NGTs: Labeling, Traceability, and Coexistence

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Setting

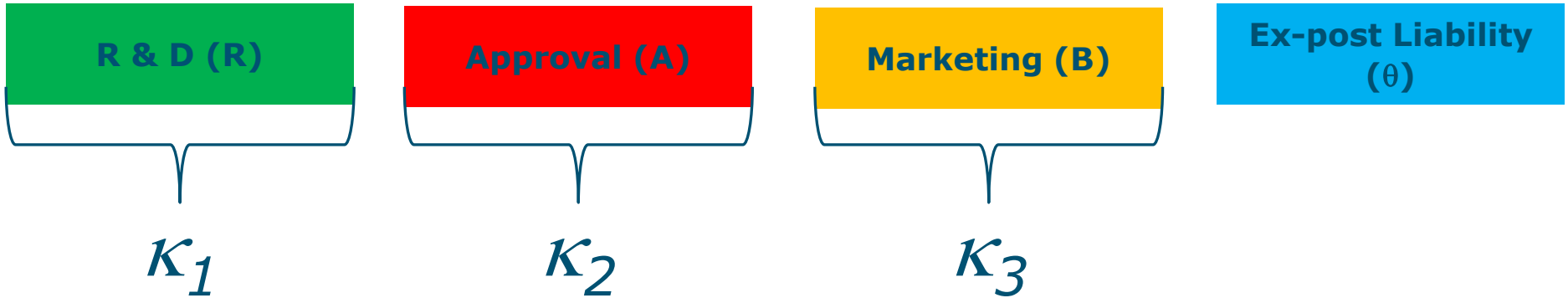
- NGTs in the EU: GMO regulation -> approval, coexistence, labeling, traceability -> costly, reduced competitiveness
- EC proposal: two categories - NGT1, NGT2 – no organic, no herbicide tolerance
- NGT1: small changes (up to 20 base pairs), labeling of seeds only, no traceability, notification and information for approval
- NGT2: larger changes, labeling and traceability, simplified risk assessment
- Amendments: labeling and traceability, patents, …

Questions

- Direct and indirect costs, complexity, administrative burden, and other costs of segregation associated with mandatory traceability, labeling, and coexistence requirements for Category 1 NGT plant products in the EU?
- Uptake and availability of NGT products in the EU in comparison to other world regions?
- Potential impact of these requirements on innovators currently investing in NGT products (including the public and private sector)?

Regulatory Implications: Model

Four phases: R&D, Approval, Marketing, Ex-post Liability



- Effect of Regulation on Immediate Investment

Model Application: simulations

Average approval length: about 6.7 years (Smart et al., 2017)

Table 1. Hurdle Rates for Different Parameter Values

$E(\kappa_1)$	10	5	2.5	1
Hurdle Rate	14.59	10.80	8.91	7.78
$E(\kappa_2)$	10	5	2.5	1
Hurdle Rate	14.59	10.70	8.76	7.59
Hurdle Rate Zero approval costs	8.66	4.88	2.99	1.86

Note: the hurdle rates are calculated applying equation 6. Other parameter values are fixed at $\mu = 0.04, q = 0.5, E(\kappa_i) = 10$ if not otherwise.

	Coefficients	*Standard Error*	*t Stat*
Intercept	0.8205	0.0015	553.39
κ_1	0.6089	0.0001	4072.26
κ_2	0.6277	0.0001	4194.04
κ_3	-0.0130	0.0001	-86.62

Simulation results

Five Crops: maize, osr, wheat, tomato, potato

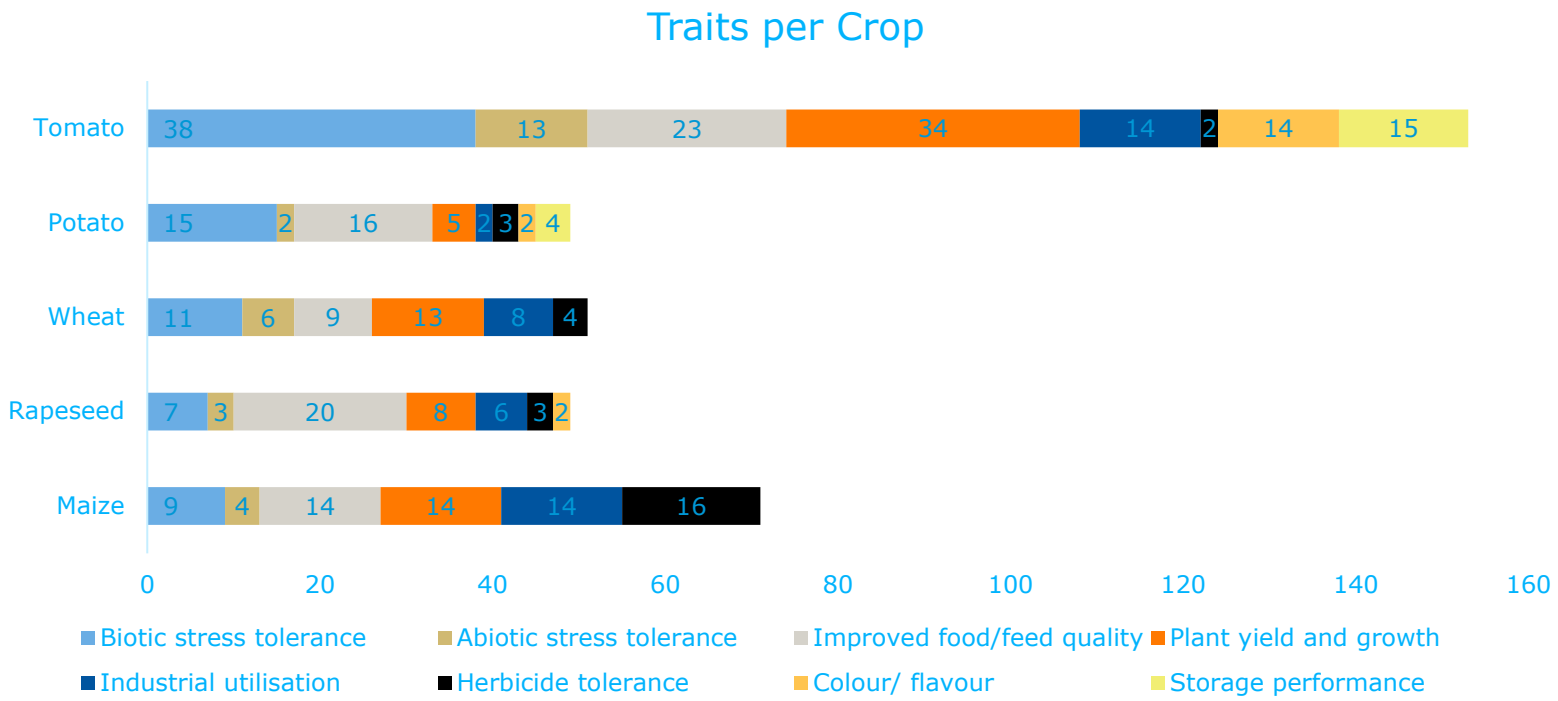
- Four scenarios:
  - Baseline: NGTs treated as “conventional” crops
  - Coexistence: NGTs treated as “GMOs” but no labeling beyond seeds required
  - NGT labeling: NGTs treated as “GMOs”, but no coexistence
  - Co-NGT: NGTs treated as “GMOs” with coexistence
  - Co-NGT in supply chain
- Comparing results: differences explain benefits and costs.

Scenario assumptions

- Assumptions:
  - EU prices and quantitities: three year average
  - Adoption: logistic, 40% after 20 years
  - K-shift: based on 10% yield increase
  - Producer and consumer surplus

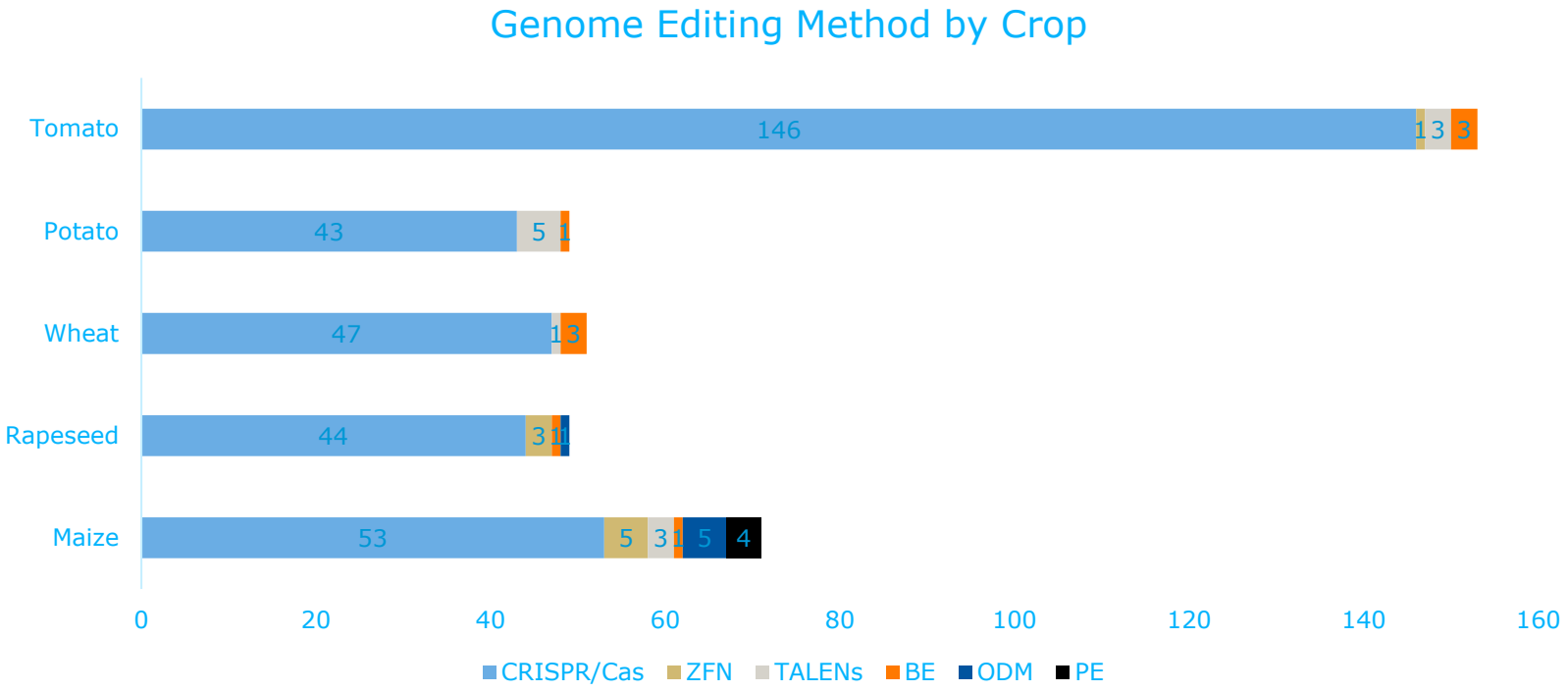
- Model: Equilibrium displacement model, supply chain analysis

Genome Editing



Source: EU Sage Database

Genome Editing



Source: EU Sage Database

NGT applications: market release

Table 1: Examples of NGT applications with the market release.

Crop	Country	Trait	Developer
Apple	Canada, US	Quality: non-browning	Okanagan Specialty Fruits
Banana	Philippines	Quality: lowering the browning process for prolonged shelf-life.	Tropic Biosciences
Lettuce	US	Non-browning romain lettuce	Intrexon
Maize	Japan	Quality: Waxy corn, Corn with high starch content	Corteva Agriscience
Mustard Greens	US	Quality: adjusted flavor (less bitter)	Pairwise
Oilseed rape/Canola	Canada, US	Quantity: herbicide tolerance	Cibus
Potato	US	Quality: less prone to bruising and black spots increasing shelf-life	Simplot
Soybean	US	Quality: oil with approximately 80 % oleic acid content and 20 % less saturated fatty acids compared to commodity soybean oil	Calyxt
Soybean	China	Quality: high oleic acid content	Shandong BellaGen Biotechnology Co.
Tomato	Japan	Quality: high levels of gamma-aminobutyric acid (GABA), amino acid supposed to aid relaxation and to help lower blood pressure	Sanatech Seed
Wheat	China	Quantity: powdery mildew resistant wheat	Suzhou, Chinese Academy of Sciences

Sources: https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/colombia-crops-food/ and those available via the hyperlinks.

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Coexistence scenario

Policy	EU Member States apply and intend to apply
ex-ante regulations	
Prohibition and approval procedures	
prohibition of planting GM-crops in specific areas	AT, DE, HU, LU, PT, SK
case by case approval for each field by local authorities	AT*, HU, IE, SK
compulsory training of farmers planting GM-crops to be paid by the GM farmer	DK, HU, SK
consent from landowner needed	AT, BE, HU, LU, SK
consent from neighbours needed	AT, BE, HU, LU, SK
Registration and information duties	
registration of areas in publicly available database	AT*, DE, DK, GR, LV, LT, SK
registration of areas in publicly available database, restricted access	AT*, PT, EE, FI, FR, HU, NL, PL
informing neighbouring farmers and landowners	DK, AT, HU, NL, PL, SK
record keeping	DE, DK, PT, CZ, ES, HU, IT, NL, PL
Technical segregation measures	
minimum distance requirements	AT, BG, CZ, DE, DK, EE, FR, HU, NL, PL, RO, SK
buffer zones	AT, CZ, EE, FR, PL, SK
rotation intervals	GR, LT, SE
Biotech free zones	BE

Policy	EU Member States apply and intend to apply
Insurance measures	
compensation fund paid by GM-farmers (levy on GM crops) plus support from the central government	DK
compensation fund paid by private stakeholders	PT, IE, FR, NL
liability fund	BE
private insurance against damages	AT*, LU
ex-post liability rules	
Legal liability for damages	
liability based on civil law	CZ, EE, HU, SK
fault based liability	AT*, DK, FR, NL
strict liability for GM-farmers	AT*, DE, IE, PL
joint and several liability	DE
Proving damage	
burden of proof lies with GM farmer	AT, DE, FR, IT
burden of proof lies with non-GM farmer	IE
Penalties	
fines for non-compliance with ex-ante regulations	AT, CZ, EE, FR, IT, LV, LT, LU, PL, PT, SK

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Coexistence Scenario

Table 4: Minimum distance requirements for selected crops in meters.

Country	Maize	Oilseed rape	Sugar beet	Potato
Bulgaria	(4000-30000)			
Czech Republic	70 (200)			3-10 (20)
Denmark	150 (150)		20 (20)	10 (10)
Germany	150 (300)			
Hungary	400 (400)			20-40 (30-60)
Ireland	50 (75)			
Latvia	200	4000	200	50
Lithuania	200	4000	50	20
Luxemburg	600		100	50
Netherlands	25 (250)		1.5 (3.0)	3 (10)
Portugal	200 (300)			
Romania	200			
Slovakia	200 (300)			
Sweden	50		3	

Note: Numbers in brackets refer to distances to organic crops. Sources: based on country reports summarized at https://food.ec.europa.eu/plants/genetically-modified-organisms/reports-and-studies_en and USDA GAIN country reports. The minimum distance requirement for Bulgaria has been placed into brackets as this is only a proposal.

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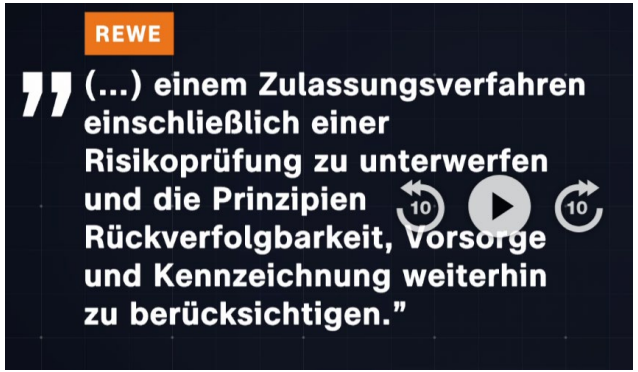
Labeling and traceability debate

Table 2: NGT labeling policies.

Country	Labeling	Thresholds (%)
EU	Mandatory Seeds (?), currently mandatory	0.9 and 0.1
China	Mandatory	*
Australia/New Zealand	Mandatory & Voluntary	1.0
Japan	Mandatory & Voluntary	5.0
US	Voluntary	5.0
Canada	Voluntary	5.0

* no specific content requirement

Sources: European Union (2003); Food Compliance International (2020); Food Standards Australia New Zealand (2023); Government of Canada (Government of Canada, 2021); Thomson (2002); USDA (USDA, 2018).



Labeling and traceability scenario

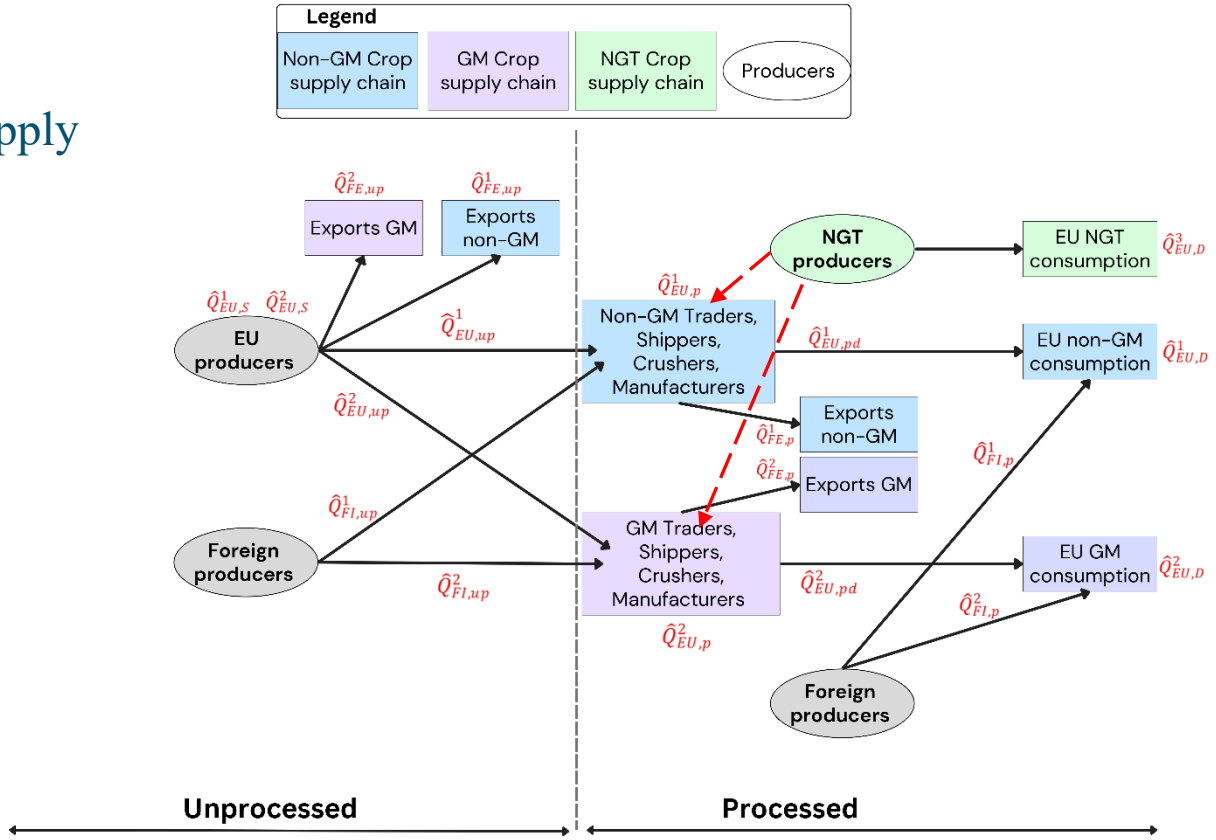
- Current policy: not workable, only PCR based tests allowed, change time consuming
- Possibilities:
    - Indication on the label: just printing costs
    - Via varieties: costs increase exponentially
    - Documentation similar to other credence goods
    - Identification for labeling (if possible): high cost scenario
- Identity Preservation: non-NGT bears the additional costs

NGT labeling scenario: market segregation

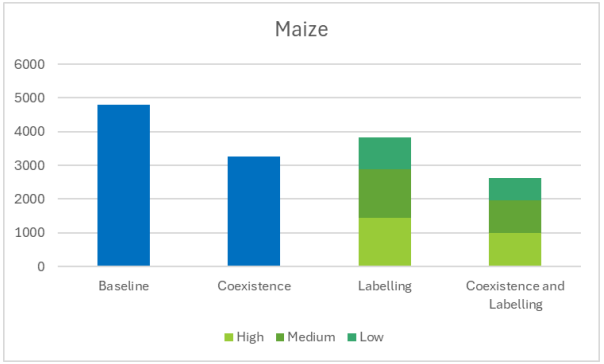
- Assumptions:
  - Market segregation: a new NGT supply chain introduced
  - Labeling and traceability along the supply chain required
  - Labeling and traceability costs: low, middle, high
    - Low: may contain NGTs, no tracing
    - Middle: contains NGTs, w/o specification but traceability
    - High: contains NGTs, with specification and traceability
- Result: lower benefits for producer, processor, consumer, import and export,
  - Difference to baseline scenario costs/benefits

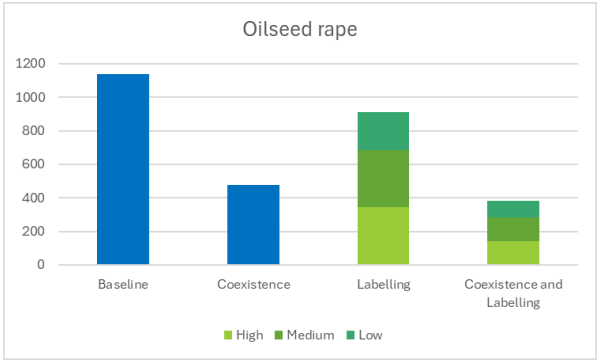
NGT labeling scenario: market segregation

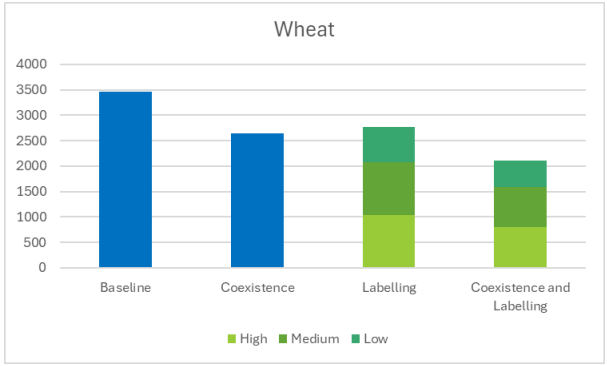
Figure 4: Crop Supply Chain in the EU



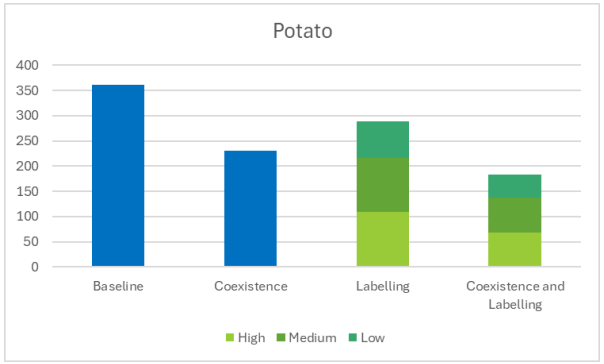
Summary scenarios w/o supply chain

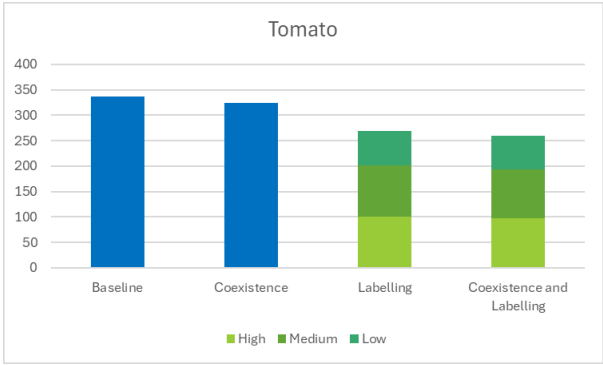






Total surplus in million Euro (average per year)





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Supply chain: maize

Table 12: Changes in the surplus of maize due to the introduction of NGT in the market and the presence of traceability for non-GM producers along the supply chain.

	ΔTS	ΔCS	ΔPS
Δ Importers of unprocessed GM (mio. Euro)	-19	-9	-9
Δ Importers of unprocessed non-GM (mio. Euro)	-16	-6	-10
Δ Traders, shippers, crushers, manufacturers GM (mio. Euro)	-33	-17	-16
Δ Traders, shippers, crushers, manufacturers non-GM (mio. Euro)	-1 721	-1 022	-669
Δ Importers of processed GM (mio. Euro)	-0 812	-0 519	-0 292
Δ Importers of processed non-GM (mio. Euro)	2	-1	-0 938
Δ non-GM producers (mio. Euro)	-326	-193	-132

Source: Authors elaboration. Model details explained in the text

Table 13: Changes in maize NGT surplus due to the presence of labeling for NTG producers.

	ΔTS	ΔCS	ΔPS
Δ NGT producers unprocessed (mio. Euro)	-189	-112	-77
Δ NGT producers processed (mio. Euro)	-327	-194	-133

Source: Authors elaboration. Model details are explained in the text.

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Conclusions

- Different scenarios: effects assessed by comparison
- OSR and potato most strongly affected by coexistence policies
- Labeling and traceability:
    - High policy dependence
    - Changing identification/traceability policies time consuming
    - Delay: Very costly (baseline scenario results)

Conclusions

- Labeling costs depend on the labeling requirements
    - Low, middle, high scenario
    - Less costly for tomato and potato, easier to segregate
- Traceability costs:
    - Linked with IP preservation
    - Less costly for tomato and potato (easier to segregate)
    - Non-GM crushers, processors, and manufactures 80% of the costs
    - Increases food prices!!!

Conclusions

- International trade effects:
  - Importers of Non-GM mainly affected (case of maize)
  - Spill-over effects on other regions

- Overall effects:
  - Labeling and traceability prevents application at EU level.
  - They act as a barrier to submitting proposals for approval for import and processing of NGTs.

Thank you for your attention!

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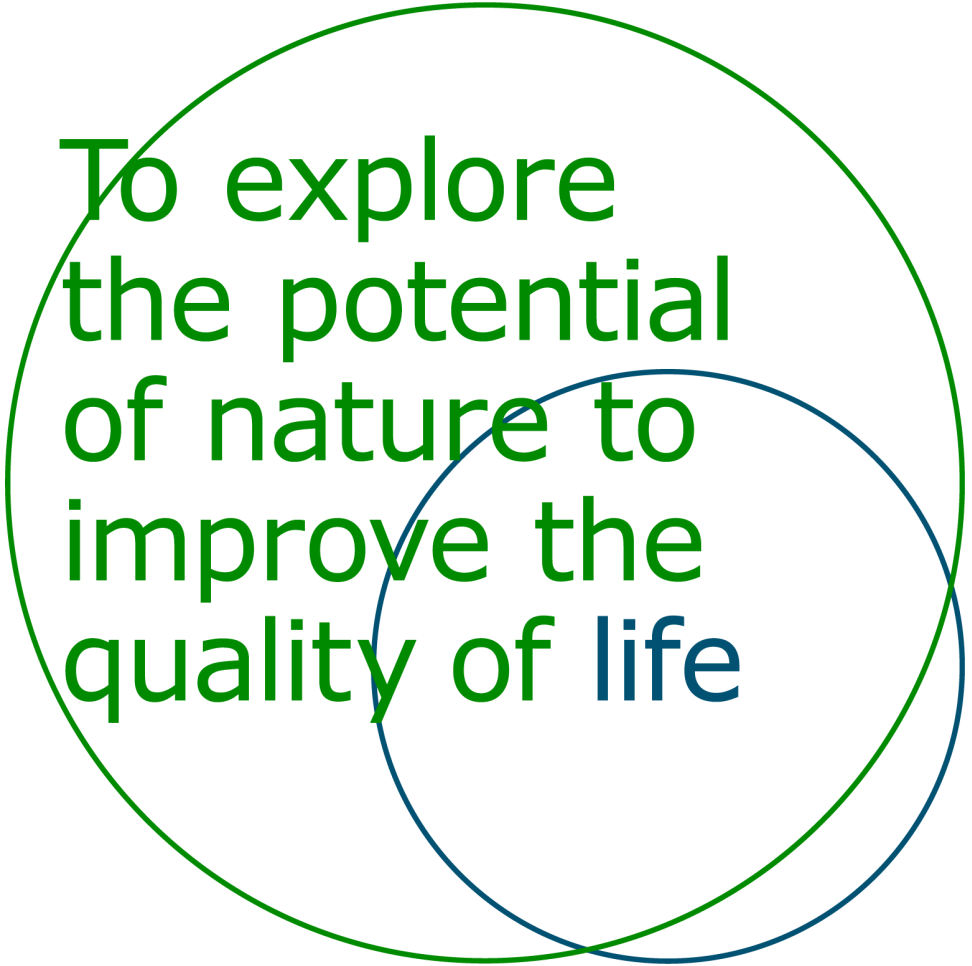

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