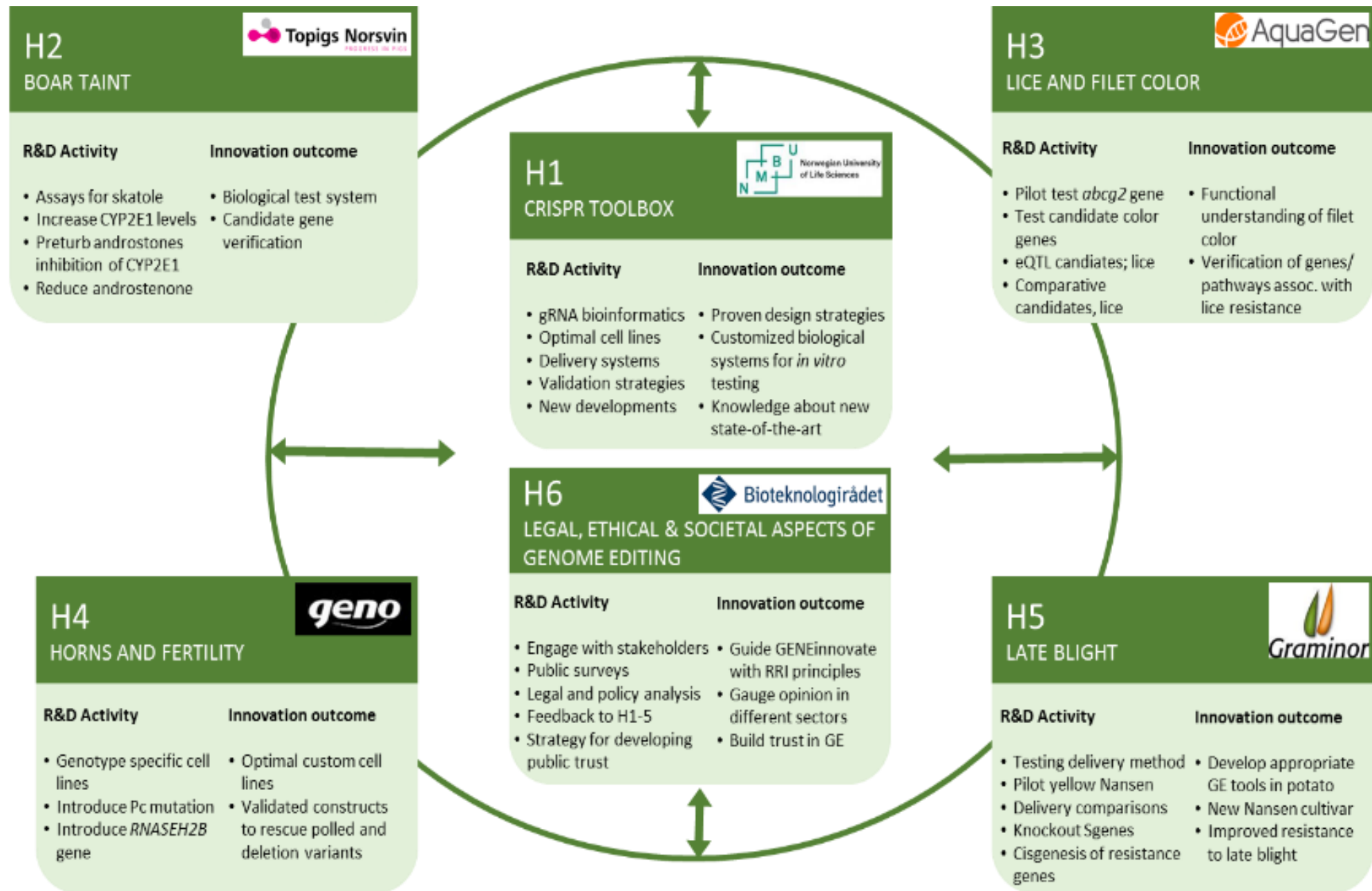


# A proposal for a smart and modern EU regulation

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# Wide range of genetic changes possible with genetic engineering:

*Temporary changes*

*Mimic genetic changes that already exist or can arise in nature*

*Genetic changes that can also be achieved with conventional breeding methods*

*Intra-species gene transfer*

*Inter-species gene transfer (transgenesis)*

*Synthetic (artificial) genetic sequences*

*Fully synthetic organisms*





## Used to address many challenges

- Food security
- Productivity/yield
- Environmental impact of agriculture
- Animal welfare
- Biodiversity
- Adaptation to and mitigation of climate change

# How positive or negative are you to using gene editing on crop plants and livestock in Norwegian agri- and aquaculture, if the purpose is to:

Crop plants

Reduce pesticides and crop loss, e.g. blight resistant potato?

Adapt a crop plant to a changing climate, e.g. wheat that better tolerates drought or precipitation?

Improve nutritional content of a crop plant, e.g. tomatoes with more Vitamin C or antioxidants?

Develop high yielding crop plants, e.g. wheat with more or larger seeds?

Change cosmetic traits in plant products, e.g. fruits or vegetables with a different colour?

Livestock

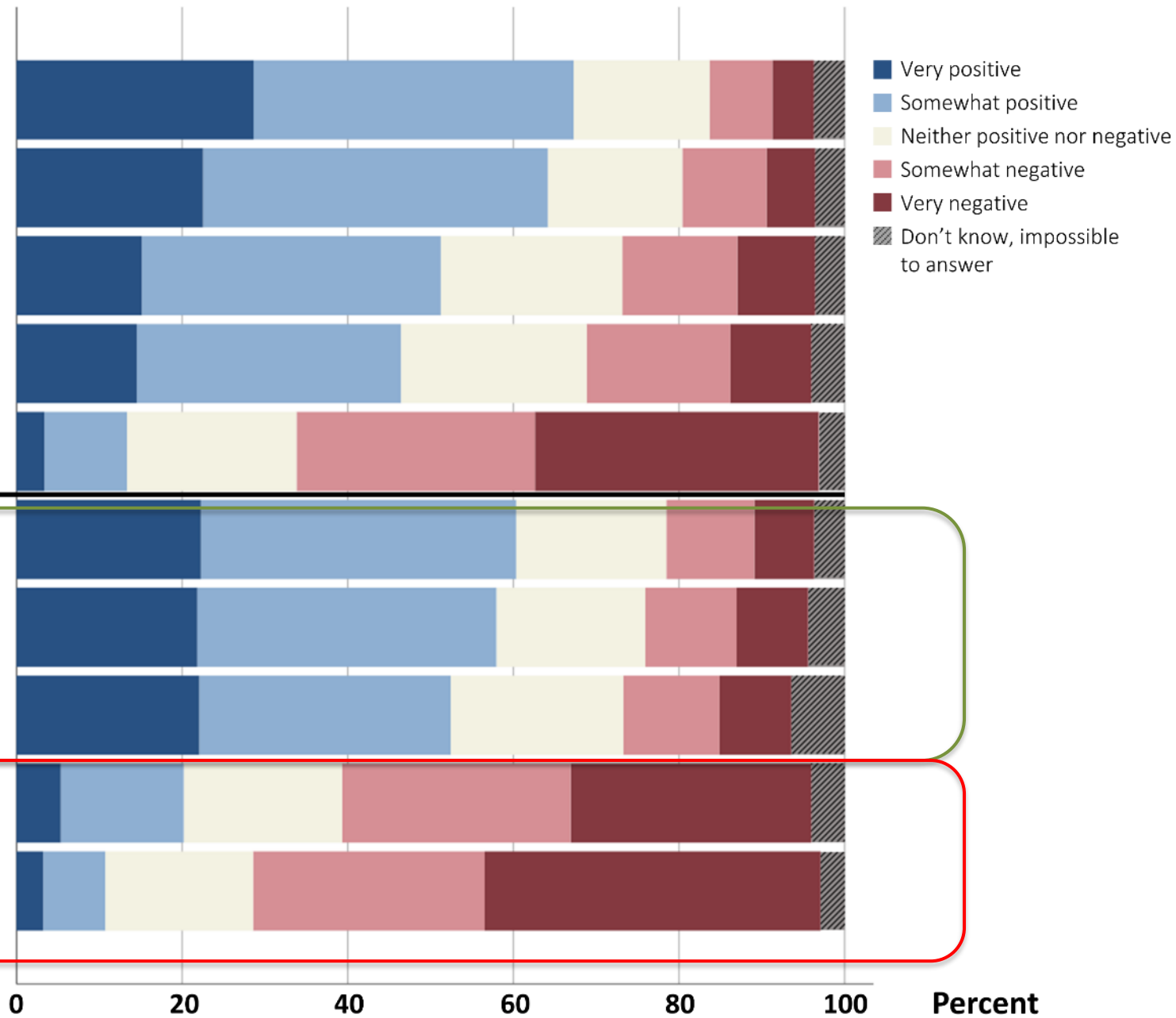
Improve animal health, e.g. cattle or pigs that are resistant to infectious disease?

Improve fish health, e.g. salmon that are resistant to sea lice?

Reduce the environmental impact of aquaculture, e.g. sterile salmon that does not interbreed with wild salmon if it escapes?

Develop high yielding livestock, e.g. cattle with increased muscle mass or milking capacity?

Change cosmetic traits in animal products, e.g. salmon with more brightly pink coloured meat?



The debate is still very black and white

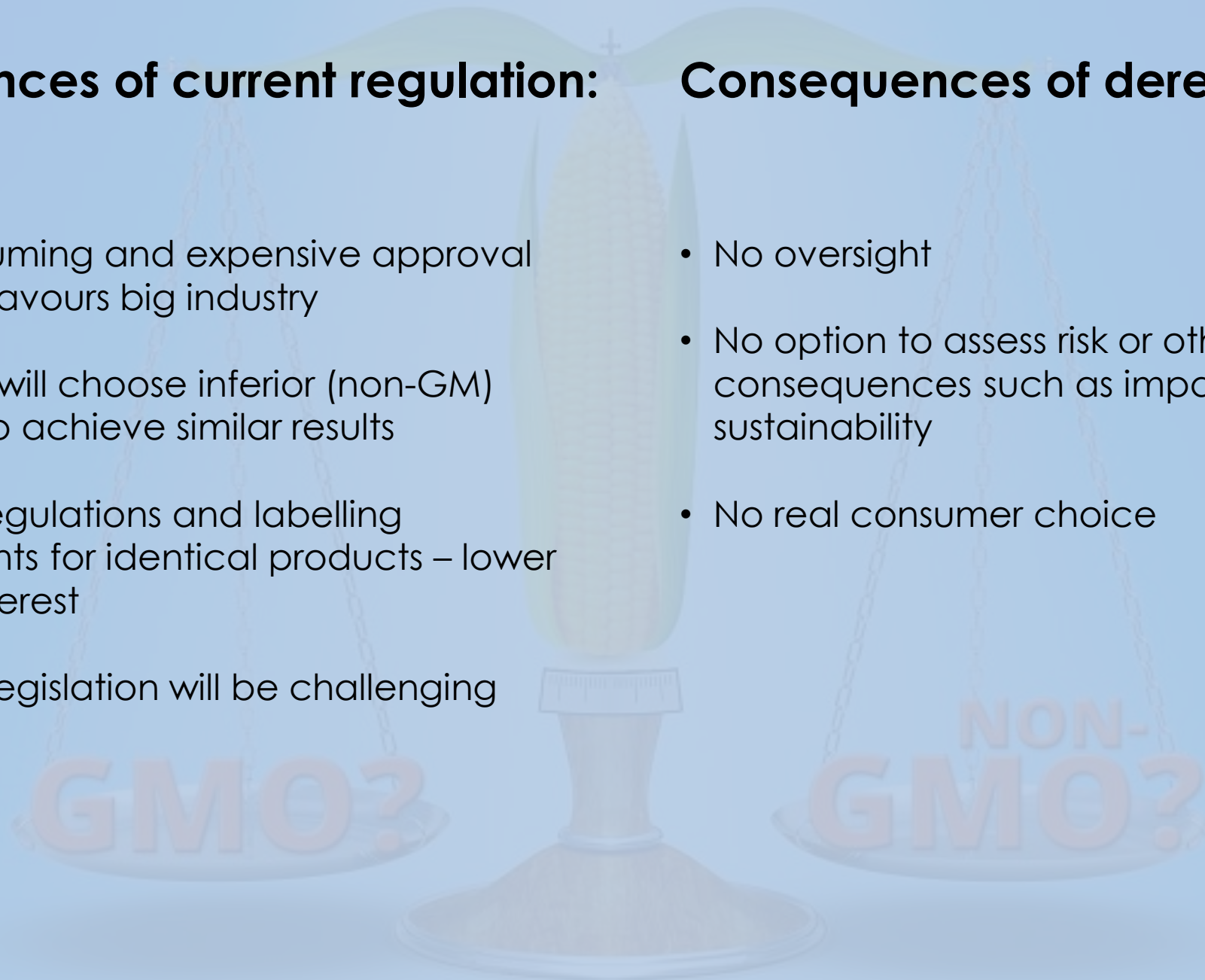
...and very polarized

## Consequences of current regulation:

- Time consuming and expensive approval process – favours big industry
- Producers will choose inferior (non-GM) methods to achieve similar results
- Different regulations and labelling requirements for identical products – lower industry interest
- Enforcing legislation will be challenging

## Consequences of deregulation:

- No oversight
- No option to assess risk or other consequences such as impact on sustainability
- No real consumer choice





How can we utilize the potential of genetic engineering in a safe and sustainable way that promotes trust and transparency?





<b>Exempted from regulation</b>	
Organisms with temporary, non-heritable changes	
<b>TIER 1</b>	
Genetically engineered organisms with changes that exist or can arise naturally and can be achieved using conventional breeding methods	<b>Notification</b> (confirmation required)
<b>TIER 2</b>	
Organisms with other species-specific genetic changes	<b>Expedited assessment and approval</b>
<b>TIER 3</b>	
Organisms with genetic changes that cross species barriers or involve synthetic (artificial) DNA sequences	<b>Standard assessment and approval</b> (current requirements)

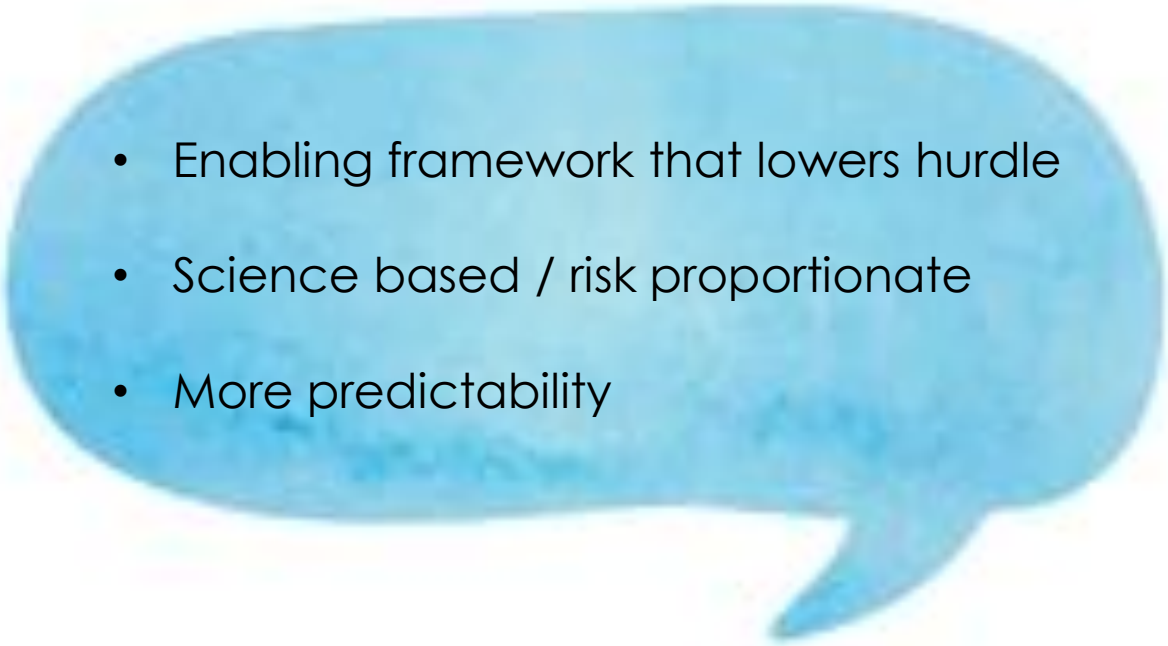
Covered by  
GMO regulation


Societal benefit,  
sustainability  
and ethics  
assessed on  
tiers 1–3

**Labelling and traceability/detection requirements can be tailored to feasibility on each tier**



Public dialogue  
at the heart

- 
- Enabling framework that lowers hurdle
  - Science based / risk proportionate
  - More predictability

- 
- Lack of experience with new technologies
  - Impact on ecosystems when rapid development
  - Need for precaution

- 
- Value of regulatory oversight and public trust
  - Gene editing and other gene technologies can contribute to sustainable agri- and aquaculture
  - Competitiveness on the international market is crucial
  - Importance of health, environment, societal benefit, sustainability and ethics



Lowering  
regulatory  
hurdle

Oversight and  
control

Public Trust

Science  
based policy

Political  
willingness



# Gene Technology Act

Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc.



**DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL**

**of 12 March 2001**

**on the deliberate release into the environment of genetically  
modified organisms and repealing Council Directive 90/220/EEC**

- Opportunity costs
- Lack of transparency

- Lack of control
- Lack of trust







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