



PARMA SUMMER SCHOOL

28 – 30 SEPTEMBER 2021, Parma

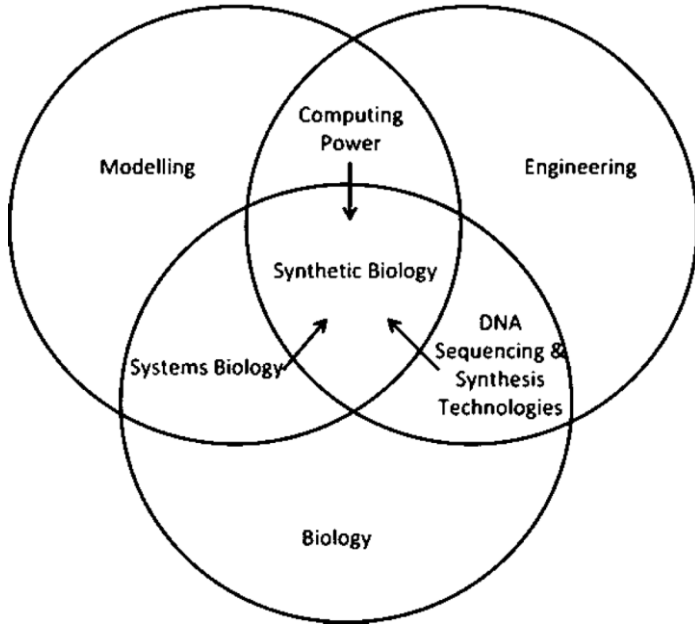
Food Safety Aspects of Integrated Food Systems

Process, Product, or Both?

The Regulation of Synthetic Biology in the EU and the US and the Need for a New Approach to Risk Assessment

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Coverage = Adequacy?



The EU

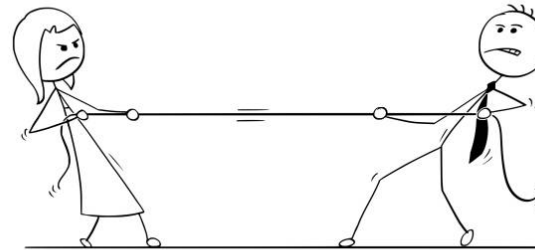
SCHER/SCENIHR/SCCS,
Synbio Opinion I and II

The US

Presidential Commission, *New
Directions Report*

Process

Product



Inherited GMO Regimes

EU: GMO-Specific

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Commission Directive (EU) 2018/350 amending Directive 2001/18/EC on GMOs ERA
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Regulation (EC) 1830/2003 concerning the traceability and labelling genetically modified organisms

EFSA GMO Panel (2011) Guidance for risk assessment of food and feed from genetically modified plants

EFSA GMO Panel (2010) Guidance on the environmental risk assessment of genetically modified plants

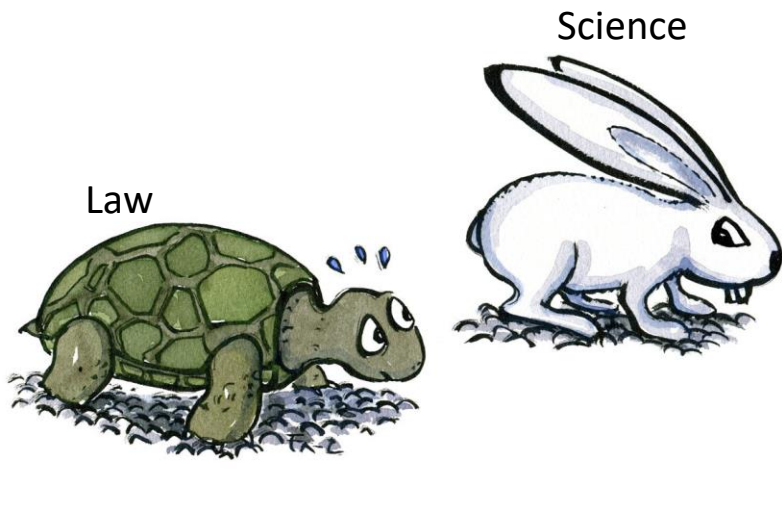
US: Non GMO-Specific



- Federal Food, Drug, and Cosmetic Act (FFDCA)
- The Plant Protection Act (PPA)
- The Toxic Substances Control Act (TSCA)
- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

A New Approach to Risk Assessment?

“Other risk assessment approaches that do not rely on the current comparative approach may need to be considered.” (EFSA 2020)



“Challenges in assessing synthetic biology are foreseeable but the existing methods of risk assessment for GMOs **and chemicals** are applicable.” (SCHER/SCENIHR/SCCS 2015)

Thank you!

Image adapted from “Turtle Rabbit race” by Frits Ahlefeldt
<https://fritsahlefeldt.com/>