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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	WP Innovation in Agriculture – Meeting of 19 November 2024 – Item 1c: Presentation of the DARWIN project

Following the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) of 19 November 2024, delegations will find in annex the presentation given by the representative of the EU-funded research project DARWIN.

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NEW GENOMIC TECHNIQUES
NEW FOOD SYSTEMS

Transition to safe and sustainable food systems through new and innovative detection methods and digital solutions for plant-based products derived from new genomic techniques, under a co-creation approach

Dr. Odd-Gunnar Wikmark, NORCE

Funded by the European Union


Project premise
01
RAPID DEVELOPMENT OF NGT TECHNIQUES AND AREAS OF USE CHALLENGES LEGISLATION WITH NEW GENETIC CHANGES, BRINGS NEW FEATURES, NEW ABILITIES AND NEW SPECIES.
02
THE ANALYTICAL FRAMEWORK TO DETECT GMOS IS THE PATHWAY TOWARDS A RELIABLE, TRANSPARENT AND EFFECTIVE LABELLING SCHEME FOR GMO PRODUCTS IN EUROPE.
03
NGT PRODUCTS CHALLENGE THE IMPLEMENTATION AND ENFORCEMENT OF THE CURRENT REGULATORY SYSTEM IN THE EU, RELATING IN PARTICULAR TO THE DETECTION OF NGT PRODUCTS THAT CONTAIN NO FOREIGN GENETIC MATERIAL.
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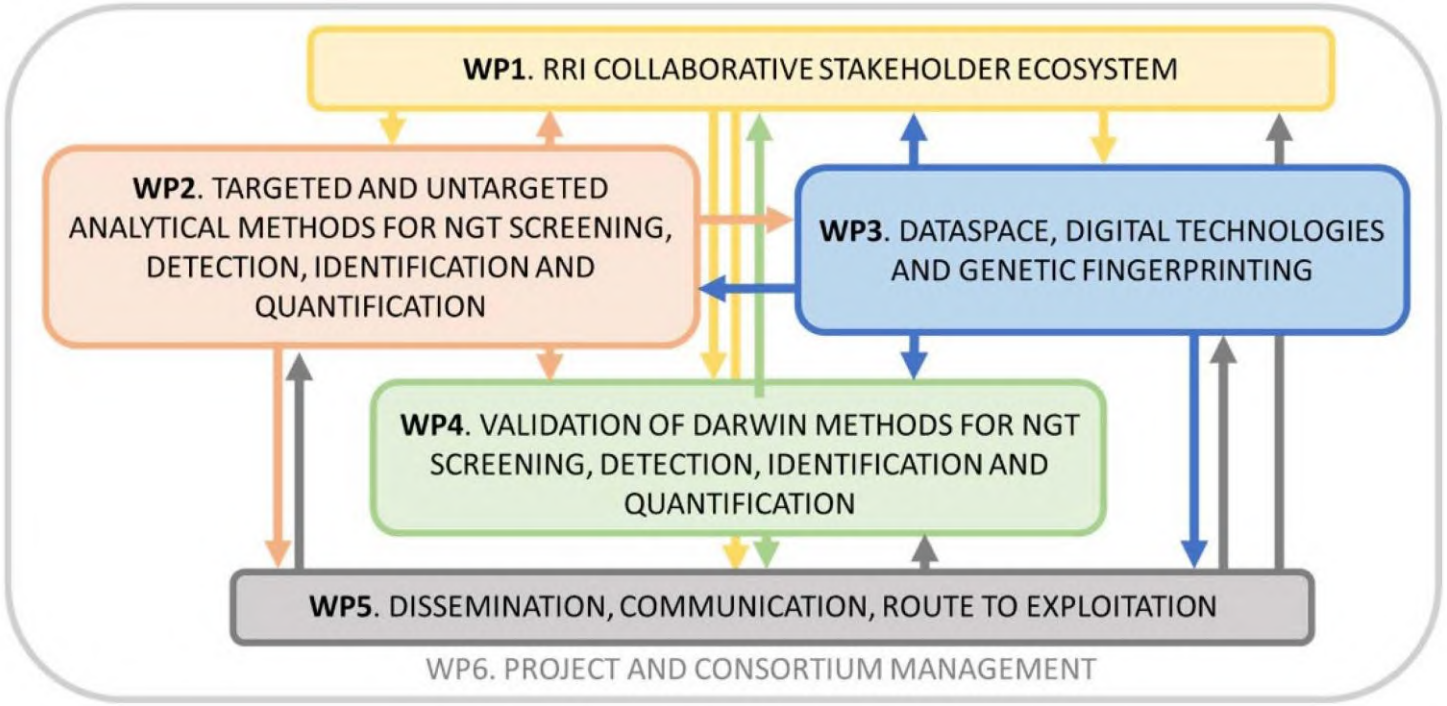
DARWINs project goals

- Development and validation of reliable detection methods
- Develop an **innovative detection strategy** by integrating targeted analytical PCR-based methods, untargeted sequencing methods, as well digital solutions
- Enable informed consumer choices by enhancing transparency/traceability across the food chain

DARWIN Project Work Packages



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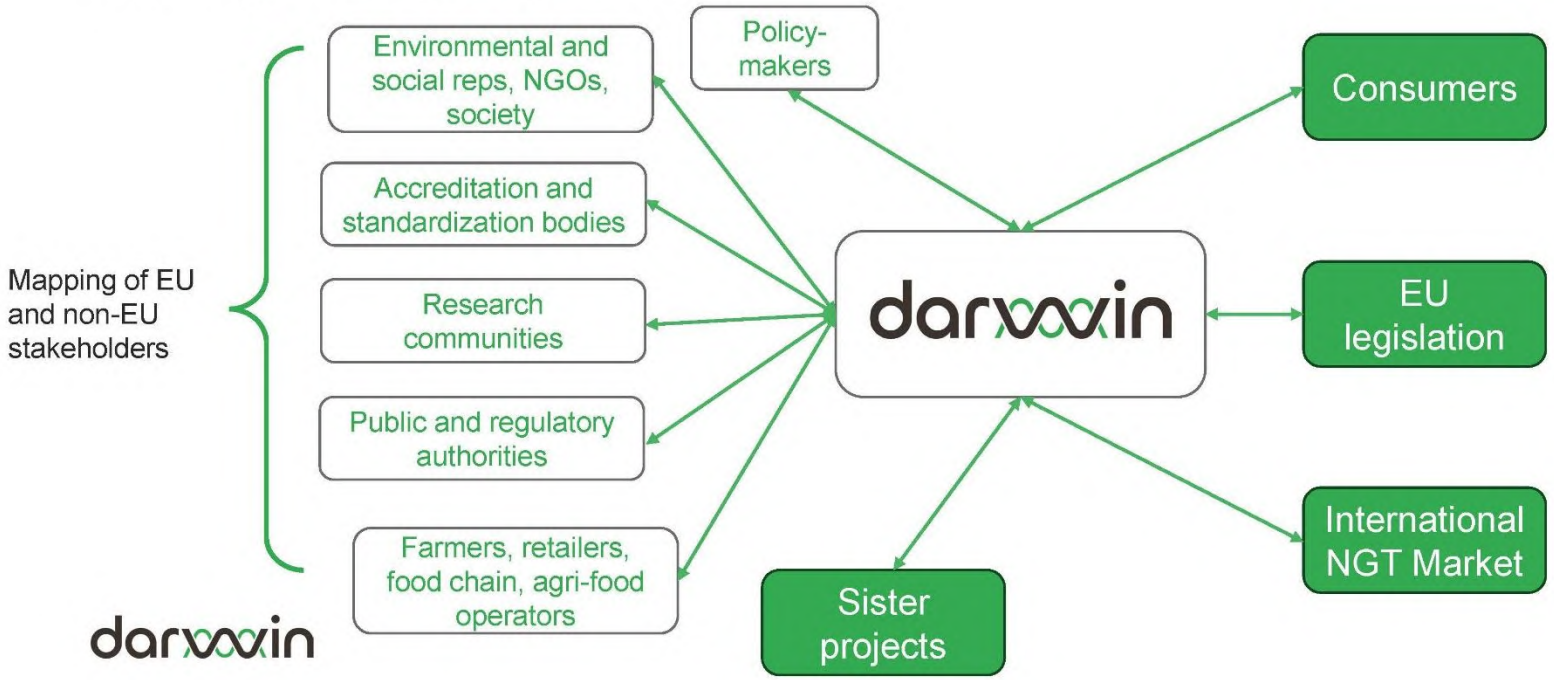
RRI Collaborative stakeholder ecosystem

Create an interdisciplinary, collaborative stakeholder ecosystem by bringing together stakeholders in Europe and internationally, promoting knowledge sharing and capacity building



Events

27/09/24 | EVENT

IFOAM ORGANISES A SCIENCE-POLICY SEMINAR ON DETECTION METHODS FOR NGT PRODUCTS

IFOAM is partner of the Horizon Europe DARWIN research & innovation project and is organising a seminar on November 18, 2024 in Brussels.

27/09/24 | EVENT

DARWIN HOSTS A TWO-PART STAKEHOLDER WORKSHOP ON TECHNICAL ADVANCES AND SOCIETAL IMPLICATIONS

Traceability and NGT Detection Methods: A Two- Part Stakeholder Workshop happening on November 25-26, 2024 NORCE Brussels Office.

The Methodology

DARWIN proposes to deliver validated analytical and digital tools for screening, detection, identification, and quantification of NGT products in the food chain under an interdisciplinary and co-creative approach.

2 PLANT SPECIES:
RICE AND TOMATO

METHODS:

- ENHANCED RT-qPCR (primers, enzymes)
- TRIPLEX RT- qPCR with enhancement
- PCR-ENRICHED MULTI TARGET SEQUENCING
- WHOLE GENOME SEQUENCING (WGS)
- METAGENOMIC HIGH-THROUGHPUT SEQUENCING

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NGT Genotypes

- Minimal genomic changes (Insertion, deletion and substitution)
- Induced mutants (chemicals, radiation)
- Different mixtures
  - Pure lines
  - Mixtures (different varieties, different species)
  - Processed food

RICE SEEDS

TOMATO FRUITS

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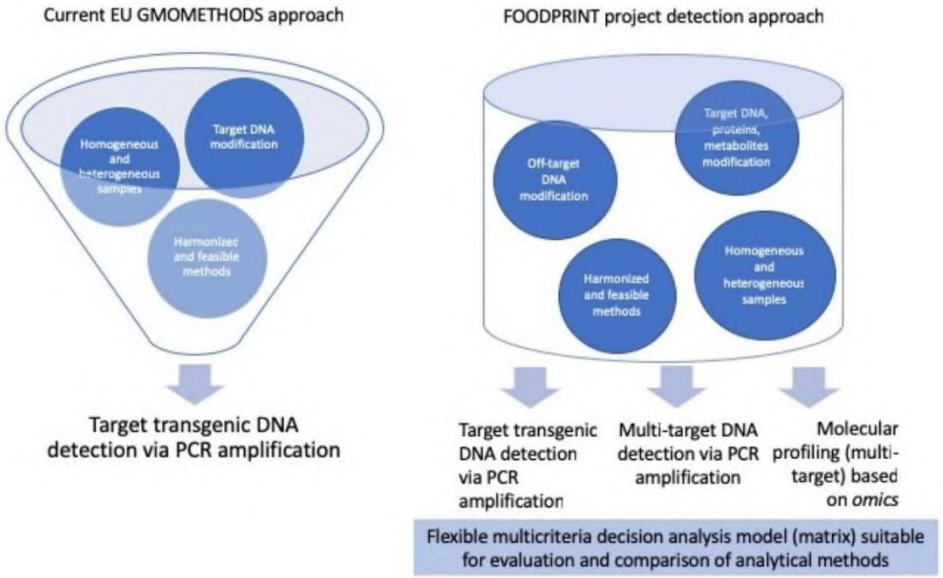
FOODPRINT: Traceability and labelling of gene-edited products in the food chain

The Research Council of Norway

- Aim: Gene-editing detection throughout the food chain



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foods

MDPI

Article

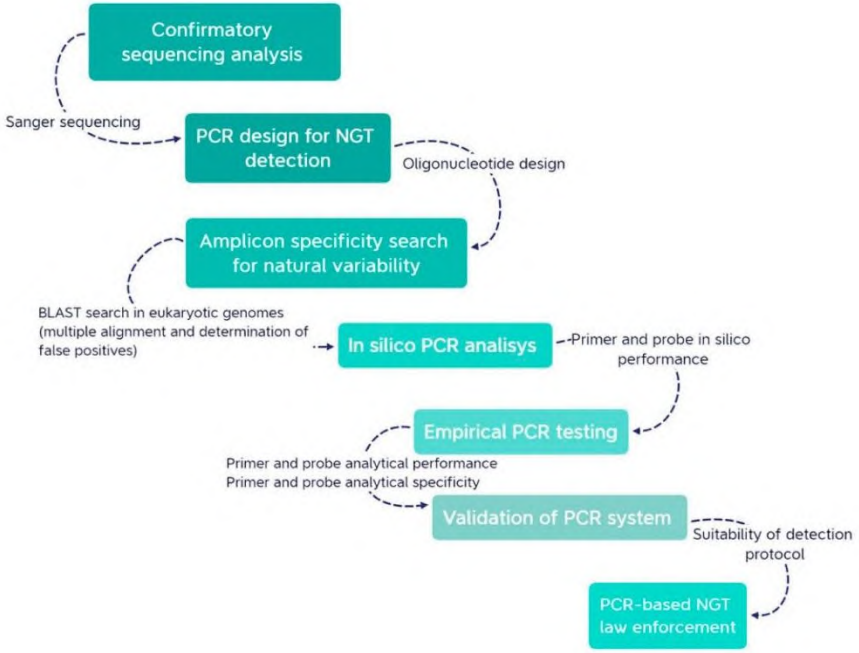
Specificity Testing for NGT PCR-Based Detection Methods in the Context of the EU GMO Regulations

Caroline Bedin Zanatta [1], Aline Martins Hoepers [1], Rubens Onofre Nodari [1] and Sarah Zanon Agapito-Tenfen [2,*]

[1] Department of Crop Science, Federal University of Santa Catarina, Florianópolis 88034000, Brazil
[2] Climate and Environmental Division, NORCE Norwegian Research AS, 5008 Bergen, Norway
* Correspondence: saag@norceresearch.no

Citation: Zanatta, C.B.; Hoepers, A.M.; Nodari, R.O.; Agapito-Tenfen, S.Z. Specificity Testing for NGT PCR-Based Detection Methods in the Context of the EU GMO Regulations. *Foods* **2023**, *12*, 4298. https://doi.org/10.3390/foods12234298

Key steps in NGT detection and quantification



Zanatta et al. 2023 Foods

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RT-qPCR Empirical Assay and future work

Despite the bioinformatic specificity assessment showing high specificity, the primers had low efficiency in the RT-qPCR assay. More work will be needed to optimize RT-qPCR design and conditions. DARWIN will continue this work.

..shows the importance of considering database results in conjunction with the performance of the primers/probe PCR systems as a critical step when planning PCR-based methods for the detection, identification, and quantification of GMO events in light of EU regulations.

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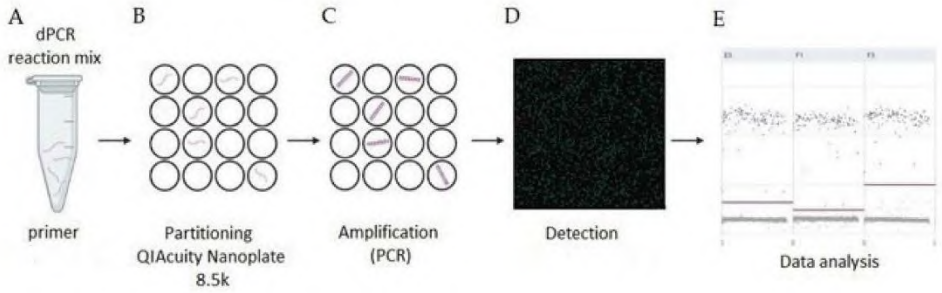
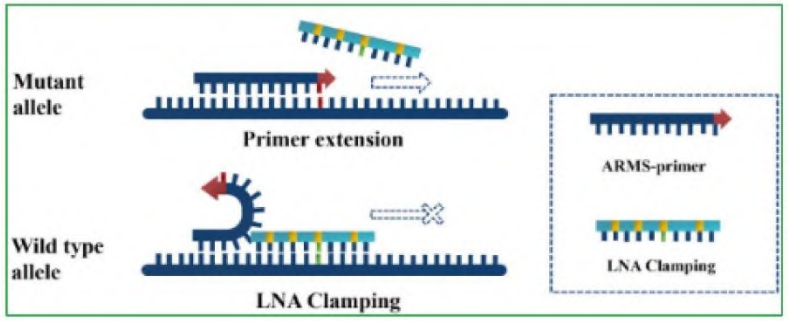
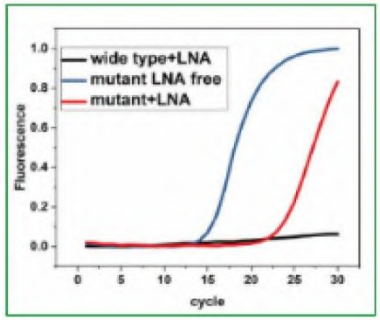
DARWIN - Targeted approach



- ENHANCED RT-qPCR (for instance LNA)
- ENHANCED RT-qPCR Enzymes





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Article

Targeted High-Throughput Sequencing Enables the Detection of Single Nucleotide Variations in CRISPR/Cas9 Gene-Edited Organisms

Marie-Alice Fraiture [1,†], Jolien D'aes [1,†], Emmanuel Guiderdoni [2,3], Anne-Cécile Meunier [2,3], Thomas Delcourt [1], Stefan Hoffman [1], Els Vandermassen [1], Sigrid C. J. De Keersmaecker [1], Kevin Vanneste [1,‡] and Nancy H. C. Roosens [1,*,‡]

[1] Sciensano, Transversal Activities in Applied Genomics (TAG), rue Juliette Wytsman 14, 1050 Brussels, Belgium
[2] CIRAD, UMR AGAP Institut, F-34398 Montpellier, France
[3] UMR AGAP Institut, Université de Montpellier, CIRAD, INRAE, Institut Agro, F-34398 Montpellier, France
* Correspondence: nancy.roosens@sciensano.be
† These authors contributed equally to this work.
‡ These authors contributed equally to this work.

Citation: Fraiture, M.-A.; D'aes, J.; Guiderdoni, E.; Meunier, A.-C.; Delcourt, T.; Hoffman, S.; Vandermassen, E.; De Keersmaecke S.C.J.; Vanneste, K.; Roosens, N.H.C Targeted High-Throughput Sequencing Enables the Detection c Single Nucleotide Variations in CRISPR/Cas9 Gene-Edited Organisms. *Foods* **2023**, *12*, 455. https://doi.org/10.3390/foods12030455

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Metagenomic to screen NGT lines in mixtures with non NGT

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Rice Seed Sample Description			
Sample n°	GE Rice Line Content		
	Percentage	Copy Number	Detection
1	100	13,733.3	+
2	99.9	13,346.7	+
3	99.1	13,273.3	+
4	95	12,113.3	+
5	90	10,753.3	+
6	50	5640.0	+
7	10	1153.3	+
8	5	528.0	+
9	0.9	85.3	+
10	0.1	10.8	+ *
11	0	0	—

How to distinguish edits from naturally occuring mutations?

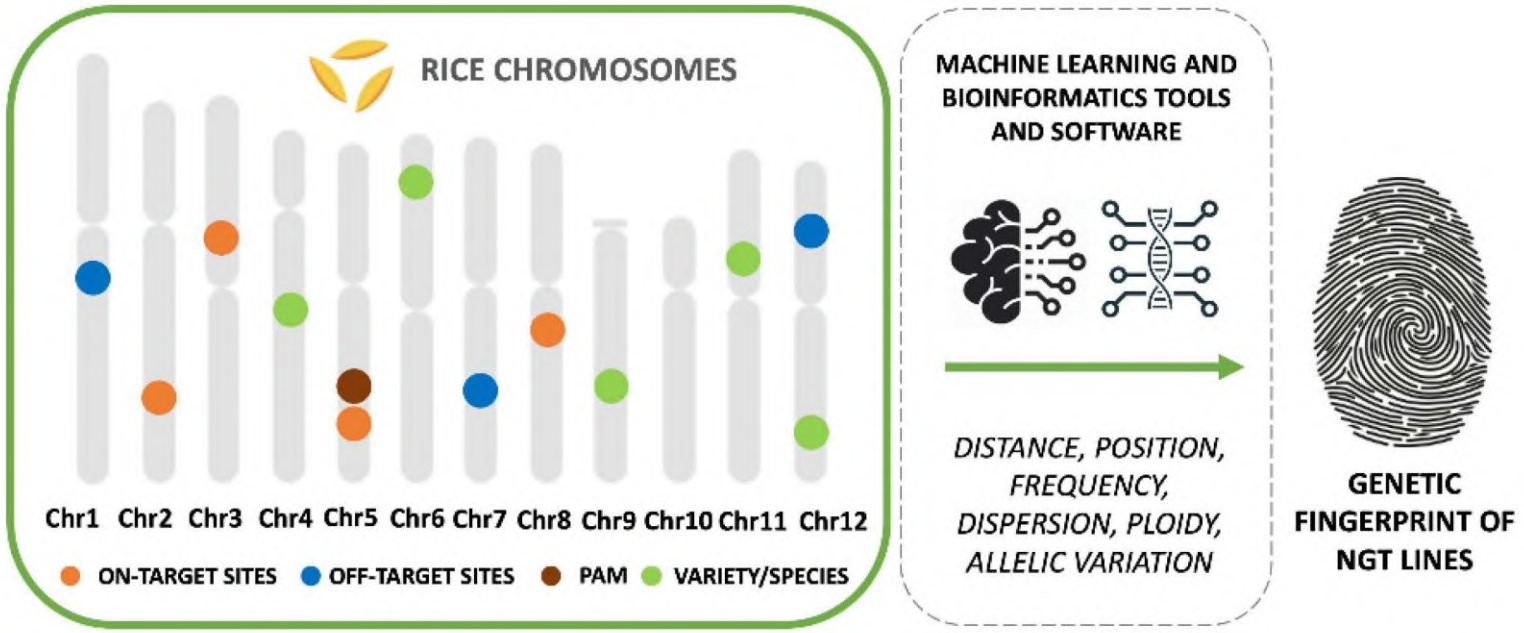

Figure 3: NGT **genetic fingerprint.**

Detection of NGTs

- Important to have sequence information on NGT edits.
- Full genome sequence will most likely become relevant for untargeted detection.
- Today, NGTs must be approved in EU and will have known sequences and structure. Can be systemized and screened for, although labor intensive.

Scenarios

GMO PRODUCT APPROVAL

The authorization process is simulated from the submission to full validation with current and potentially changed regulation.

ORGANIC FOOD CERTIFICATION

Application of a validated PCR method & proposal of an alternative traceability systems to be applied to EU value chains.

GMO COMPLIANCE

Simulation of a possible approach to build a workflow for the implementation of official analytical control at EU member state level.

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Dataspace, digital technologies and genetic fingerprinting

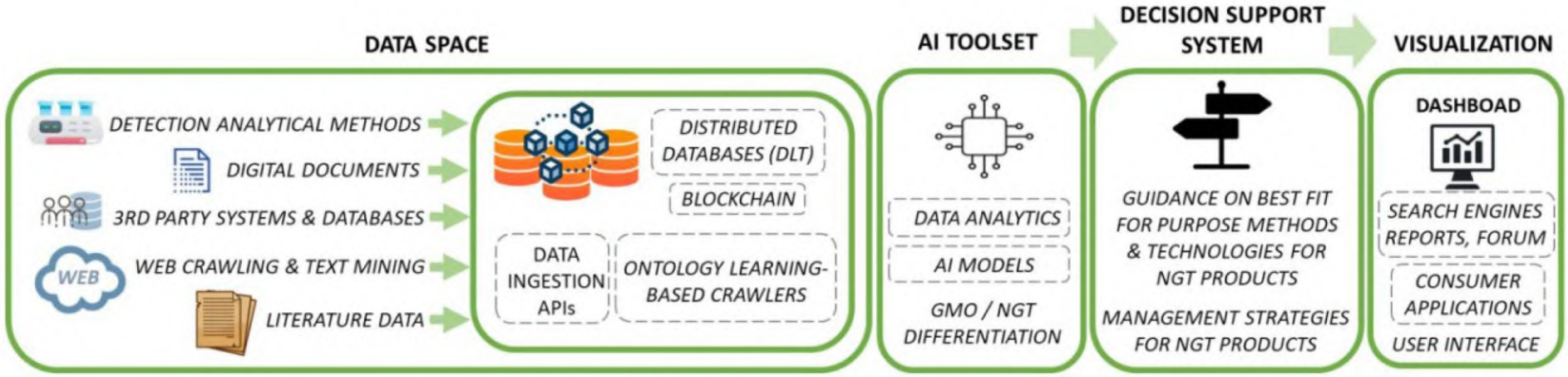

Figure 4: **DARWIN Digital platform.**

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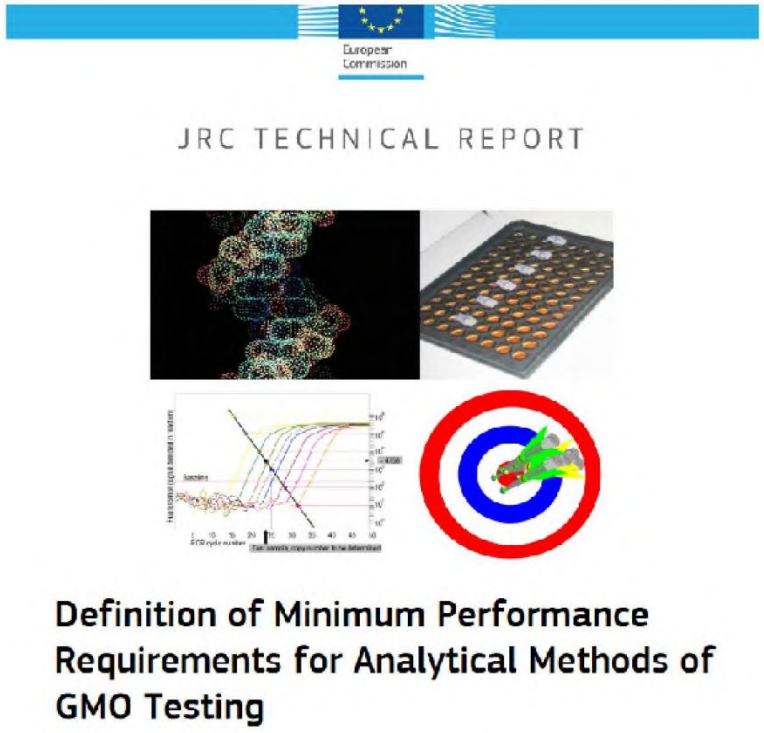
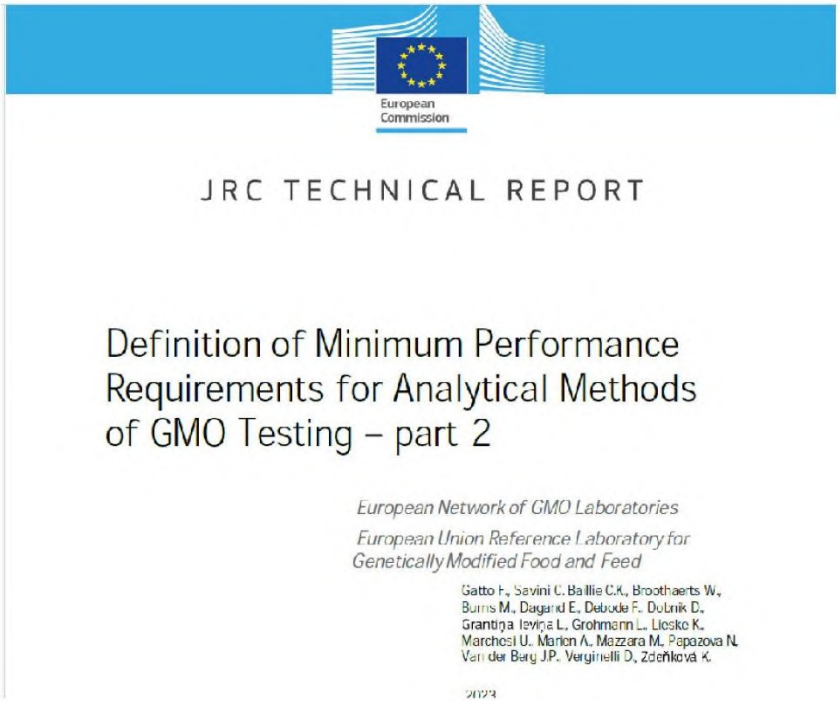
Validation of DARWIN methods





European Network of GMO Laboratories (ENGL)

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Expected outputs

Reliable detection methods to address the challenges

Development and validation of detection tools for enforcement authorities as well as for developers and agri-food operators

Empower enforcement authorities, developers and agri-food operators for the authenticity and traceability of products obtained through NGTs

Enable informed consumer choices by enhancing transparency and traceability across the food chain

Enable innovation in the food system linked to NGTs

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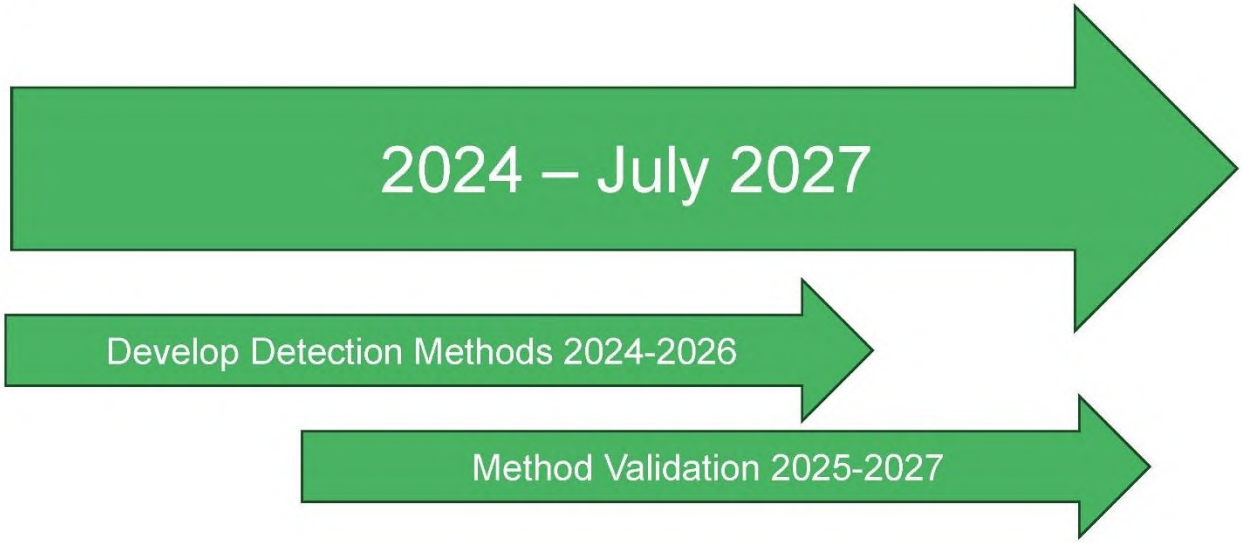
Timeline


2024 – July 2027
Develop Detection Methods 2024-2026
Method Validation 2025-2027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