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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**

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

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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 sent	193*
Responses received	75*
Response rate (%)	38.86%

* includes European Union

1.2. Regional response rate

Table 2. Regional response rate

Region	Number of FAO Members	Number of respondents	Regional distributions (share)	Regional response rate (%)
Africa	48	14	18.67	29.17
Asia	23	10	13.33	43.48
Europe	54*	26*	34.67	48.15
Latin America and Caribbean	33	16	21.33	48.48
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	-

* includes European Union

Figure 1. Regional distributions (share)

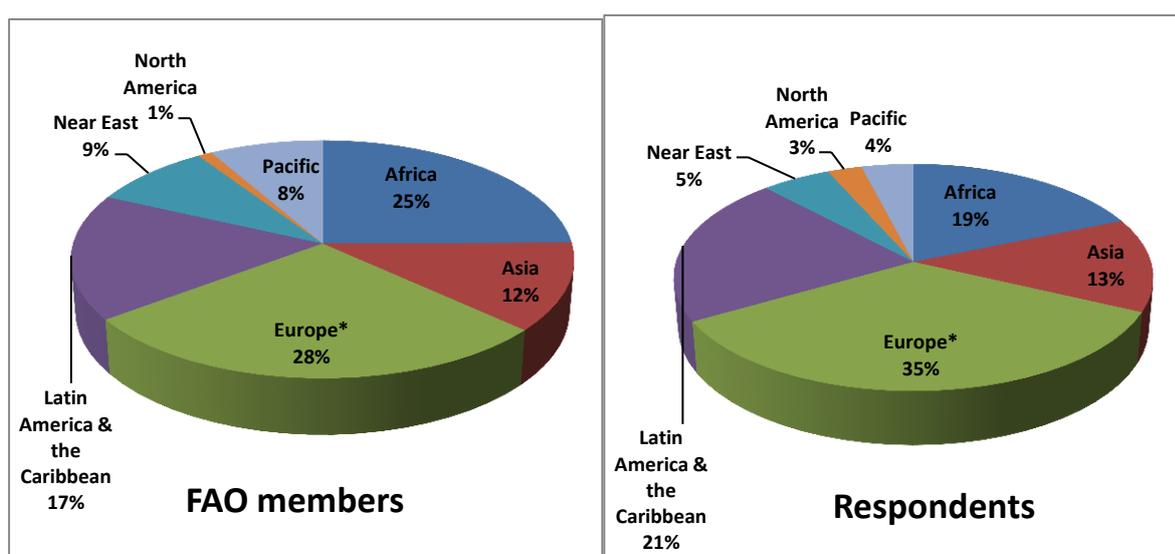
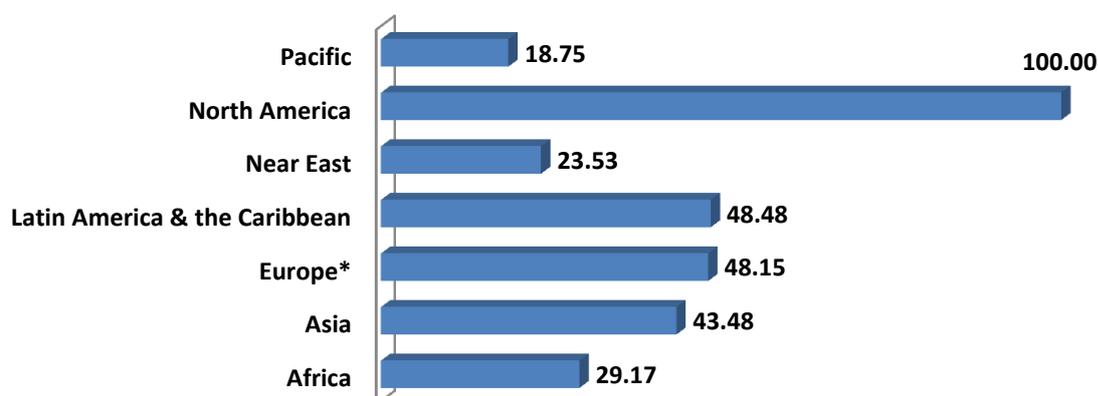


Figure 2. Regional response rate

Regional response rate, %



1.3. List of responding countries

Argentina	Estonia	Myanmar
Australia	European Union	Namibia
Austria	Finland	Netherlands
Bahamas	France	New Zealand
Bangladesh	Gambia	Niger
Barbados	Germany	Norway
Bolivia	Grenada	Pakistan
Botswana	Honduras	Philippines
Brazil	Hungary	Poland
Bulgaria	Iran	Qatar
Cambodia	Ireland	Samoa
Canada	Italy	Seychelles
Cape Verde	Jamaica	Slovakia
Colombia	Japan	Slovenia
Congo	Laos	Somalia
Costa Rica	Latvia	Spain
Croatia	Lithuania	Sudan
Cuba	Luxemburg	Sweden
Cyprus	Madagascar	Syria
Czech Republic	Malaysia	Thailand
Denmark	Mali	Togo
Dominican Republic	Moldova	Trinidad and Tobago
DRC Congo	Mongolia	Turkey
Ecuador	Morocco	Uruguay
El Salvador	Mozambique	United States of America

2. GM Crop Production

Q1. Does your country produce GM crops?

Table 3. GM crop producing countries

Response option	Response (%)	Yes and No %
Yes - Research only (field trials)	18.92	40.54
Yes – Both research and commercial production	21.62	
No	59.46	59.46
Total	100	100

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?

Table 5. GM events 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

*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?

Table 7. Export situations of GM commodities

Commodity	Yes (%)	No (%)	Not applicable (%)	No response (%)	No information (%)	Total (%)
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

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

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

Reporting Country	Commodity	Proportion of GM Crops in Total Exports of this Commodity, %	Major Trading Partners
Argentina	Maize	90	N. Africa, S. America, Asia
	Soy	99	Asia, Middle East, EU
	Cotton	95	S.E. Asia
Australia	Rapeseed	23	Pakistan, Japan, UAE, Bangladesh
	Cotton	100	China, Japan, Republic of Korea, USA
Bolivia	Soy	99	Peru, Colombia, Ecuador, Brazil
Brazil	Soy	-	China, EU, S. Korea, Japan
Canada	Maize	Ca. 85	USA, Spain, Egypt, Iceland, Hong Kong
	Soy	Ca. 50	China, Japan, USA, Netherlands, Belgium, Egypt, Malaysia.
	Rapeseed	Ca. 95	China, Japan, Mexico, USA
Colombia	Cotton lint	70	-
Uruguay	Maize	70-80	Several African countries (90%), especially Senegal and Tunisia
	Soy	100	China (77%), Holland (9%), Egypt (3%)
United States	Maize	-	Japan, Mexico, China, South Korea, Venezuela
	Soy	-	China, Mexico, Japan, Indonesia, Germany
	Cotton	-	China, Turkey, Mexico, Vietnam, Indonesia
	Alfalfa	-	-

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?

Table 9. Import situations of GM commodities

Commodity	Yes (%)	No (%)	Not applicable (%)	No response (%)	No information (%)	Total (%)
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

*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 Crops in Total Imports of this Commodity	Major Trading Partners
Argentina	Cotton	100	Brazil
Australia	Rapeseed	56	Canada, USA
	Cotton seed	100	USA
Austria	Soy	81.4	USA, Brazil
Bolivia	Maize	99	Argentina, Brazil
	Soy	99	Argentina
Brazil	Maize	-	Argentina, Paraguay
	Soy	-	Argentina, Paraguay
Bulgaria	Soybean Meal	90	Brazil, Argentina
Canada	Maize	95-100	USA
	Soy	95-100	USA.
	Sorghum	-	USA
	Rapeseed	95-100	USA
Colombia	Maize & Soy	-	-
Croatia	Soy	15	Brazil, Argentina
Cuba	Maize	70	USA, Brazil, Argentina
	Soy	90	Brazil, Argentina
	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
Iran	Maize	-	Brazil, Argentina, Ukraine
	Soy	-	Brazil, Argentina, Ukraine
	Rapeseed	-	Canada
Ireland	Maize	37	USA, Brazil, Canada
	Soy	94	Argentina, USA, Brazil
	Rapeseed	20	Canada, USA
Italy	Maize & Soy (feed)	-	USA, Argentina, Brazil
Japan	Maize & Soy	-	USA, Brazil
	Rapeseed	-	Canada, Australia
	Cotton	-	Australia, USA
Latvia	Soybean Meal	89	Argentina, USA
Lithuania	Soy	74	China, Russia, Israel, S. Korea, India,

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

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?

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

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

Q8. Please provide the following information for each regulation:

Table 12. Information on regulations*

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

*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. Labelling requirements (multiple responses)

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 negative labelling and subject to threshold level	2.70	Turkey: 0.9 %
Voluntary + positive labelling	2.70	-
Mandatory + positive labelling + subject to threshold level	1.35	Brazil: 1%
Mandatory + positive labelling	37.84	-
Mandatory + positive and negative labelling	1.35	Mongolia: No further explanation was provided
Mandatory + subject to threshold level	2.70	Thailand: labelling is required by weight, if each ingredient constitutes 5 percent or more of the final product and 5 percent or more of that ingredient is derived from GMO ingredients. Syria: < 1%
Positive labelling + subject to threshold level	1.35	Sudan: No further explanation was provided
Mandatory + Other	1.35	Malaysia: Future possibility
Other	1.35	Rely on certifications of 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-tolerance¹” policy for unauthorized GM crops?

Table 14. Zero-tolerance policy

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 option	Response (%)	Note
According to the international guidelines (Codex principles and guidelines)	12.16	-
According to the domestic guidelines	6.76	Note that the respondents who selected this option do 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 guidelines (regional, private, trade-partner countries' etc)	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.
We do not conduct food safety assessment of GM crops	24.32	-
According to the international guidelines (Codex principles and guidelines) + according to the domestic guidelines	12.16	-
According to the international guidelines (Codex principles and guidelines) + according to the domestic guidelines + according to the other guidelines (regional, private, trade-partner countries'	2.70	-

¹ 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 guidelines (Codex principles and guidelines) + according to the other guidelines (regional, private, trade-partner countries' etc)	1.35	-
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?

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

Response option	Response (%)	Note
According to the international guidelines (OECD)	9.46	-
According to the domestic guidelines	9.46	Note that the respondents who selected this option do 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 guidelines (regional, private, trade-partner countries' etc)	32.43	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.
We do not conduct feed safety assessment of GM crops	29.73	-
According to the international guidelines (OECD) + according to the domestic guidelines	6.76	-
According to the international guidelines (OECD) + according to the domestic guidelines + according to the other guidelines (regional, private, trade-partner countries' etc)	2.70	-
According to the domestic guidelines+ according to the other guidelines (regional, private, trade-partner countries' etc)	2.70	-
No response	5.41	-

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 guidelines (IPPC, OECD, Cartagena Protocol)	10.81	-
According to the domestic guidelines	9.46	Note that the respondents who selected this option do 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 guidelines (regional, private, trade-partner countries' etc)	31.08	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.
We do not conduct environment safety risk assessment of GM crops	21.62	-
According to international guidelines (IPPC, OECD, Cartagena Protocol) + according to the domestic guidelines	14.86	-
According to international guidelines (IPPC, OECD, Cartagena Protocol) + according to the other guidelines (regional, private, trade-partner countries' etc)	2.70	-
According to international guidelines (IPPC, OECD, Cartagena Protocol) + according to the domestic guidelines + according to the other guidelines (regional, private, trade-partner countries' etc)	1.35	-
Not applicable	1.35	-
No response	5.41	-
No information	1.35	-
Total	100	

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

Table 18. Authorization policy for imports (multiple responses)

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

*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.

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

Response option	Response (%)	Note
Yes, testing in the exporting country	33.78	-
Yes, testing in the importing country (domestic laboratories)	12.16	-
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 and other (specify)	1.35	New Zealand: For living modified 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 and importing countries as well as	2.70	Norway: Samples of food, feed, and seeds are analysed for the presence of

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

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

Table 20. Threshold level

Response option	Response (%)	Note
Yes	33.78	-
No	54.05	-
Yes and No	1.35	Japan: Yes-Feed safety (Use of unauthorized GM crop as feed is, in principle, prohibited. If the LLP crop of concern has already been approved as a safe GM feed in a country whose GMO safety assessment system is equivalent to or better than that of Japan, the presence of that LLP crop in feed consignments up to 1% will be tolerated. No: Environment (LLP situations are managed in some different ways depending on the GMO's approved status in exporting country, characteristics or 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)?

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

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 developed	1.35	
No, but capacity is being developed	10.81	
No	24.32	
No response	4.05	4.05

Total	100	100
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Q18. What kind of detection methods does your country use?

Table 22. Detection methods

Response option	Response (%)	Note
Quick methods (presence or absence)	12.16	
Detection and quantification	39.19	Japan: Detect specific DNA sequences by qualitative PCR method and if 1 % threshold level for feed is applied, quantify the LLP crop by quantitative PCR New Zealand: We don't use Quantification PCR methods as they cannot report below 0.1% GM content Norway: Screening and event-specific methods
Other	2.70	Cambodia: we have no idea Gambia: Samples are sent to reference laboratories in neighbouring countries Mali: Eliza, PCR Samoa : Use Scientific Research of Samoa (SROS) USA: We would use whatever methods deemed most appropriate to the situation presented
We don't conduct 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, when applicable (unapproved GMO) Germany: DNA-based sequencing and event-specific 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?

Table 23. LLP/AP incidents 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 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

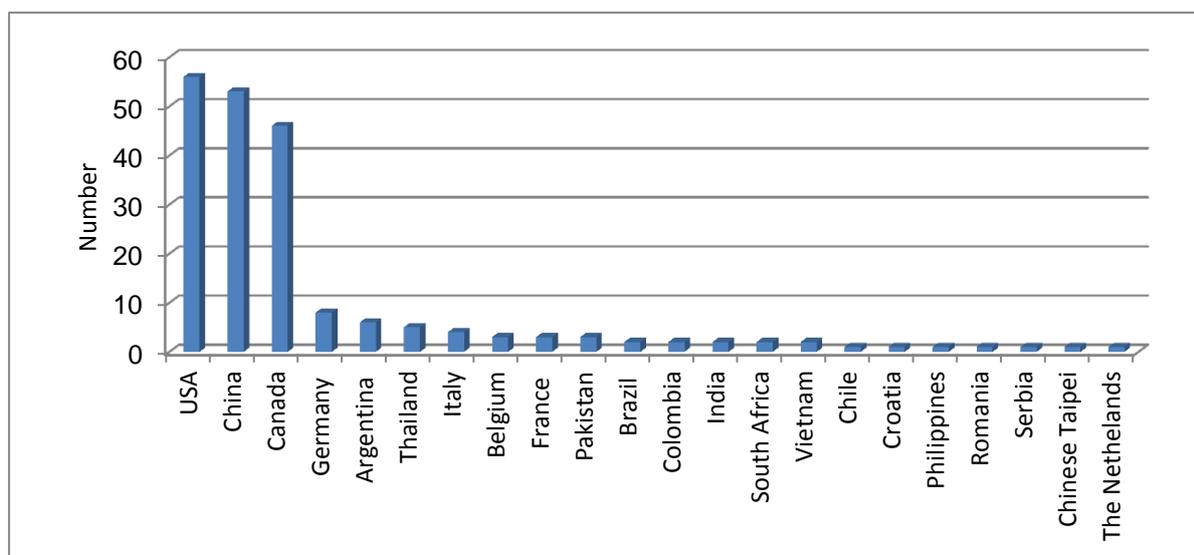


Figure 4. LLP/AP incidents by commodity

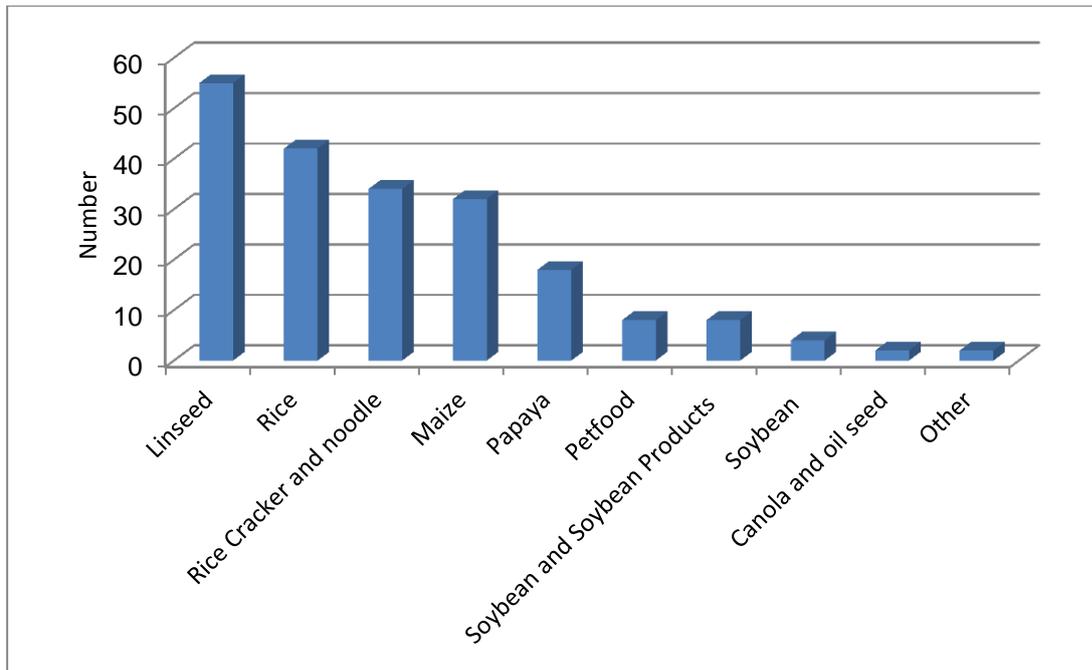
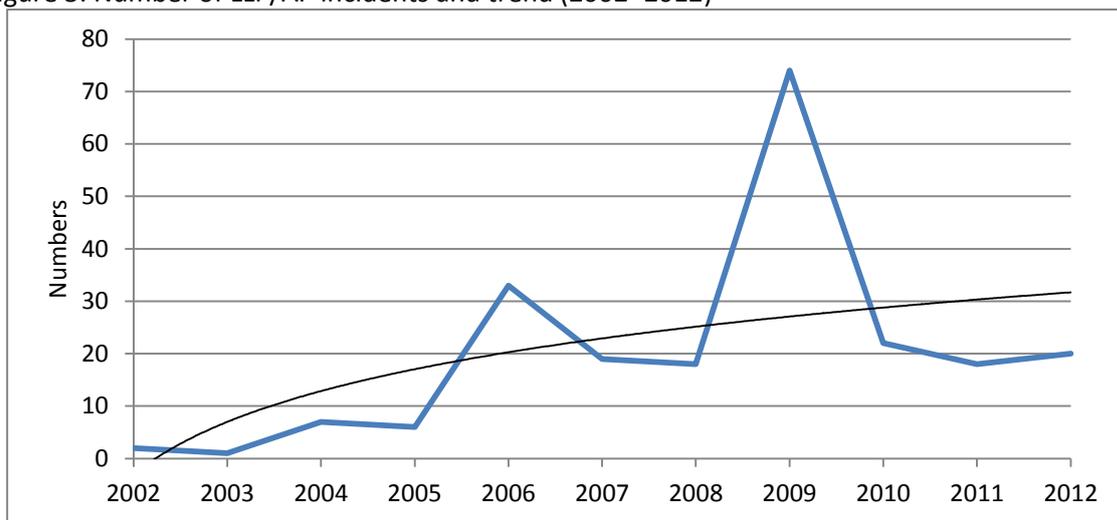


Figure 5. Number of LLP/AP incidents and trend (2002–2012)



Q20. If yes, please provide the details below:

Table 25. LLP/AP incidents reported by countries

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

	2007	Pet food	2.16	United States/ 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 (feed use)	1.5	Presumably originating from Canada (bought via supplier in Germany)	A sample of linseeds showing a low level of Flax CDC Triffid (FP967) was identified in the official control of feed	Affected batches were destroyed
	2009	Linseed (food use)	Different lots	Canada via other EU 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 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 MON88017	-	United States	RASFF of member	Blocked, pending EU approval
	2009	Maize MIR604	-	United States	RASFF of member	Blocked, pending EU approval
	2012	Rice Kefeng6 and KMD	-	China	Official control	Market withdrawal and consumer recall
	2012	Rice OGM	-	Pakistan/ India	Operator auto control	Market withdrawal and consumer recall
	2012	Papaya	-	Thailand	Official control	Market withdrawal and consumer recall

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

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

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

	2009	Flax (FP967)	N/A	Canada	Notification by the industry involved	After the notification, consignments already imported into Japan were tested and found to be free of or < 1% FP967. If FP967 was detected at < 1%, the consignment could be used as feed but only for processing under appropriate measures to limit the contact with the environment. After the above phase, import became acceptable only when consignments for Japan were tested and certified as under the threshold. Without such certification, consignments are tested in Japan, and if FP967 is detected: at < 1%, the consignment can be imported but only for processing under appropriate measures to limit the contact with the environment; at > 1%, the consignment will be rejected
	2009	Flax seed (fresh, roasted)	31	Canada	Testing at the time of importation	Consignment rejected
	2010	Flax seed (roasted)	5.6	Canada	Testing at the time of importation	Consignment rejected
	2011	Papaya	N/A	Chinese Taipei	By testing conducted in response to information from a researcher	Recalled unplanted seeds from their distributors Destroyed all plants germinated from the seeds of concern
	2011	Flax seed (granola)	0.04	Canada	Testing at the time of importation	Consignment rejected
	2011	Rice (powder, noodle)	1.1	China	Testing at the time of importation	Consignment rejected
	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 meal	5451.5	Argentina	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2	Consignment was released for free circulation in EU
	2012	Hipro soybean meal and soybean expeller (feed materials)	5700	United States	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2 (1 from all consignments was selected for sampling and tested for quality and quantity of Monsanto 40-3-2)	Consignment was released for free circulation
	2012	Soybean meal	7615.23	Argentina	Manufacturing enterprise attested GMO certificate Monsanto Roundup 40-3-2	Consignment was released for free circulation in EU
Luxembourg	2009	Linseed	55	Germany/ 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 sent samples of maize for testing in South Africa and found that these products contained genetically modified maize	The Namibian Agronomic Board (NAB) has reprimanded those responsible for producing and marketing maize products that a consumer lobby alleged contain so-called genetically modified maize
Netherlands	2005	Bt10 maize in feed	-	United States	Announcement by company	Consignments held for testing and later released on basis of negative results; EU emergency measure put in place (19 April 2005)
	2006	Chinese rice (Bt63) in food	-	China	Greenpeace/ Friends of the Earth	EU emergency measure (9 April 2008)
	2006	LLRICE601 in food	-	United States	Announcement by company	Blocking of US rice consignments by Dutch companies until negative test results were obtained, risk assessment by Dutch Food safety authority (NVWA-front office); EU emergency measure (23 August 2006)
	2007	Maize in maize gluten, brewers grain Herculex RW 59122	-	United States	Greenpeace	Consignments traced and held for testing by Dutch food safety authority, tests negative, no need for further measures. Action plan put in place by US company for voluntary testing of consignments to EU and certification
	2009	FP967 linseed (CDC Triffid) in food	-	Canada	Detection by third country authorities	Consignments traced and held for testing by Dutch food safety authority, recalls performed, risk assessment done by the Netherlands Food and Consumer Product Safety Authority-front office, action plan by Canadian government
New Zealand	2001	Maize seed	-	United States	In-house testing of growing crop by company	Crops 'held' while information was sought and then released

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

Spain	2009	Maize, soy cake	-	United States	-	Border rejection
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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
	1	2	3	4	5				
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 regulations²

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

² In original language.

Which authority is responsible for implementing the regulation?	Office of the Gene Technology Regulator
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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 regulation?	Department of Environment, Ministry Of Environment & Forest

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

In what year did the regulation go into effect?	2011
What is the scope/objective of the regulation?	To protect biodiversity, environmental impact and human health
Is a safety/risk assessment required?	No
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?	Ministry of Environment and Water

Botswana (Not applicable)**Brazil**

In what year did the regulation go into effect?	1995 and then revised in 2005
What is the scope/ objective of the regulation?	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
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?	Not as an obligation, but is a possibility
Which authority is responsible for implementing the regulation?	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

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 established a stringent process for evaluating the safety of foods derived through genetic modification (often referred to as biotechnology-derived foods or 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 genetically modified foods, where safety concerns such as allergenicity and compositional or nutritional changes are identified. In this situation, labelling is required to alert consumers or susceptible groups in 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 regulation?	Food and Drugs Act. Division 28 of part B of the Food and Drugs Regulations.

Feed Safety Regulations:

In what year did the regulation go into effect?	Although the Novel Feeds regulations were promulgated in 1996, the CFIA had authority to conduct pre-market assessment under the current 1983 <i>Feeds Regulations</i> . The rationale being that Canada regulates biotech based on a product (novelty) rather than a process used to create a product.
What is the scope/ objective of the regulation?	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. 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.
Is a safety/ risk assessment required?	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. Feeds must also be shown to be effective for their intended purpose.
Is there a labelling requirement?	Not GM specific. Yes, regarding general feed labelling 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 <i>Feeds Act</i> and <i>Regulations</i>

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

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 regulation?	Canadian Food Inspection Agency under the <i>Seeds Act</i> and <i>Seeds Regulations</i>

Cape Verde (Not applicable, but Decreto Lei_24/2009 was mentioned)

Colombia

In what year did the regulation go into effect?	1998 (Agreement 003 and Resolution ICA 3492), 2002 (Law 740 of 2002), 2005 (Decree 4525)
What is the scope/objective of the regulation?	Agreement 003: Establishes the National Technical Council for the introduction, production, release and commercialization of Genetically Modified Organisms (GMOs) for agricultural use. Resolution ICA 3492: Regulates and determines the procedure for the introduction, production, release and commercialization of Genetically Modified Organisms (GMOs) and contains other provisions. Law 740 of 2002: Approves the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity", done in Montreal, on 29 January 2000. Decree 4525 of 2005: Regulates Law 740 of 2002
Is a safety/risk assessment required?	Yes
Is there a labelling requirement?	There must be labelling on all containers and packages of foods for human consumption derived from GMOs that are not substantially equivalent to their conventional counterpart and when presenting any of the following conditions: <ul style="list-style-type: none"> • The values of nutritional composition of the food containing a GMO or made from raw materials containing a GMO are not substantially equivalent to those of their conventional counterpart or the food product found on the market. • The form of storage, preparation or cooking of the food containing a GMO or made from raw materials with a GMO differs because of this, in comparison with the conventional counterpart or the equivalent food product existing on the market. • The presence of an allergen introduced as a result of genetic modification in a food containing a GMO or made from raw materials with a GMO which consumers do not expect to be present. • The existence of a difference in organoleptic

	<p>properties of a food, as a consequence of genetic modification, in comparison with its conventional counterpart.</p> <p>In the case of seeds involving GMO materials, the packaging must be clearly stamped with the indication "Genetically Modified Organism"</p>
Is there a LLP test requirement?	No, work on this is under way.
Is there a traceability requirement?	No
Is a socio-economic assessment required?	No
Which authority is responsible for implementing the regulation?	<p>The Ministry of Agriculture and Rural Development, through the Colombian Institute of Agriculture (ICA), will be responsible for the authorization of Living Modified Organisms (LMOs), exclusively for use in agriculture, livestock, fisheries, commercial forest plantations and agro-industry.</p> <p>The Ministry of Environment, Housing and Territorial Development will be responsible for the authorization of LMOs exclusively for environmental use.</p> <p>The Ministry of Social Protection will be responsible, directly or through a duly delegated body, for the authorization of LMOs for exclusive use in human health and nutrition.</p>

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

In what year did the regulation go into effect?	1996, 2006
What is the scope/objective of the regulation?	To protect the environment, human and animal health.
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?	Yes
Is a socio-economic assessment required?	No
Which authority is responsible for implementing the regulation?	Ministry of Agriculture and Livestock, Ministry of Health, Ministry of Environment and Energy, Ministry of Science and Technology.

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 protection of human life, animal health and welfare , environment, provide objectives of facilitating 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 regulation?	Ministry of Healthy, Ministry of Environmental and nature protection, Ministry of sciences, education and sport, Ministry of Agriculture

Cuba

In what year did the regulation go into effect?	2005
What is the scope/objective of the regulation?	To ensure food safety
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?	Institute of Nutrition and Food Hygiene, National Biosafety Centre, National Toxicology Centre.

Cyprus (EU)

Food

In what year did the regulation go into effect?	2012
What is the scope/ objective of the regulation?	Prevent LLP and AP presence of GMO's in conventional maize seed lots (0% threshold)
Is a safety/ risk assessment required?	NO
Is there a labelling requirement?	NO
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 regulation?	Department of Agriculture, Ministry of Agriculture, Natural Resources and Environment

Feed

In what year did the regulation go into effect?	2006
What is the scope/ objective of the regulation?	Traceability and Labelling of GM Feed
Is a safety/ risk assessment required?	NO
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 regulation?	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)

In what year did the regulation go into effect?	2004
What is the scope/ objective of the regulation?	Contained use and deliberate release of all GMOs, except authorisation of GM food and feed, environmental risk assessment of all GMOs and products consisting of or containing GMOs
Is a safety/ risk assessment required?	Environmental risk assessment is required
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 (for food and feed safety, Ministry of the Agriculture of the Cech Republic)

Denmark (EU)**Dominican Republic (Not applicable)**

DRC Congo (Not applicable)**Ecuador**

In what year did the regulation go into effect?	2008
What is the scope/objective of the regulation?	The Constitution of the Republic declares Ecuador free of transgenic seeds and crops.
Is a safety/risk assessment required?	Existing legislation does to provide for risk assessment.
Is there a labelling requirement?	Yes there is a legal framework but this is not yet applied.
Is there a LLP test requirement?	No
Is there a traceability requirement?	No
Is a socio-economic assessment required?	Not yet applied
Which authority is responsible for implementing the regulation?	Ministry of Environment

El Salvador

In what year did the regulation go into effect?	2007
What is the scope/objective of the regulation?	Safe handling of GMOs.
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?	Only for risk analysis.
Which authority is responsible for implementing the regulation?	Ministry of Environment and Natural Resources, Ministry of Public Health and Social Welfare, Ministry of Agriculture and Livestock.

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 protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market Lay down Community procedures for the authorisation and supervision of genetically modified food and feed Lay down provisions for the labelling of genetically 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 food and seeds. Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the

	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 regulation?	Board for Gene technology

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 regulation?	Ministry of Health, National Nutrition Agency and Ministry of Agriculture

Germany (EU)**Grenada (Not applicable)****Honduras**

In what year did the regulation go into effect?	1998
What is the scope/objective of the regulation?	To regulate the use and handling of GM crops.
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?	The Secretariat of Agriculture and Livestock through the Department of Seed Certification of SENASA.

Hungary (EU)

In what year did the regulation go into effect?	1998: Hungarian Act on gene technological activities (Act No. XXVII of 1998), later harmonised with the current EU legislations. and also several national implementing regulations
What is the scope/ objective of the regulation?	authorisation system and procedure of GM field

	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 regulation?	Dept Agriculture, Food & Marine, Environmental 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 regulation?	The Natural Resources Conservation Authority

Japan**Food**

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 and their processed food were provided based on the JAS Law and Food Sanitation Act and labelling became

	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.

Environment and Feed

	Environment	Feed
In what year did the regulation go into effect?	2003	2003 (GM feed safety assessment procedure was developed in 1996 has been used since. It was put 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 animal health and to ensure animal 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 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 regulation?	Ministry of Science and Technology

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 transposed the requirements laid down in the Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of GMOs. Rules on Co-Existence of Genetically Modified Crops with Conventional and Organic Crops approved by the Order of Minister of Agriculture and Minister of Environment No 3D-504/D1-608, 16-11-2007.
What is the scope/ objective of the regulation?	The Law on Environmental Protection shall regulate

	<p>public relations in the field of environmental protection, establish the principal rights and duties of legal and natural persons in preserving the biodiversity, ecological systems and landscape characteristic of the Republic of Lithuania, ensuring a healthy and clean environment, rational utilisation of natural resources in the Republic of Lithuania, the territorial waters, continental shelf and economic zone thereof.</p> <p>The purpose of Law on GMOs is to establish the spheres of activities involving genetically modified organisms and genetically modified products, their state management and regulation, also the rights, duties and responsibility of the users of the said organisms and products.</p> <p>The Law does not establish compulsory safety requirements for the carriage of genetically modified organisms and genetically modified products across the territory of the Republic of Lithuania in transit, also by rail, road, inland waterway, sea or air.</p> <p>Lithuania has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs („Order on Regulation of Risk Assessment on GMOs“; „Regulation on GMOs Deliberate Release into the Environment, Placing on the Market“, and etc.).</p> <p>Rules on Co-Existence of Genetically Modified Crops with Conventional and Organic Crops approved by the Order of Minister of Agriculture and Minister of Environment No 3D-504/D1-608, 16-11-2007. Published in Official Journal „Valstybės žinios“ No 121-4978 (2007); 58-2848 (2010). These rules establish GM crop cultivation, maintenance, harvesting, storage and transportation requirements in order to avoid the presence of GMOs in conventional and organic crops, and provides the liability for latter contamination by GMOs.</p>
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?	No
Is there a traceability requirement?	No
Is a socio-economic assessment required?	No
Which authority is responsible for implementing the regulation?	The Ministry of Agriculture of the Republic of Lithuania and the Ministry of Environment of the Republic of Lithuania

Luxembourg (EU)

Madagascar

In what year did the regulation go into effect?	2011
What is the scope/objective of the regulation?	Ban on GMOs
Is a safety/risk assessment required?	Yes

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 regulation?	Ministry of Environment and Forests

Malaysia

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 contained use of LMO/GMO, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the 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

In what year did the regulation go into effect?	2008
What is the scope/objective of the regulation?	Import/export, transit, contained use, release or commercialization of all GMOs.
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?	Agency for Sustainable Development of the Environment (Ministry of Environment).

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 representatives of relevant state institutions and whose composition and functioning is adopted by 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 respect of producing, handling and use of living modified organisms, its trans-boundary movement through the state border protection of bio-safety

	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, MoEGD, National Biosafety Committee.

Morocco

In what year did the regulation go into effect?	1999
What is the scope/objective of the regulation?	Ban on the marketing of GM products.
Is a safety/risk assessment required?	-
Is there a labelling requirement?	-
Is there a LLP test requirement?	-
Is there a traceability requirement?	-
Is a socio-economic assessment required?	-
Which authority is responsible for implementing the regulation?	ONSSA (National Office for Food Safety)

Mozambique

In what year did the regulation go into effect?	National biosafety framework by Decree nr. 6/2007 of 25 th 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? What is the scope/ objective of the regulation?	<i>Biosafety Act (Act 6 of 2006)</i> To provide for measures to regulate activities involving the research, development, production, marketing, transport, application and other uses of genetically modified organisms and specified products derived from genetically modified organisms; to establish a Biosafety Council and define its powers, functions and duties; and to make provision for 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?	1. Ministry of Agriculture, water and Forestry

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

In what year did the regulation go into effect?	- The Gene Technology Act regulates living GMOs and entered into force 1 September 1993. This act is an implementation of EU Directive 2001/18/EC with some national adaptations. - The Norwegian Food Act regulates processed GM food and feed products and entered into force 1 January 2004.
What is the scope/ objective of the regulation?	- 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. - 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.
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?	- Regulations concerning living GMOs are the responsibility of the Ministry of the Environment. - The responsibility of regulations concerning GM products is shared between the Ministry of Health and Care Services, the Ministry of Agriculture and Food, and the Ministry of Fisheries and Coastal Affairs.

Pakistan

In what year did the regulation go into effect?	April, 2005
What is the scope/ objective of the regulation?	a- Prevention of unintentional negligence leading to misuse and irresponsibility by laboratory workers/researchers as well as the end users. b- Regulation of manufacturing, import and storage of recombinant gene

	<p>technological products research whether conducted in laboratory</p> <p>c- Regulation of field trials and commercial release of GM plants, animals, import/export and purchase of GMOs</p>
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

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 regulation?	At the moment, the regulations are for GM crops only 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 and safe 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 regulation?	Ministry of Agriculture and Fisheries for the Bio-security and Ministry of Natural Resource and Environment (MNRE) for SNBF. Ministry of Health for the Food Act and Regulations

Seychelles (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 regulation?	MoH and Min. of Agri and livestock

Spain (EU)

Sudan

In what year did the regulation go into effect?	2010
What is the scope/ objective of the regulation?	<ul style="list-style-type: none"> Promoting the application of Biotechnology as a tool in the sustainable development of the country to benefit the people of the Sudan To protect the environment and economics, and regulate the import and export system. To gain the advantages of the Biotechnology without incurring any harm to biological diversity or to human health.
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?	All Ministries and National Authorities which work on 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?	<p>Objectives:</p> <ul style="list-style-type: none"> - 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. - Contribute to the development of a regulatory framework for research and development in the field of genetic engineering <p>Scope: This law applies to:</p> <ul style="list-style-type: none"> A. LMOs, including plants, animals and micro-organisms intended for research and experiments or for agricultural or industrial production in place of containment. B. B. LMOs intended for release into environmental and agricultural systems C. Non-living products of living genetically modified organisms either locally produced or imported and intended for industrial production or for human or animal consumption of raw or processed. <p>The following are excluded from the application of the provisions of this law:</p> <ul style="list-style-type: none"> a. Living modified organisms and their products for pharmaceutical and therapeutic purposes or for the production of medical and pharmaceutical materials in containment for the purpose of human or veterinary use which are subject to the regulations and the Ministries of Health and Agriculture and Agrarian Reform. b. Materials or products that contain genetically modified ingredients below the level determined by the executive instructions.
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 Agriculture and Aarian Reform. The other bodies involved in implementation of the law are as follows:

	<p>A. The ministry of Agriculture and Agarian Reform: follow up the implementation of all the LMOs and products intended for agricultural use (plant and animal) and veterinary and feed and to issue the necessary instructions.</p> <p>B. Ministry of Economy and Trade: the implementation of legislation relating to the provisions of the Foreign Trade and deception and fraud, consumer protection, property protection and food safety with respect to LMOs and their products.</p> <p>C. Ministry of Health: the implementation of all the control and use of LMOs and their products intended for medical or therapeutic purposes or for pharmaceutical manufacturing in containment and the potential effects on human health.</p> <p>D. Ministry of Environmental Affairs: implement everything related to living modified organisms and products intended for processing vital environmental and monitor and study the introduction of LMOs and their impact on the environment, and management of Biosafety Clearing House (BCH). The competent ministries and authorities concerned with the implementation of this law provide the General Authority for Environmental Affairs of the information relating to the circulation of LMOs and their products and their effects and the actions and decisions taken thereon.</p> <p>E. General Commission for Biotechnology: Development of organizational principles for research and development and future plans for Biotechnology-related research institutions in accordance with the provisions of Law No. 33, of 04/07/2002.</p> <p>F. General Customs Directorate: the implementation of the provisions of this law in coordination with the Ministry of Agriculture and the competent authority.</p>
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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 regulation?	Department of Agriculture

Togo

In what year did the regulation go into effect?	6 January 2009
What is the scope/objective of the regulation?	<ul style="list-style-type: none"> - to ensure the prevention of risks relating to the development, contained use, import, export, transit, storage, intentional or unintentional release into the environment and commercialization of Genetically Modified Organisms (GMOs) and their derived products; - to define the institutional framework for the prevention of biotechnology risks; - to define the mechanisms of control of the transboundary movement of GMOs and/or their derived products, of assessment and management of biotechnology risks, of management of incidents resulting from the use of GMOs and/or their derived products, and the regime of liability and redress; - to harness the benefits of modern biotechnology as compared with traditional biotechnologies.
Is a safety/risk assessment required?	<p>Title III of the law sets out provisions for the safe use of modern biotechnology, GMOs and/or their derived products and comprises 9 chapters:</p> <p><u>Chapter 1</u> : Safety measures <u>Chapter 2</u> : Intentional movement <u>Chapter 3</u> : Unintentional movement and emergency measures <u>Chapter 5</u> : Quarantine <u>Chapter 6</u> : Laboratory analyses <u>Chapter 7</u> : Identification and labelling <u>Chapter 8</u> : Confidential information <u>Chapter 9</u> : Export of GMOs and/or their derived products</p>
Is there a labelling requirement?	All GMOs and/or their derived products must be clearly labelled and packaged in accordance with the rules laid down by the relevant national authority. (Article 60 and 61)
Is there a LLP test requirement?	
Is there a traceability requirement?	As part of a traceability and self-regulation procedure, laboratory analyses may be conducted to verify the presence of nucleic acids or proteins resulting from the genetic modification and to identify the raw materials, the ingredients or the final products. (Article 58 and 59)
Is a socio-economic assessment required?	The impact of GMOs on human and animal health, biological diversity, the socio-economic fabric and cultural values must be taken into account. (Article 73)
Which authority is responsible for implementing the regulation?	The ministry responsible for the environment serves as the competent national authority. (Article 9)

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

Turkey

In what year did the regulation go into effect?	26 September 2010
What is the scope/ objective of the regulation?	<p>Objective of the Biosafety Law:</p> <p>To prevent risks that may arise from GMOs and</p>

	<p>products thereof which are produced by using of modern biotechnology by taking account the scientific and technological developments; to establish and implement biosafety system to ensure protection and sustainability of environment, biological diversity and health of human, animal and plant; and, to determine the procedures and principles governing the control, regulation and monitoring of these activities.</p> <p>The present Law governs all activities including but not limited to the research, development, processing, placing on the market, monitoring, utilization, importation, exportation, transit, transportation, preservation, packaging, labeling and storage regarding the Genetically Modified Organisms and products thereof.</p>
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

In what year did the regulation go into effect?	1996
What is the scope/objective of the regulation?	Risk analysis to determine whether or not to authorize the use of genetically modified crops.
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?	In authorizations under biosafety conditions (research at laboratory, greenhouse and field level, production of seeds for export and cultivar registration trials).
Is a socio-economic assessment required?	Yes, but considered part of risk management, not as part of risk assessment and for requests for commercial release.
Which authority is responsible for implementing the regulation?	The National Biosafety Cabinet (GNBio) whose executive arm is the Commission for Risk Management (CGR). The cabinet comprises six ministers corresponding to the ministries of: agriculture, health, environment, economy, industry and foreign affairs.

United States of America

In what year did the regulation go into effect?	For FDA, existing statutes and regulations are used, For EPA, existing statutes and regulations are used For USDA/APHIS: 1987 (APHIS regulation 7 CFR Part 340)
What is the scope/ objective of the regulation?	Food, feed and the introduction (move into or through the United States, release into the environment, or move interstate) of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be

	plant pests.
Is a safety/ risk assessment required?	All food and feed marketed must be safe, the need for pre-market authorization may depend upon the nature of the crop.
Is there a labelling requirement?	As with all food, foods derived from through genetic engineering must be labeled in accordance with existing regulations. The name of the food, the ingredient statement if more than one ingredient, net quantity of contents, name and address of manufacturer, allergen information as applicable, and nutrition labeling (unless exempt), are required on all foods. However, food labeling disclosing the fact that a food was produced through genetic engineering is voluntary, provided such labelling is truthful and not misleading. For USDA/APHIS: There are no labelling requirements once a GE plant has nonregulated status under the APHIS regulation 7 CFR Part 340.
Is there a LLP test requirement?	A detection method necessary to detect the crop is not required in order for a developer to complete FDA's voluntary consultation process. An analytical test method is required for all plant incorporated protectants (PIPs) registered by EPA for detection of 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 for purposes of the National Environmental Policy Act of 1970, which applies to all major Federal decisions (not just genetic engineering). USDA/APHIS does not require a socio-economic assessment under APHIS regulation 7 CFR Part 340 regarding plant-pest risks. FDA and EPA do not require socio-economic assessments.
Which authority is responsible for implementing the regulation?	The U.S. Government agencies responsible for oversight of the products of agricultural modern biotechnology are the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA). Depending on its characteristics, a product may be subject to review by one or more of these agencies.