GMO testing requirements and approaches world-wide

IHCP - Institute for Health and Consumer Protection

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http://ihcp.jrc.ec.europa.eu/

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GMO testing requirements along the production chain

- GMO producers
  - To assure purity and segregation of products
  - To trace genetic modification in breeding
- Food & feed industry, seed companies
  - To assure purity and segregation of products
  - To assure compliance with legislation
- Competent (enforcement) authorities
  - Product control, compliance with legislation
  - When needed, to withdraw specific products
- Laboratories
  - To provide analytical services to customers

Labelling Policies of Genetically Modified Food

Voluntary labelling (e.g. Canada or Hong Kong)

- guidelines dictate rules that define which foods are called GM or non-GM. They allow food companies to decide if they want to use such labels on their products.

Mandatory labelling (e.g. EU, Australia, Japan, China)

- requires that food handlers (processors, retailers and sometimes food producers or restaurants) display whether the targeted product/ingredient contains or is derived from GM materials.

Labelling Policies of Genetically Modified Food (ctd.)

Among countries with mandatory labelling, regulations differ according to:

a) Coverage: countries may require labelling for a list of particular food ingredients or all ingredients that include detectable transgenic material; highly processed products derived from GM ingredients, even without quantifiable presence of transgenic material; animal feed; additives and flavorings; meat and animal products fed with GM feed; food sold at caterers and restaurants; and unpackaged food.

b) Threshold level for labelling of GM ingredients: can be applied to each ingredient or only to three or five major ingredients; and its level ranges from 0.9% to 5% (with the exception of China).

c) Labelling content: "genetically modified" item on the list of ingredients, or in the front of food packages.

GM approval and labelling regulations in major trading countries

	Mandatory or voluntary safety assessment M/V)	Political approval required	Mandatory or voluntary labelling (M/V)	Labelling based process (P) or end product (E)	Labelling tolerance level
Australia/New Zealand	M	Y	M	E	1%
Brazil	M	Y	M	P	1%
Canada	M	N	V	E	5%
China	M	Y	M	E	0%
EU	M	Y	M	P	0.9%
Japan	M	Y	M&V	E	5%
Korea	M	Y	M	E	3%
Russia	M	Y	M	P	1%
United States	V	N	V	E	5%

(Carter and Gruère, 2006)

GM Labelling Policy Status in selected countries

(Gruère et al 2009)

Region	Countries with GM labelling (voluntary or mandatory)	Countries considering GM labelling	Countries with no labeling
Africa	Mauritius, South Africa	Cameroon, Ethiopia, Ivory Coast, Namibia, Sudan, Zambia	Algeria, Angola, Benin, Botswana, Burkina-Faso, Central Africa, Chad, Congo, Congo DR, Egypt, Gambia, Ghana, Guinea, Kenya, Libya, Madagascar, Malawi, Mali, Morocco, Mozambique, Niger, Nigeria, Senegal, Syria, Tanzania, Togo, Tunisia, Uganda, Zimbabwe
Asia	China, Japan, Hong Kong, Indonesia, Philippines, South Korea, Taiwan, Thailand,Vietnam	India, Malaysia, Singapore	Bangladesh, Bhutan, Cambodia, Kazakhstan, Myanmar, Nepal, North Korea, Pakistan, Papua New Guinea, Sri Lanka, Uzbekistan
Europe	European Union, Croatia, Czech Republic, Germany, Hungary, Norway, Poland, Russia, Serbia, Spain, Switzerland	Georgia	Albania, Belarus, Bulgaria, Iceland, Macedonia, Romania, Turkey, Ukraine
Middle East	Saudi Arabia	Israel, United Arab Emirates	Iran, Jordan, Oman,Yemen
North America	Canada, United States	Mexico	
South America	Argentina, Brazil, Chile	Bolivia, Ecuador	Colombia, Costa Rica, Cuba, El Salvador, Guatemala, Honduras, Panama, Paraguay, Peru, Uruguay,Venezuela
Oceania	Australia, New Zealand		

EU Policy Basis

- Horizontal **Directive 2001/18/EC** on **deliberate release** and **marketing** of genetically modified organisms (GMOs)

- **Regulation (EC) No 1829/2003** of the European Parliament and of the Council of 22 September 2003 on **genetically modified food and feed**

- **Regulation (EC) No 1830/2003** of the European Parliament and of the Council of 22 September 2003 concerning the **traceability and labelling** of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

- The **Cartagena Protocol** in force since 11 September 2003 provides provisions for international exchange of information on transboundary movements

- **Regulation (EC) No 882/2004** of the European Parliament and of the Council of 29 April 2004 on **official controls** performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

JRC Scientific and Technical Reports

The EU Legislation on GMOs

An overview

Damien Plan, Guy Van den Eede

http://mbg.jrc.ec.europa.eu/home/docs.htm

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Salient points of the EU legislation:

- Labelling of GMOs and derived food and feed products at all stages (when present above 0.9%);
- Traceability from the point of production or import down to the table and vice versa;
- Co-existence between organic, traditional and GM plant from the seed throughout the production chain;
- Post-market monitoring;
- Exchange of information on GMOs cultivated among MS and the EC and GMOs transported among MS and third Countries

LABELLING RULES
Regulation (EC) 1830/2003

Article 4: products consisting **or** containing GMOs**:**

→ mandatory indication that the product contains GMOs or consists in GMOs.

EXCEPT if GMOs < 0.9 %

Article 5: products elaborated from GMOs **:**

→ mandatory indication that each raw material or feed additive produced from GMOs

EXCEPT if GMOs < 0.9 %

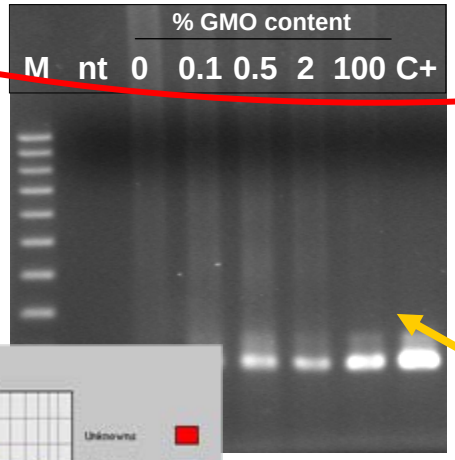
But WATCH OUT !

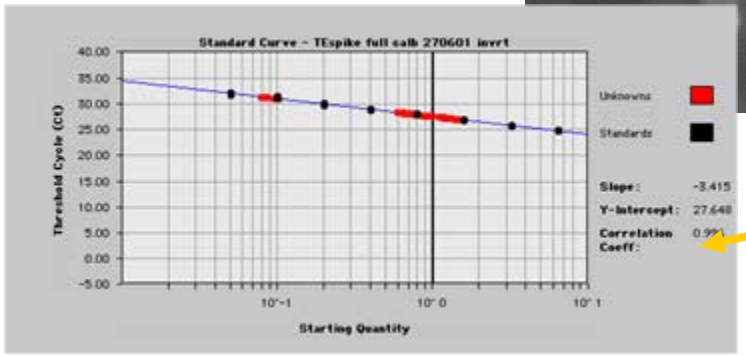
Exemption of labelling obligations ONLY if the presence of GMOs is "**adventitious or technically unavoidable**".
unexpected presence + adoption of "adequate" preventive measures.

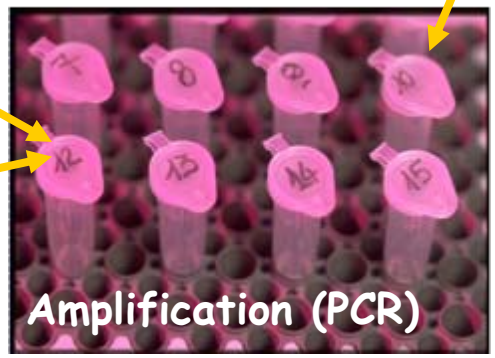
Moreover :

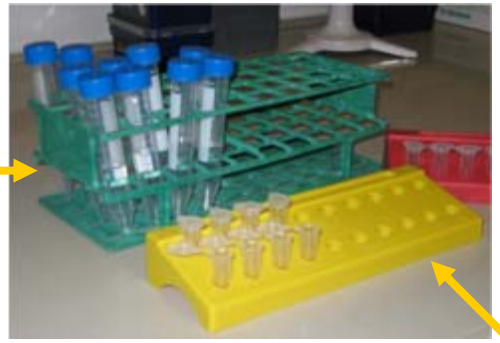
Quantification per ingredient

Sampling steps

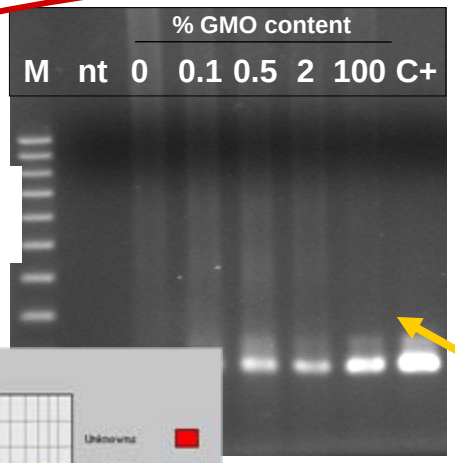


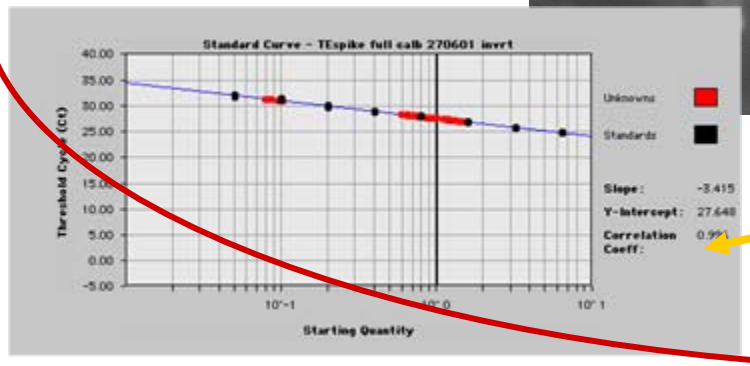






Analytical steps





Operation of GMO laboratories to comply with EU legislation

GMO detection

Positive — Negative

GMO ? Yes/No

GMO identification

Yes — No — Illegal

Are they Authorised ? Yes/No

GMO quantification

Assay individual ingredients

< threshold — No need for labelling

> threshold — Labelling required

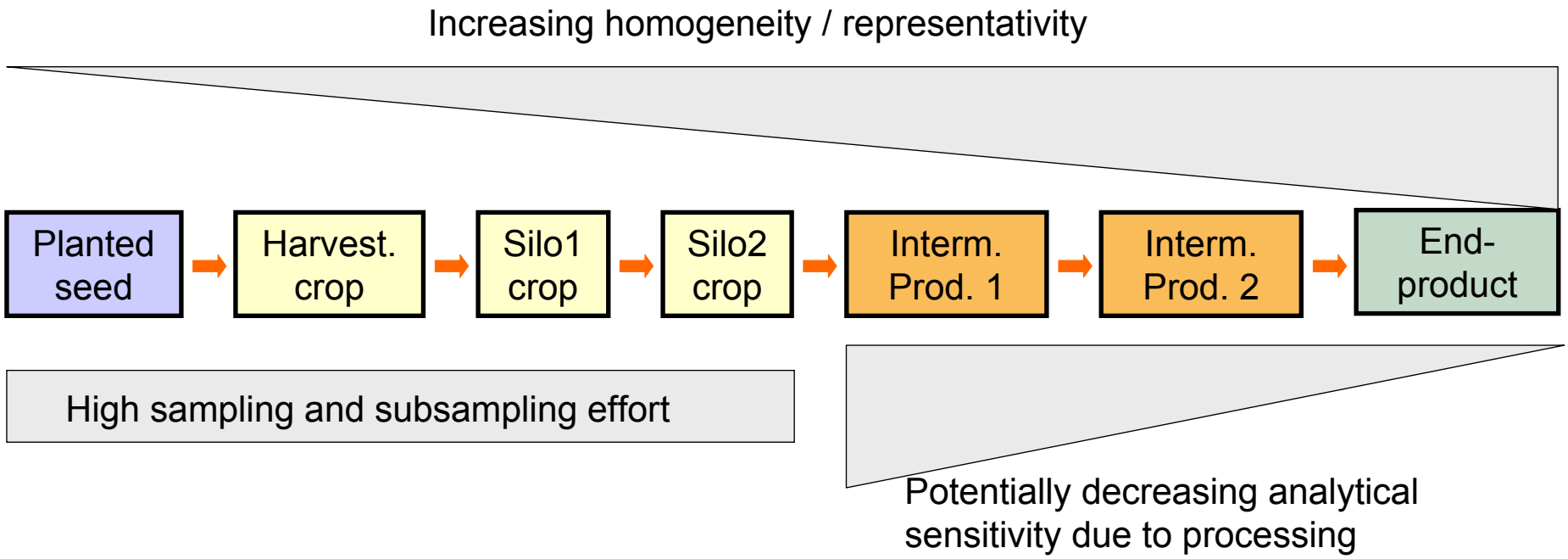
Must be Labelled ? Yes/No

GMO testing approaches, which strategies to select?

Step	Purpose	Suitable methods
(Detection) Screening	Broad screening for the presence of GMOs	Element-specific (Modification-specific)
Identification	Exclude non-approved, identify approved GMOs	Modification-specific (Event-specific)
Quantification	Check for labelling requirements	Event-specific (Validated EURL methods)

Detection strategies, which method to select?

Experience along the production chain



Current context

- Worldwide adoption and use of GMOs is rapidly increasing (acreage, countries);
- Constant rise in GMO complexity, number of traits and events;
- In the EU:
    - Mandatory labelling of GMOs and derived food/feed products (if above 0.9%) requires event-specific methods;
    - Post-market monitoring requirements;
    - GMO control based on combination of screening + event-specific detection methods;
    - Increasing number of GMOs under approval;
    - Asynchronous approval process complicates the analytical procedure.

↑ Higher number of methods to be applied for full product characterisation.

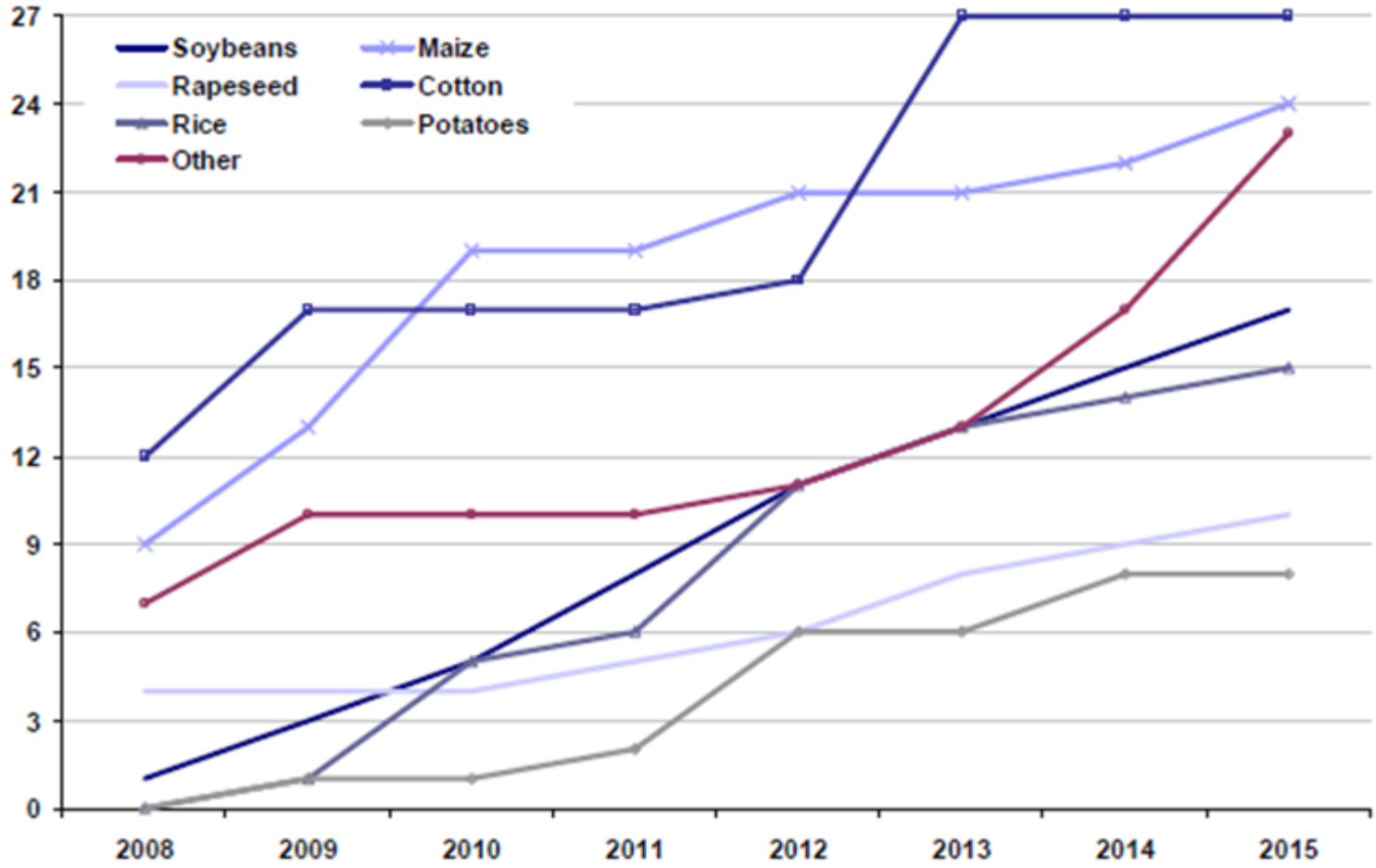
↑ Increased time and cost of analysis/sample.

Table 17: Events in commercial GM crops and in pipelines worldwide, by crop

Crop	Commercial in 2008	Commercial pipeline	Regulatory pipeline	Advanced de-velopment	Total by 2015*
Soybeans	1	2	4	10	17
Maize	9	3	5	7	24
Rapeseed	4	0	1	5	10
Cotton	12	1	5	9	27
Rice	0	1	4	10	15
Potatoes	0	0	3	5	8
Other crops	7	0	2	14	23
All crops	33	7	24	61	124

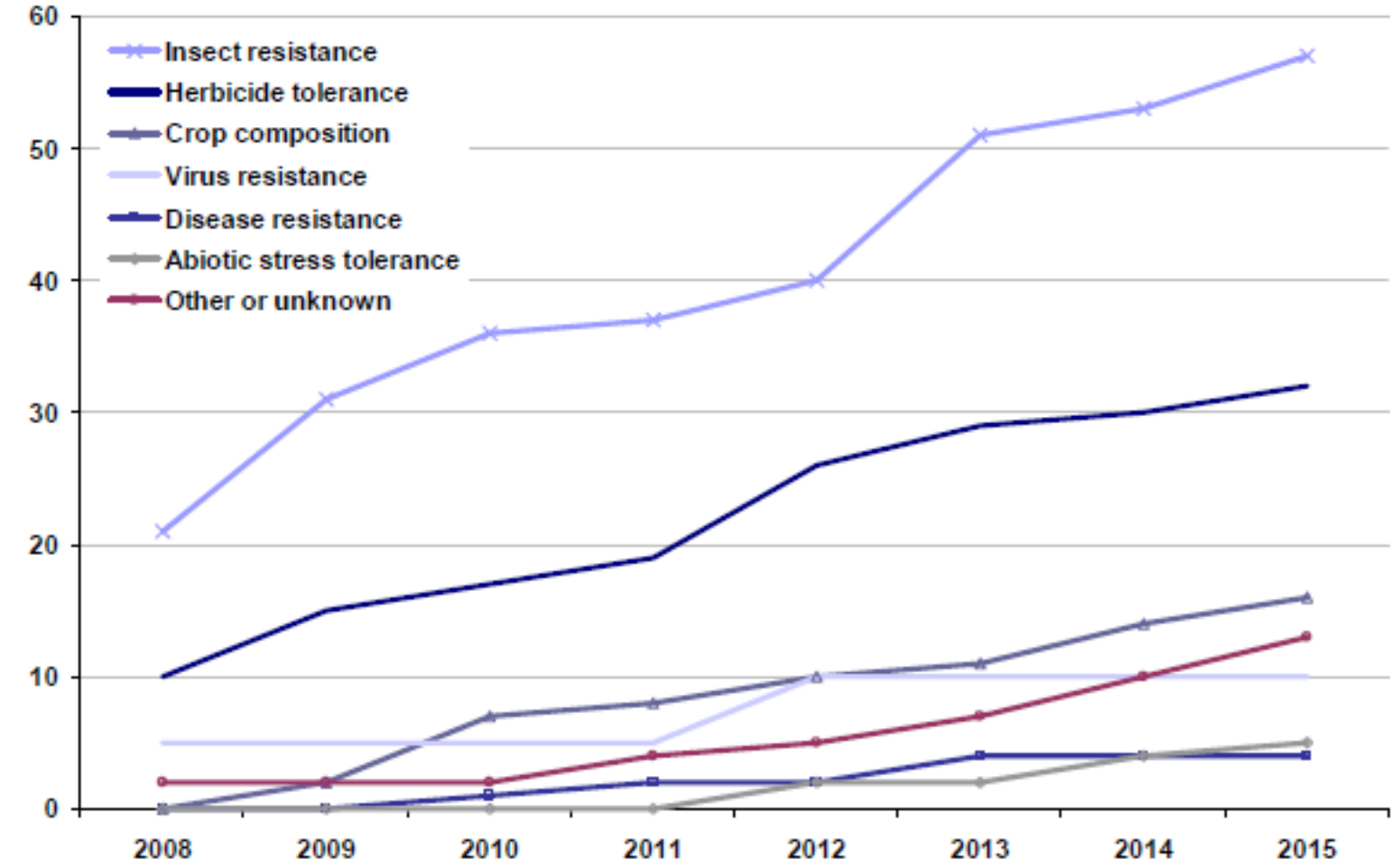
(Stein & Rodríguez-Cerezo, 2009)

Figure 7: Projected number of events in GM crops worldwide, by crop



(Stein & Rodríguez-Cerezo, 2009)

Figure 8: Projected number of events in GM crops worldwide, by trait



(Stein & Rodríguez-Cerezo, 2009)

Some examples of points that require further reflection:

- Low Level Presence of non-approved GMOs;
- Seed thresholds;
- Quantification of stacks;
- Botanical impurities,
- Sampling,
- Definition of %.

Thank you!