New GMOs

EU legal situation

This is not a gmo.

The Greens

How were different EU institutions positioned before the ECJ decision?

- DG HEALTH/EU Commission is openly supporting the quick spreading of these techniques
- The EU Parliament has no position yet – reports addressing these techniques since 2015 have been so controversial that the concerned parts were removed before or during the vote
- The Council has no position yet, and the member States have diverse opinions
  - Austria already declared they would consider these techniques are GMOs (but it was the previous government)
  - The Dutch government already circulated a proposal to change the Directive in a way that would exempt all the new techniques
  - Sweden, Belgium and the UK authorized trials outside of the GMO framework.

What's in the ECJ decision?

- Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive
- Only organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and **have a long safety record** are exempt from those obligations
- The GMO Directive is also applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption (aka gene editing)
- MS states can regulate nationally on techniques which are exempted
- Organisms obtained by exempt techniques don't have to respect specific labelling under the seed directive
- It could be deducted from this opinion that cisgenesis (which is not derived from mutagenesis) cannot be exempt but needs to be checked

What does it mean?

- Organisms obtained by gene editing techniques need to be **evaluated** by EFSA, **approved** by a standing committee of MS's representatives, **traced**, **labelled** for the final consumers and subjected to a program of **biosecurity**. Also, there are specific obligations for trials.
- This means:
  - Trials which have been authorized out of the GMO regulation need to be stopped (UK, Sweden, Belgium)
  - EFSA needs an adequate protocol to assess these organisms
  - Laboratories and authorities needs to have available testing methods, for example to ensure that rapeseed imports are not contaminated (= the EU Commission need to start the work on that NOW)
  - Imports of these organisms (for example, the Cibus ODM rapeseed coming from Canada and the USA) needs to stop until they are assessed and approved.
  - Any imports from North America where Cibus is grown must be certified that they are Cibus free tested or rejected

What is going to happen?

- The ECJ decision is final, there is no appeal possible.
- From there, two possible scenarios:
  - The decision is accepted and implemented:
    - New GMOs follow the same path as transgenesis (probably only used in feed with very limited cultivated surfaces in the EU).
    - This might mean the industry specialize in “old style” mutagenesis from now on as it is exempt.
  - Some MS push for re-opening the GMO directive:
    - Either to include new techniques in the list of exempt ones, or to change its spirit entirely (product based instead of process based)
    - This would probably happen after the next EU elections (May 2019) as the current EP is globally hostile to GMOs.
    - As this is a co-decision process (involving both member states and EU Parliament) it can last several years.

The EU GMO regulation in short

- Directive 2001/18 and regulation 1829/2003:
  - definitions (What is a GMO),
  - Authorization procedures
  - Labelling of GMOs,
  - Traceability measures,
  - Biosecurity measures,
  - How and when a state can ban a GMO (« opt out »),
  - Exemptions (techniques producing GMOs but not covered by the regulation, like mutagenesis and cell fusion)
- Guidelines: coexistence measures, detailed evaluation procedure for EFSA

The Dutch proposal

- Replaces annex IB of the directive, which deals with exemptions
  - Could only be exempt techniques which ***produce organisms which no longer contain*** recombinant nucleic acid molecules instead of techniques which do not ***involve*** the use of recombinant nucleic acid molecules
  - Release of an organism obtain by one the listed techniques must submit a written justification
  - The list, which has today only 2 items (mutagenesis and cell fusion) is replaced by the following:
    - "A) the following techniques, methods or applications thereof:
      - (1) conventional random mutagenesis methods using ionising radiation or mutagenic chemical agents;
      - (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods;
    - B) techniques, methods or applications thereof resulting in plants, provided that:
      - (1) no other genetic material is introduced into the resulting plant than genetic material from the same plant species or from a plant species with which it can exchange genetic material through traditional breeding methods, and
      - (2) recombinant nucleic acid molecules that are used for or during modification are no longer present in the resulting plant that is meant for deliberate introduction into the environment., »
  - ➢ B) covers almost all of the so-called « new breeding techniques », especially cisgenesis and CRISPR CAS
  - The list must be reviewed every 5 years