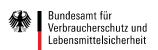
#### New Breeding Techniques and the EU Legislative Framework



# Genome Editing – Where precaution meets innovation

Detlef Bartsch, BVL Berlin

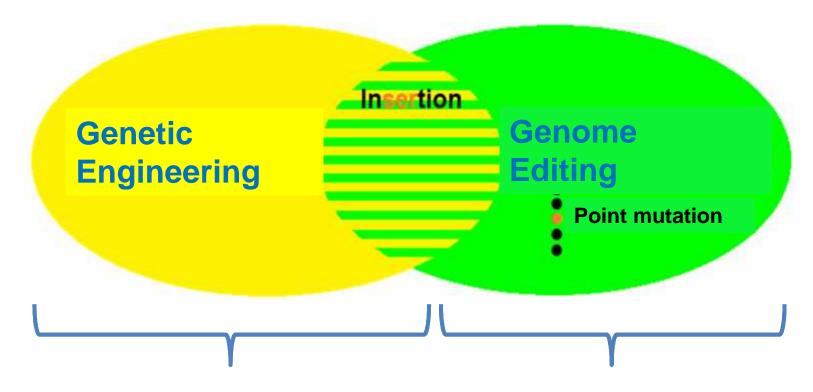


### State of play

- Genome editing already used in agriculture, forestry, bioeconomy, medicine (e.g. living GM vaccines for cats)
- NBT = GMO according to EU GMO regulation?
- EU Member State WG from 2007 has finalised a technical report in 2012 (still not officially released)
- A EU Joint Research Centre report published in 2011 and Scientific Advisory Mechanism report in 2017
- EFSA opinion on safety of techniques (cisgenesis, zinc finger 3)
- Germany, Sweden, UK, Ireland, Spain, Finland with single case decisions on some applications
- Court of Justice of the European Union to decide summer 2018 (Statement of Advocate General in Jan. 2018)



### **BVL-Interpretation**

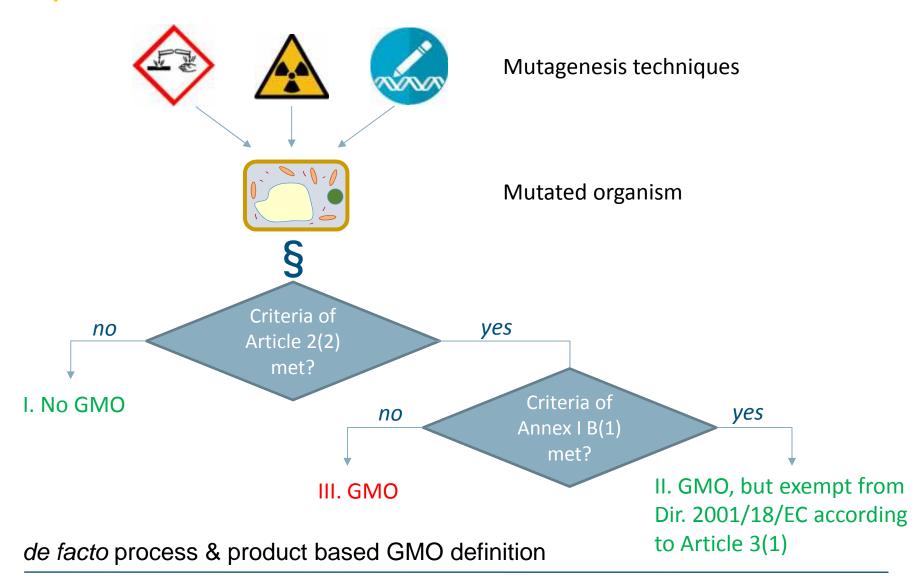


GMO falling under Dir. 2001/18/EC

No GMO or exempt from Dir. 2001/18/EC



# Regulation of organisms obtained by mutagenesis according to AG Bobek (Court of Justice of the EU)





# Precautionary Principle

- Precautionary principle Zero risk
- Existence of GM regulation = implementation of the precautionary principle
- Refusal to use new techniques also bears risks
- Even if genetic engineering law does not apply to an organism, there are still other provisions



#### **Four Dimensions of Innovation**



Economy & Ecology (viability)

No INNOVATION without risks & benefits

Regulation (limits & encouragement)

**Technology** (feasibility)









#### Wissenschaftlicher Bericht zu den neuen Techniken in der Pflanzenzüchtung und der Tierzucht und ihren Verwendungen im Bereich der Ernährung und Landwirtschaft

Bundesinstitut für Risikobewertung

- überarbeitete Fassung vom 23.02.2018 -

Bartsch, D.<sup>1</sup>, Bendiek, J.<sup>1</sup>, Braeuning, A.<sup>2</sup>, Ehlers, U.<sup>1</sup>, Dagand, E.<sup>1</sup>, Duensing, N.<sup>1</sup>, Fladung, M.<sup>3</sup>, Franz, C.<sup>4</sup>, Groeneveld, E.<sup>5</sup>, Grohmann, L.<sup>1</sup>, Habermann, D.<sup>4</sup>, Hartung, F.<sup>6</sup>, Keilwagen, J.<sup>6</sup>, Leggewie, G.<sup>1</sup>, Matthies, A.<sup>1</sup>, Middelhoff, U.<sup>1</sup>, Niemann, H.<sup>5</sup>, Petersen, B.<sup>5</sup>, Scheepers, A.<sup>1</sup>, Schenkel, W.<sup>1</sup>, Sprink, T.<sup>6</sup>, Stolz, A.<sup>1</sup>, Tebbe, C.<sup>3</sup>, Wahler, D.<sup>1</sup>, Wilhelm, R.<sup>6</sup>

Report of 5 Federal
German Institutions
on scientific aspects,
e.g.
detection &
identification of
Genome Editing



### **Key question**

Does today's fear of potential risks caused by New Breeding Methods makes us unable to carry out necessary actions for a better life?



## Thank you for your attention!

