

Developing a Generalized Framework for Regulatory Scenario Identification and Applying Real Options Methodology in Innovation Policy

Panel Session – Evenson Room

Speakers: Margherita Simonetti, João Godinho, Zuzana Smeets
Kristkova, Tomasz Zimny, Justus Wesseler

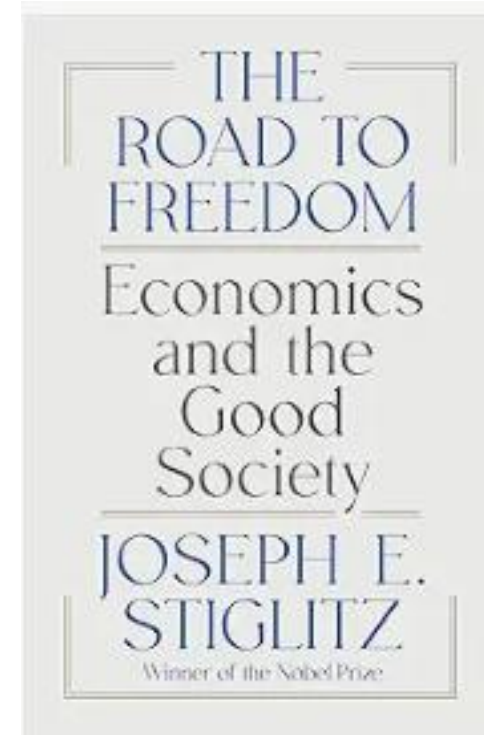
Program

- **13:35h-14:15h** – The RO framework
 - Regulatory scenario classification and the RO model (*Tomasz Zimny and Justus Wesseler*)
- **14:15h-14:45h** – Case Studies
 - DETECTIVE: How does the new EU NGT regulation impact food business operators? (*Margherita Simonetti*)
 - BrightSpace & Act4CAP: How can MAGNET help calibrate the RO model, and vice versa (*Zuzana Smeets Kristkova*)
 - RATION: What are the implications for LRP developers and applicants? (*João Godinho*)
- **14:45-15:00h** – Open Q&A and General Discussion

Opportunities, Sustainability, Bioeconomy

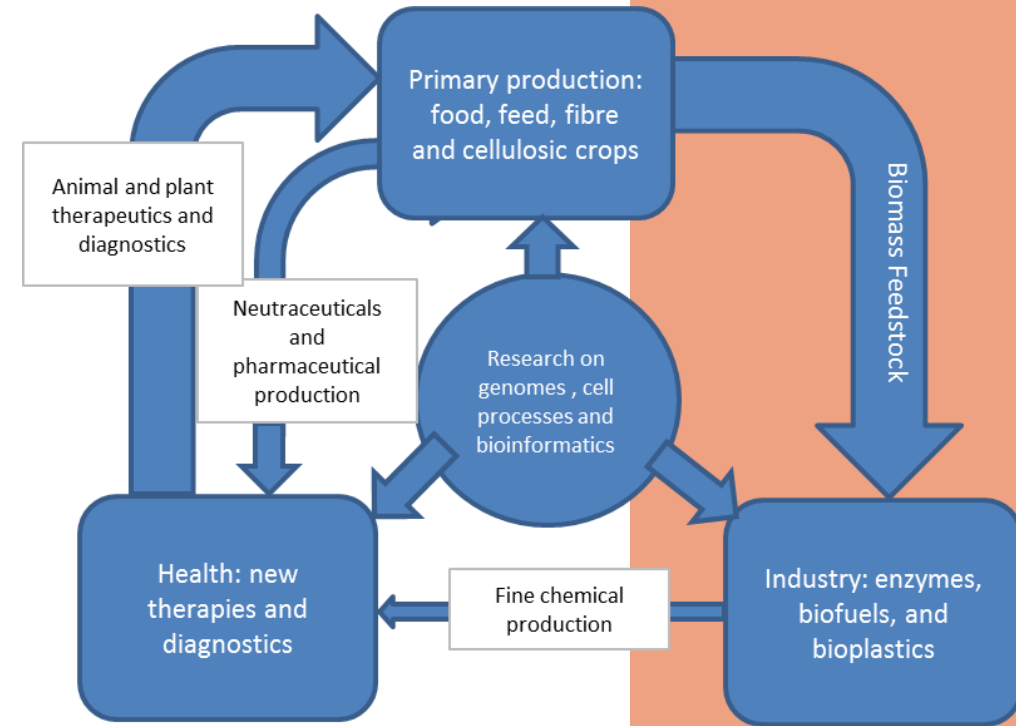
- Freedom and well-being: hand-in-hand
- Depends on the opportunity set
- Poverty reduces opportunities
- Bioeconomy increases opportunities
- Opportunities increase well-being => sustainability

BTW: GHG emissions is not an externality



Opportunities, Sustainability, Bioeconomy

The bioeconomy is generally understood as *the production, utilization, conservation, and regeneration of biological resources, including related knowledge, science, technology, and innovation, to provide sustainable solutions (information, products, processes and services) within and across all economic sectors and enable a transformation to a sustainable economy* (International Advisory Council of the Global Bioeconomy Summit 2018).



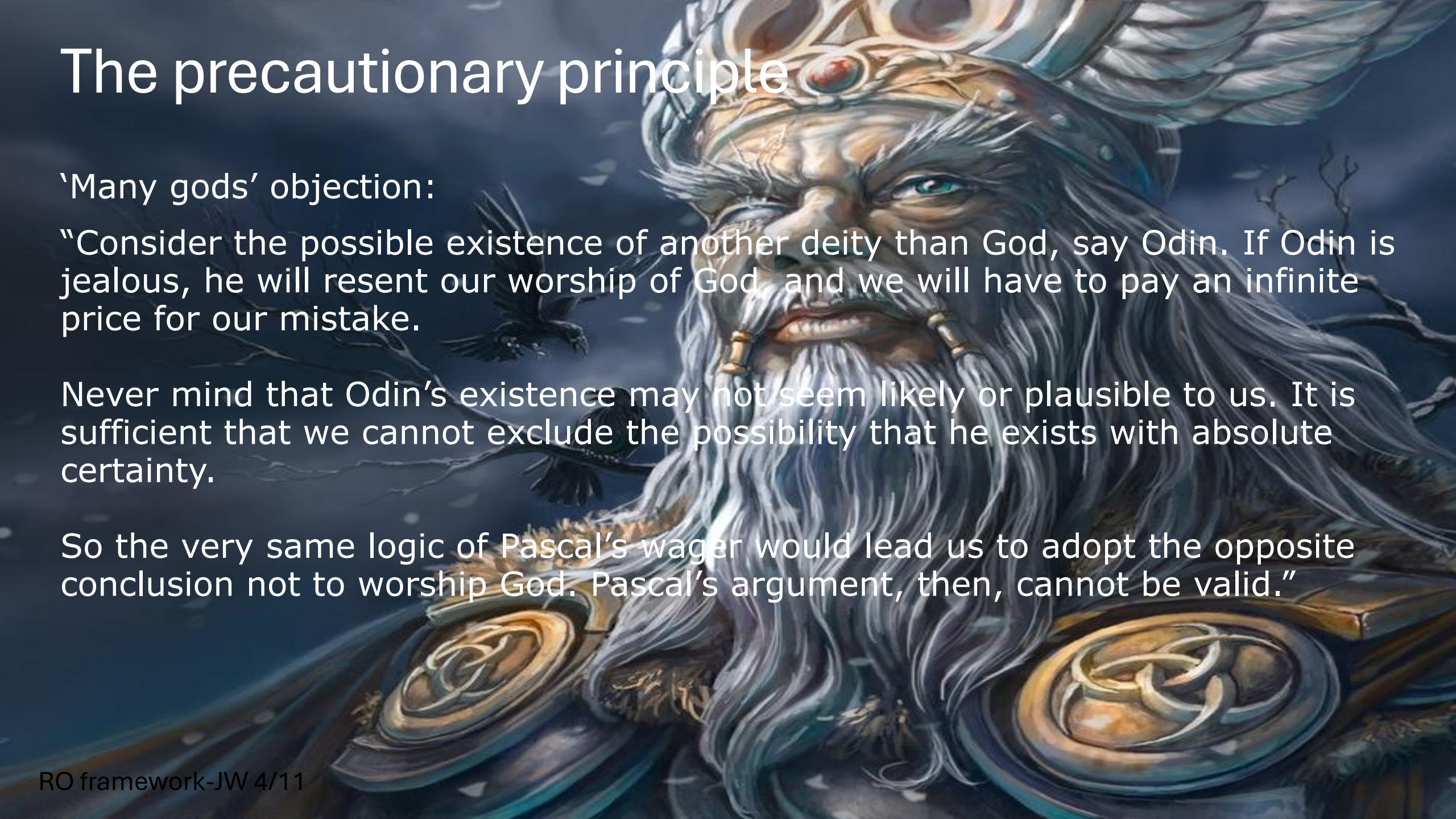
Source: EC, 2007.

The precautionary principle

The logic of Pascal's wager (Henk van den Belt, 2003)

"Given an unknown but non-zero probability of God's existence and the infinity of the reward of an eternal life, the rational option would be to conduct one's earthly life as if God indeed exists."

The precautionary principle



'Many gods' objection:

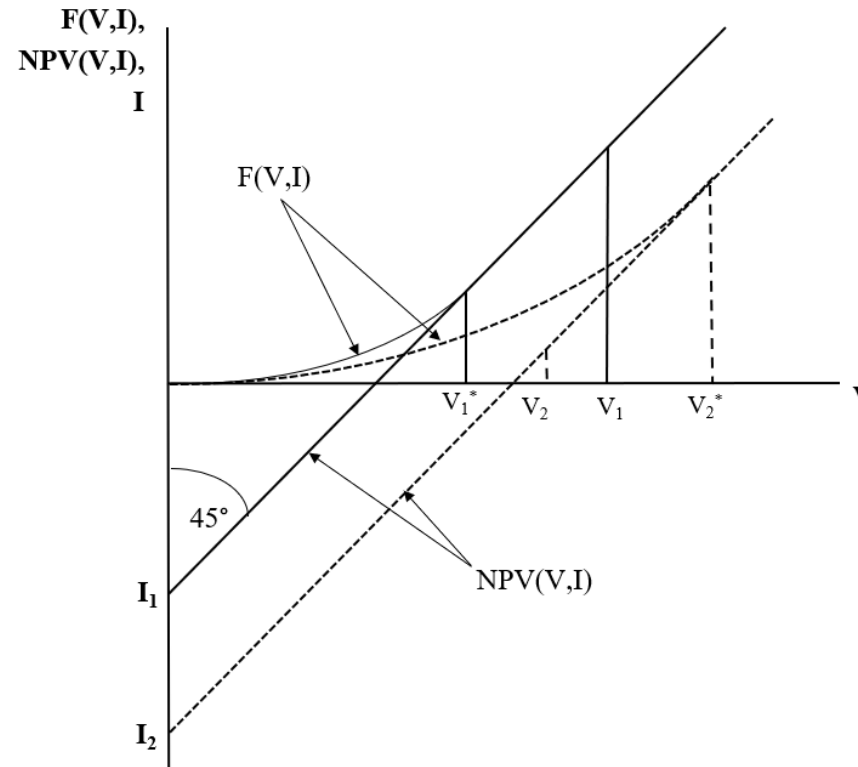
"Consider the possible existence of another deity than God, say Odin. If Odin is jealous, he will resent our worship of God and we will have to pay an infinite price for our mistake.

Never mind that Odin's existence may not seem likely or plausible to us. It is sufficient that we cannot exclude the possibility that he exists with absolute certainty.

So the very same logic of Pascal's wager would lead us to adopt the opposite conclusion not to worship God. Pascal's argument, then, cannot be valid."

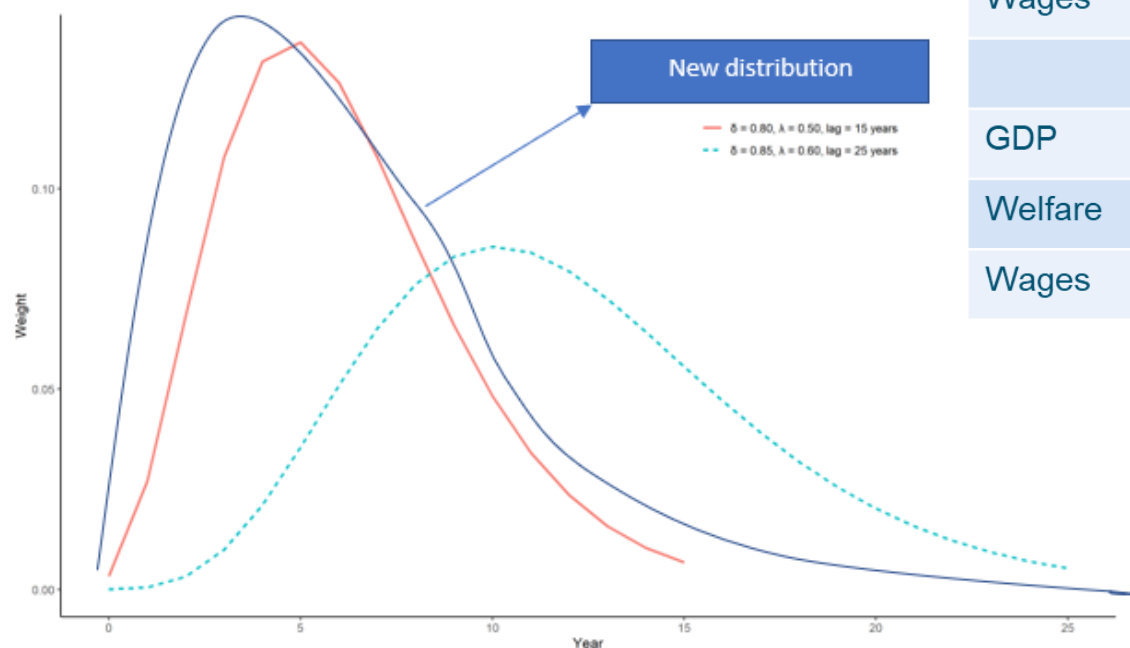
Real Options and Regulation

- Investments are options
- Regulations increase the sunk costs of investment
- Threshold level for immediate investment increases by a ratio larger than one.



Source: Wessler (2014). Agriculture in the Bioeconomy.

Benefits of R&D Improvements



Indicator	EU27	USA	China	India	MENA	SSA	World
Percentage change in indicators by region: high-income countries shocked.							
GDP	0.18	0.01	0.01	0.05	0.01	0.02	0.04
Welfare	1.81	0.14	-0.04	-0.02	-0.09	-0.03	0.30
Wages	11.75	-0.61	1.02	1.08	3.13	1.08	2.30
Percentage change in indicators by region: all countries shocked.							
GDP	0.16	0.02	0.33	0.74	0.18	0.68	0.19
Welfare	1.33	0.29	1.43	2.29	1.26	2.84	1.15
Wages	8.49	6.73	16.18	15.20	8.41	10.85	10.39

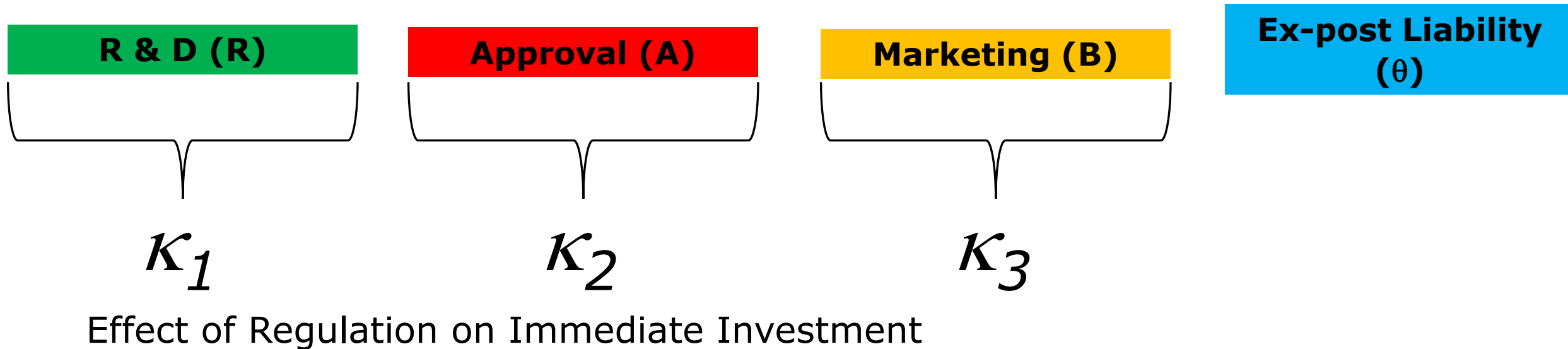
Note: wages - unskilled wages to the cereal price index. GDP reflects a country's total economic output. Welfare is measured using the equivalent variation. Source: Jin et al. 2025. GM Crops & Food.

RO Framework

- Investment in new technologies by the private sector
- Investment includes sunk costs
- Values depend on future uncertain developments
- Investments and future values depend on policy environment
- (New) technologies comply with regulations
- Regulations: time and costs, reversible and irreversible

Regulatory Implications: Model

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

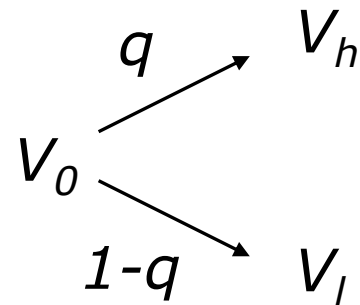


Source: Purnhagen, Wessler (2019). Pest Management Science 75: 2310–2315.

Regulatory Implications: Model

- Objective: $\max E[F[V(R, A, B, \theta, \kappa_i, t)]]$
- $f(\kappa) = h e^{-h\kappa}$, $F(\kappa) = \int_0^\kappa h e^{-h\kappa} d\kappa = 1 - e^{-h\kappa}$, $E[\kappa] = \frac{1}{h}$

- Future:



Regulatory Implications: Model

- Simplified: $\max F\{E(V_0), E(V_p)\}$

$$E(V_0) = \left\{ -R + \int_0^\infty \left(\int_0^\infty \left(\int_0^{\kappa_1} r_t e^{-\mu t} dt - A e^{-\mu \kappa_1} - \int_{\kappa_1}^{\kappa_1 + \kappa_2} a_t e^{-\mu t} dt + B e^{-\mu(\kappa_1 + \kappa_2)} - \theta e^{-\mu(\kappa_1 + \kappa_2 + \kappa_3)} \right) g(\kappa_1) d\kappa_1 \right) g(\kappa_2) d\kappa_2 \right\} g(\kappa_3) d\kappa_3 \right\} \mathbb{P}$$

- Assumption: $E(V_l) < 0 < E(V_0) < E(V_p)$

$$E(V_0) = -R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1\mu}{\mu(\mu + h_1)(\mu + h_2)} + \frac{B_0 h_1 h_2}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)},$$

$$E(V_p) = q \left(-R - \frac{r + Ah_1}{\mu + h_1} - \frac{ah_1\mu}{\mu(\mu + h_1)(\mu + h_2)} + \frac{B_h h_1 h_2}{(\mu + h_1)(\mu + h_2)} - \frac{\theta h_1 h_2 h_3}{(\mu + h_1)(\mu + h_2)(\mu + h_3)} \right) e^{-\mu}$$

$$B_0 > (1 - qe^{-u}) \left(R \frac{(\mu + h_1)(\mu + h_2)}{h_1 h_2} + \frac{r(\mu + h_2)}{h_1 h_2} + \frac{A(\mu + h_2)}{h_2} + \frac{a}{h_2} + \frac{\theta h_3}{(\mu + h_3)} \right) + qe^{-u} B_h,$$

Insights from 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

The maximum-minimum harmonization spectrum

Minimum harmonization reduces research and approval costs
Fragmentary access to the market
Uncertainty and irreversibility affect postponing investments
Maximum harmonization may formally provide uniform access on the market, still at risk of *de facto* limiting actions by the member states.

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Transformation of biosafety legislation in agriculture in the EU law and the laws of its selected trade partners, with respect to the scientific development

Perspective



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Maximum vs minimum harmonization: what to expect from the institutional and legal battles in the EU on gene editing technologies

Kai P Purnhagen and Justus HH Wesseler*

Abstract

New plant-breeding technologies (NPBTs), including gene editing, are widely used and drive the development of new crops. However, these new technologies are disputed, creating uncertainty in how their application for agricultural and food uses will be regulated. While in North America regulatory systems respond with a differentiated approach to NPBTs, the Court of Justice of the European Union (EU) has in effect made most if not all NPBT subject to the same regulatory regime as genetically modified organisms (GMOs). This paper discusses from a law and economics point of view different options that are available for the EU's multi-level legal order. Using an ex-ante regulation versus ex-post liability framework allows the economic implications of different options to be addressed. The results show that under current conditions, some options are more expensive than others. The least costly option encompasses regulating new crops derived from NPBTs similar to those used in 'conventional' breeding. The current regulatory situation in the EU, namely making the use of NPBTs subject to the same conditions as GMOs, is the most costly option.

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Keywords: approval costs; European Union; ex-ante regulation; ex-post liability; gene editing; investment; new plant breeding technologies; regulation; minimum harmonization; maximum harmonization; real options

Regulation (EU) 2026/1388 of the European Parliament and of the Council of 17 June 2026 on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625

Two categories of NGT plants:

Category 1 NGT plants

- considered equivalent to conventional plants
- not regulated by the EU rules on GMOs
- excluded from organic production

Category 2 NGT plants

- generally covered by the GMO legislation
- subject to all post-approval limitations, including opt-outs from cultivation, labelling, separation from other production chains

Main features of Cat. 1 regulation

Very low authorization threshold and costs (verification of status)

Provision of access to the common market

Decision irreversible

So far no coexistence rules or obligations regarding the separation of production chains

Category 1 NGT status to be mentioned in

- registry
- variety catalogues
- marketing materials for PRM

Main features of Cat. 2 regulation

Very high authorization threshold

Obligatory separation from other production chains

Significant post-authorization risks of limitations (opt-outs)

Significant level of post-authorization liability

Obligatory post-market monitoring (subject to limitations in justified cases)

Obligatory provision of detection, identification and quantification (DIQ) methods, subject to modalities with regard to performance parameters

Main takeaways for DIQ methods

The NGT regulation **does not deregulate use of any NGT plants**

- no obligation to develop DIQ methods by entities requiring verification of category 1 status
- obligation to develop such methods for category 2 plants and products dependent on feasibility (Art. 14(1)(l), 19(2))

Detection and identification methods still needed for:

- screening purposes,
- detection of not verified category 1 NGT plants,
- detection and identification of unauthorized category 2 NGT plants

Challenges for the development of analytical methods

- challenges connected with the nature of modifications (SNVs, sequences characteristic for a given species, etc.)(Broothaerts *et al.* 2023, Broll *et al.* 2019, Sowa *et al.* 2021)

Challenges stemming from the contents of the regulation:

- very broad scope of category 2
- overlaps between category 1 and category 2
 - 20 modifications limit applies only to modifications introduced through NGTs,
 - a plant can be „progeny” or a separate NGT plant without any significant differences in genotypes (or phenotypes)
 - phenotypes mentioned in Annex II exclude a plant from category 1 only if:
 - a) they result from application of NGTs
 - b) are intentional (sic!)

Difficult to distinguish between legally different plants using analytical methods

Particular liability areas

Separation of categories

- overlap between category 1 and 2
- the problem of "near category 1 category 2" plants
- very significant consequences of mis-categorization
- exclusion of phenotypes potential sources of problems with verification

Separation of organic and conventional production chains with respect to NGTs

Separation responsibility of producers and providers of components

No labelling of NGT-1 food and feed

Organic producers can rely on the labelling (or lack thereof) when it comes to products other than PRM and on the PRM labelling

Difficulties in providing analytical evidence of non-compliance (characteristic for the rest of organic sector)

Patenting issues

NGT plants and the genetical material therein patentable

Change of the state of play for EU breeders and farmers

- obligation to obtain a license for authorization
- potentially multiple licensors for one plant
- impact on both breeding and farming activities
- risk of accidental patent infringement
- both breeders and farmers potentially liable for infringements

Patenting issues

Patenting issues addressed mainly through transparency

- listing of patents in the registry of category 1 NGT plants
- NGT 1 designation in registries
- lower capability of proving patent infringement, due to the lack of efficient DIQ methods

De-regulation of plants developed through NPBTs in third countries

- plants not subjected to GMO legislation in third countries may fall into either of the categories
- liability dependent on trust in paper trail
- very limited capabilities of infringement detection through existing screening and analytical DIQ methods

Minimum-maximum harmonization - outtakes

- maximum harmonization authorization procedures
- unified verification and authorization requirements for all NGT plants
- low entry threshold for NGT-1, very high entry threshold for NGT-2

Lower level of harmonization of functioning of NGT-1 on the market:

- enforcement dependent on the capabilities of national authorities
- currently unknown status of national „non-GMO” labelling requirements
- enforcement of IPR dependent on local authorities outside the UPC or CPVO systems
- other legal limitations

DETECTIVE: Detecting NGT Products



4 yrs

Horizon Europe project, 2024–
2027

20

Partner organizations, led by SLU

10

Countries: EU Member States,
Switzerland, China

DETECTIVE develops, validates, and promotes detection methods for NGT plant and animal products, supporting labelling, traceability, and consumer choice across the EU food chain.

Today's case study sits inside this traceability challenge: do food business operators have an economic incentive to invest in NGT-free segregation?

Extending the Real Options Framework

Standard RO Application

Investor: innovator seeking market authorization

Regulatory channel: ex-ante approval costs and timelines

Question: when to file for authorization

This Case Study

Investor: supply-chain operator (food business)

Regulatory channel: ex-post, regulatory-induced uncertainty (NGT1 traceability gap)

Question: when to invest in NGT-free segregation

A different investor, a different regulatory channel, the value of the identity-preserved chain is modelled as a continuous stochastic process subject to discrete contamination shocks.

The Model: Investment Under Contamination Risk

σ

Market volatility, fluctuations in NGT-free premia

γ

Contamination arrival rate (policy-sensitive), shaped by NGT1's lack of mandatory product-level labelling

φ

Proportional loss per event, share of chain value lost in one contamination or certification failure

IR^{IP}

Irreversible investment, segregation, testing, traceability infrastructure

$$\text{Invest when } \pi \geq \pi^* = \frac{1}{Q_t} \left(\frac{\beta}{\beta - 1} IR^{IP} + C_t^{IP} \right) .$$

$\beta/(\beta-1)$: the irreversibility premium, always > 1 under uncertainty and irreversibility

Results: Both Crops Predict WAIT

Parameter	Maize	Soybean
β (positive root)	1.681	1.546
Irreversibility premium $\beta/(\beta-1)$	2.47×	2.83×
Break-even premium (€/t)	€33	€47
Critical premium π^* (€/t)	€69.74	€111.11
Observed market premium (€/t)	€15	€55
Gap vs π^* (€/t)	-54.74	-56.11
Decision	WAIT	WAIT

Soybean's market premium clears break-even but not the real-options threshold, rational operators still wait.

Beyond NGTs: A General Pattern

- The framework applies wherever regulatory design **creates asymmetric information** that shifts the burden of differentiation onto private actors.
- The NGT1 traceability gap is one instance of this.
 - The model quantifies the investment consequence of the gap, without taking a position on how it should be closed.
- This makes the approach potentially relevant beyond the NGT context, wherever a similar **regulatory asymmetry** shapes **private investment decisions**.

Open question for discussion: how do we calibrate γ and ϕ empirically as real NGT markets emerge?

How can MAGNET help calibrate the RO model, and vice versa

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Advancing Capacity and
analytical Tools for supporting
Common Agricultural Policies
post 2027



**BRIGHT
SPACE**



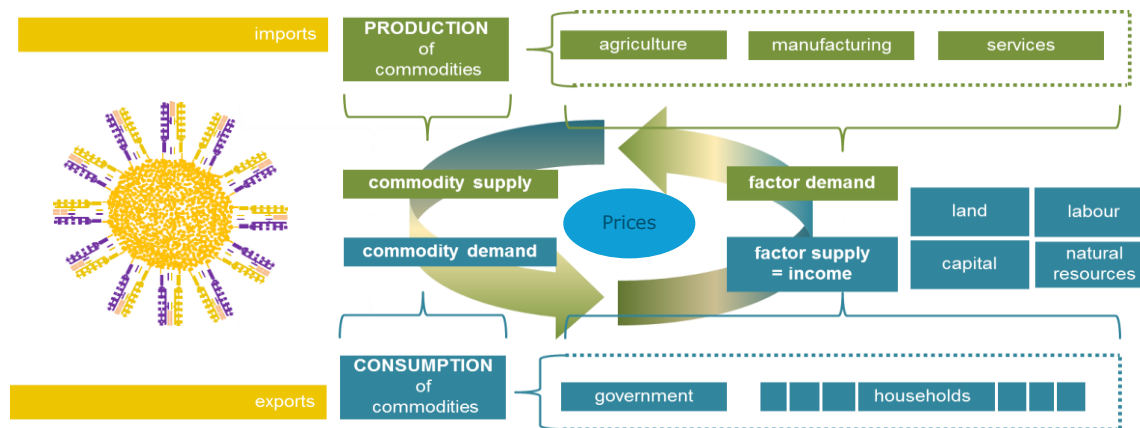
RATI**ON**



Key strenghts of Computable General Equilibrium (CGE) models



- Holistic approach: cross-sectoral linkages, welfare calculation
- Trade-offs and leakages: food security, sustainability, health
- Decomposition of drivers
- Dynamic and global perspective



Feeding CGE models outcomes to RO models

- Quantification of the private **streams of benefits**:
 - Can be approximated by the market share (i.e. market sales or production volume) of the investment option
 - Can inform about different categories of benefits : instantaneous benefits at market entry (B_0) and the distribution of high/low benefit states (B_h and B_l)
 - Can provide development of benefits in time: reflecting the dynamic interactions of economic agents
- Inputs for the quantification of the **irreversible costs**

Example – pesticide study

- Jin et al. (2026): the economic, environmental, and health impacts of a 50% reduction in hazardous pesticide use across all EU27 Member States
- Scenario approach:
 - **Uncompensated scenario:** Reduction of pesticide use in the agricultural sectors resulting in yield and production losses,
 - **Compensated scenario with low-risk pesticides*:** Hazardous pesticides are gradually replaced with non-hazardous alternatives in each pesticide zone (max adoption rate is 50%).
 - **Upper** and **lower** bound range of productivity impacts is considered.

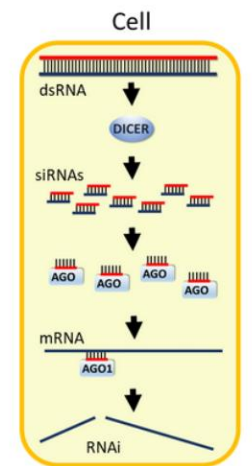


Figure 1. Schematic representation of the RNAi mechanism induced by dsRNAs

Mapping CGE outcomes to RO benefits

- B_l (low-benefits) -> the uncompensated scenario
- B_0 and B_h (instantaneous and high benefits) -> compensated scenario with upper and lower bound estimates on cost differentials
- The benefits can be quantified for different stakeholders:
 - For the technology developer (LRP applicant)
 - For the technology user (farmer)
 - For the whole economy

Table 2. Technical parameters of hazardous pesticides (in grey) and their corresponding low-risk alternatives

	<i>Chlorantraniliprole</i>	Low-risk Product 1	<i>Metrafenone</i>	Low-risk Product 2	<i>Etoxazole</i>	Low-risk Product 3
Application rate (grams of active substance/ha)	10 - 12	6 - 8	100 - 160	20	100	20 - 40
Unit cost (€/ha)	16 - 22	18 - 24	64	70	59 - 89	65 - 98

Source: Authors' elaboration based on information provided by industrial stakeholders in the RATION project

Benefits for the LRP applicant

- Assume price differential for B_0 and B_h
- Total benefits represent price * quantity of pesticide used (sold)

	LRP Application (kg or tonnes)		
	Price LRP US\$ per kg		Benefits US \$
BL	not on market	0	0
B0	P_LRP0(lower premim)	Q_LRPlower	P_LRP0*Q_LRPlower
BH	P_LRPH(higher premim)	Q_LRPUpper	P_LRPH*Q_LRPUpper

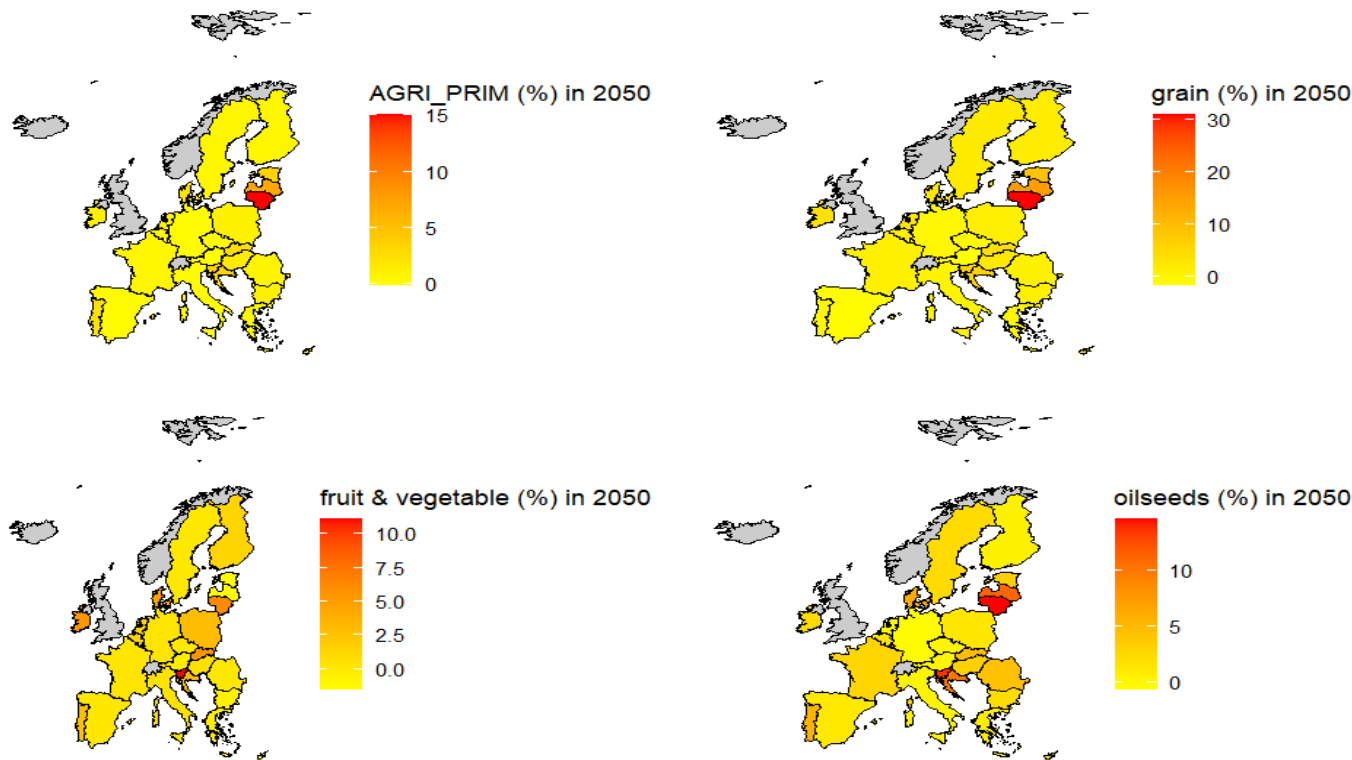
Pesticide use in 1000t in 2050

	Baseline	Uncompensated	Compensated L = QLRPlower	Comensated H = QLRPUpper
AUT	4	3	2	2
BGR	3	2	2	2
BLX	5	5	3	3
CZE	4	3	2	2
DEU	48	40	26	26
DNK	3	3	2	2
ESP	70	58	38	38
EST	1	1	0	0
FIN	5	4	2	2
FRA	65	52	35	35
GCM	8	6	4	4
HRV	2	1	1	1
HUN	10	8	5	5
IRL	5	4	3	3
ITA	40	34	22	22
LTU	5	3	2	2
LVA	2	1	1	1
NLD	11	9	6	6
POL	29	23	16	15
PRT	7	5	4	4
ROU	8	6	4	4
SVK	2	1	1	1
SVN	1	1	1	1
SWE	2	1	1	1
EU27	336	275	182	180

Source: MAGNET

Benefits for the farmer

- Can be expressed by production value of crops or primary agriculture sector
- Expressed either in levels, or differences from baseline



Source: MAGNET

Figure. Percentage change in production volume (million US dollars in 2050) in Scenario 2 (substitute 50% hazardous pesticides with low-risk alternatives) compared with Scenario 1 (reduce 50% hazardous pesticides)

Estimating irreversible costs

- The monetized environmental and health cost reductions (EU27 annuity of approximately €9.2 million/year at a 3% discount rate) provide a social welfare benchmark, representing the irreversible costs.

Table. Average annual benefits from reduced environmental and health costs of adopting low-risk alternatives up to 50% in Europe (1,000 €)

	Annuity (r=3%)	Annuity (r=5%)
BLX	154	150
FRA	2110	2049
EST	21	21
DNK	68	66
CZE	98	95
GCM	185	180
HUN	251	244
BGR	88	85
DEU	1281	1242
AUT	99	96
HRV	50	49
SVK	46	44
SWE	30	29
FIN	115	112
SVN	38	37
IRL	127	123
ROU	240	234
PRT	206	200
POL	760	740
NLD	279	272
LTU	130	127
LVA	50	49
ITA	1344	1310
ESP	1707	1656
EU27	9187	8930

Using RO to parametrize MAGNET

- Parameters reflecting the expected length of the benefit phase
 - Diffusion (adoption) curves: pesticide study (below)
 - Regulatory approval lag TL: NGT study (next slide)

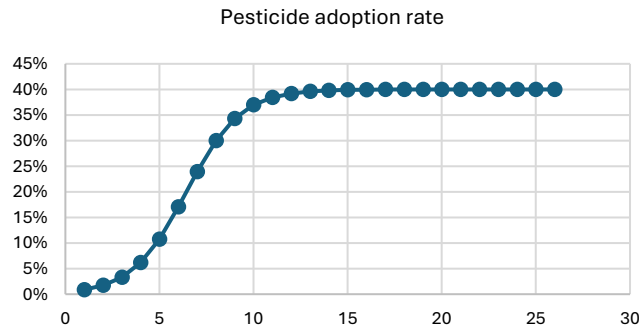
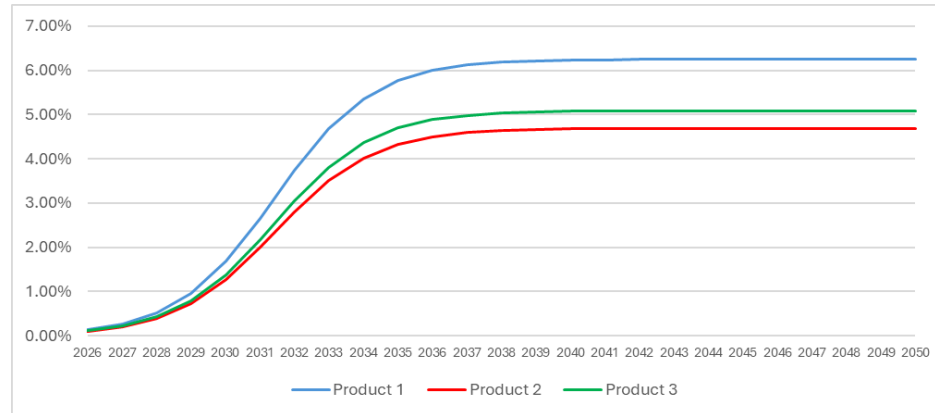


Figure: Increase in costs per adoption of low-risk pesticides (MAGNET, 2025)



Regulatory approval lag -> shifts in R&D stock

- The gamma distribution functions which translate the agricultural R&D investments in productivity (Alston, Huffman, etc.) are adjusted to reflect reduction of the regulatory lag TL in line with the study of Kardung et al. (2026)
 - NGT stocks are cumulated faster than knowledge from traditional breeding methods because of the “**breeding efficiency**” - **gE** (5-7 years shorter)
 - Relaxation of the **regulatory framework** shortens lags between 2-4 years - **gR**

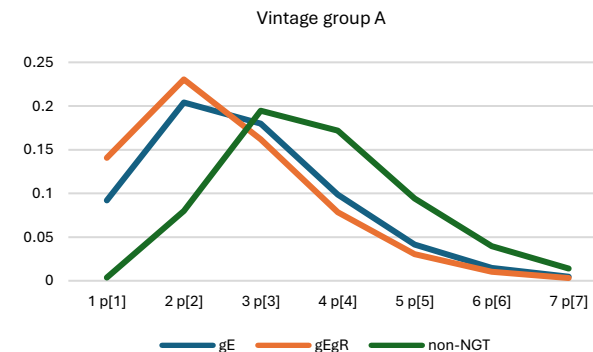
European Review of Agricultural Economics, Vol 0 (0) (2026) pp. 1–46
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Advance Access Publication 2 June 2026

Comparing the effects of regulating new genomic techniques on investment decisions in the European Union

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Group	Countries	T	breeding efficiency	regulatory delay
			gE	gR
A	USA, Canada, Australia, New Zealand	35	5	2
B	EU 15	25	5	4
C	EU 12	15	5	4
D	Latin America	25	2	2
E	Asia, the Pacific, and Africa	15	2	2



Conclusion

- Contributions of CGE models in RO analysis:
 - Projections of benefits and costs including market feedback effects
 - Sensitivity analysis under varying assumptions
- Contributions of RO in CGE analysis:
 - Parametrization of productivity effects and adoption timeline
 - Calculation of annuity of benefits
- Open-ends:
 - Scoping needs to be defined
 - Concept of baseline/reference case – how to link to RO?
- Potential for iterative linking: e.g. streamlining R&D investments in line with the optimal delay in investment from RO

LRPs and EU Pesticide Policies

- F2F: reducing hazardous pesticides by 50% by 2030
- Expected significant effect on agriculture productivity and farm income (example ban of Neonicotinoids for sugar beet farmers in France)
- LRP offset some of the impacts

RATION main goal

To develop a novel risk assessment scheme for LRPs, supported by the necessary guidance, methods, and tools for its implementation.

This scheme will consider the specific characteristics of currently available and known LRP categories (LRPs of biological origin), like:

1. Microbials
2. Plant extracts, Semiochemicals, e.g., Pheromones
3. dsRNA pesticides

Scan this QR:



Or visit

<https://www.ration-lrp.eu/>

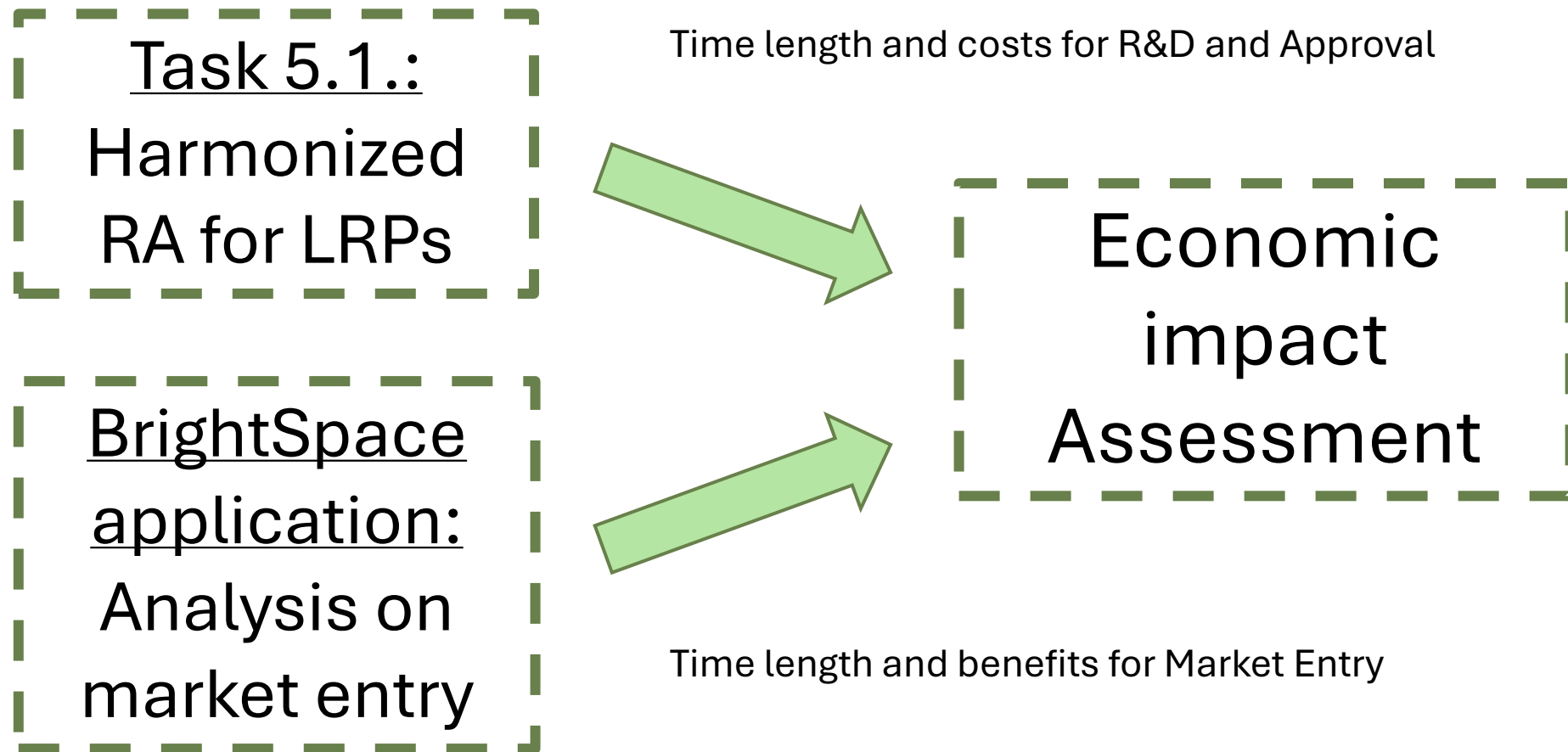
Case study objective

Economic impact assessment of proposed regulatory changes: Calculating the potential impact on investment

How can LRP developers/applicant companies make better informed investment decisions?

- Six regulatory options, following:
 - Purnhagen & Wesseler (2019)
 - Kardung et al. (2026)
 - Godinho et al. (2026) – From Terminology to Approval
 - Vryzas et al. (2026) – Generic Pathways to Harm (GPtH)

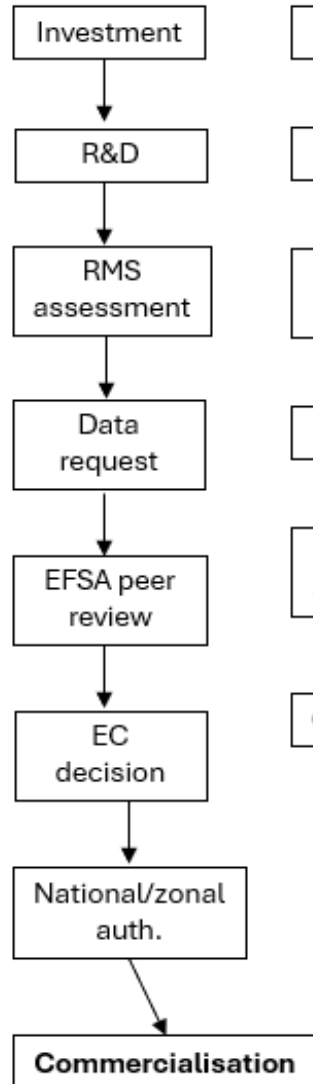
Link to the Real Options Model



Preliminary Regulatory Options

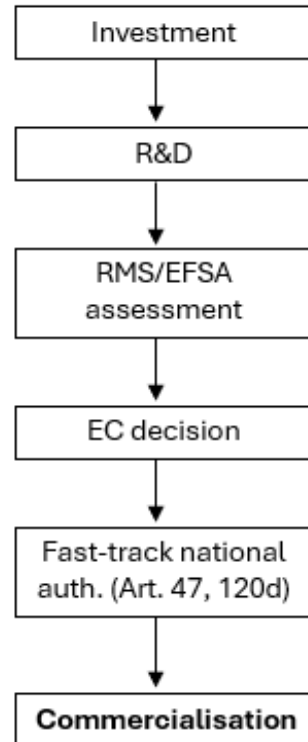
Option 1

Status quo



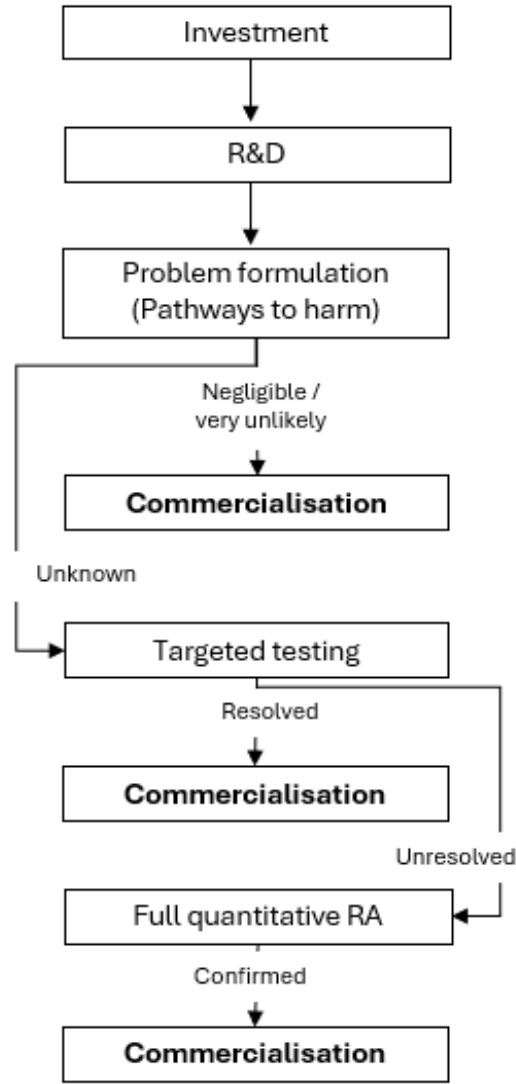
Option 2

Adjusted/fast-track



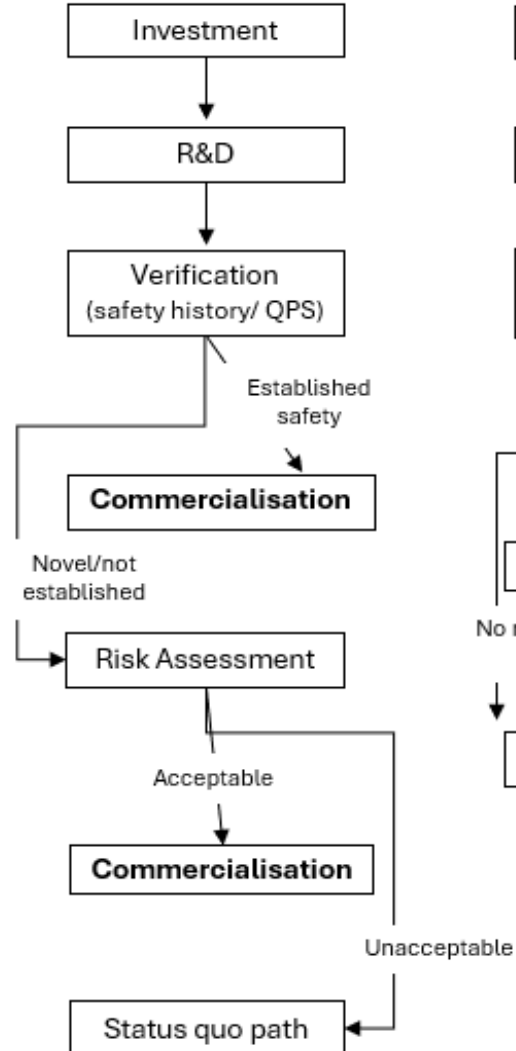
Option 3

Category profiling (GPtH)



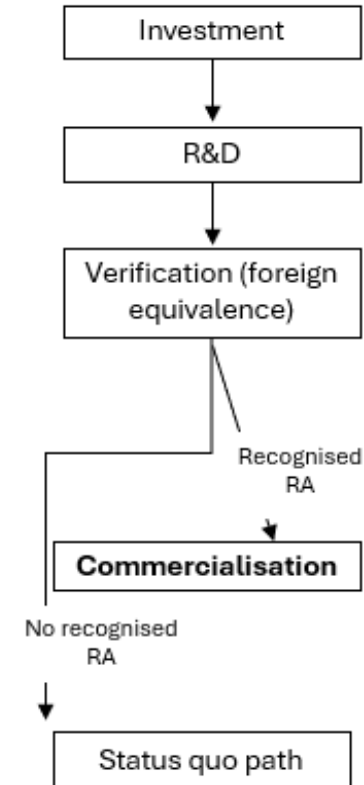
Option 4

Established safety



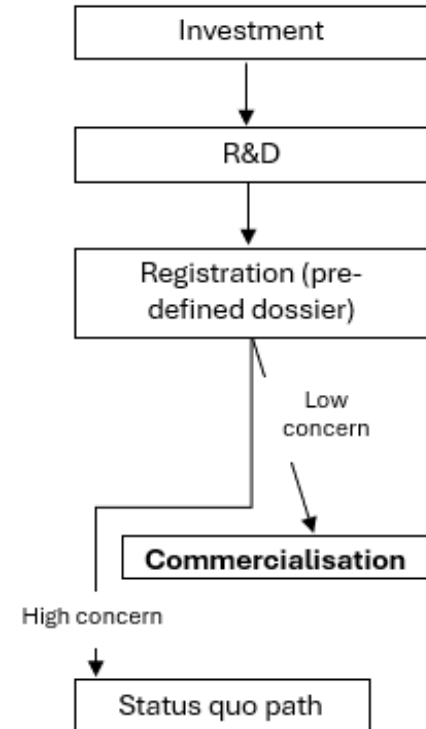
Option 5

Mutual recognition



Option 6

REACH-like registration



Thank you!

Q&A