

# Regulatory status of genome edited crops; Europe & beyond

# Are genome edited crops subject to the EU GMO legislation?

First and foremost:

1. The EU GMO legislation is *NOT purely process based*
  - The use of modern techniques is a first regulatory trigger
  - The resulting organism has to fulfill certain criteria
2. There is a difference between *being a GMO* and *being an organism subject to the GMO legislation*

# a GMO is ...

'... 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;'

Article 2(2) of EU Directive 2001/18/EC

# Techniques of genetic modification listed in annex IA part 1

(1) recombinant nucleic acid techniques involving the formation of *new combinations of genetic material* by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation *into a host organism in which they do not naturally occur* but in which they are capable of continued propagation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with *new combinations of heritable genetic material* are formed through the fusion of two or more cells by means of methods that do not occur naturally

# Process *AND* product

'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;

- 1) "*...has been altered in a way that does not occur naturally...*" in the GMO definition refers to **both the method of alteration AND the end result of the genetic modification**.
- 2) The words '*...does not occur naturally...*' should be interpreted as meaning '*cannot occur naturally*' or at least as '*is very unlikely to occur naturally*'

→ a GMO has to differ in a meaningful way from what can occur naturally;  
one should be able to distinguish a GMO on the DNA level from what can occur naturally

# In other words

An organism is only then a GMO when the application of a technique has led to the *formation of combination of genetic material beyond what can occur through mating and/or natural recombination*

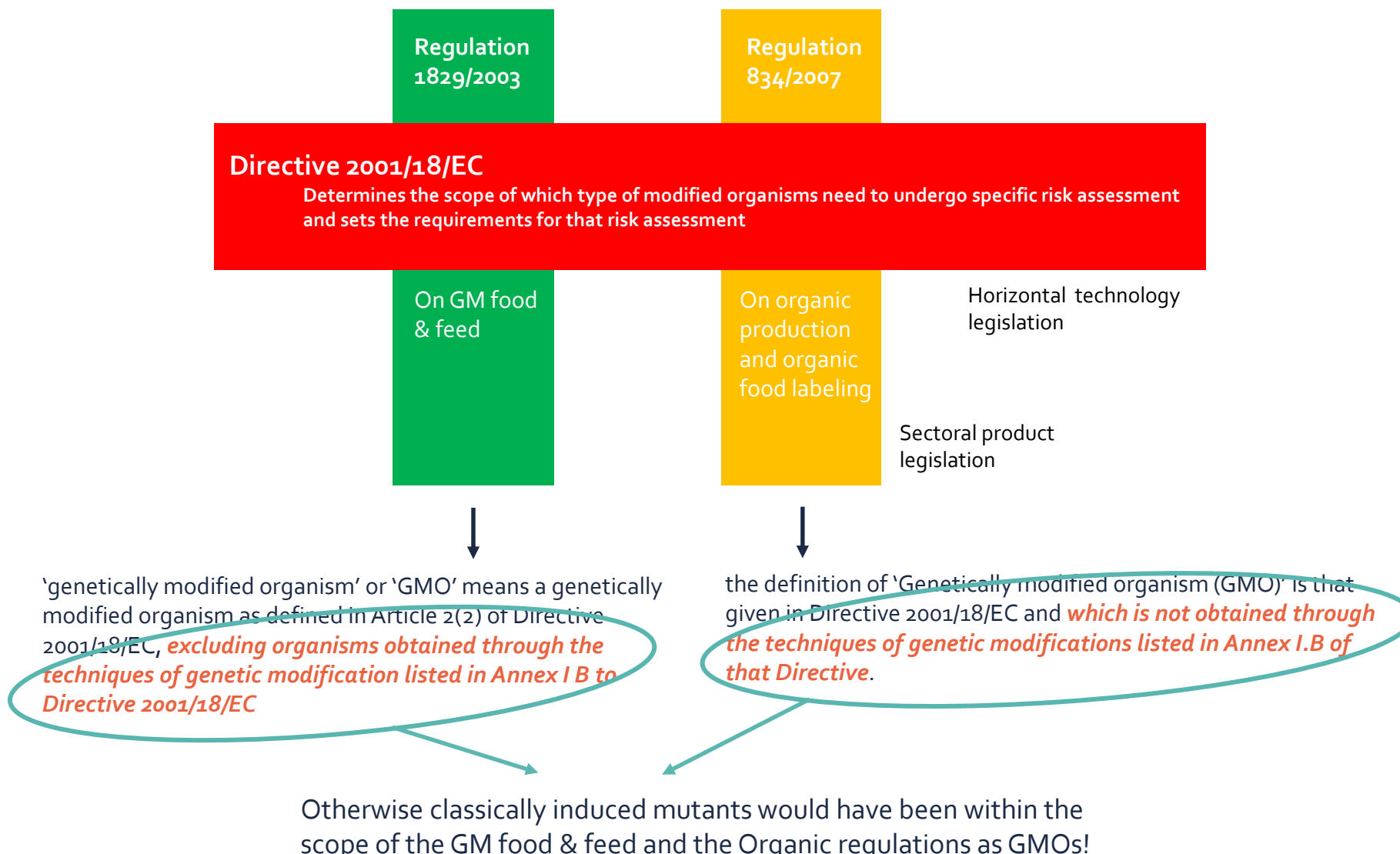
→ The mere application of a certain technique is not enough to become a GMO!

# The exemptions

*Organisms* that have been obtained through the techniques of genetic modification listed in Annex IB are not subject to the provisions of the directive (article 3 and Annex IB of EU directive 2001/18/EC).

Annex IB lists the following *techniques of genetic modification*:

1. *mutagenesis*,
2. *cell fusion* (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.





# Are genome edited crops subject to the EU GMO legislation?

1. The organism can be out of scope because **it does not fall under the definition of a GMO** (article 2.2 of Directive 2001/18/EC)

→It's not a GMO in the first place

2. The organism can be out of scope because **it is exempted from the scope** of the Directive (via article 3 of Directive 2001/18/EC)

→It's a GMO, but its exempted

# What does this mean for genome edited organisms?

Technically genome editing is a form of mutagenesis – as it leads to the formation of a mutation (a stable, heritable alteration to the genetic material).

But:

1. Only when a combination of genetic material is formed beyond what can occur naturally through mating and/or natural recombination, a GMO is formed.
2. Genome editing that results in the formation of a combination of genetic material that can occur naturally through mating and/or natural recombination, *does not lead to the formation of a GMO*.

# These are not GMOs



ATCCGATCCGTT CAGTTGA A CACTGGGAACTTCTA



ATCCGATCCGTT CAGTTCA A CACTGGGAACTTCTA

ATCCGATCCGTT CAGTT-- AACACTGGGAACTTCTA

ATCCG----- AACACTGGGAACTTCTA

ATCCGATCCGTT CAGTTG A A CACTGGGAACTTCTA

# What do the authorities say?

## The European Commission

- Confirms that the GMO definition contains both process AND product related criteria
- No further guidance, no answers to concrete questions
- Explanatory note by the SAM

## Seven EU member states (BE, ESP, IER, S, FIN, D, UK)

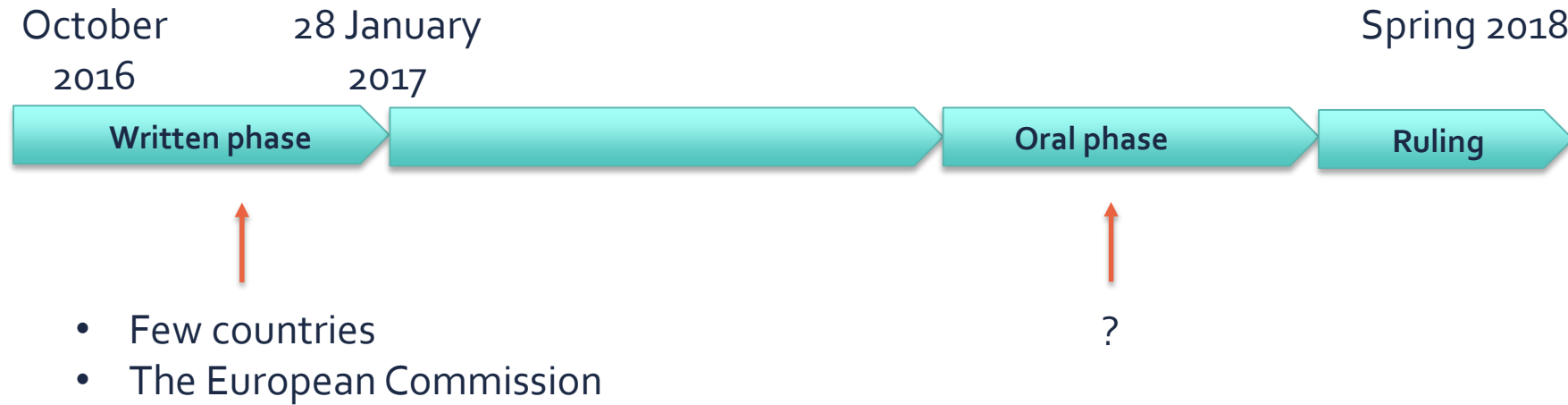
- State that certain forms of genome edited organisms are not subject to the GMO legislation the editing is a form of mutagenesis, and therefore falls under the exemption

# Only the ECJ can legally decide

## Prejudicial questions from the French Council of State

1. Do organisms obtained by mutagenesis constitute a GMO according to Article 2 of Directive 2001/18/EC?
2. Do varieties obtained by mutagenesis constitute genetically modified varieties according to Article 4 of the Plant Variety Common Catalogue Directive 2002/53/EC?
3. Do Articles 2 and 3 and Annex IB of Directive 2001/18/EC constitute a harmonization measure? Or do Member States (MS) dispose of a margin of discretion?
4. May the validity of Article 2 and 3 and Annex IB of Directive 2001/18/EC, be put into question as it doesn't submit GMOs obtained by mutagenesis to precautionary measures and evaluation processes taking into account scientific uncertainties and the potential risks that may arise for the environment and human and animal health?

# ECJ procedure



# What has been submitted to the ECJ?

## Netherlands:

- ?

## Austria:

- Certain crops case-by-case

## Sweden

- Rational opinion that substantiates their position

## European Commission

- ?

# What will the SAM say?

- Key characteristics of the NBTs
- Comparison with conventional breeding and established GM techniques
  - ▶ Differences in safety
  - ▶ Possibilities for detection
  - ▶ Speed and cost to achieve expected results



# The US

## New legislative proposals

| Are genome edited organisms a regulated article? |   |  |  |
|--|---|--|--|
|  | USDA  | EPA  | FDA  |
| YES  | If the edit introduces additional nucleic acids   | if the edit results in the introduction of a Plant-Incorporated Protectant (PIP) | If it's an animal*                                       |
| NO   | <ol style="list-style-type: none"><li>1. If the edit is a deletion of any size</li><li>2. If the edit is a single base pair substitution</li><li>3. If the edit introduces naturally occurring nucleic acid sequences</li></ol> | if the edit does not constitute a PIP  | No, if it's a crop. But a voluntary consultation process |

\*Full risk assessment and market approval as an animal drug

## Argentina

- Procedure in legislation to determine case-by-case whether GMO permit is necessary

## Brazil

- Proposal by CTNBio to place organisms obtained with SDN-1 outside of scope of legislation

# So?

## The EU

- Good legal arguments to state that certain types of genome edited crops are not subject to the GMO legislation
- The final word is with the ECJ in spring 2018, and this may open a new regulatory debate

## Outside the EU

- Moving towards not regulating certain types of genome edited crops

# Beware: there's not only a regulatory issue

## The safety issue

- Do certain genome edited crops require government oversight?

## The societal issue

- How do we build trust that genome editing is not going to be used irresponsibly?