requirement?                                | Yes  |
| Is there a traceability requirement?                            | Yes  |
| Is a socio-economic assessment required?                        | Yes  |
| Which authority is responsible for implementing the regulation? | The responsible authority is the Ministry of<br>Agriculture and Aarian Reform. The other bodies<br>involved in implementation of the law are as follows:   |
|   | <ul> <li>A. The ministry of Agriculture and Agarian<br/>Reform: follow up the implementation of all<br/>the LMOs and products intended for<br/>agricultural use (plant and animal ) and<br/>veterinary and feed and to issue the<br/>necessary instructions.</li> <li>B. Ministry of Economy and Trade: the<br/>implementation of legislation relating to the<br/>provisions of the Foreign Trade and<br/>deception and fraud, consumer protection,<br/>property protection and food safety with<br/>respect to LMOs and their products.</li> <li>C. Ministry of Health: the implementation of all<br/>the control and use of LMOs and their<br/>products intended for medical or therapeutic<br/>purposes or for pharmaceutical<br/>manufacturing in containment and the<br/>potential effects on human health.</li> <li>D. Ministry of Environmental Affairs: implement<br/>everything related to living modified<br/>organisms and products intended for<br/>processing vital environmental and monitor<br/>and study the introduction of LMOs and their<br/>impact on the environment, and<br/>management of Biosafety Clearing House<br/>(BCH). The competent ministries and<br/>authorities concerned with the<br/>implementation of this law provide the<br/>General Authority for Environmental Affairs<br/>of the information relating to the circulation<br/>of LMOs and their products and their effects<br/>and the actions and decisions taken thereon.</li> <li>E. General Commission for Biotechnology:<br/>Development of organizational principles for<br/>research and development and future plans<br/>for Biotechnology-related research<br/>institutions in accordance with the provisions<br/>of Law No. 33, of 04/07/2002.</li> </ul> |

|  | F. General Customs Directorate: the<br>implementation of the provisions of this law<br>in coordination with the Ministry of<br>Agriculture and the competent authority. |
|--|---|
|--|---|

## Thailand

| In what year did the regulation go into effect?     | 2507 (B.E.)                                   |
|---|---|
| What is the scope/ objective of the regulation?     | To regulate the import/production of GM crops |
| Is a safety/ risk assessment required?              | Yes   |
| Is there a labelling requirement?                   | Yes   |
| Is there a LLP test requirement?                    | Yes   |
| Is there a traceability requirement?                | Yes   |
| Is a socio-economic assessment required?            | -   |
| Which authority is responsible for implementing the | Department of Agriculture                     |
| regulation?   |   |

| Тодо  |  |
|---|--|
| En quelle année la réglementation est-elle entrée en vigueur?       | 06 janvier 2009  |
| Quel(le) est la portée / objectif de la réglementation?             | <ul> <li>- assurer la prévention des risques liés au<br/>développement, à l'utilisation confinée, à<br/>l'importation, à l'exportation, au transit, à la<br/>production, au stockage, à la dissémination volontaire<br/>ou involontaire dans l'environnement et à la mise sur<br/>le marché des organismes génétiquement modifiés<br/>(OGM) et de leurs produits dérivés ;</li> <li>- définir le cadre institutionnel de prévention des<br/>risqué biotechnologiques ;</li> <li>- définir les mécanismes de contrôle des mouvements<br/>transfrontières des OGM et/ou de leurs produits<br/>dérivés, d'évaluation et de gestion des risques<br/>biotechnologiques, de gestion des accidents résultant<br/>de l'utilisation des OGM et/ou de leurs produits<br/>dérivés, et le régime de responsabilité et de<br/>réparation ;</li> <li>- valoriser les avantages de la biotechnologie</li> </ul> |
|   | moderne par rapport aux biotechnologies traditionnelles.   |
| Une évaluation de la sécurité / des risques est-elle<br>nécessaire? | traditionnelles.Le titre III de la loi consacre les dipositions pour unrégime de sécurité en matière d'utilisation de labiotechnologie moderne, des OGM et/ou de leursproduits dérivés et comporte 09 chapitres <u>Chapitre 1er</u> : mesures de sécurité <u>Chapitre 2</u> : mouvements intentionnels <u>Chapitre 3</u> : mouvements non intentionnels etmesuresD'urgence <u>Chapitre 5</u> : Mise en quarantaine <u>Chapitre 7</u> : Identification et étiquetage <u>Chapitre 8</u> : Informations confidentielles <u>Chapitre 9</u> : Exportations des OGM et/ou de leursproduits dérivés   |
| Y a-t-il une obligation d'étiquetage?                               | Tout OGM et/ou ses produits dérivés doivent être clairement étiquetés  |

|   | et emballés conformément aux normes fixées par<br>l'autorité nationale<br>compétente. (Article 60 et 61)   |
|---|--|
| Y a-t-il une obligation d'essais de la PFQ?                               |  |
| Y a-t-il une obligation de traçabilité?                                   | Dans le cadre d'une démarche de traçabilité et<br>d'autocontrôle, des analyses de laboratoire peuvent<br>être effectuées pour vérifier la<br>présence d'acides nucléiques ou de protéines<br>résultant de la modification génétique et identifier les<br>matières premières, les<br>ingrédients ou les produits finis. (Article 58 et 59). |
| Une évaluation socio-économique est-elle exigée?                          | Doit être pris en compte le niveau des impacts des<br>OGM sur la santé humaine et animale, la diversité<br>biologique, les tissus socio-économiques et les valeurs<br>culturelles (Article 73)   |
| Quelle autorité est responsable de la mise en œuvre de la réglementation? | Le ministre chargé de l'environnement assure la mission d'autorité nationale compétente. (Article 9)   |

**Trinidad** (Not applicable, Ministry of Housing and Environment was mentioned for the authority responsible for implementing the regulation)

| т | u | r | k   | e | v |
|---|---|---|-----|---|---|
| • | - | - | ••• | - |   |

| Turkey   |  |
|--|--|
| In what year did the regulation go into effect?  | 26 September 2010  |
| In what year did the regulation go into effect?<br>What is the scope/ objective of the regulation? | Objective of the Biosafety Law:<br>To prevent risks that may arise from GMOs and<br>products thereof which are produced by using of<br>modern biotechnology by taking account the scientific<br>and technological developments; to establish and<br>implement biosafety system to ensure protection and<br>sustainability of environment, biological diversity and<br>health of human, animal and plant; and, to determine<br>the procedures and principles governing the control,<br>regulation and monitoring of these activities. |
|  | The present Law governs all activities including but<br>not limited to the research, development, processing,<br>placing on the market, monitoring, utilization,<br>importation, exportation, transit, transportation,<br>preservation, packaging, labeling and storage<br>regarding the Genetically Modified Organisms and<br>products thereof.   |
| Is a safety/ risk assessment required?   | Yes  |
| Is there a labelling requirement?  | Yes  |
| Is there a LLP test requirement?   | No   |
| Is there a traceability requirement?   | Yes  |
| Is a socio-economic assessment required?   | Yes  |
| Which authority is responsible for implementing the regulation?                                    | Biosafety committee and Ministry of Food, Agriculture and Livestock  |

#### Uruguay

| ¿En qué año fue aplicada la regulación?    | 1996   |
|--|--|
| ¿Cuál es el fin/objetivo de la regulación? | Análisis de riesgo para determinar si se autoriza o no |
|  | el uso de cultivos genéticamente modificados.          |

| ¿Se requiere de una evaluación de seguridad/riesgo?            | Si  |
|--|---|
| ¿Existe algún requisito de etiquetado?                         | No  |
| ¿Existe algún requisito de análisis de LLP?                    | No  |
| ¿Existe algún requisito de rastreabilidad?                     | En autorizaciones bajo condiciones de bioseguridad<br>(investigación a nivel de laboratorio, invernáculo,<br>campo, producción de semilla para exportación y en<br>ensayos de registro cultivares).   |
| ¿Se requiere la evaluación socio-económica?                    | Si, pero considerada como parte de la gestión del<br>riesgo, no como parte de la evaluación del riesgo y<br>para solicitudes de liberación comercial.   |
| ¿Cuál es la autoridad competente responsable de la regulación? | Gabinete Nacional de Bioseguridad (GNBio) cuyo<br>equipo ejecutivo es la Comisión para la Gestión del<br>Riesgo (CGR). El gabinete esta conformado por 6<br>ministros correspondientes a los ministerios de:<br>agricultura, salud, ambiente, economía, industria y<br>relaciones exteriores. |

## United States of America

| United States of America                        |  |
|---|--|
| In what year did the regulation go into effect? | For FDA, existing statutes and regulations are used,<br>For EPA, existing statutes and regulations are<br>used For USDA/APHIS: 1987 (APHIS regulation 7 CFR<br>Part 340)   |
| What is the scope/ objective of the regulation? | Food, feed and the introduction (move into or<br>through the United States, release into the<br>environment, or move interstate) of organisms and<br>products altered or produced through genetic<br>engineering that are plant pests or are believed to be<br>plant pests.  |
| Is a safety/ risk assessment required?          | All food and feed marketed must be safe, the need for<br>pre-market authorization may depend upon the<br>nature of the crop.   |
| Is there a labelling requirement?               | As with all food, foods derived from through genetic<br>engineering must be labeled in accordance with<br>existing regulations. The name of the food, the<br>ingredient statement if more than one ingredient, net<br>quantity of contents, name and address of<br>manufacturer, allergen information as applicable, and<br>nutrition labeling (unless exempt), are required on all<br>foods. However, food labeling disclosing the fact that<br>a food was produced through genetic engineering is<br>voluntary, provided such labelling is truthful and not<br>misleading.<br>For USDA/APHIS: There are no labelling requirements<br>once a GE plant has nonregulated status under the<br>APHIS regulation 7 CFR Part 340. |
| Is there a LLP test requirement?                | A detection method necessary to detect the crop is<br>not required in order for a developer to complete<br>FDA's voluntary consultation process. An analytical<br>test method is required for all plant incorporated<br>protectants (PIPs) registered by EPA for detection of<br>the PIP trait in the commodity (e.g., grain).   |
| Is there a traceability requirement?            | Applicable traceability requirements are not specific  |

|   | to genetically engineered foods and apply generally to all foods under FDA's purview.  |
|---|--|
| Is a socio-economic assessment required?                        | USDA/APHIS: requires a socio-economic assessment<br>for purposes of the National Environmental Policy Act<br>of 1970, which applies to all major Federal decisions<br>(not just genetic engineering). USDA/APHIS does not<br>require a socio-economic assessment under APHIS<br>regulation 7 CFR Part 340 regarding plant-pest risks.<br>FDA and EPA do not require socio-economic<br>assessments.   |
| Which authority is responsible for implementing the regulation? | The U.S. Government agencies responsible for<br>oversight of the products of agricultural modern<br>biotechnology are the U.S. Department of<br>Agriculture's Animal and Plant Health Inspection<br>Service (USDA-APHIS), the U.S. Environmental<br>Protection Agency (EPA), and the Department of<br>Health and Human Services' Food and Drug<br>Administration (FDA). Depending on its<br>characteristics, a product may be subject to review by<br>one or more of these agencies. |