

# Breaking the impasse: Towards a future looking governance framework for gene editing with plants

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**RESEARCH ARTICLE**

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# Breaking the impasse: Towards a forward-looking governance framework for gene editing with plants

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## **Societal Impact Statement**

The debate in Europe over how to govern novel techniques of gene editing in plants is fast developing into an impasse with actors rapidly consolidating positions on either side of the debate. Such polemic is not good for science nor for public policy if we are to develop the kinds of socio-technical innovations that are needed to harness socially resilient solutions to pressing global societal challenges, such as food security and climate change. We analyze how we arrived at this impasse and explore novel ways to move beyond it.

# Four elements to the paper

- First, we review social science scholarship, drawing lessons from the public controversy over GM crops and foods.
- Second, we describe the European policy debate on the gene editing of plants with a particular focus on how the debate is framed by dominant actors.
- Third, we review solutions other countries have sought, and in particular touch on a level-based approval system that Norway is proposing, articulated recently in a Dutch Rathenau Instituut report.
- Fourth, we introduce frameworks of responsible innovation as a way of aligning innovation trajectories with articulations and negotiations of broader societal values.



# Food Security

## The wider context

- Feeding a growing world population
- Two paradigms
  - Sustainable intensification approaches with a prominent role for novel biotechnologies (productivism)
  - Agroecological approaches designed to be productive, biodiversity conserving, socially just, culturally sensitive
- Why do GM crops continue to evade policy resolution?
- Can a better understanding help new biotechnologies avoid controversy, misunderstanding and polemic?

# I. Lessons from GM crops (1)



- First, the revolutionary promises that were claimed for the technology by its early promoters—that GM technology would help the poor, alleviate hunger, address nutritional deficiencies, feed the world, contribute towards sustainability, and better quality food—were not reflected in practice.
- 1<sup>st</sup> generation GM crop—HT and IR crops—were designed to help the large producer, not the consumer or the environment, enabling farmers to reduce labour costs and to farm larger acreages of crops, such as soya and maize



# Lessons from GM crops (3)



- The third factor arose from the evolution of different approaches to regulation
  - In the US, a regulatory regime emerged that considered genetic engineering as a process that presented no special risks
  - In EU, a regulatory system developed in which the process of genetic modification became an appropriate basis for determining policy
- This provided an “opportunity structure” for NGOs—and later other actors—to operate at the interface between governments and concerned publics, helping define the issue as a public issue through appealing to the technology as an imperial and colonizing force

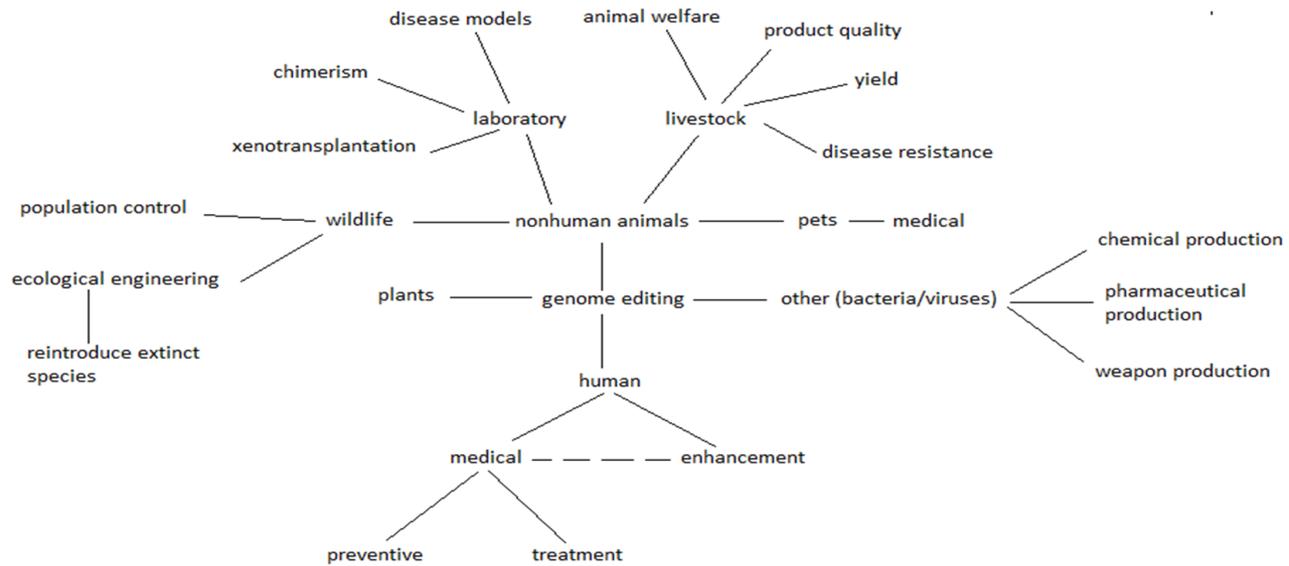
# II. Policy debate on gene edited plants



**CRISPR**

- The CRISPR-Cas system – “has made editing of the genome much more precise, efficient, flexible, and less expensive relative to previous strategies” (National Academy of Sciences 2017: 1)

# Potential applications of CRISPR



# Why govern CRISPR?



To make sure it is  
safe



To make sure it  
contributes to  
societal challenges



To make sure it is  
conducted with and  
for society

Should gene edited  
organisms be except from  
the GMO Directive?

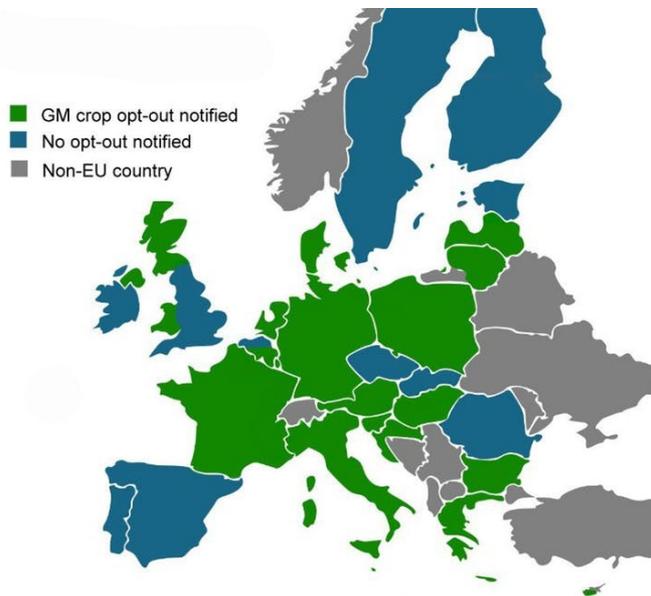


# Current regulation of GMOs in Europe

## Directive 2001/18/EC

- Case-by-case environmental risk assessment before deliberate release
- Systematic and independent research on potential risks involved in deliberate release or the placing on the market
- Monitoring of products once released
- Labeling of products
- Ensure traceability
- Safety and consumer choice

# Broader considerations are taken into consideration



17 countries and 4 regions opt out of EU GM crop approvals

## Directive (EU) 2015/412

Member States are entitled to restrict or prohibit the cultivation of GMOs in their territory.

Grounds can be i.e.:

- Environmental or agricultural policy objectives
- Town and country planning
- Land use
- Socioeconomic impacts

# Arguments of the two dominant policy options in the current debate in Europe

Exemption from the European GMO Directive

Economic consequences for Europe

Reputational consequences

Ecological consequences

Problems and costs of labelling

Genome editing subject to the European GMO Directive

Technological risks

Uncertainty

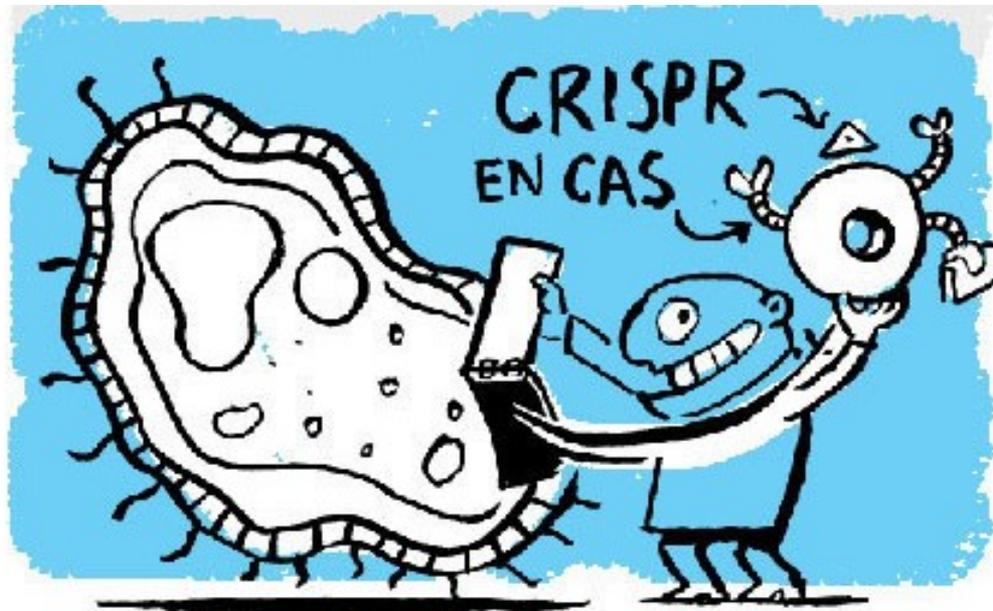
Decrease in genetic diversity

No freedom of choice

Organic sector could be damaged

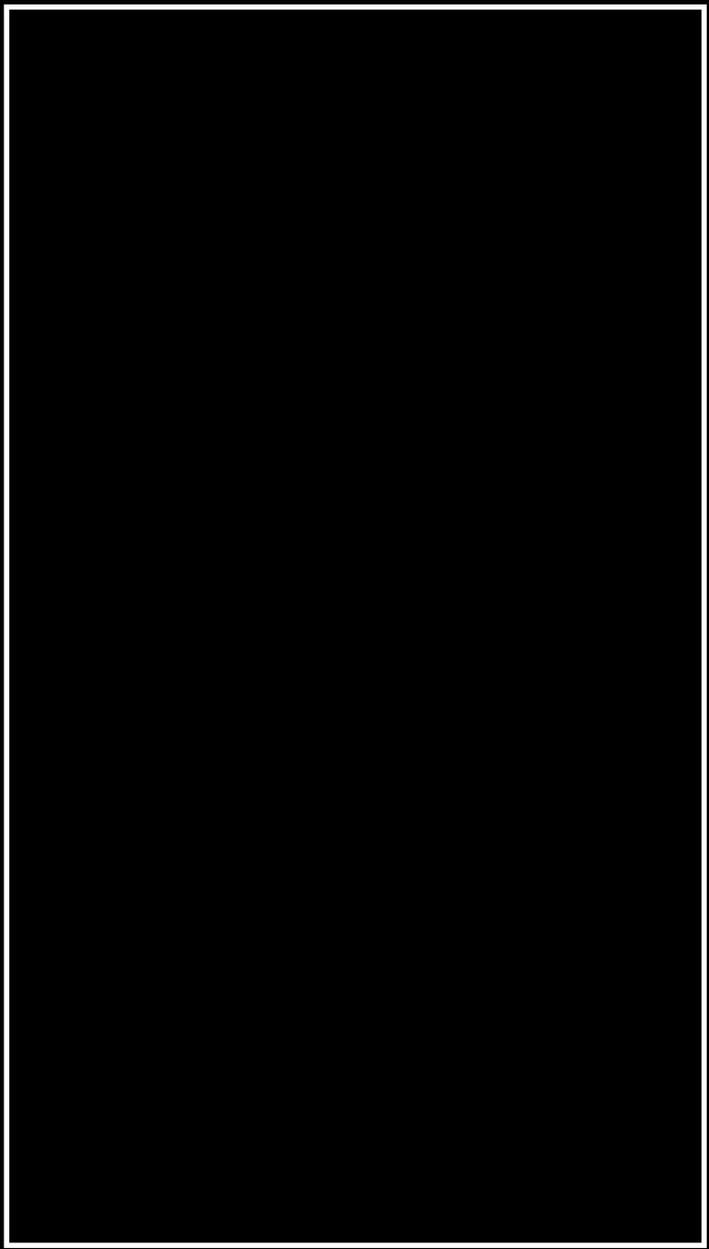
No broader considerations

Reinforce current monopoly position



# Lessons (partially) learnt from GM crops

- Some consideration of benefits and contributions to societal challenges (promissory)
- Debate heavily mediated by considerations of risk
- Impasse facilitates opportunity structure for NGOs



Innovations in  
regulation: A level-  
based approach



Innovations in research  
governance: A  
framework of  
responsible innovation



# ■ Taking serious the arguments of both policy options

Exemption from  
the European  
GMO Directive

Genome editing  
subject to the  
European GMO  
Directive

Level-based  
policy option

Rathenau Instituut

## Genome editing in plants and crops

Towards a modern biotechnology policy focused on differences in risks and broader considerations



Report

# Option 3: A new, level- based approach



2015/412.

Bioteknologirådet (2018). The Gene Technology Act – Invitation to Public Debate



ian Gene  
Act, and  
with EU  
of

## Breaking the impasse

- Broaden the debate on governance away from a narrow technical discussion on risks
- Level-based approach of risk assessment
- Include broader societal and ethical considerations in the regulatory framework



# IV.

Responsible  
research and  
innovation

A methodology  
to align  
innovation with  
and for society

*“Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)”*

(von Schomberg 2011)

*“taking care of the future through collective stewardship of science and innovation in the present”*

(Stilgoe, Owen and Macnaghten 2012)

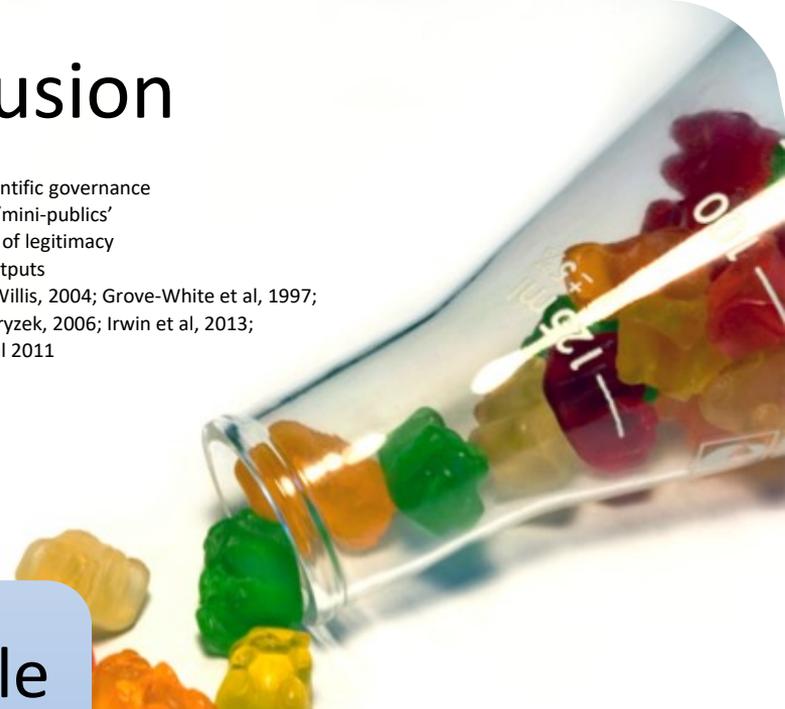
# Anticipation

- From predictive to participatory
- Expectations and Imaginaries
- Tools
  - Anticipatory Governance
  - Vision assessment
  - Scenarios
- Barriers to anticipation
- Guston, 2012; van Lente, 1993;
- Fortun, 2005; Barben et al, 2008



# Inclusion

- The 'new' scientific governance
- Dialogue and 'mini-publics'
- The challenge of legitimacy
  - Input and outputs
- Wilsdon and Willis, 2004; Grove-White et al, 1997;
- Goodin and Dryzek, 2006; Irwin et al, 2013;
- Lovbrand et al 2011



## IV. Responsible innovation

# Reflexivity

- From 1<sup>st</sup> to 2<sup>nd</sup> order
- Tools
  - Codes of conduct
  - Midstream Modulation
- Wynne, 1993; Schuurbiens, 2011;
- Swiestra, 2009; Fisher et al, 2006



# Responsiveness

- Answering and reacting
- Diversity and resilience
- Value-sensitive design
- De facto governance
- Political economy of innovation
- Responsibility as metagovernance
- Pellizoni, 2004; Collingridge, 1980; Friedman, 1996; Stirling, 2007; Kearnes and Rip, 2009



A (radical)  
rationale for  
responsible  
innovation

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# A forward-looking governance framework for gene editing with plants

## Argument:

- If innovations in the plant sciences are to fulfil their potential in contributing towards the global grand challenges of the twenty-first century they need to be developed with and for society

## Diagnosis

- we reviewed the current debate on the regulation of gene-edited crops in Europe, finding not only that lessons from the GM controversy had been inadequately learnt but that the struggle over whether or not to amend the current GMO Directive had reinforced established positions and mobilizations

## Beyond the impasse

- Learn the lessons from GM crops
- Innovations in regulation: a level-based regulatory framework that moved the focus away from arguments on safety to a tiered assessment of broader socio-economic considerations
- Innovations in research governance: a framework of responsible innovation to transform the cultures and practices of research