

Why we decided that some CRISPR-Cas9 gene-edited plants are not regulated by the GMO-directive

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Competent Authority for GM plants
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Regulatory environment in Sweden

- Independent authorities
- Service obligation
 - no bias
 - rule of law – limit proff. activities only if in common interest
 - proportionality
 - speed
 - simple
 - the need for help



Need for help?

Lack of clarity is no reason not to follow the legislation.

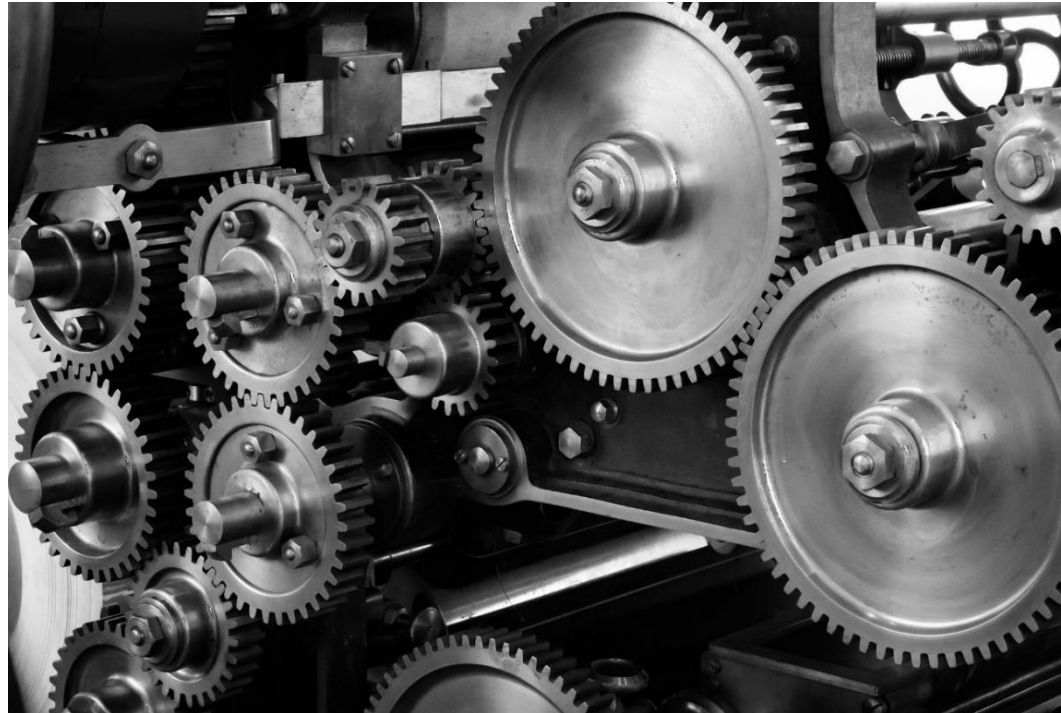
Very unclear situation. Not predictable. Risks for potential consequences. Risk for unequal treatment.

Also in the interest of the Authority - Central interpretation would mean that unauthorised use according to our interpretation does not happen.

But we do not take over the responsibility.



matter



response

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Cases

Arabidopsis thaliana, transformed with a T-DNA construct carrying the Cas9 and one or two sgRNAs.

One double strand break and non-homologous end-joining.
Or two double strand breaks, resulting in deletion of the sequence in between.

Some lines sexually crossed to separate T-DNA from the mutated sequence. Some lines not.



Interpretation

1. one of the outspoken GMOs? >
2. fits the general criterion for GMO? >
3. mutagenesis? >
4. recombinant nucleic acid? >
5. earlier presence of GMO?



1. outspoken GMO?

1. one of the outspoken GMOs? > 2. fits the general criterion for GMO? > 3. mutagenesis? > 4. recombinant nucleic acid? > 5. earlier presence of GMO?

(Directive 2001/18/EC, Annex 1A, part 1.) Description fits with lines still carrying T-DNA. They are also classic GMOs, that always have been regulated. Description does not fit with NHEJ.

- Yes T-DNA containing lines are GMOs.

2. Fits the general criterion for GMO?

1. one of the outspoken GMOs? > 2. fits the general
criterion for GMO? > 3. mutagenesis? > 4. recombinant
nucleic acid? > 5. earlier presence of GMO?

(Article 2.2 in Directive 2001/18/EC)

The genetic material has been altered in a way that does
not occur naturally by mating and/or natural recombination

- Yes they are all GMOs



3. mutagenesis?

1. one of the outspoken GMOs? > 2. fits the general criterion for GMO? > 3. mutagenesis? > 4. recombinant nucleic acid? > 5. earlier presence of GMO?

(Directive 2001/18/EC, Article 3 + Annex 1B)

No definition!

Preamble 17 "long safety record" = molecular process.
The intention of the legislator.

Insert of foreign DNA is a new mol. process. Change with the cells own building blocks is not.

- T-DNA is no mutation. NHEJ is mutation.

4. recombinant nucleid acids?

1. one of the outspoken GMOs? > 2. fits the general criterion for GMO? > 3. mutagenesis? > 4. recombinant nucleic acid? > 5. earlier presence of GMO?

No definition! Different definitions in literature.

Directive 2001/18/EC, Annex 1A, part 1, indent 1 describes recombinant nucleic acid techniques.

- (This) NHEJ does not involve the use of recombinant nucleic acid molecules.

5. earlier presence of GMO?

1. one of the outspoken GMOs? > 2. fits the general criterion for GMO? > 3. mutagenesis? > 4. recombinant nucleic acid? > 5. earlier presence of GMO?

(Annex 1B) Recombinant nucleic acid and GMO had been used previously to make the mutations, since T-DNA was inserted.

- A) The plants for assessment shall be assessed, not previous generations.
- B) Impossible to analyse if the mutation is natural. Equal treatment.

- Not regulated.

Right or wrong?

*So far right for this type of CRISPR/Cas9-modified plants
- in Sweden.*



Chany Gov

