

# Commercialisation and control

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- **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;**
- Extensive exchange of information on GMOs cultivated among MS and the EC and GMOs transported among MS and Third Countries (“**Biosafety Clearing House**”)





**Member States are responsible for enforcement and control**



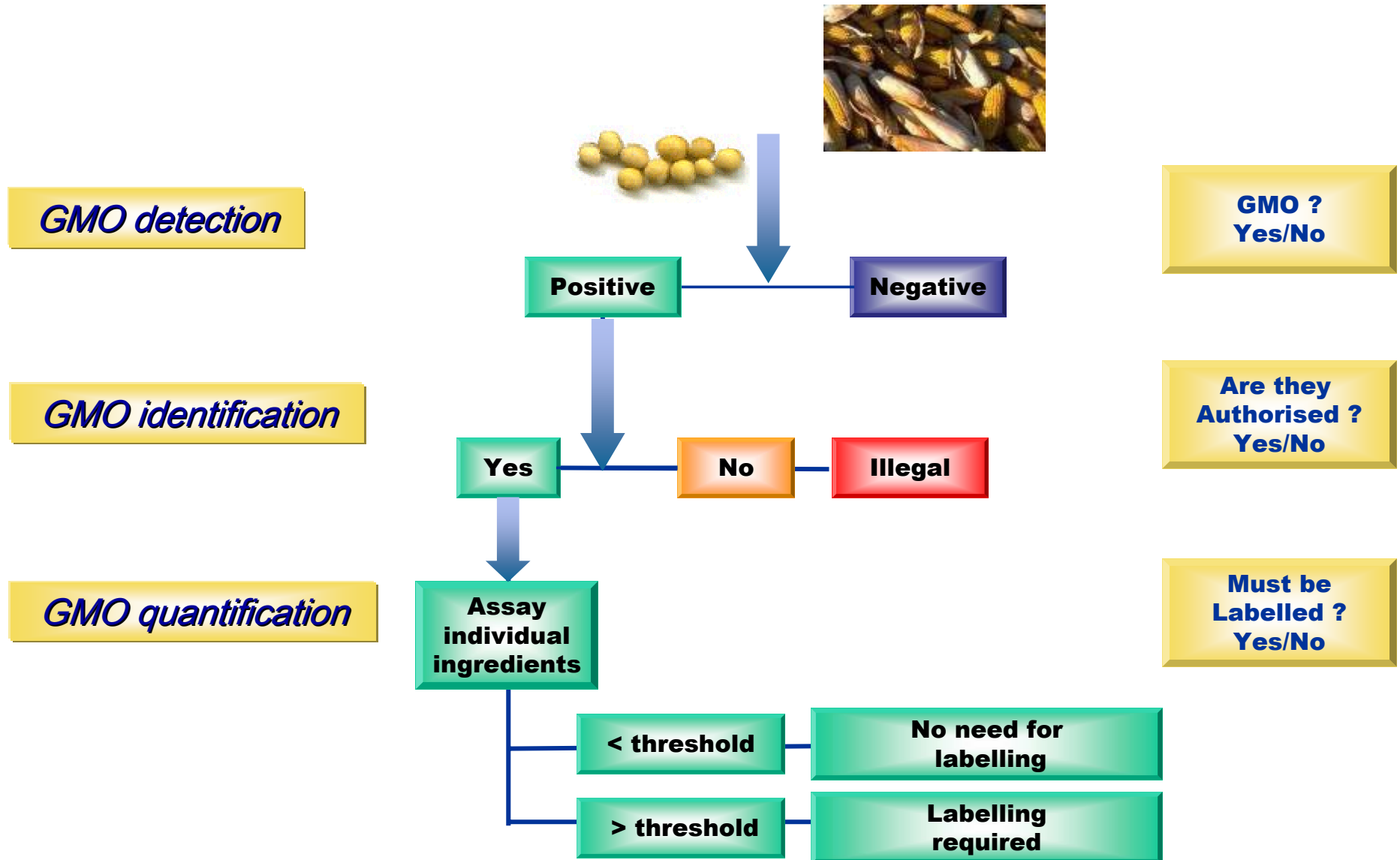
**All MS have designated Competent Authorities and facilities for the control of GMOs and GM-products**



**Commission has responsibility for ensuring the proper functioning and development of the single European market; CRLs coordinate and manage the network of NRLs**



**The aim is to ensure that EC food law is enforced with equal rigor in all Member States.**



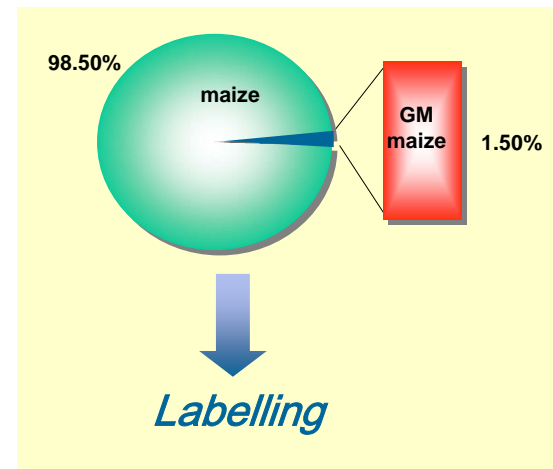
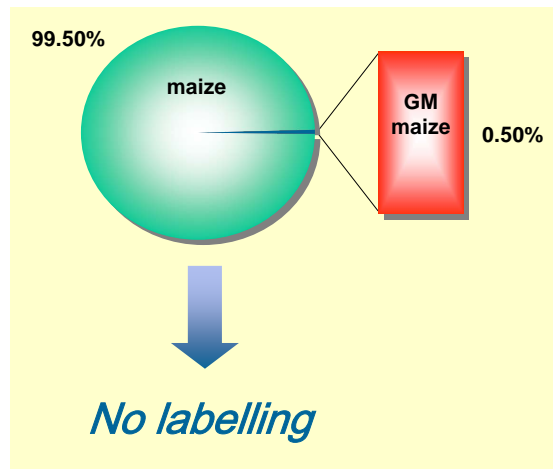
How much "maize" is present?

How much "GM-maize 1" is present?

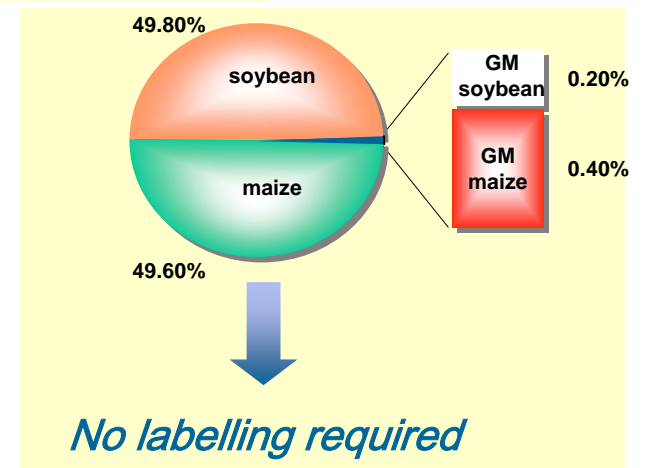
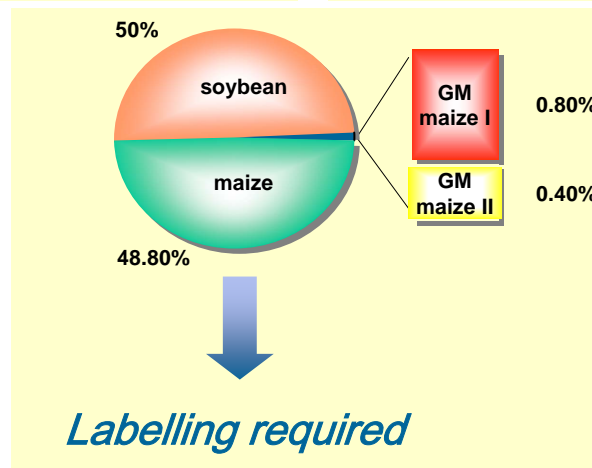
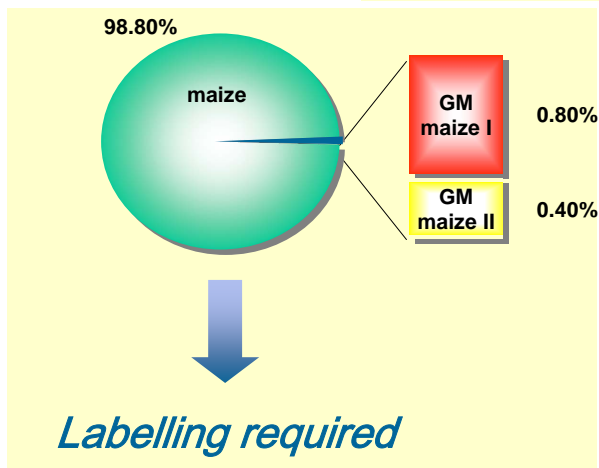
How much "GM-maize 2" is present?

*Make calculations*

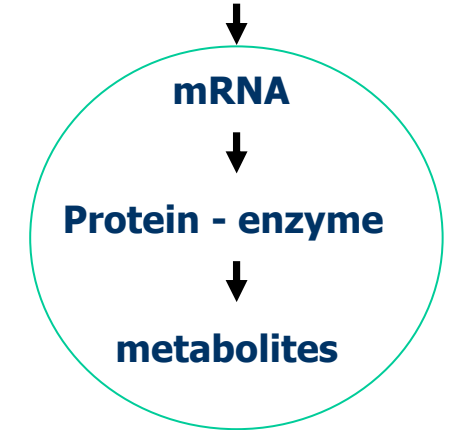
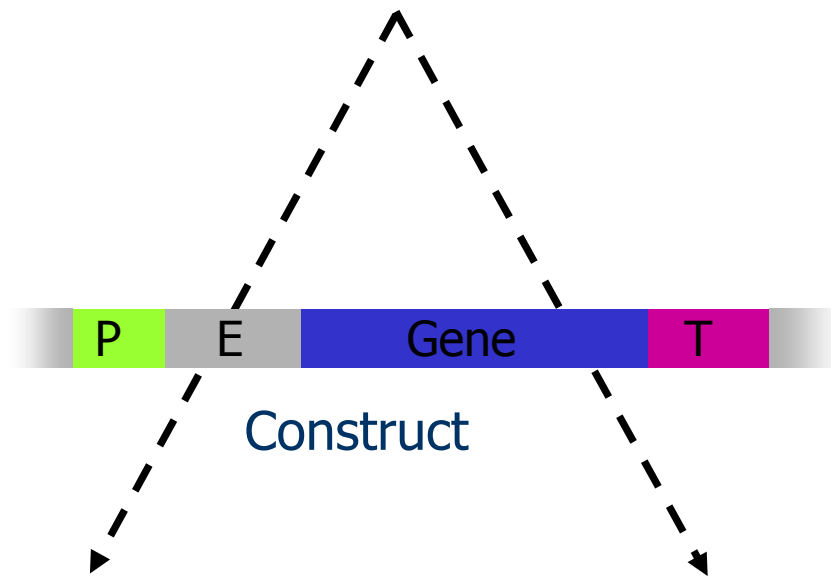
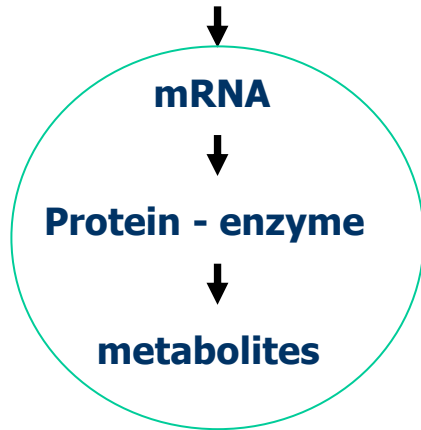
# Quantification of GMOs and labelling



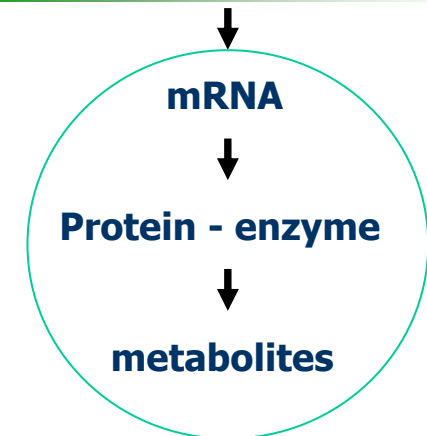
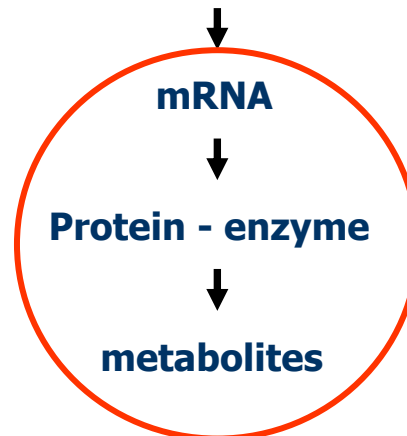
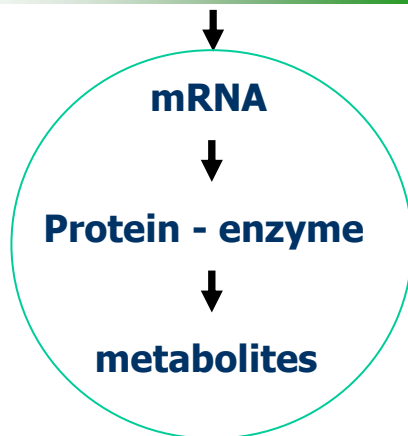
- maize
- soybean
- GM maize I
- GM maize II
- GM soybean



WT



GMO



## How Do You Know if a Product is Genetically Modified ?



### Approaches:

Phenotype identification/  
Bioassays

→ Most genetically modified marketed products appear identical to traditional counterparts.

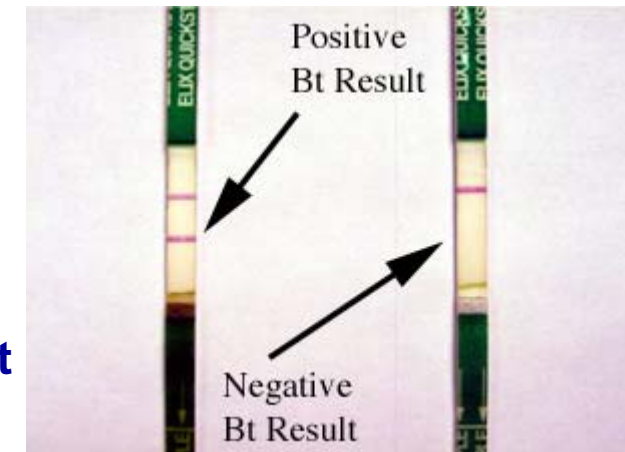
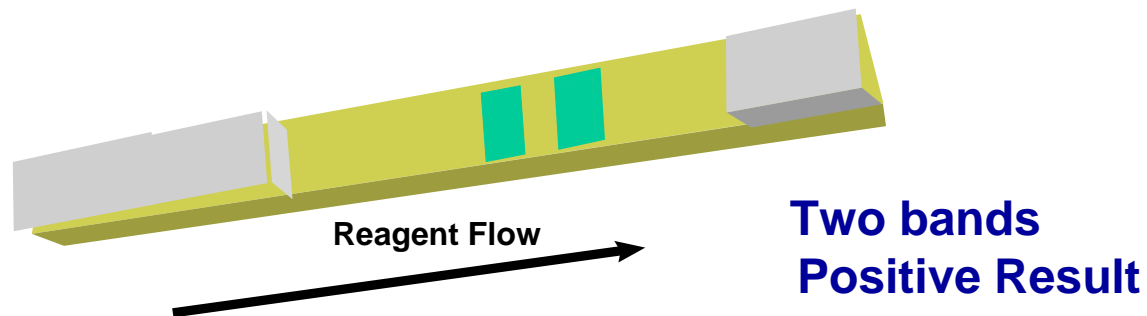
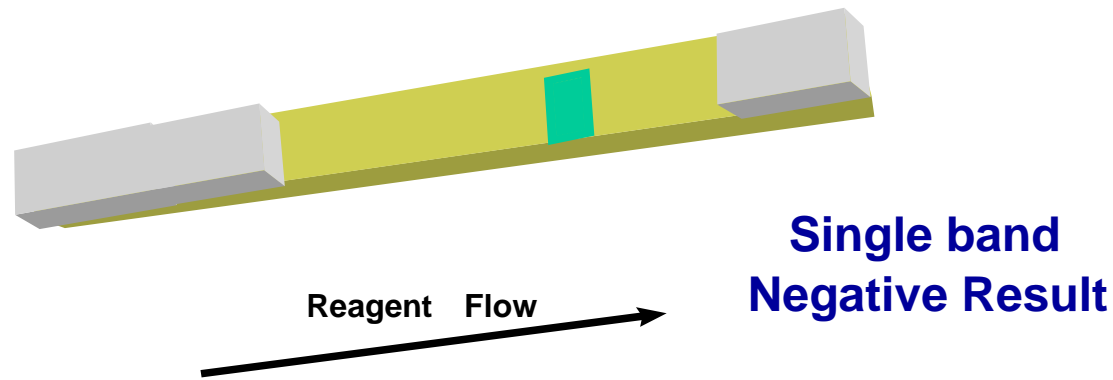
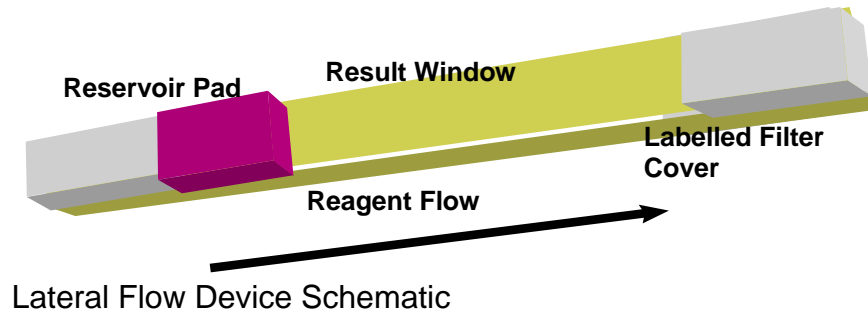
DNA-based methods

→ Genetic differences can always be found in the DNA sequences, provided that the genetic modifications introduced to produce the GMO are known.

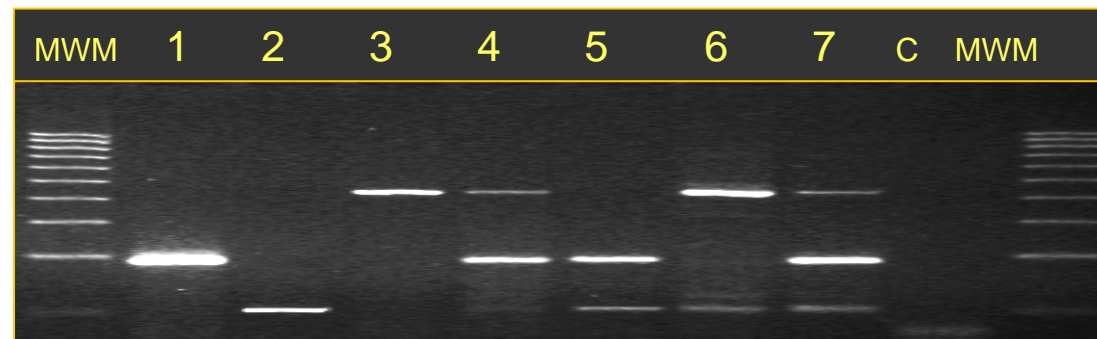
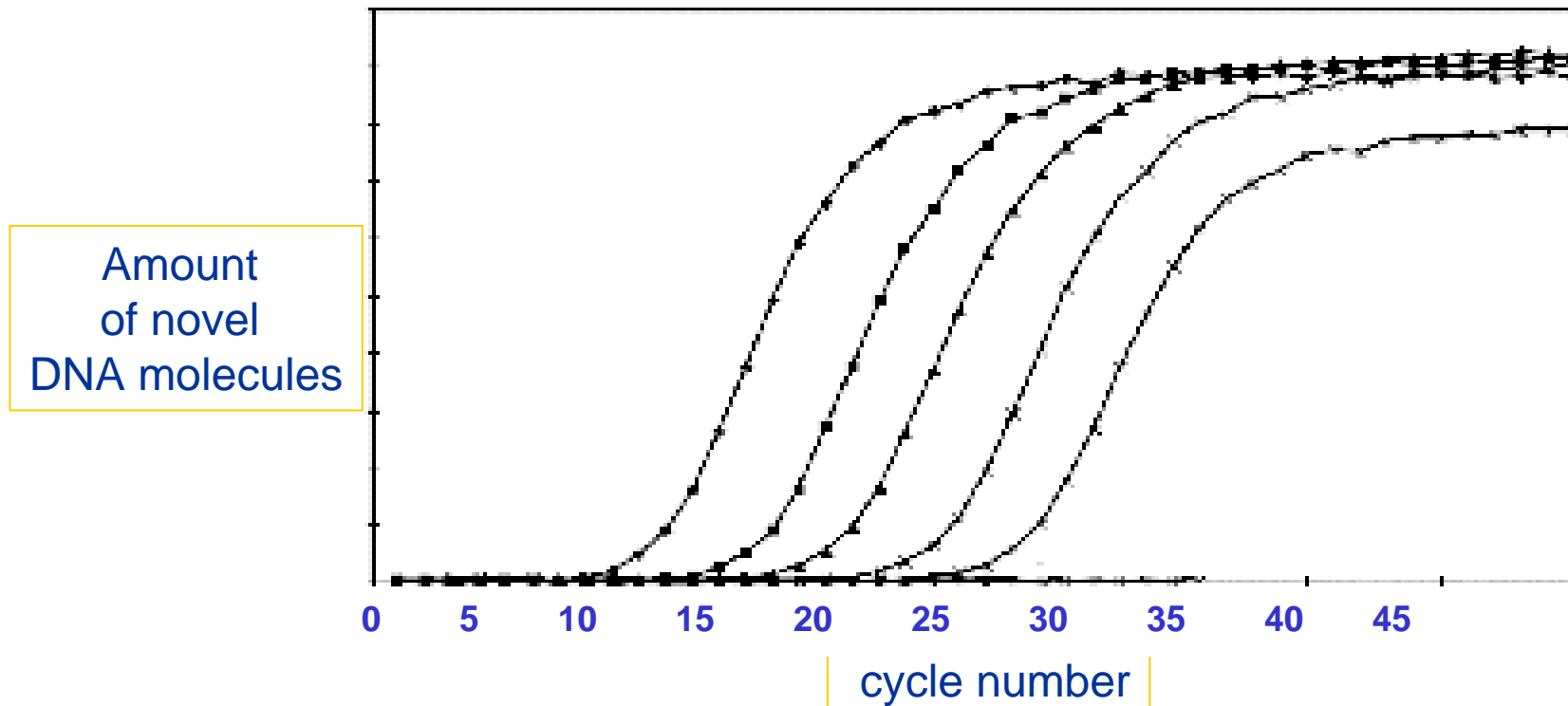
Protein-based methods

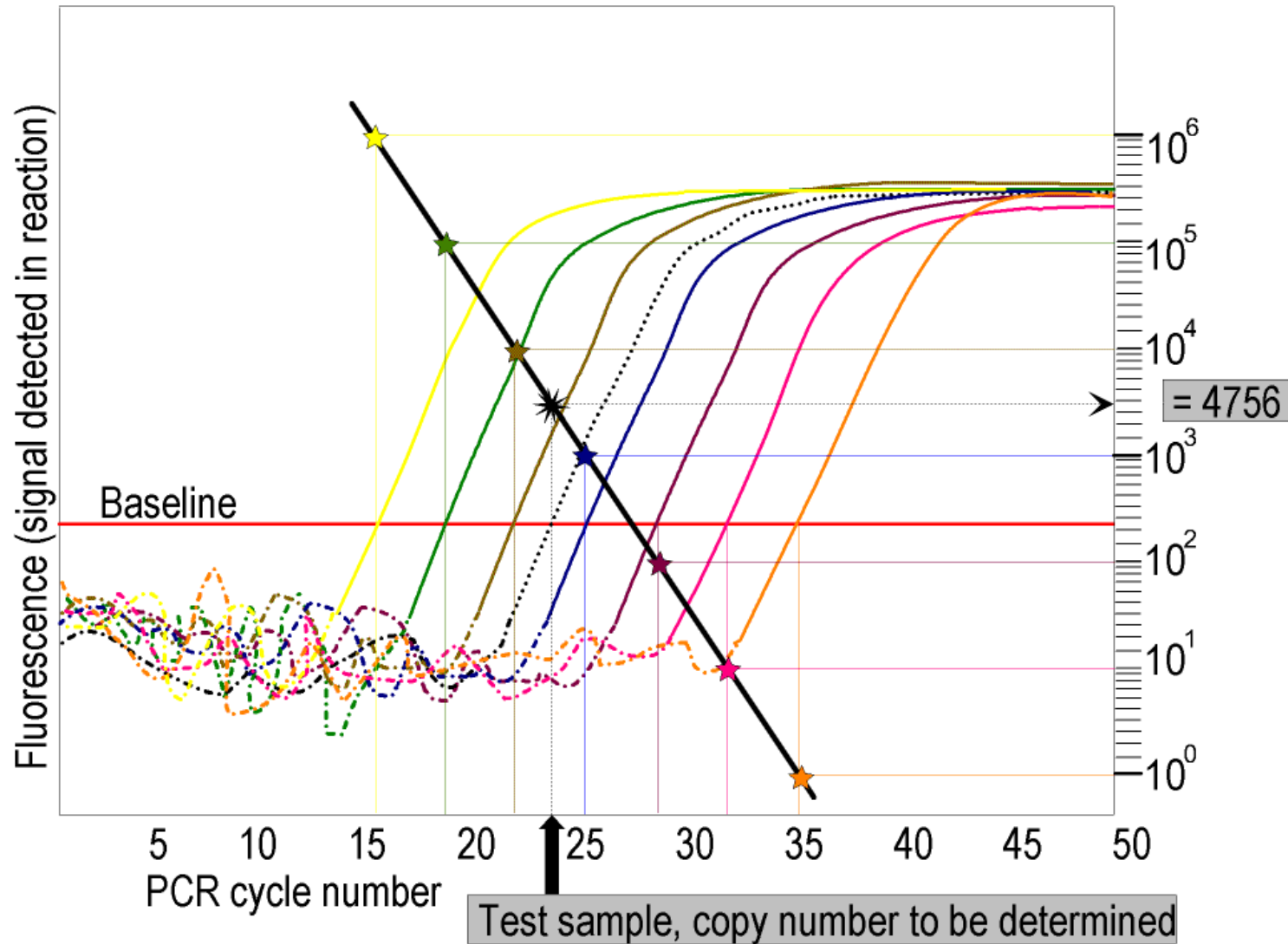
→ Genetic transformation generally leads to the presence of a new protein that can be detected using immunological methods.

# Protein-based method: Lateral-Flow Strips, 5 minutes test



## Amplification plot of a PCR reaction



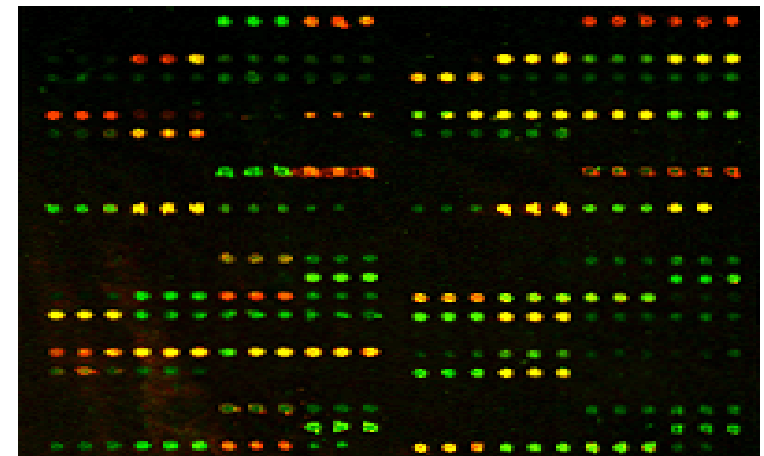


Based on hybridisation reactions among specific probes and labelled targets

Probes are immobilised on a glass surface in array format

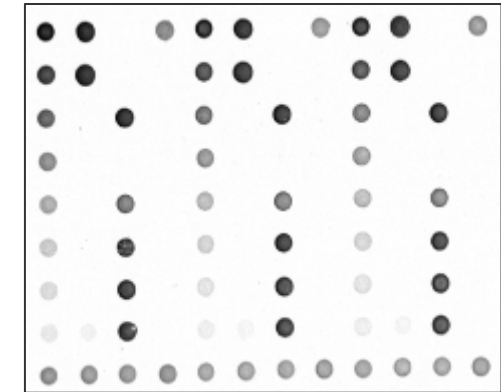
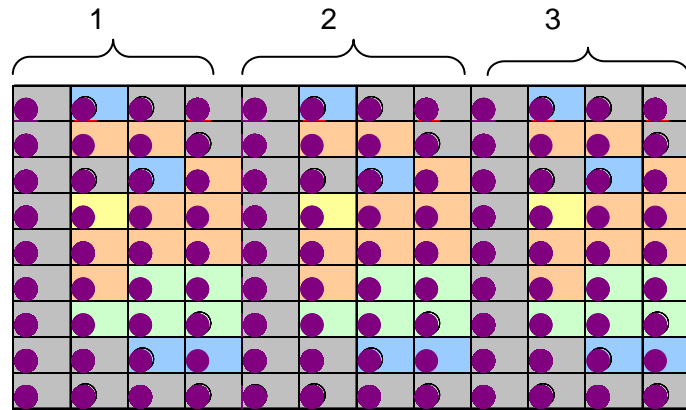
Targets are commonly labeled by fluorescence or chromogenic molecules through an amplification step

Primarily developed for gene expression studies, are finding application also in other fields, e.g. **unknown GMOs** (Nesvold *et al.* 2005).



# GMO-chip Design

Each spot is present in triplicate



det ctl 1	positive hyb ctl	negative det ctl	det ctl 4
det ctl 2	P 35 S	T nos	negative det ctl
det ctl 3	negative det ctl	PCR ctl	Pnos-nptII
det ctl 4	CaMV	EPSPS-1	EPSPS-2
det ctl 5	Cry1Ab-1	Cry1Ab-2	Cry1Ab-3
det ctl 6	Pat	Maize	Rapeseed
det ctl 7		Plant	Soybean
det ctl 8	det ctl 9	positive hyb ctl	negative hyb ctl
det ctl 4	det ctl 4	det ctl 4	det ctl 4

EPSPS -1: GA21  
EPSPS -2: RRS

Cry1A1-1: Bt176  
Cry1A1-2: Mon 810  
Cry1A1-3: Bt11

## Pre-spotted plates coated with primer/probes for several GM events: a JRC initiative contributing to effective high throughput detection of unauthorised GMOs

	1	2	3	4	5	6	7	8	9	10	11	12
A	HMG Maize Ref	SAH7 Cotton Ref	PLD Rice Ref	CruA Oilseed Ref	Lectin Soybean Ref	GS Sugarbeet Ref	UGPase Potato Ref	Bt11 Maize	NK603 Maize	GA21Maize Monsanto	MON863 Maize	1507 Maize
B	T25 Maize	59122 Maize	H7-1 Sugar beet	MON810 Maize	281-24-236 Cotton	3006-210-23 Cotton	LLRICE62 Rice	T45 oilseed rape	EH92-527-1 Potato	Ms8 Oilseed rape	Rf3 Oilseed rape	GT73 (RT63) Rapeseed
C	LLCotton2 5 Cotton	MON 531 Cotton	A2704-12 Soybean	MIR604 Maize	Rf1 Rapeseed	Rf2 Rapeseed	Ms1 Rapeseed	Topas 19/2 Rapeseed	MON1445 Cotton	Bt176 Maize	MON15985 Cotton	40-3-2 Soybean
D	GA21 Maize Syngenta	MON88017 maize	LY038 Maize	3272 Maize	MON89788 soybean	MON89034 Maize	DP-356043 soybean	MON88913 cotton	Rice GM events P35S::bar	LLRice601 Rice	Bt63 Rice	Bt10 Maize
E	HMG Maize Ref	SAH7 Cotton Ref	PLD Rice Ref	CruA Oilseed Ref	Lectin Soybean Ref	GS Sugarbeet Ref	UGPase Potato Ref	Bt11 Maize	NK603 Maize	GA21Maize Monsanto	MON863 Maize	1507 Maize
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H	GA21 Maize Syngenta	MON88017 maize	LY038 Maize	3272 Maize	MON89788 soybean	MON89034 Maize	DP-356043 soybean	MON88913 cotton	Rice GM events P35S::bar	LLRice601 Rice	Bt63 Rice	Bt10 Maize

**Methodological approach:** real-time PCR (probe based)

**Format:** 96-well plate format

**Analytical target(s):** Event-specific targets of EU approved and unapproved GM events

**Product format:** Ready-to-use pre-spotted plates containing, in lyophilized format, all primers and probes for the individual detection of 39 GM events and of the corresponding 7 plants species (maize, cotton, rice, oilseed rape, soybean, sugar beet, and potato).

**Just add DNA and cycle !!**

**We need to get information about a food/feed item by submitting the sample to analysis, applying a specific method;**

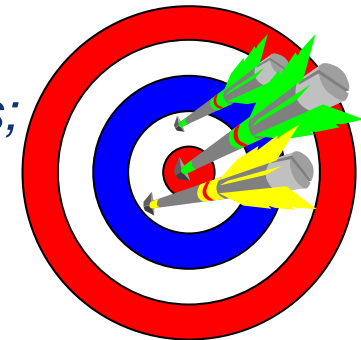
**The analytical problem defines the purpose of the method;**

**Conducting a validation study is a tool to check whether the method is fit for the purpose;**

**The validation study delivers *performance characteristics*;**

**How to validate the analytical method?**

- By performing an in-house validation
- By conducting a collaborative study



## **The Community Reference Laboratory for GM Food and Feed: legal basis and mandates**

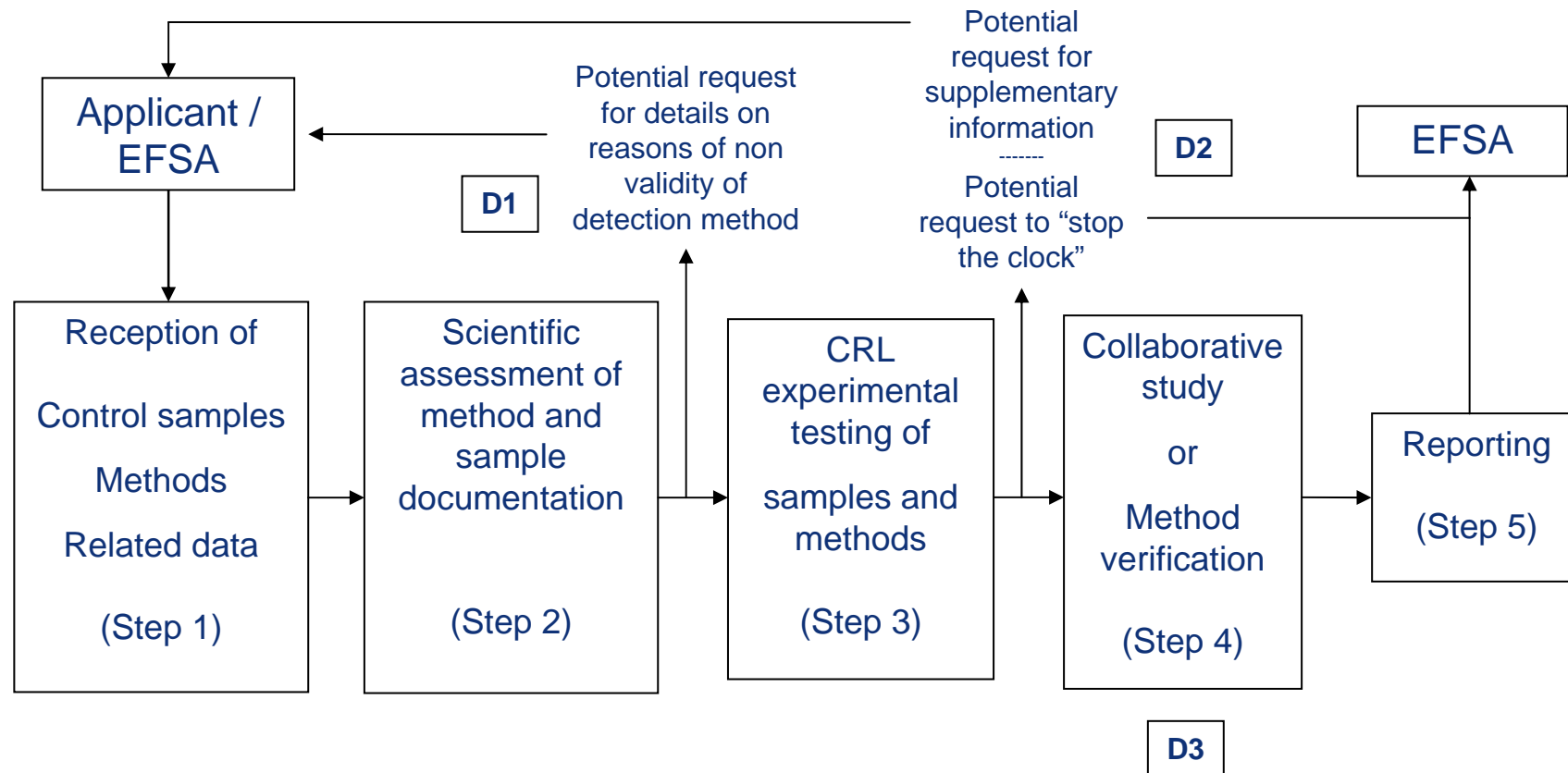
**Regulation (EC) No 1829/2003 on GM Food and Feed (Annex):**

**“ The Community Reference Laboratory referred to in Article 32 is the Commission's Joint Research Centre.”**

**Regulation (EC) No 882/2004 on official control:**

**“ Community reference laboratory for genetically modified organisms (GMOs): the laboratory referred to in the Annex to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (2).**

## CRL-GMFF operational procedures



Stepwise procedure that can be stopped and re-started

- It has a crucial role in (dis)approval of methods that are “fit for the purpose of regulatory compliance”.
- It has a key role in disputes and in response to crises (e.g. Bt10, rice 601, rice Bt63, corn E-32)
- It is unique in the worlds’ GMO regulatory system.
- Method assessment is done according to ENGL-CRL set performance criteria (see “Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing”)
- 76 dossiers have been submitted to the CRL since April 2004
- Applicants contribute to the costs of validation.

The CRL-GMFF is ISO 9001 certified and ISO 17025 accredited.

All validated methods and validation reports are published at:

<http://gmo-crl.jrc.ec.europa.eu/>

## Regulation (EC) No 1981/2006: structure

- a) Establishment of National Reference Laboratories assisting the CRL for testing and validating the methods of detection and identification
  
- b) Financial contribution for method validation
  - *ANNEX I*: Requirements for laboratories assisting the Community Reference Laboratory for testing and validation of methods for detection
  - *ANNEX II*: List of National Reference Laboratories
  - *ANNEX III*: Amendments to the Annex to Regulation (EC) No 1829/2003

## Regulation (EC) No 1981/2006: NRLs

### *Article 6*

#### **National reference laboratories assisting the CRL for testing and validating the methods of detection and identification**

1. Laboratories which assist the CRL in testing and **validating the method of detection** and identification, as provided for in Articles 6(3)(d) and 18(3)(d) of Regulation (EC) No 1829/2003, **shall fulfil the minimum requirements laid down in Annex I** to this Regulation. The laboratories listed in Annex II, are meeting those requirements, and **are hereby appointed as national reference laboratories under Regulation (EC) No 1829/2003** to assist the CRL for testing and validating the method of detection.

## The role of the CRL-GMFF in response to emergencies and crises related to the spread of GMOs into the EU market



The CRL-GMFF has become a key actor in emergency/crises cases for fast validation/verification of detection methods, gathering and provision of specific information to NRL (e.g. sequence, molecular structure), preparation and distribution of suitable control samples to NRL

## COMMISSION DECISION

of 18 April 2005

on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products

*(notified under document number C(2005) 1257)*

*(Text with EEA relevance)*

*(2005/317/EC)*

-Art. 2. Member States shall allow the first placing on the market...**only where an original analytical report based on a suitable and validated method for..... maize Bt10....demonstrates that the product does not contain Bt10 maize or feed produced from Bt10 maize.**

- ....**the Community Reference Laboratory...(the CRL) has been asked to validate the detection method for this product... ..**

<http://gmo-crl.jrc.ec.europa.eu/>

