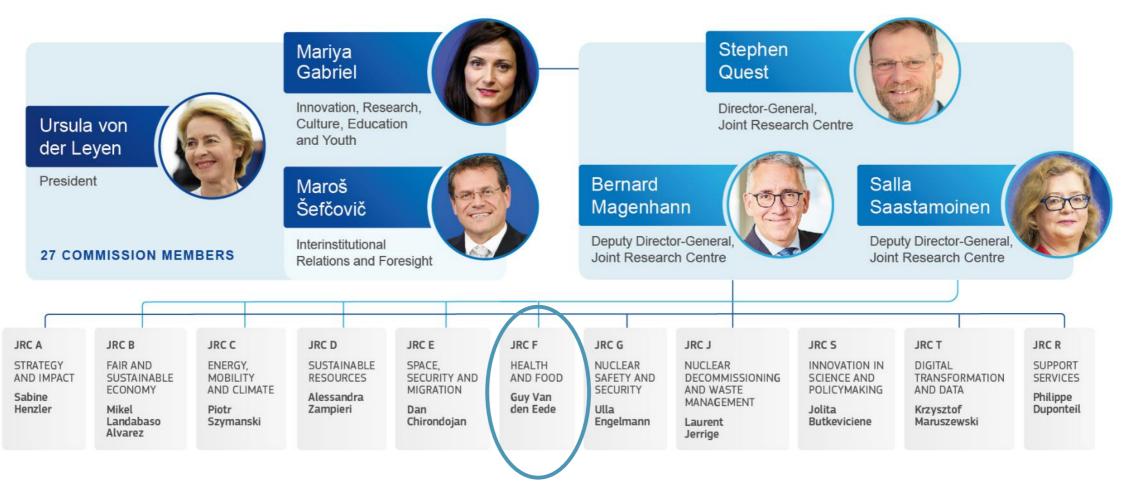
Achievements and future perspectives of GMO detection

Guy Van den Eede, Director Health and Food, DG Joint Research Centre

International Conference on GMO Analysis and New Genomic Techniques Berlin, 14-16 March 2023



The Joint Research Centre within the Commission





The need for evidence to implement legislation

Between 1992 and 1998, 18 GMOs have been approved under the environmental Directive. Labelling was required but validated detection methods were <u>not</u> required or foreseen and no thresholds existed.





1995: 1st scientific publication on GMO detection

Z Lebensm Unters Forsch (1995) 201: 583-586

Zeitschrift für Lebensmittel-Untersuchung und-Forschung © Springer-Verlag 1995

Originalarbeit

Nachweis gentechnologisch veränderter Pflanzen mittels der Polymerase Kettenreaktion (PCR) am Beispiel der FLAVR SAVRTM-Tomate

Rolf Meyer

Universität Bern, Institut für Biochemie, Abteilung für Lebensmittelchemie, Freiestrasse 3, CH-3012 Bern, Schweiz

Eingegangen: 13. April 1995 / Endfassung: 29. Mai 1995



1997: First validated method, first CRMs

Roundup Ready soybean - LMBG 24.01-1 (1997) Official Collection of Test Methods in Accordance with Article 35 LMBG (Lebensmittel und Bedarfsgegenständegesetz), Classification No. L 24.01-1, Beuth Verlag GmbH, Berlin, Germany



Recommendations deriving from the conclusions of the

AD HOC NOVEL FOODS MEETING

(Ispra, 11th and 12th November 1999)

Enforcing EU policy on Genetically modified organisms

Demand for setting up a network for the laboratories of the Member States' Competent Authorities

Objectives

The Competent Authorities (CA) of the Member States highlighted their strong need of a permanent network for the CA's-dependent laboratories responsible for the detection arid identification of GMO's, al least in food. This network should not duplicate or overlap the work carried out by others such as CEN TC233 or TC275 groups. It should rather fill the gap between public standardisation and all regulatory commitments of the Community.

Such a network is understood as a tool facilitating and speeding up:

- the information collection (e.g., data bases on gene sequences and analytical methods) and exchange, noteworthy the technical confidential data,

- the coordination of tasks to reduce the upscaling of the related costs,

- the identification and solution of the technical gaps (e.g., analytical methods and their interpretation) or needs such as reference material and sampling plans,

- the on-line access to shared expertise.

The CA's have precised that such a network should be structurally and functionally coordinated by the Commission. Considering the positive experience of European Commission's Joint Research Centre (JRC) in providing coordinated facilities to the CA's for what concerns GMO's, JRC appears as a convenient coordinating body.

Implementation and priorities

- Network restricted to all-GMO's concerned CA's and their associated laboratories,
- Fast information flow on urgent topics within the network,

- Organisation of meetings, exchanges of scientists or technicians between the laboratories and technical training,

- GMO Reference materials and appropriate sampling plans.

Please distribute this document within your Competent Authority and return the attached reply form with your comments.



European Network of GMO Laboratories

Support for the European Union Reference Laboratory on Genetically Modified Food and Feed

Validation studies

- Harmonisation of control
- Exchange of information
- Forwarding information to national networks
- Initiating research (EU-FP7)





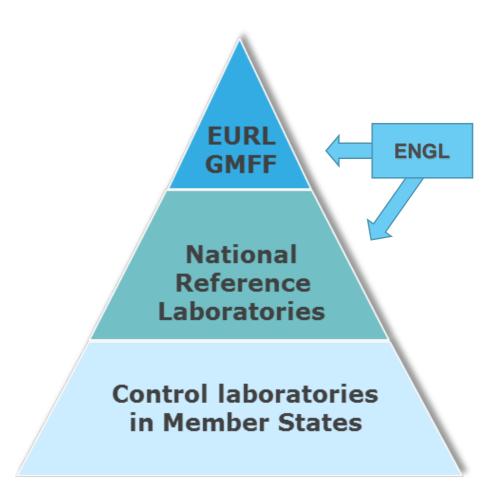








EURL GMFF tasks within the EU-GMO policy mandate Regulation (EU) 2017/625

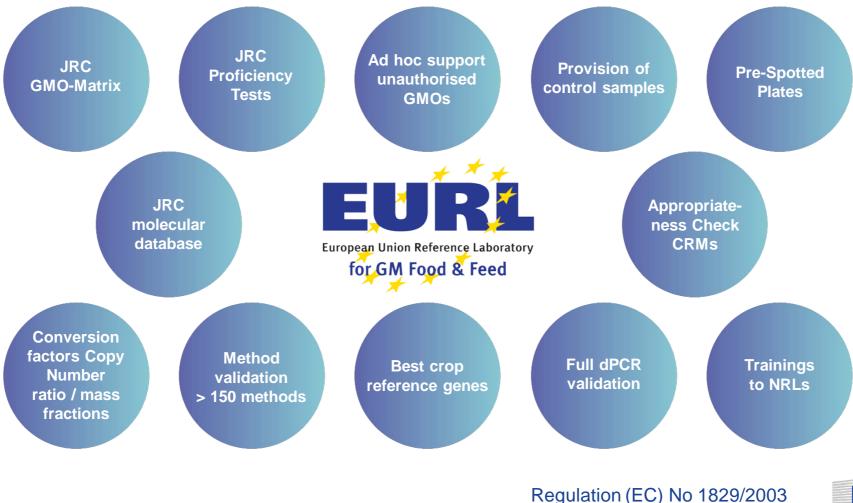


Support to Feed and Food law & official controls:

- Coordination of EU National Reference Laboratories (NRLs);
- Providing NRLs with reference analytical methods and with control samples (incl. screening approaches);
- Coordinating the accurate application of analytical methods;
- Organising comparative testing (CT) for NRLs and EU control laboratories;
- Ad hoc support, e.g. for emergency situations (unauthorised GMOs on EU market);
- Provision of training support.



EURL GMFF: tasks and support for EU-GMO policy, NRLs and official control



Regulation (EU) 2017/625

European Commission

https://gmo-crl.jrc.ec.europa.eu/method-validations

9

The European Network of GMO Laboratories (ENGL)

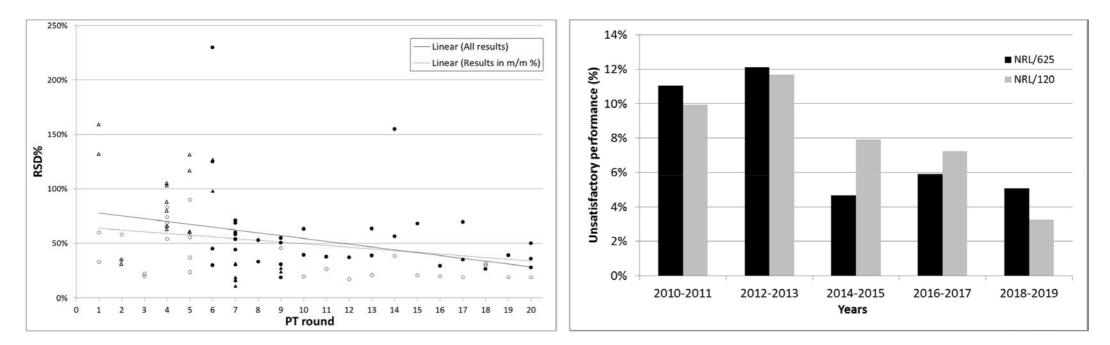


Mission: to support the EURL GMFF – to serve as technical EU platform

- Working Procedures & mandate defined by the ENGL Consortium Agreement;
- Operational: since December 2002;
- Structure: Unique network of technical expertise in GMO analysis:
 - Laboratories from 27 EU Member States
 - + Norway, Switzerland, Turkey
 - + observers from non-EU countries (China, India, others)



Ten years of proficiency testing



Variability of the reported results per dataset for each PT round, expressed as RSD%. Each symbol corresponds to one dataset expressed in m/m % (circles) or cp/cp % (triangles). Open and closed symbols refer to simple or challenging test item matrices, respectively.

Evolution of the performance of NRL/625 and NRL/120 with time, expressed as percentage of unsatisfactory scores obtained per time window of two years.

Broothaerts, W., Cordeiro, F., Robouch, P. and Emons, H. (2020) Ten years of proficiency testing reveals an improvement in the analytical performance of EU National Reference Laboratories for genetically modified food and feed. Food Control 114:107237



Expanding the Horizon of Nucleic Acid Analysis

Full Validation of a digital PCR Method for GMO Detection and Beyond

- Minimum Performance Criteria for digital PCR results (MPR Part-2)
- Conversion factors to express GM content determined by digital PCR in mass fraction
- Harmonised measurement system for official GMO controls in the EU
- Full validation of dPCR method for Mon 810 as a model in the field
- Application of conversion of measurement results from copy number ratios to mass fractions.





The era of new genomic techniques...

Four groups of NGTs are distinguished based on interactions with the genome:

- 1. NGTs creating a double-strand break in the DNA;
- 2. NGTs achieving genome editing without breaking the DNA double helix or generating only a single-strand DNA break;
- 3. NGTs inducing epigenomic changes;
- 4. NGTs acting specifically on RNA





Detection of food and feed plant products obtained by new mutagenesis techniques

European Network of GMO Laboratories (ENGL)

Report endorsed by the ENGL Steering Committee

Publication date: 26 March 2019

- Can we detect DNA changes?
- Are the changes 'natural' or the product of gene modification?
- What are the comparators?

"In conclusion, validation of an event-specific detection method and its implementation for market control will only be feasible for genomeedited plant products **carrying a known DNA alteration that has been shown to be unique**. Under the current circumstances, market control will fail to detect unknown genome-edited plant products."



'Global Harmonisation of GMO Analysis Support to Regional Networking' Project

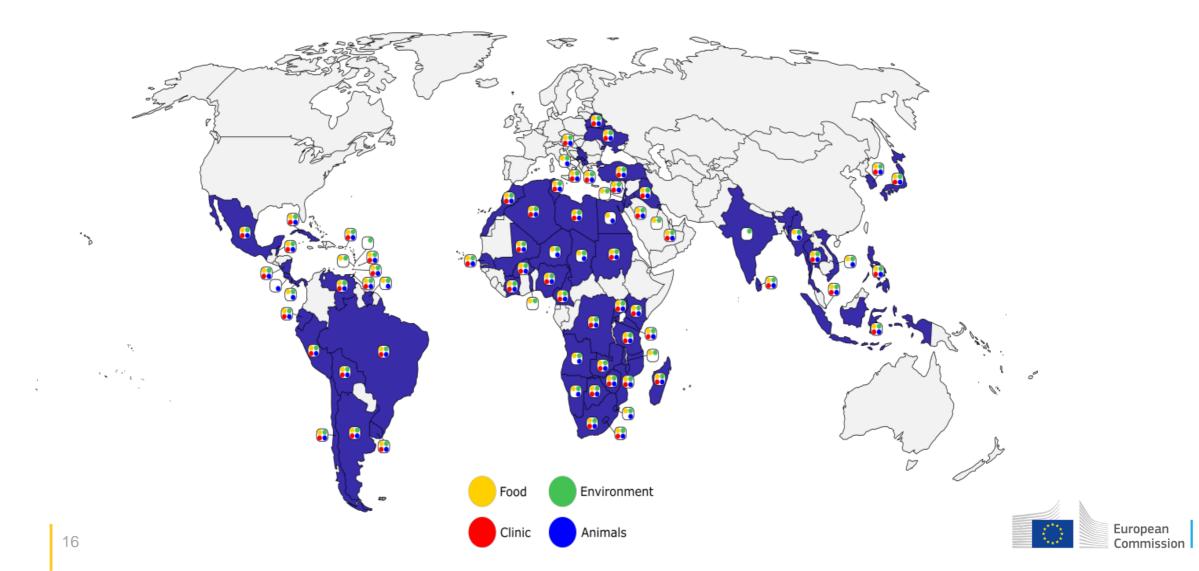
- Technical capacity progressively increasing in most countries
- Connection among labs within and among the regions
- Increase exchange and sharing of information
- Establishment of new Networks of GMO laboratories (e.g. RLAC-OGM, MENANGL)
- Collaboration among existing Networks and other countries in the regions (e.g. ASEAN- Asia; SANGL – Africa)
- Participation to EURL GMFF comparative testing rounds, control samples, ad hoc support from EURL GMFF
- Mapping regional technical capacities & regional road maps
- Regional testing projects and regional capacity-building initiatives



✓ > 20 Global and regional workshops involving more than 130 EU and non-EU countries



Our partners in the global network are involved also in fields other than GMOs



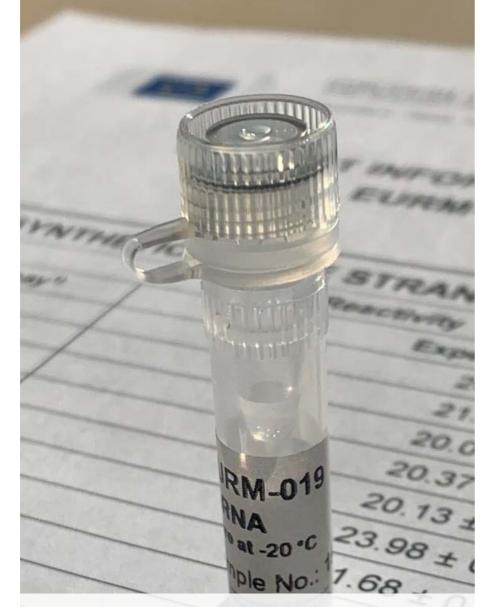
"

PCR: the long and winding road from GMOs to Omicron

... a tribute to all colleagues that with their talents and motivation have made this journey possible.

Guy Van den Eede Director, JRC Directorate F – Health and Food





Response to the COVID crisis (1/4/2020)

- Rapid, world-wide distribution of a synthetic single stranded RNA molecule to be used
- as positive quality control sample
- as calibrant
- for testing the presence of SARS-CoV-2 by RT-PCR.

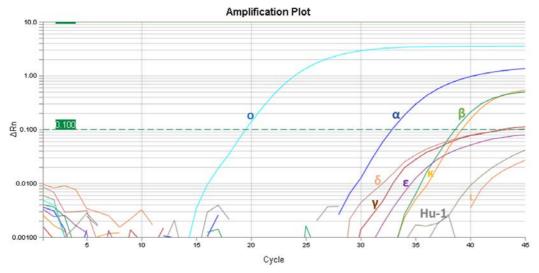
Distributed to more than 1000 laboratories worldwide





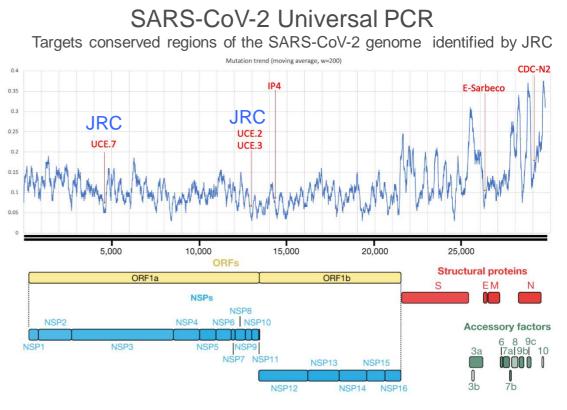
Development of novel assays for SARS-CoV-2 and other emerging pathogens

OmMet: RT-PCR assay specific for Omicron Targets specific mutations only present in Omicron



- The method shows high sensitivity and selectivity for the Omicron variant
- Validated with clinical samples, wastewater samples and synthetic RNA genomes
- The method represents an advantageous alternative to sequencing

Corbisier et al. JCV (2022)



In collaboration with Tamir Abdelrahman and Amy Parish (LNS, Luxembourg) Marchini *et al.* Viruses (2023)



To summarise: we cannot summarise...

Twenty + years of 'GM detection activities' has had an enormous impact and the impact exceeds by far the "GMO field":

- Technological;
- Societal;
- Health;
- Global;
- •

The world is watching you!



Keep in touch

EU Science Hub

joint-research-centre.ec.europa.eu

- @EU_ScienceHub
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- in) EU Science, Research and Innovation
- **E**U Science Hub
- @eu_science





Thank you



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Slide 22: image hand, source: stock.adobe.com

