

Detection strategies for non-authorized GMO products on the European market



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Introduction:

- Genetically modified plants are grown in a wide range worldwide.**
 In 2008, genetically modified (gm) plants were grown on 125 million hectares in 25 countries. A significant growth in stacked traits in maize and cotton was observed. By the year 2015, 40 countries or even more are expected to adopt biotech crops. (Figure 1, Figure 2)
- In the European Union (EU), import and planting of gm plants are strictly regulated.**
 The EU has a regulatory framework for authorising GMO (genetically modified organisms). The application must clearly define the scope of the application and must include a monitoring plan, a labelling proposal and a detection method.
- The competent authority of each country in Europe has the responsibility and obligation to control regulatory compliances.**
 Therefore constant survey of the market is necessary. Validated methods of detection for approved GMO and products are available via the European Community Reference Laboratory (<http://gmo-crl.jrc.ec.europa.eu/>).
- However, only inadequate information on non-approved GMO in Europe are available.**
 Experience of the last years has shown that non approved GMO (e.g. gm-papaya, Bt10-maize, LL601-rice and Bt63-rice) were detected on the European market. No validated detection method or sequence information are available for most non-approved GMO. Therefore, to detect contaminations with non-approved GMO, specific detection methods need to be on hand.
- In the framework of a research project, data of all biotech crops intended for commercialisation are collected.**
 The Bavarian Health and Food Safety Authority collects data to register all harvested biotech crops worldwide in a database. This register will contain specific gene information, construct information, detection methods, availability of reference material, a list in which countries the GMO is legally or illegally produced, which processed food and feed contains this GMO, etc. The aim of the research project is to build an own matrix for unauthorised genetically modified plants.

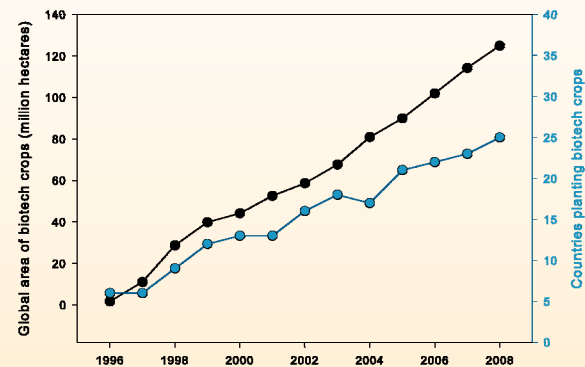


Figure 1: Cultivation areas with genetically modified plants, 1996 - 2008, in millions of hectares (black line) and countries planting biotech crops (blue line). (James, ISAAA Brief No 39-2008)

Scientific approach:

- For the development of verified detection methods, it is of importance to have access to gene-specific information and adequate reference material.
 - Research in international databases
 - Research in trade and industry
 - Availability of reference material
 - Research in patent databases
 - Specific detection methods

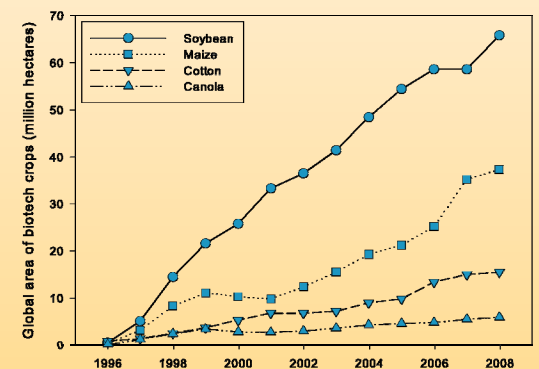


Figure 2: Cultivation areas with genetically modified plants by crop, 1996 - 2008, in millions of hectares. (James, ISAAA Brief No 39-2008)

Preliminary results:

- Research in international databases**
 - 264 gm plants are currently registered, partly with unknown genetical modification
 - Stacked traits gain importance
- Availability of reference material**
 - For the detection of GMO, reference material needs to be available
 - Reference material is provided by
 - BVL
 - Institute for Reference Material (IRMM, European Commission)
 - European Reference Materials (ERM)
- Specific detection methods**
 - Validated detection methods are provided by
 - Community Reference Laboratory (CRL)
 - BATS – Zentrum für Biosicherheit und Nachhaltigkeit (Switzerland)
 - GMO detection method database (GMDD)
 - Gesellschaft Deutscher Chemiker e.V. (GDCH)
 - Communication & Information Resource Center Administrator (CIRCA)
 - Bavarian Health and Food Safety Authority
 - Bund/Länder-Arbeitsgemeinschaft Gentechnik (LAG)

Future prospects

- Development of detection methods for non-approved GMO
- Status of GMO approval in different countries
- Import risk assessment for non-approved GMO (trade and industry)

Table 1: Detail of the GMO register by the Bavarian Health and Food Safety Authority

Plant	Unique Identifier	Event name	Promotor	Terminator
Mais	SYN-EV176-9	Bt 176	CDPK (<i>Z.mays</i>)	CaMV 35S 3'
			p-PEPC (<i>Z.mays</i>)	CaMV 35S 3'
			CaMV 35S	CaMV 35S 3'
Mais	SYN-IR162-4	MIR162	bacterial promoter	CaMV 35S 3'
			ubiZM+1.Intron	nos 3'
Mais	SYN-IR604-5	MIR604	p-MT-like (<i>Z.mays</i>)	nos 3'
			ubiZM+1.Intron	nos 3'
Mais	MON-80200-7	MON802	eCaMV 35S	nos 3'
			eCaMV 35S, HSP70 (<i>Z.mays</i>)	nos 3'
			CaMV 35S	nos 3'
Mais	PH-MON809-2	MON809	CaMV 35S	nos 3'
			e35S	nos 3'
			e35S	nos 3'
Mais	Not assigned	MON832	e35S + HSP70 intron (<i>Z.mays</i>)	nos 3'
			CaMV 35S	nos 3'
			bacterial promoter	
Mais	MON-87460	MON87460	P-ract1/ract1 intron	3'Tr7
			loxP-CaMV 35S	nos -loxP 3'
Mais	PH-000676-7, PH-000678-9, PH-000680-2	676, 678, 680	CaMV 35S	CaMV 35S 3'
			5120del (<i>Z.mays</i>)	pin II 3'
Mais	MON-89034-3, xDAS-01507-1, xMON-88017-3, xDAS-59122-7	MON89034xTC1507x, MON88017xDAS-591	CaMV 35S	CaMV 35S 3'
			CaMV 35S	nos 3'
			act1/ract1 intron	ORF25 3'
			ubiZM+1E+11	hsp17.3 3'
			CaMV 35S	nos 3'
			FMV 35S, HSP70 intron	tahsp17.3'
			2xAS1+35S, ract1 intron	pin II 3'
ubiZM+1.Intron	Pin II 3'			
	Peroxidase(<i>Triticum aestivum</i>)	pin II 3'		