



Department
for Environment
Food & Rural Affairs

Harnessing the opportunities of New Breeding Techniques

Are NBTs captured by GMO
legislation?

Louise Ball: EU Crops and GMO Team, Defra



- **Need for regulatory clarity:**
 - Regulatory trigger
 - Regulatory framework and its operation (differential impact e.g. GM crop cultivation and GM medical products).

Regulatory trigger:

EU:

- One regulatory trigger for all organisms and their uses.
- Triggered (at least in-part) by how organisms are made (i.e. so-called 'process-based')
- Open to interpretation



Genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

Annex 1A Part 1: examples of **GM techniques** (non-inclusive)

Annex 1A Part 2: **non-GM techniques** (limited list)

Annex 1B: **GM techniques** producing organisms that are **excluded** from the legislation (e.g. mutagenesis)



- **6 x EU Member States issued views on plants for use in field trials (case-specific)**
 - England, Germany, Ireland, Finland, Spain & Sweden.

- **EU Commission view by end of 2016 (?)**
 - Important milestone but not a definitive ruling

 - Expectation: address key questions and use examples of NBTs (incl. gene editing) to interpret GMO definition.



Techniques:

Agro-infiltration

Cisgenesis/intragenesis

Grafting on GM rootstock

Oligonucleotide directed mutagenesis (ODM)

Reverse breeding

Site-directed nucleases (e.g. zinc finger nucleases)

RNA-dependent DNA methylation

*Lusser *et al.* (2012), “Deployment of New Biotechnologies in Plant Breeding”, *Nature Biotechnology*, 30, pp. 231-239.



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Outside the EU

Most countries have regulatory triggers with a 'process-based' element. Need for interpretation. Canada is the exception.

Where regulators are coming to views, these are on individual cases

EU exit: opportunities