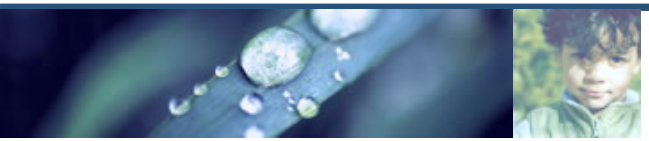

Setting up a GMO analysis laboratory in a GMO growing and commercialising country – aspects of the production chain quality

Mariana Daher, Eurofins do Brasil

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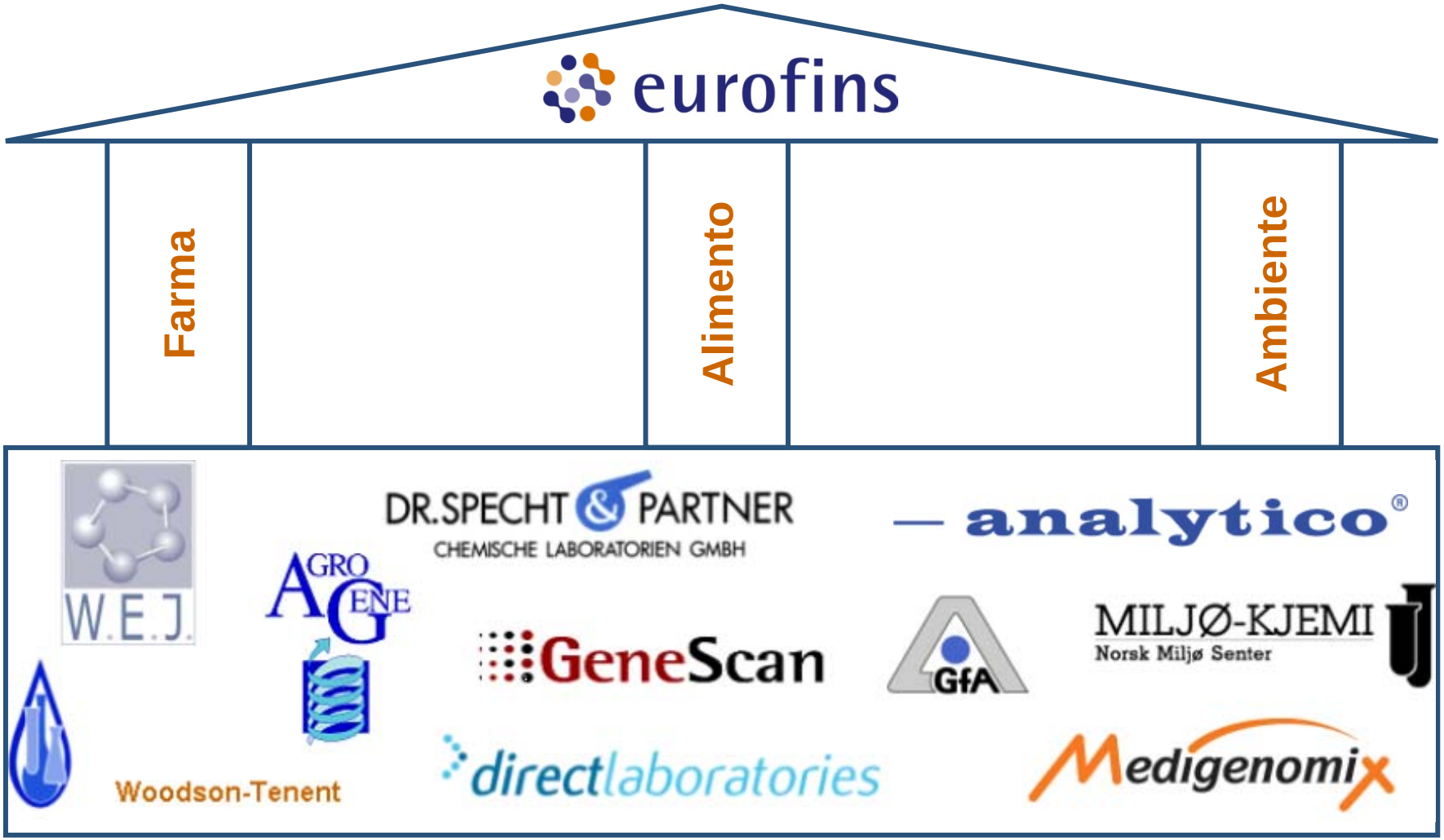
Agenda

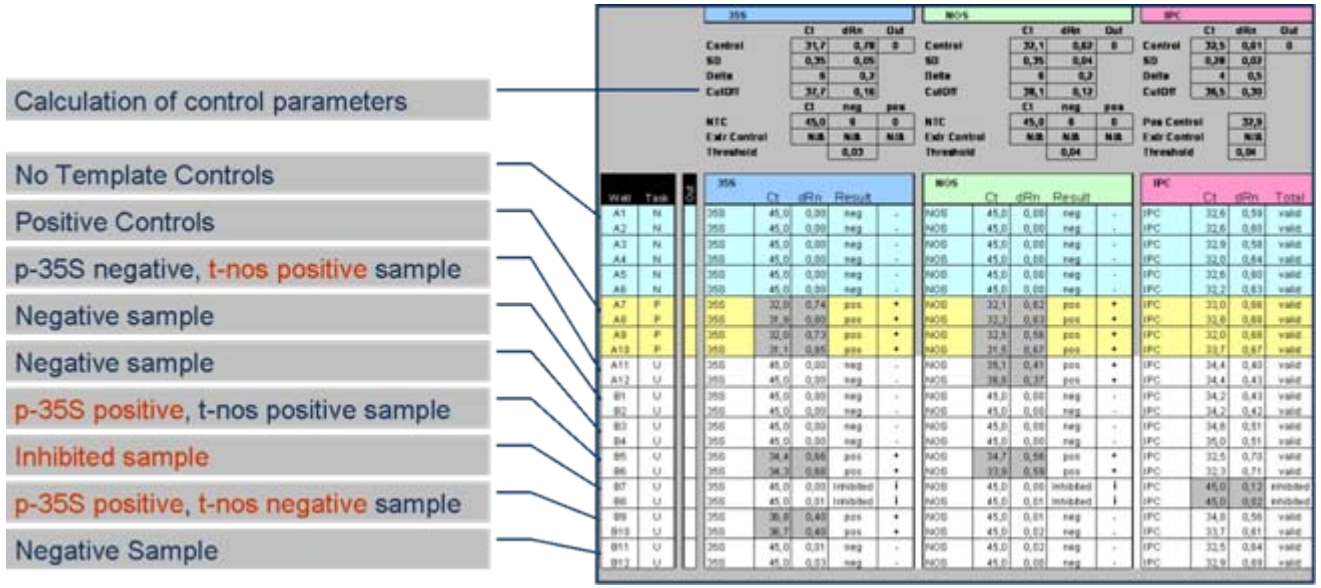
- Introduction
- Relevant dimensions (specific customer requirements and cost efficiency)
- Quality dimensions
- Challenges in practice

Eurofins Group - Overview



Cost Efficiency

- GeI based assays vs qualitative realtime Assays,
- Qualitative versus quantitative assays
- Event versus screening assays
- IT infrastructure (documentation effort) and tools (e.g. valid. Excel sheets)
- Automation of sample preparation or PCR setup
- Multiplexing



Customer Requirements

Examples:

- Short delivery times (express services)
- Complex analytical strategies, confirmations etc. dependent on screening results
- Electronic data exchange (EOL)
- Import and Export - Eurofins/GeneScan labs (Germany/USA/Brazil)
- High quality technical support

Quality

- **Quality**
  - ISO 17025 accreditation – Brazil - Inmetro
  - MAPA accreditation – official analysis
  - CQB – CTNBio (not mandatory) – routine analysis
  - Proficiency testing schemes
  - CRL list of methods and guidance documents for method validation
  - ISO 21569:2005, ISO 21570:2005…
    (general and specific GMO testing prerequisites)
  - GLP-OECD/Inmetro: Eurofins do Brasil is also in process of GLP recognition – for GMO analysis (before and post-monitoring approvals)

Quality – Information/Knowledge

UP-to date information

- Customer consultancy to apply the right systems and the right analytical strategy to be cost efficient
- Cover all relevant GMO (may depend on area/approval situation, origin of product etc.)

Requires

- Suitable method portfolio of validated methods
- Knowing what GMO are relevant (commercially and other)
- Knowing how a given GMO is detectable (analytical screening strategy)
- Knowing about up-coming GMO

Quality – Staff & Infrastructure

Contamination control

- Specifically trained staff (from cleaning personnel to labmanager)
- Specific training aspects (grinding, pipetting, disposing …)
- Internal “traffic” and air flows
- Number and location of work areas
- All primer, mastermix and standards are produced (ISO9001) and validated (R&D) by Eurofins/GeneScan GmbH

Quality - Process

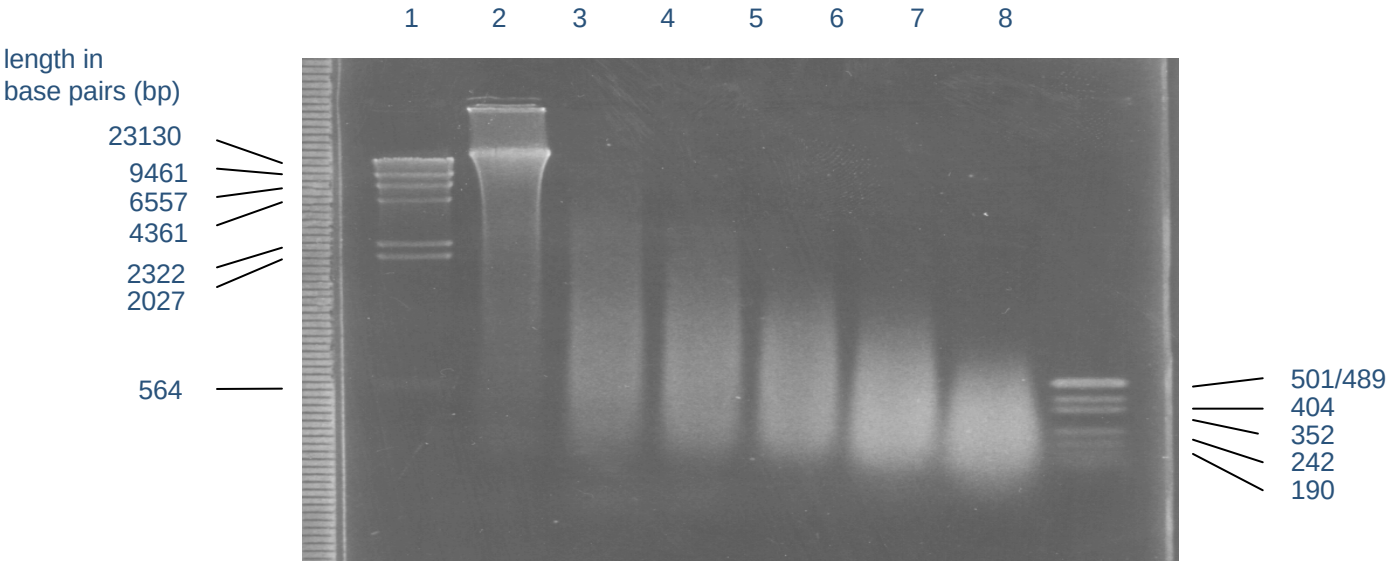
Process architecture and IT (LIMS)

- To avoid human error
- To improve documentation
- To improve “best practices”

Quality – Analytical Controls

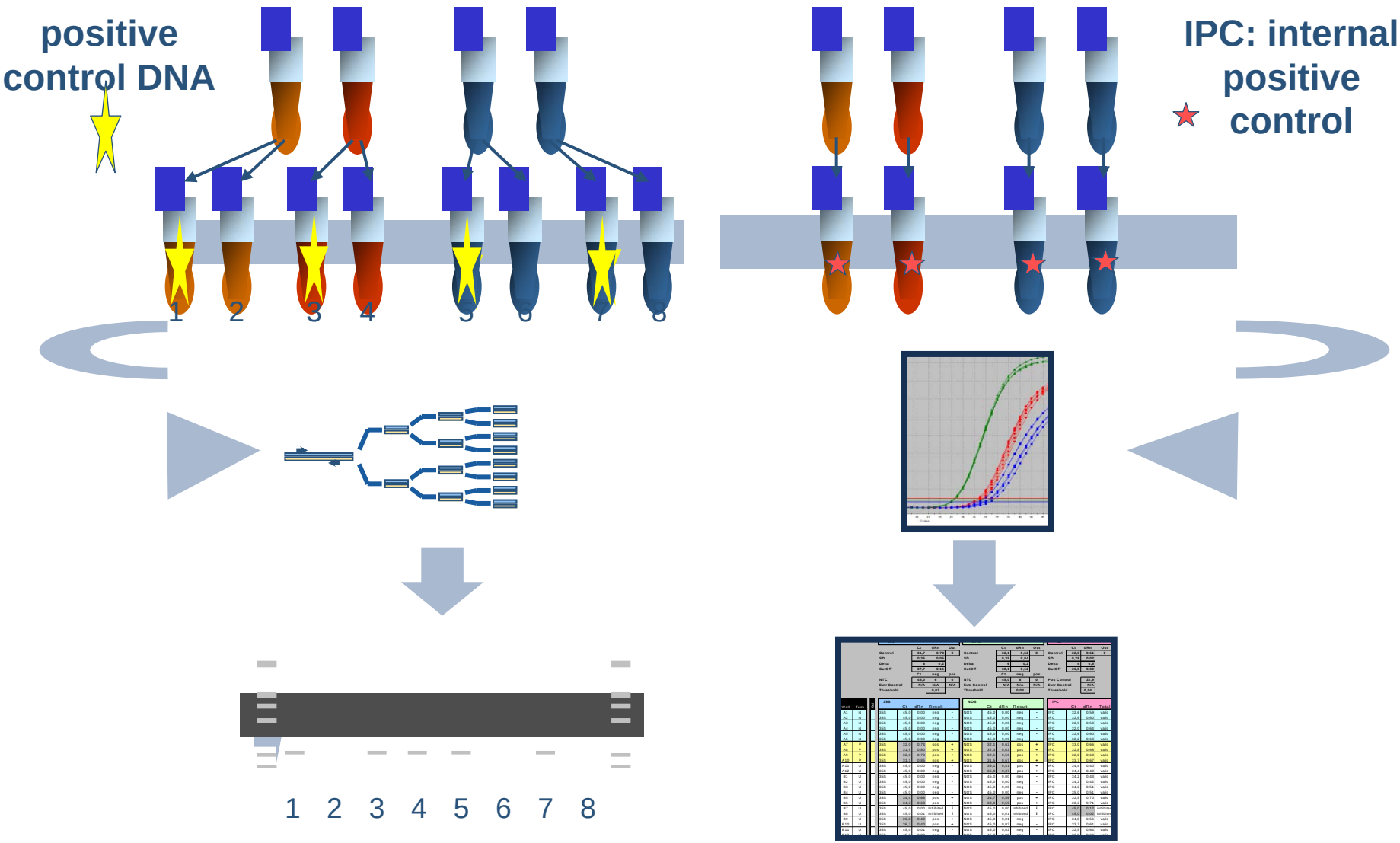
Analytical controls

- DNA amount (misleading results of OD, fragmentation)
- Positive control (should include extraction process)
- Negative control (enough in number as compared to sample numbers)
- Inhibition control: Prefer low level spiked or quantitative IPC controls



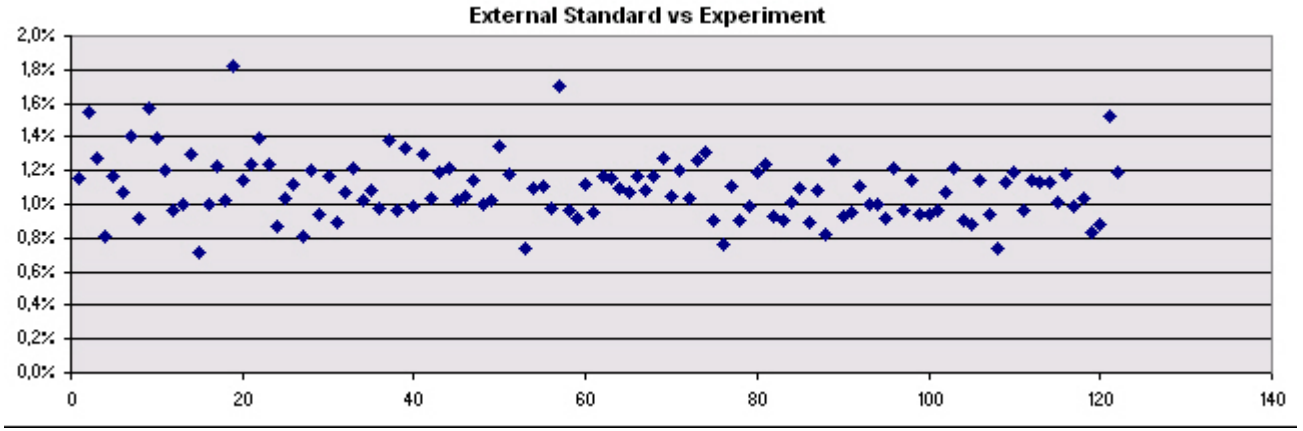
Shortening of DNA Fragments by Heat

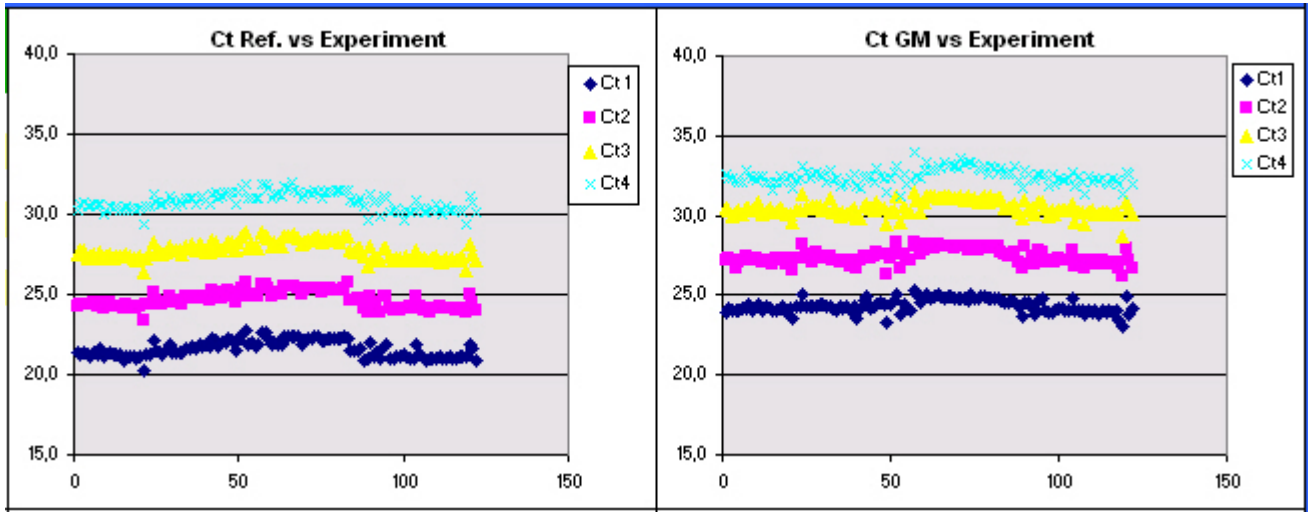
Qualitative Analysis



Quality – Controls / Monitoring

QC Charts as indicators to alert failure





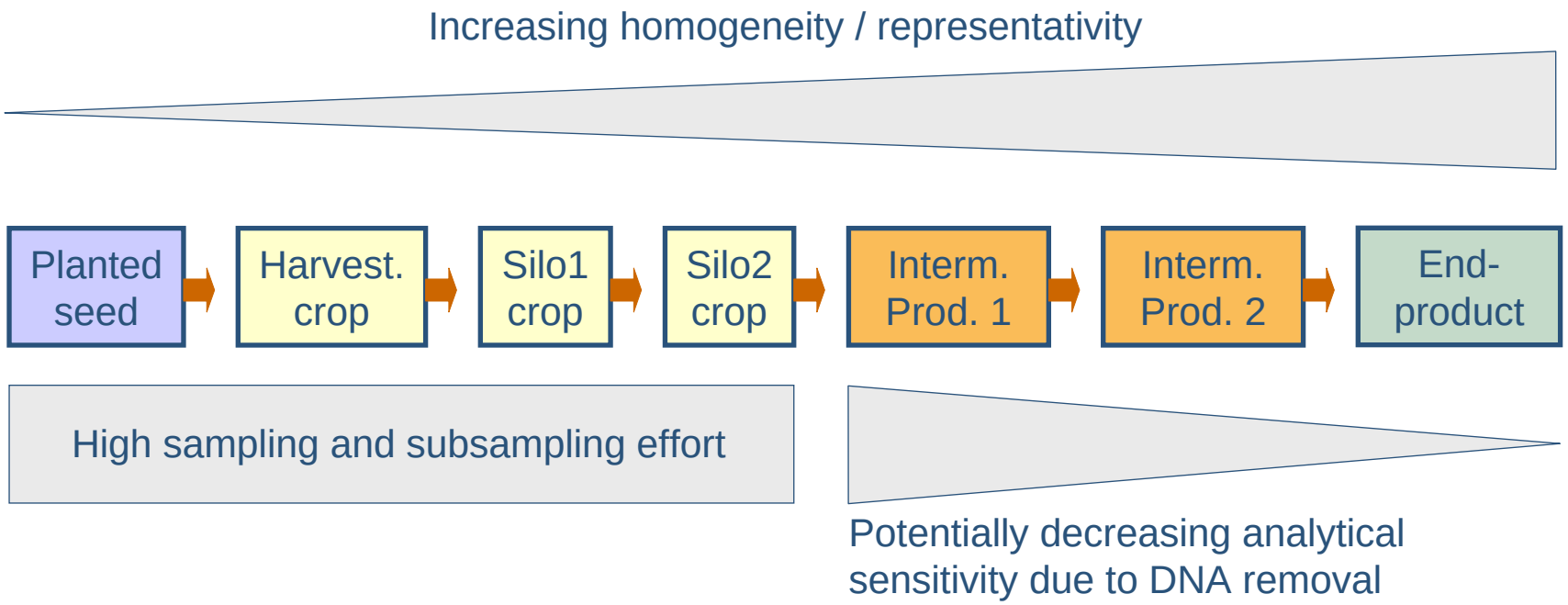
Quality – Interpretation of Results

Experience and evaluation of results

- If DNA content is low: Is it method failure or matrix property?
- A positive result could be misleading (e.g. CaMV, soy contamination in corn)
- Quantitative results can only be interpreted in a meaningful way if statistical knowhow is applied – evaluation sheet , controls and expertise

Experience along the Chain

Statistics and matrix experience



Challenges

- Increase number of approved events in Brazil (new strategies)

Crop	# Approved events (CTNBio)
Soy	1
Corn	11 (8 last two year)
Cotton	6

- New approvals at exporter countries
- Country infra-structure for segregation (GMO and Non-GMO)
- Presence of non-approved events (seeds contamination, country boundaries, GMO experimental fileds) – eg: Flax Triffid (Canada)
- Stacked events (3 corn and 2 cotton varieties)
- Reagents and sample importation (Proficiency Tests)

“Real-life” GMO testing

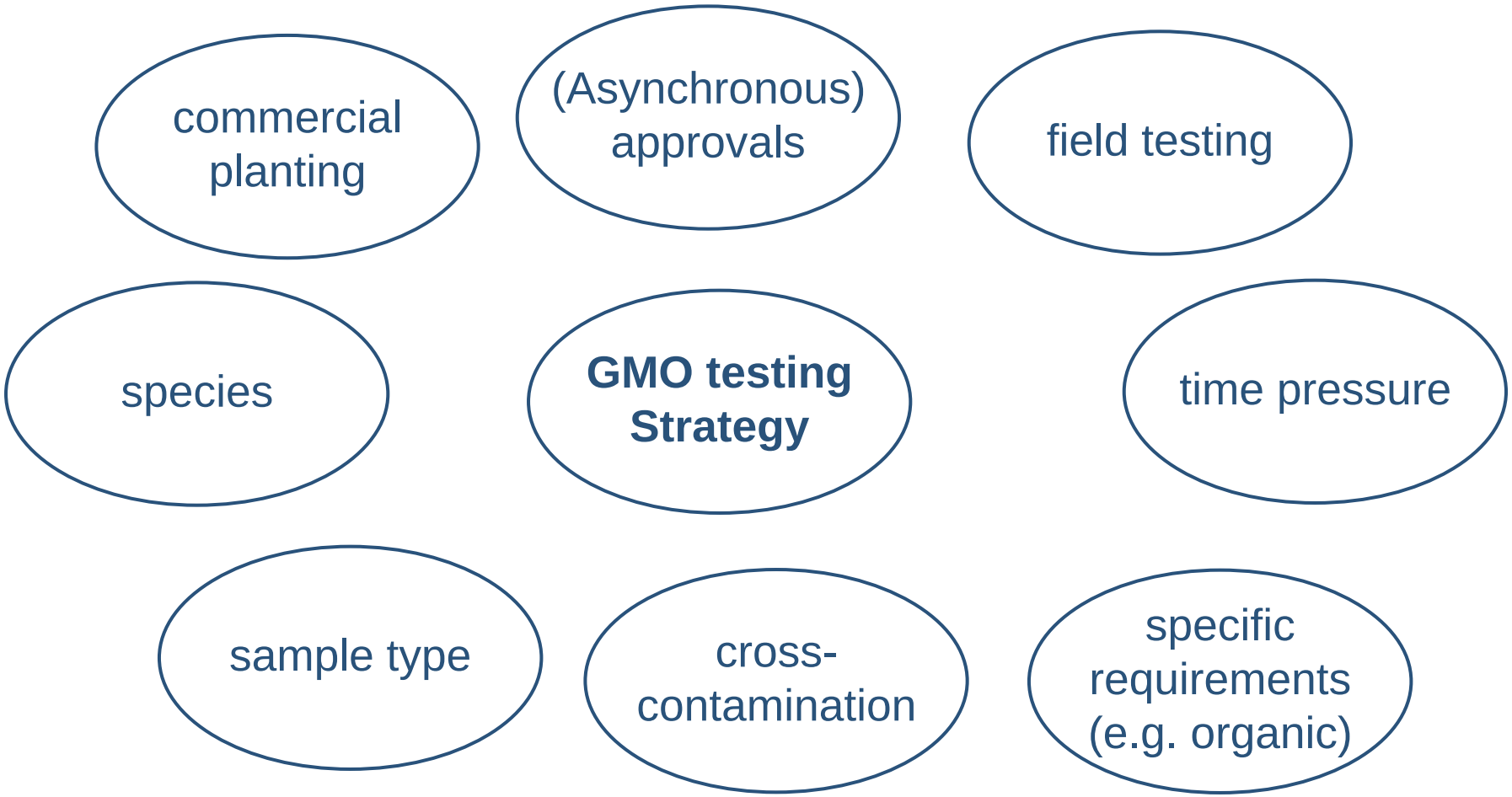
eurofins | GeneScan

Intelligent strategies for modern GMO testing

Step	Purpose	suitable methods
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 CRL methods)

“Real-life” GMO Testing

→ **Finding the right solution ….**



Thank you for your attention!

Mariana C. Daher

marianadaher@eurofins.com.br

www.eurofins.com.br

www.eurofins.com

Special thanks: Dr. Andreas Wurz