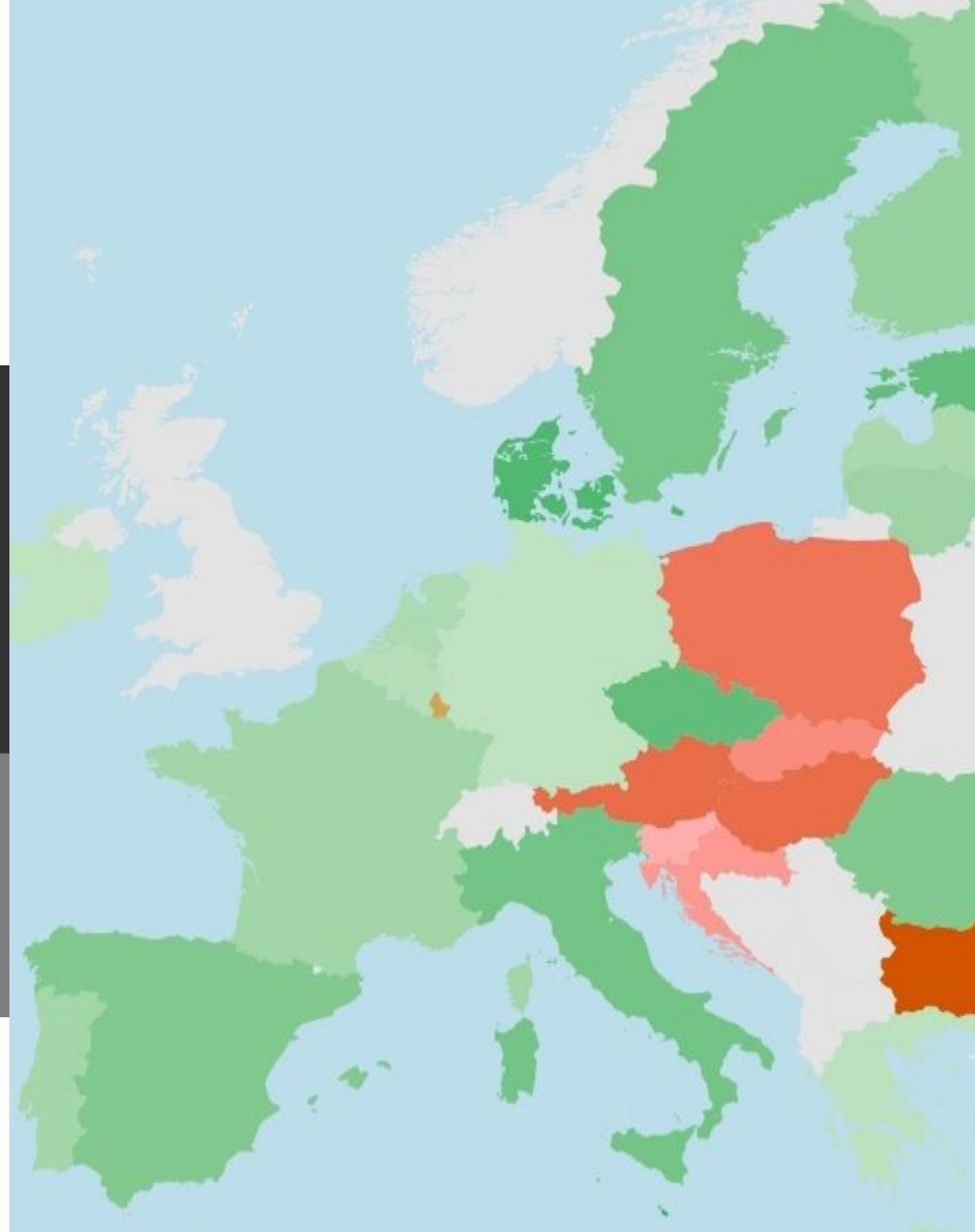


# Norway – Regulation and Innovation

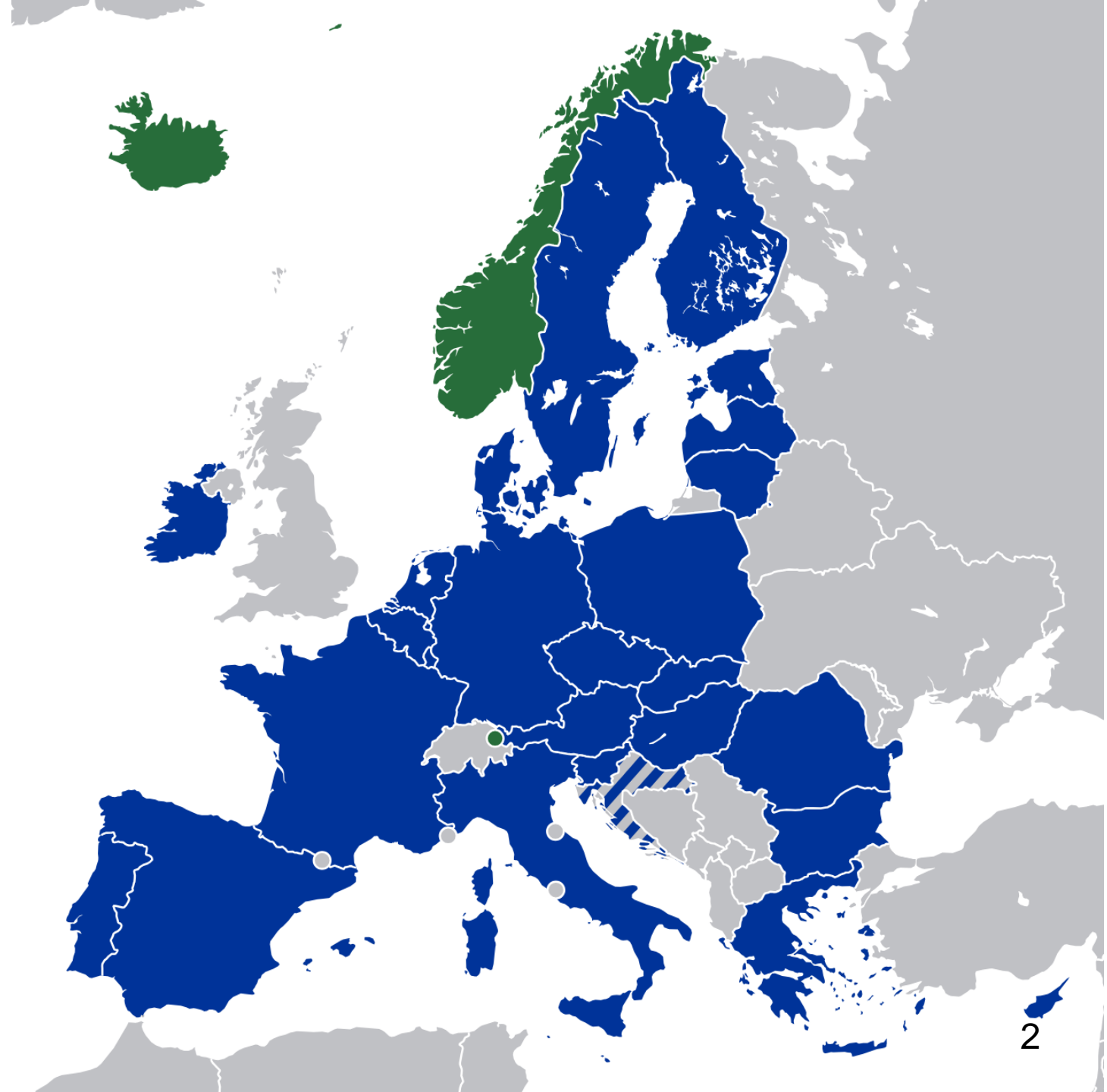
Knut Berdal, Specialist Director

5th International Workshop on Regulatory Approaches  
for Agricultural Applications of Animal Biotechnologies  
August 27th 2024



# Norway and the EEA

- Norway is not a member of the EU
- Part of the European Economic area (EEA)
- Single market with free movement of
  - Goods
  - Capital
  - Services
  - People



# EU Food law and GMO regulations

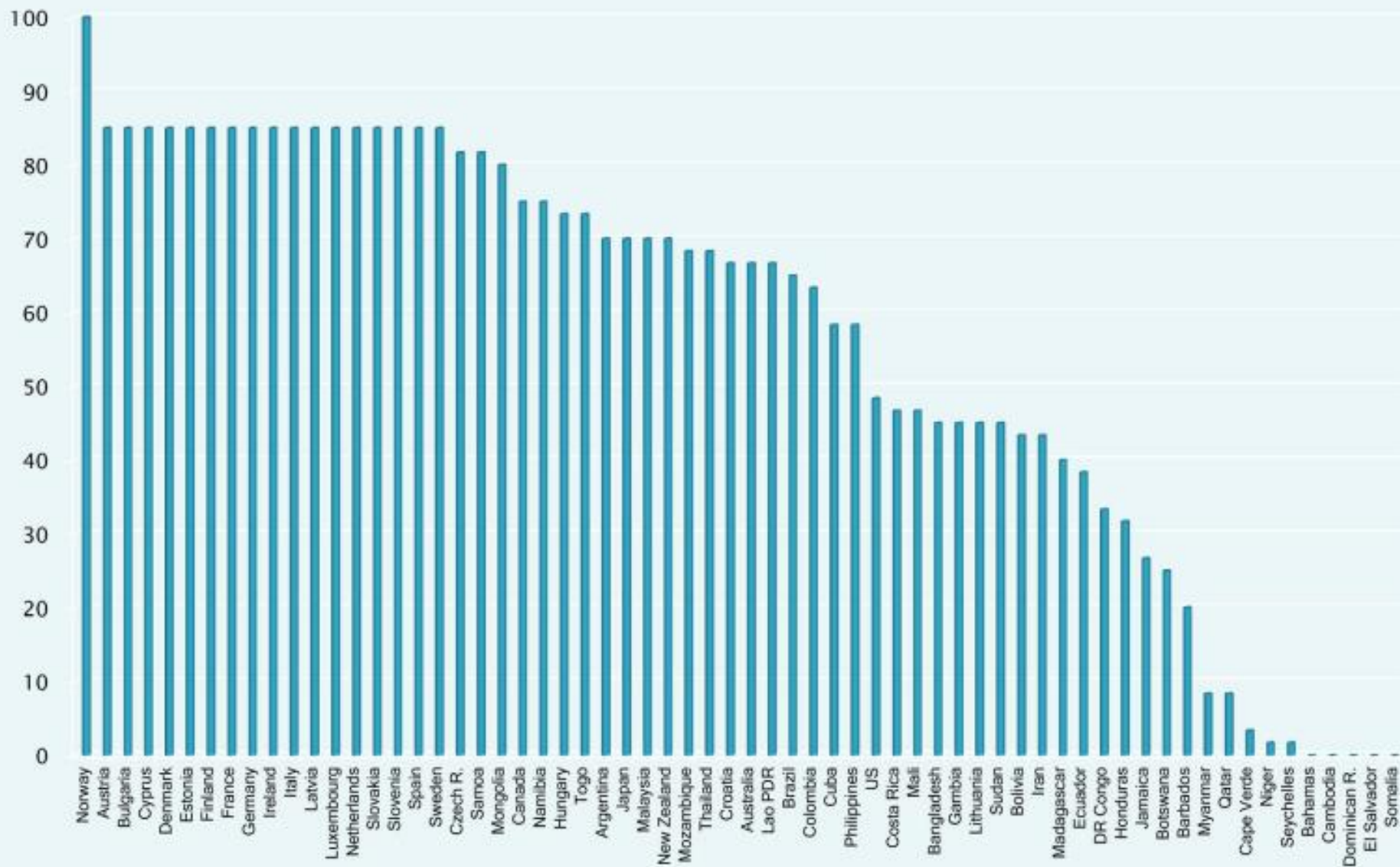
- EU General Food Law (178/2003)

- EU GMO Directive (2001/18)
  - EU approvals under 2001/18 valid in Norway, unless being prohibited
    - Adaptation; ethics, sustainability and societal utility

- EU GMO food and feed regulation (1829/2003)
  - not yet implemented in EEA and Norway

- National rules are partly harmonized

# GMO Regulation Index



**Low Levels of  
Genetically Modified  
Crops in International  
Food and Feed Trade:  
FAO International Survey  
and Economic Analysis**

**FAO 2014**

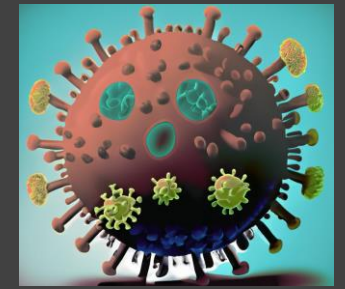
# National reports on genome editing in Norway

- **The Norwegian Biotechnology Advisory Board - 2018**
  - Majority advice; Tiered approach including notification
  - Plants, animals and microorganisms
- **Norwegian Official Report (Green Paper) – 2023**
  - Plants, animals and microorganisms
  - Public hearing 2023/2024

# Summary of the Norwegian Official Report

## General agreement

- Include all living organisms – plants, animals and microorganisms
- Promote development of sustainable products
- Include assessment of the trait of product/organism
- Consumer interests and transparency is important
- Promote research and innovation
- Modernisation of the 3 additional criteria (sustainability, societal utility and ethics) into ethical justifiability
- Minority ask for a continuation of GMO framework, with updates
- Majority ask for a substantial liberalization (similarities with EU proposal on NGT)



# Majority recommendation in official report

Exempt  
from GMO  
regulation

PB –precision  
breeding

Exempt  
from GMO  
regulation

GMO

Non-  
heritable  
modificaton

Modificaton within  
species (PB)

Conventional  
breeding

Transgenes  
(old GMO)

Level of genetic change

# Animal breeding in Norway is important globally



- Norwegian pig, cattle and salmon breeding companies with joint consultation input to the green paper;
  - «*The current regulatory requirements for approval are prohibitive and deny commercialisation of products from genome editing*»
  - «*Should be regulated similarly as conventional breeding*»
  - «*Risk-proportional*»
  - «*No labelling*»

# The road ahead

- The Norwegian government currently considers the Green paper, inputs and the overall development
- The future EU regulation will be important to Norway
- International regulatory cooperation is important

# International Regulatory Cooperation



# Risk assessments as global public goods



Norwegian Ministry of Agriculture and Food

<b>UN</b>	<b>JEMRA</b>	<b>JMPR</b>		<b>JECFA</b>	<b>JECFA</b>
<b>EU</b>	<b>BIOHAZ</b>	<b>PPR</b>	<b>GMO</b>	<b>ANS/CEF</b>	<b>CONTAM</b>
<b>NO</b>	<b>fg1</b>	<b>fg2</b>	<b>fg3</b>	<b>fg4</b>	<b>fg5</b>
	<b>Micro-organisms</b>	<b>Pesticides</b>	<b>GMO</b>	<b>Food additives</b>	<b>Natural toxins</b>

# Thank you!

Please stay in touch for  
further discussion or  
questions;

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