



Schweizerische Eidgenossenschaft  
Confédération suisse  
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Confederaziun svizra

Federal Department of Economic Affairs,  
Education and Research EAER  
**Federal Office for Agriculture FOAG**

# How will gene editing be regulated in Switzerland in the future?

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Markus Hardegger:



# Present Regulation



## The Legal basis

- in Switzerland is the same as in EU

<b>Act on Agriculture</b> Authorization to put varieties on the market through listing in the catalogue of varieties	new breeding technologies	<b>Gene Technology Act</b> <ul style="list-style-type: none"><li>• principles</li><li>• measures</li><li>• Freedom of choice</li><li>• precautionary principle</li></ul>
product safety	grey or not	considering process
history of safe use	clearly defined	and product
	area	<b>unknown?</b>

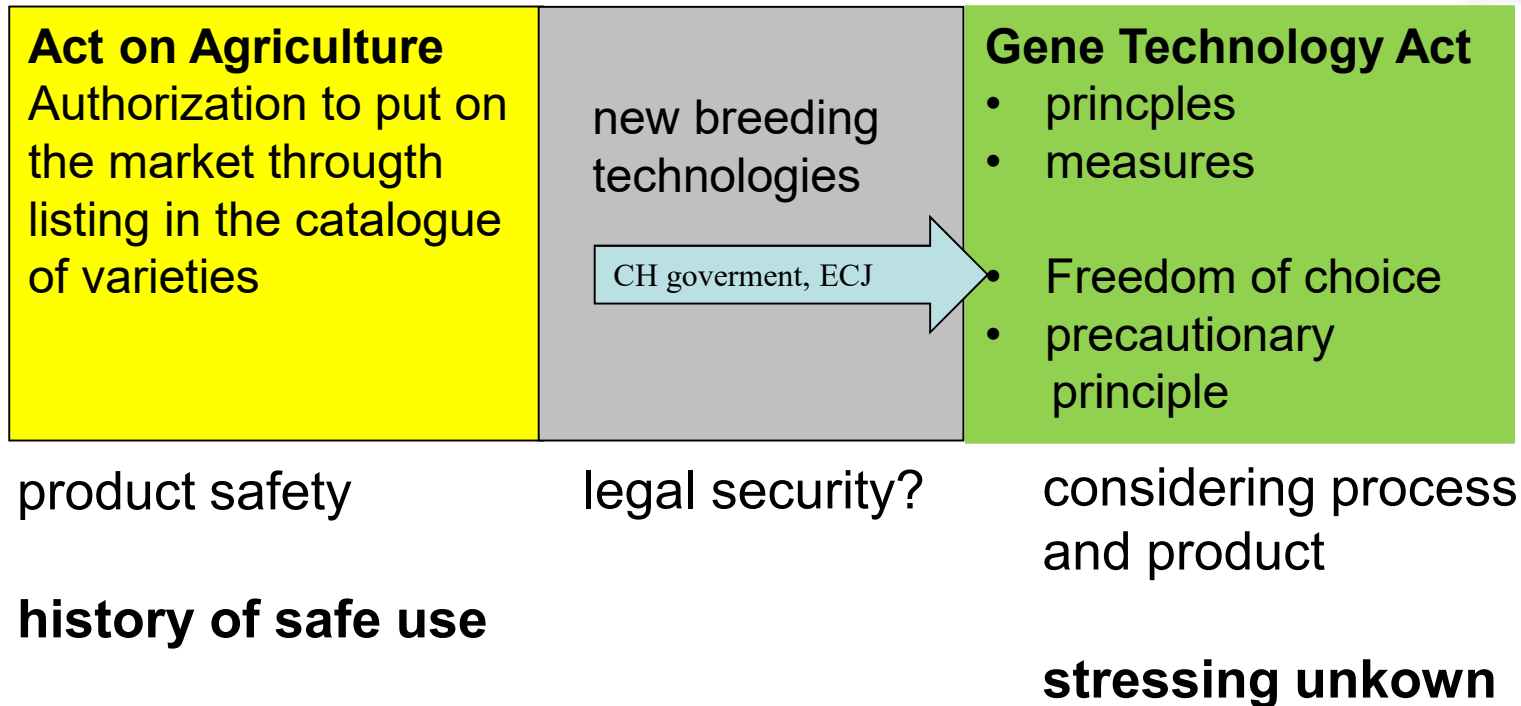


# Present Regulation



## Legal basis

- after the decision of the government





# Definition EU

## Law

GMO: means an organism, in which the genetic material has been altered in a way that **does not occur naturally** by mating and/or natural recombination

## Exception

- This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B
- (mutations by chemicals or radiation)



# Definition Switzerland

Law:

GMO: means an organism, in which the genetic material has been altered in a way that **does not occur naturally** by mating and/or natural recombination

Ordinance

GMO: means organisms in which the genetic material has been altered by **methods of gene technology** in accordance with Annex 1

Exception:

Self-cloning and the following methods shall not be regarded as methods of gene technology, as long as they are not used in association with recombinant nucleic acid molecules or genetically modified organisms:

- mutagenesis



# Defition EU - CH

## EU

Definition

Regulation

Regulation does not  
apply to exceptions

Mutations are GMO  
but regulation isn't  
applicable

## Switzerland

Definition

Regulation

Exception is part of  
specification of the  
**definition (loop)**

provoked mutations  
results not in GMO's



# Modification of the definition

No modification of the definition needed (Switzerland)

On ordinance level

Modification of the exception:

Self-cloning and the following methods shall not be regarded as methods of gene technology, as long as they are not used in association with recombinant nucleic acid molecules or genetically modified organisms:

- mutagenesis (**by chemicals or radiation**)



# Exception (I)

Regulation 1829/2003

“genetically modified food/feed” means food/feed **containing, consisting of or produced** from GMOs

– mandatory labelling

pure additives, produced with the help of gene technology

- no mandatory labelling
- GMO authorization requirements not applicable

## Case of early flowering gene in apple

1) GM plant is crossed with conventional plant

- Using offsprings without genetic modifications
- In Switzerland defined not als GMO
- In EU not regulated





## Exception (II)

### CRISPR/Cas Mutation

- CRISPR/Cas System is integrated into the plant genome
- Mutations are made on both alleles
- Crossing or for example heat treatment to obtain plants or offsprings without CRISPR/Cas System in the genome
- Apple Golden Delicious 50% more resistant against fire blight
- New Apple variety with the same knock out resistance

=> Freedom of choice, mandatory labelling



# Freedom of Choice – mandatory labelling - traceability

Requirement for authorization is an specific analytical method

CRISPR/Cas Mutations:

- Mutation can be detected
  - but, the method used to obtain the mutations can not be determined
  - Statistical analysis of thousand of single nucleotide polymorphisms (SNP) on a chip
- ⇒ Provoked mutation of the apple Golden Delicious is possible
- ⇒ Provoked mutations of new variety cannot be determined
- 1) Burden of proof is with the compliance authority (government)
  - 2) Accuracy of the result is unknown, but a lot below 99.9%



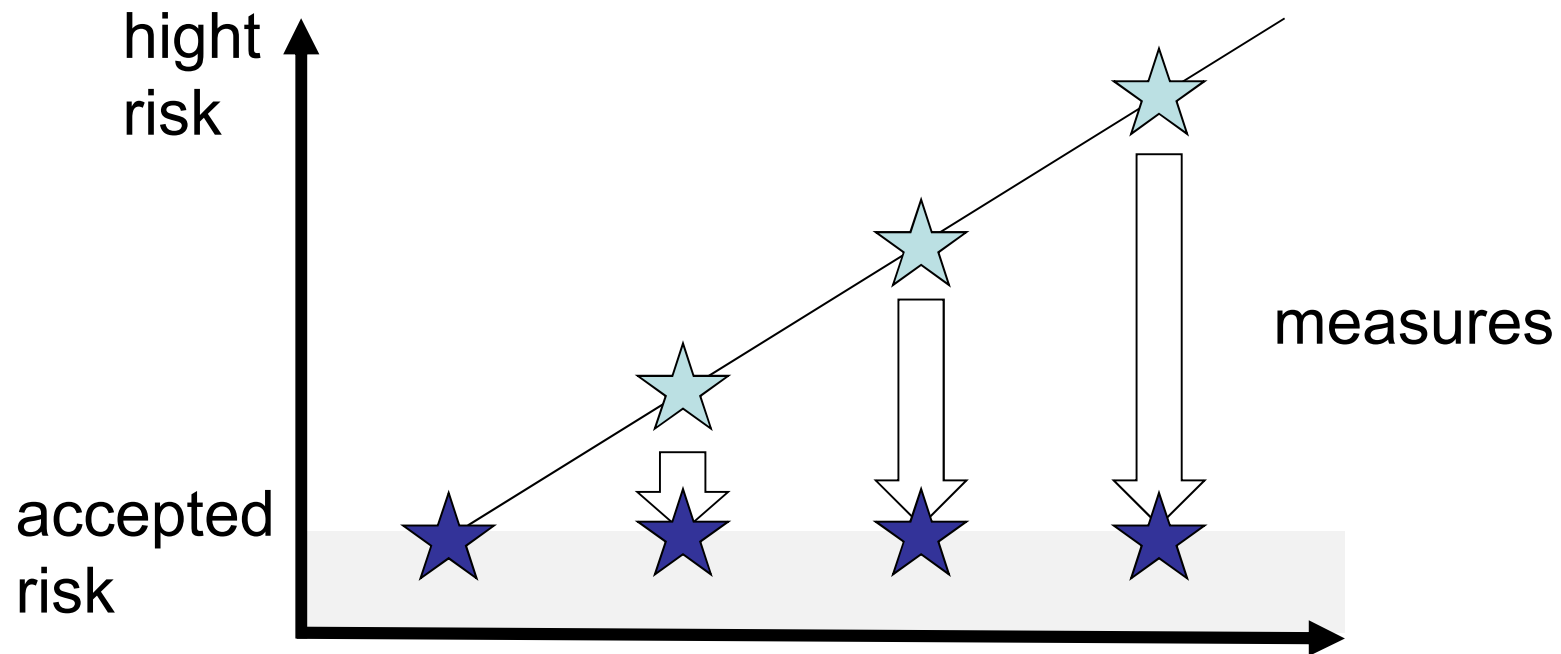
# Risk based approach

- Modification of definition
- Modification of rigid labelling requirement as **genetically modified** – to create more flexibility
  - GMO # GEO (Genome edited organism)
  - Analytics
  - Food and feed can be put on the market EU/CH  
(not covered by opt out clause, Moratorium)
- risk assessment requirements
  - legally this is delegated from the parliament (law) to the government (ordinances)
  - Existing example: contained use of organisms



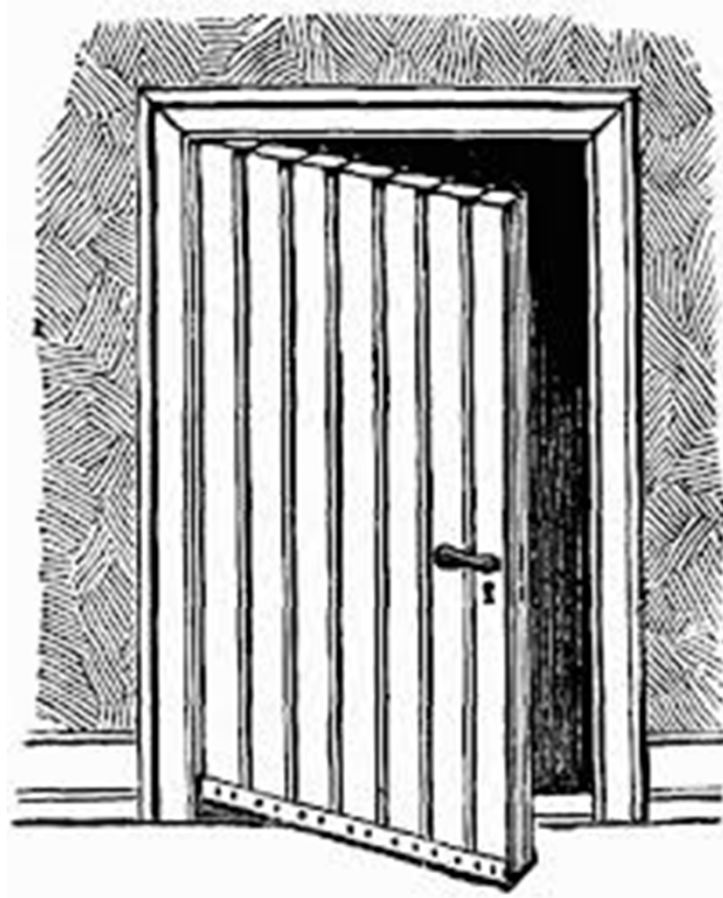
# Risk based approach

- Contained use:
  - classification of organisms in 4 groups
  - classification of activities in 4 groups





# Future of gene edited products!





# Risk based approach proposed modifications



- Modification of definition
  - on ordinance level
- **Modification of the fixed labelling requirement as “genetically modified organism”**
  - on law level
- Modification of risk assessment requirements
  - Existing, modifications not necessary
- co-existing rules
  - Missing, but not proposed



# Thank you and enjoy your meal

## Your Swiss Agricultural Product

