



Ministry of Infrastructure and the  
Environment

Proposal for discussion  
on actions to improve the  
exemption mechanism for  
genetically modified plants  
under Directive 2001/18/EC

# Genetically modified plants under Directive 2001/18/EC

Introduction of a proposal  
for discussion

Brussels, 7 September 2017



# Introduction

- Welcome!
- Thank you for devoting your valuable time by attending this meeting
- Order of the day
  - Lunch (1.00-1.30)
  - Introduction (1.30-1.50)
  - Questions and answers (1.50-2.15)
  - Start of discussion (2.15- 3.00)



Decades-old GMO  
regulation  
21st  
fit for

Commission  
new  
tech  
mon

since 1995. But when asked about the boundary dispute, Wei Zheng, the centre's vice-director, said: "It still is a problem." She declined to comment further, citing the sensitivity of the issue.

Choi, for example, says that he and his colleagues would like to conduct a deep seismic

says that the project would need permission and protection from China's coastguard to prevent passing fishing boats causing any damage to the kilometres-long cables and attached equipment.

Both Liu and Yang say that an agreement would similarly foster collaborations to look

Yellow Sea in the past, and how new dams on China's rivers have changed that process. "The Chinese cannot only study the western side, or Koreans cannot only study the eastern side," Liu says. "They have to work together to know the whole picture of the area." ■

POLICY

# Europe's genetically edited plants stuck in legal limbo

Scientists frustrated at delay in deciding if GM regulations apply to precision gene editing.

BY ALISON ABBOTT

Plant geneticist Stefan Jansson is championing at the bit to start field trials on crops tweaked with powerful gene-editing technologies. He plans to begin by using edits to study how the cress plant *Arabidopsis* protects its photosynthetic machinery from damage in excessively bright light.

But the future of his work depends on the European Commission's answer to a legal

including the popular CRISPR-Cas9 method.

The commission has repeatedly stalled on delivering its verdict, which will apply to edited animals and microorganisms as well as plants. It now says that it will make its legal analysis public by the end of March. Swedish authorities, meanwhile, have told Jansson that unless the commission specifies otherwise, they will not require his cress to be subject to GM regulations.

GENETIC EDITING

projects hit a dead end," he says.

At issue is the interpretation of a 2001 European Commission directive on releasing GM organisms into the environment, which covers field trials and cultivation. It defines GM organisms as having alterations that cannot occur naturally, which were made by genetic engineering.

What is unclear is how this relates to experiments, such as Jansson's, in which researchers introduce foreign DNA to direct a precise edit in a plant's own genetic material but then use



## Brief background

- New Plant Breeding Techniques (NPBTs) emerged in first decade of 21st century
- Discussion on applicability of GMO Directive towards NPBTs
- At the request of Competent Authorities under Directive 2001/18/EC, a working group was established (October 2007)
- Expert Working group analysed a non-exhaustive list of techniques for which it was unclear whether they would result in a GMO.
- Working Group delivered a report in 2011 which is still confidential but available on the internet.
- Report was envisaged to be considered by Authorities and Commission at policy level
- Commission preferred making a legal analysis prior to policy discussion



## NPBTs scrutinised by MSs Working Group

- Oligonucleotide Directed Mutagenesis (ODM)
- Zinc Finger Nuclease Technology (ZFN-1, ZFN-2 and ZFN-3)
- Cisgenesis (comprising also intragenesis)
- Grafting
- Agro-infiltration
- RNA-dependent DNA methylation (RdDM)
- Reverse Breeding
- Synthetic Genomics (**set aside by working group**)



## Results to date

- No legal analysis from EU Commission
- No policy discussion among authorities for almost 10 years
- Biotechnology develops further at a rapid pace
- More techniques are emerging
- Uncertainty and unclarity remains and increases
- Continued discussion among *scientists* without common and agreed understanding
- Continued discussion among *legal experts* without common and agreed understanding
- Numerous attempts to initiate a policy debate were unsuccessful



## Most recent developments

- The European Court of Justice has been requested to provide clarity regarding the interpretation of the Directive with regard to mutagenesis (case C-528/16)
- The Scientific Advisory Mechanism (SAM) has provided a scientific report describing the technical characteristics of NPBTs at the request of the European Commission
- Some EU MSs consider interpreting the applicability of the directive unilaterally
- Increased urgency calls for decisiveness in EU, both in terms of policy steering as in terms of addressing societal concerns expressed by stakeholders



# What is the problem?

From policy perspective:

- Need for clarity and policy steering
- Annex IB does not reflect current knowledge and is not up to date with technical progress
- Policy development is in a deadlock as regards NPBTs
- Lengthy and unresolved debates during the past decade yielded much information, but resulted in insufficient or no progress

**Consistent policy approaches are required to improve the functioning of the internal market in EU and to ensure safety for human health and the environment**





## What is the problem?

From civil society and stakeholder perspective:

- Disproportionate effects in terms of costs, duration and predictability of market authorisation procedures – especially for SMEs – hamper use of innovative technologies in the EU;
- Lack of clarity and legal certainty leads to disharmonisation
- Impediments to use innovative NPBTs for addressing societal sustainability challenges such as ensuring food availability, adapting to climate change, enhancing circular/biobased economy, etc.
- Need for transparency and freedom of choice (particularly for organic sector and consumers)

**Consistent policy approaches are required to improve the functioning of the internal market in EU and to ensure safety for human health and the environment**



## Why this proposal for discussion?

- Initiate and re-install a policy discussion among EU authorities
- Discuss whether policy makers can share the view that the Directive
  - should not apply to plants resulting from the use of New Plant Breeding Techniques (NPBTs),
  - provided that these plants are at least equally safe as plants obtained by traditional breeding.
- Explore means to achieve this aim:
  1. Interpreting the existing legislation in an EU harmonised manner, providing predictability (legal) certainty, accountability and reliability
  2. Using the means the Directive provides to achieve the intended aims



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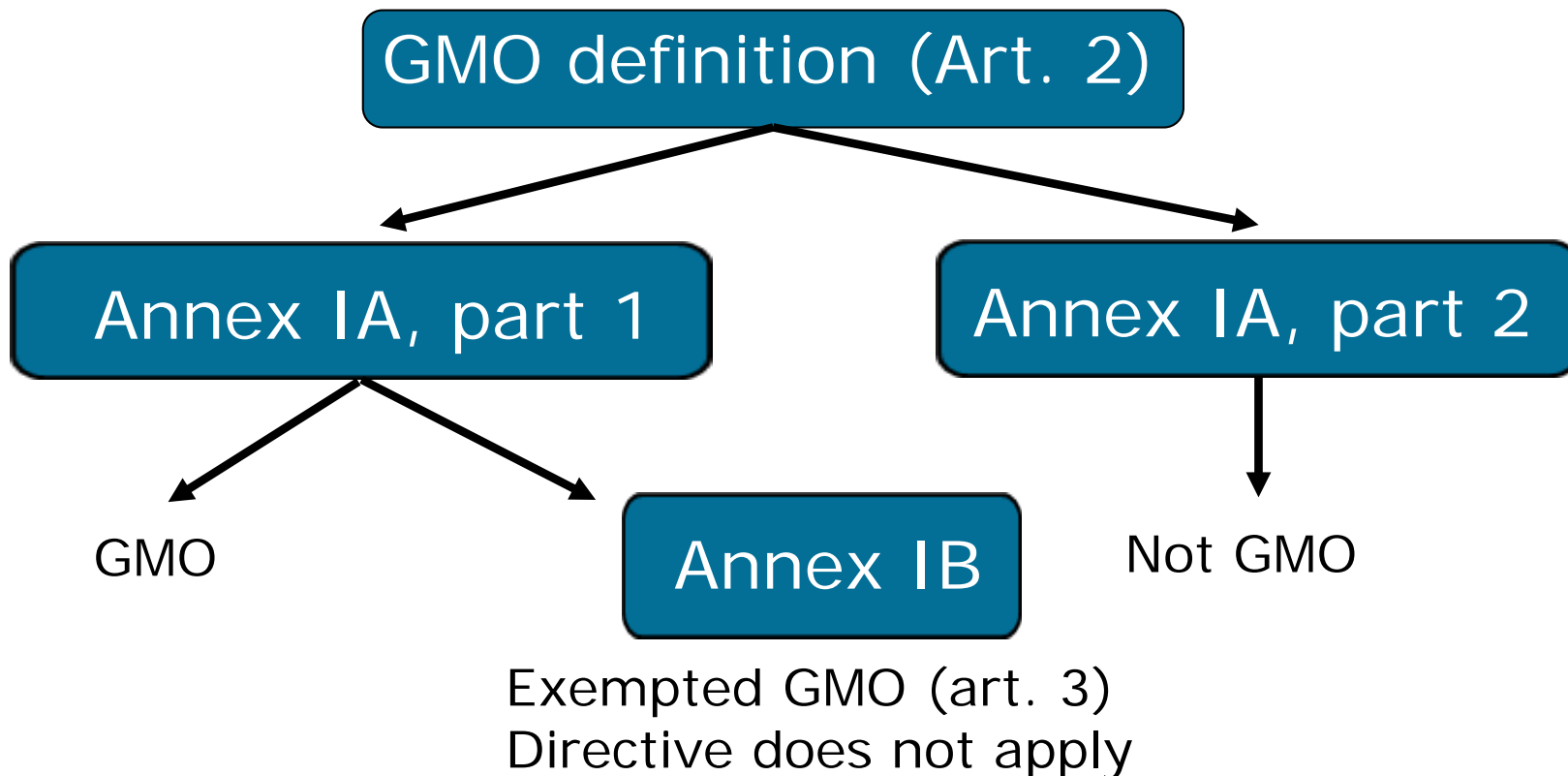


## Why THIS particular proposal for discussion

- Science has so far not provided means to resolve policy discussions
- Legal interpretations are not commonly shared and agreed in EU
- Perhaps the ECJ may provide clarity on how to interpret mutagenesis but will its decision resolve all NPBT issues satisfactorily?
- All feasible options have been explored (to no effect) except one:
  - Using improved means the directive provides in Annex IB
- The proposal for discussion therefore outlines how this unexplored option could be used.



## Directive 2001/18/EC





# Content

- No intention to review the Directive as a whole
- For regulatory efficiency, amending the Directive should remain restricted to Annex IB
- The proposal describes how potentially an amendment of Annex IB could be formulated
- The currently exempted techniques remain unchanged
- The proposal encompasses all potential outcomes of C-528/16 ECJ
- No more listing of techniques on case by case evaluations
- Instead criteria are proposed, based on current scientific knowledge and experience, to ensure that exempted plants are at least equally safe as plants obtained by traditional breeding



## Policy principles

Policy and legislation need to be based on principles of:

- Predictability
- Reliability
- Accountability and transparency

Aiming at:

- Ensuring safety for human health and the environment
- Improving the functioning of the EU internal market
- Enhancing innovation, endorsed by better regulation
- Maintaining science based decision making
- Keeping up with the pace of scientific and technological change



## Further steps

- Proposal is a public document and is shared with stakeholders
- **Invite EU MS authorities** to collaborate, engage in discussions at EU level and provide comments and feedback
- Proposal for discussion contributes to EU Conference:  
*“Modern Biotechnologies in Agriculture – Paving the way for responsible innovation 28 September 2017 – Brussels”*
- **Request European Commission** to:
  - include this proposal for discussion in the agenda of Competent Authorities meetings at the earliest convenience
  - recognise the political need to make progress on this matter
  - consider taking the lead in re-installing policy discussion





## The EU must deliver!

- All policy options are open for discussion
- Dutch proposal adds a yet unexplored approach
- Harmonised EU policy and interpretation of Directive are key for success
- First step is to (re-)start a dialogue and discussion at EU level
- Biotechnology continues to develop further
- Future proof policy and legislative framework are required
  
- Do authorities choose the ECJ to determine the course of policy due to their lack of decisiveness or do they wish to take the lead themselves?



**Thank you for your kind attention  
Invitation to initiate discussions**





## Contact details

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