Vitenskapskomiteen for mat og miljø
Norwegian Scientific Committee for Food and Environment

Hvordan gjøres helse- og miljørisikovurderinger av GMO i Norge og EU?

Monica Sanden, leder av faggruppen for GMO – mat og fôr

30. januar 2024

VKMs samfunnsoppdrag

- VKM er en faglig uavhengig komité på mat-, helse- og miljøområdet
- Formålet med VKM er å sikre uavhengige vitenskapelige vurderinger av forhold som har direkte eller indirekte betydning for helsemessig trygg mat langs hele matkjeden og for miljøet
- VKM skal ikke gi råd eller ta stilling til hvordan risiko og annen kunnskap skal håndteres

VKMs kjerneverdier

- Vitenskapelig
- Tverrfaglig
- Uavhengig
- Åpen

Komiteen er delt inn i 13 faggrupper

- Mikrobiell økologi
- Hygiene og smittestoffer
- Plantehelse
- Plantevernmidler
- Tilsetningsstoffer, aroma, mat-emballasje & kosmetikk
- Fôr
- Forurensing, naturlige toksiner & medisinrester
- Handel med truede arter (CITES)
- GMO – mat og fôr
- GMO - legemidler
- Dyrehelse & dyrevelferd
- Biologisk mangfold
- Ernæring, dietetiske produkter, ny mat og allergi

VKM

VKM leverer vitenskapelige vurderinger i form av:

- Risikovurderinger
- Nytte- og risikovurderinger
- Kunnskapsoppsummeringer
- Andre vitenskapelige vurderinger og innspill

VKM

VKMs oppdragsgivere

- VKM gjør risikovurderinger og andre vitenskapelige vurderinger innen mattrygghet, matproduksjon og miljø på oppdrag fra Mattilsynet og Miljødirektoratet
- Oppdrag fra Direktoratet for medisinske produkter (DMP)
- Intensjonsavtale med Helsedirektoratet

Mattilsynet

Miljø-direktoratet

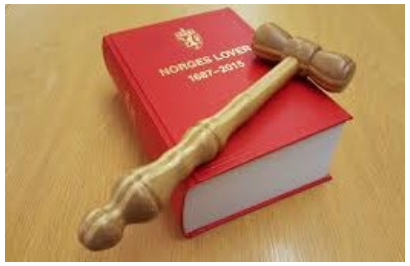
Direktoratet for medisinske produkter

Helsedirektoratet

Rammene for risikovurdering av GMO i Norge/EU

- Bruksområde(r) for søknaden i EØS-området

- Genteknologiloven
- Matloven



- EU-direktiv 2001/18
- EU-forordning 1829/2003
- **EFSAs retningslinjer**

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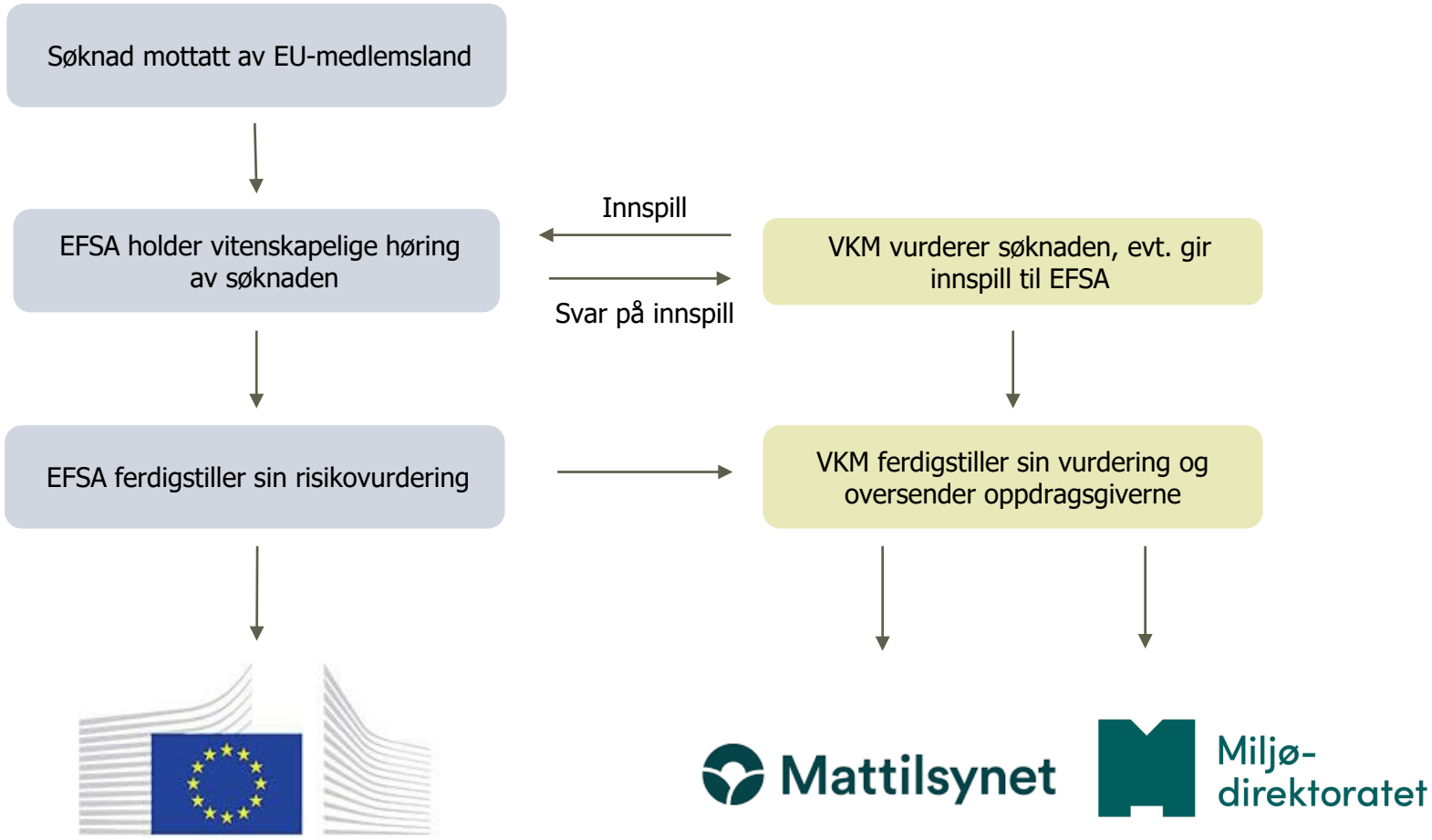
VKMs tilknytning til prosessen i EU



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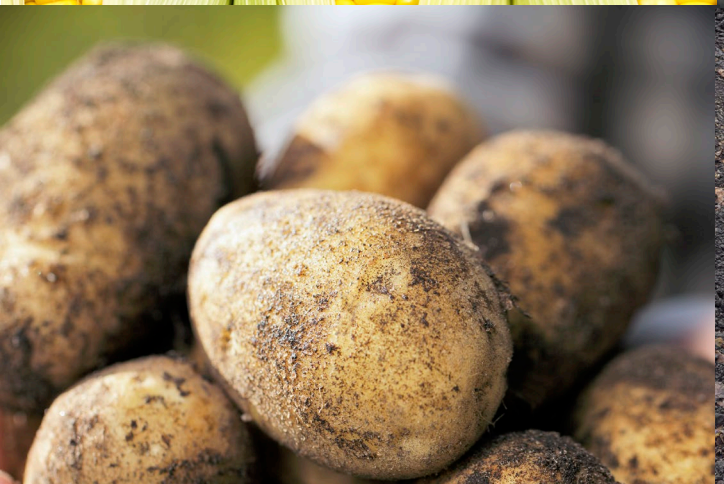
Løpende oppdrag

- Mattilsynet – 2004
- Miljødirektoratet - 2007
- ~250 GMO-søknader vurdert fram til i dag



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Nytt fellesoppdrag januar 2020

- Fokus på særnorske forhold
- Vektlegging av EFSAs vurdering

Helserisiko

Miljørisiko

Sameksistens for arter som kan dyrkes i Norge

VKM

Kunnskapsgrunnlaget for risikovurdering

- Søkers dokumentasjon
- **Uavhengig, vitenskapelig litteratur**
- Vitenskapelige kommentarer fra EFSA og andre EØS land
- Risikovurderinger og andre vitenskapelige vurderinger fra nasjonale og internasjonale organer

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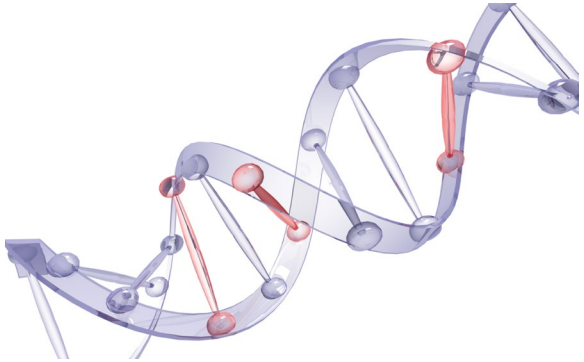
Vår vurdering av GMO-søknader

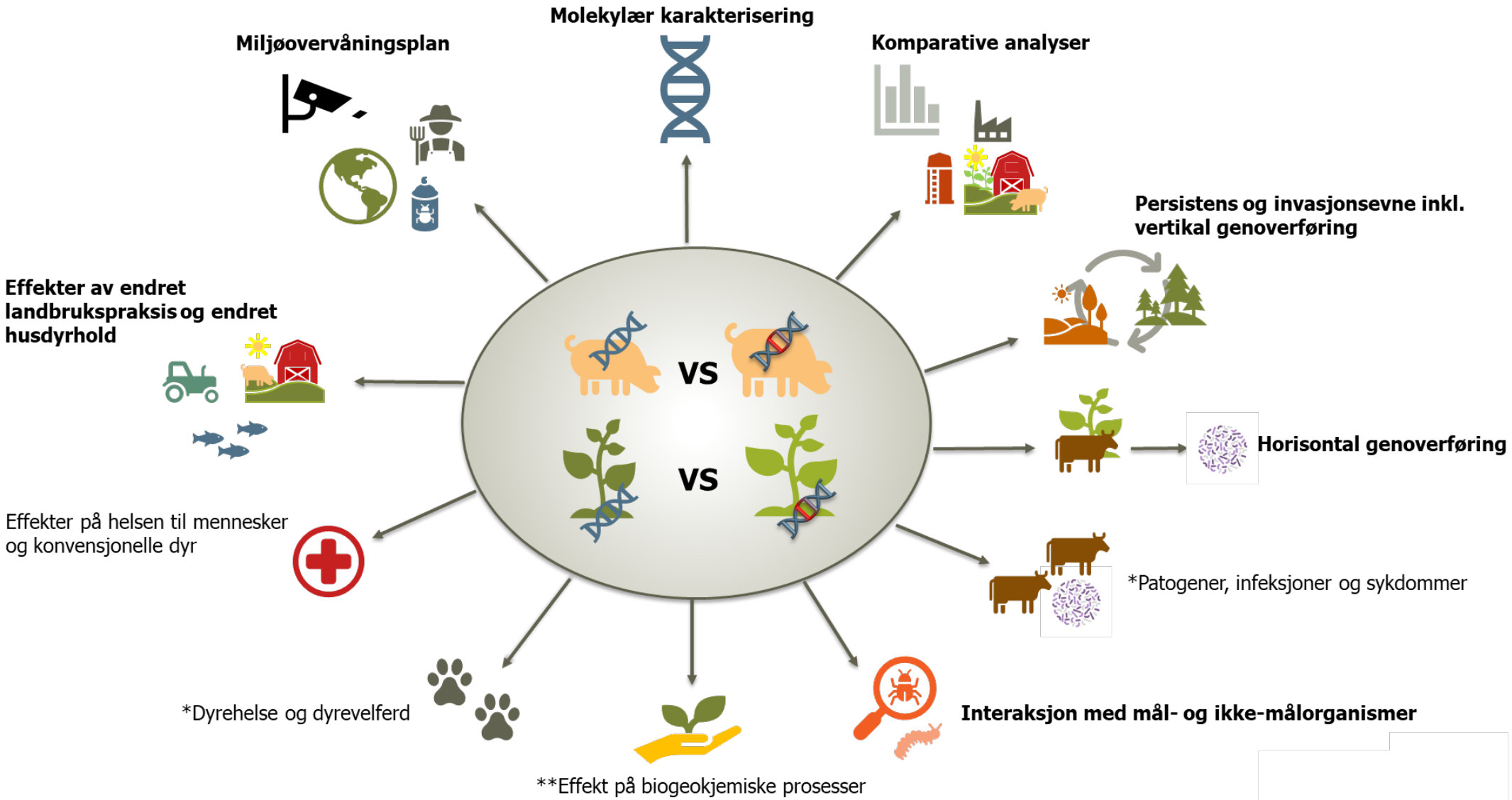


Molekylær karakterisering

Helserisikovurdering: Komparative analyser og toksikologiske analyser

Miljørisikovurdering: Komparative analyser og miljøeffekter

VKM



* Risikovurdering av genmodifiserte dyr, ** Risikovurdering av genmodifiserte planter.

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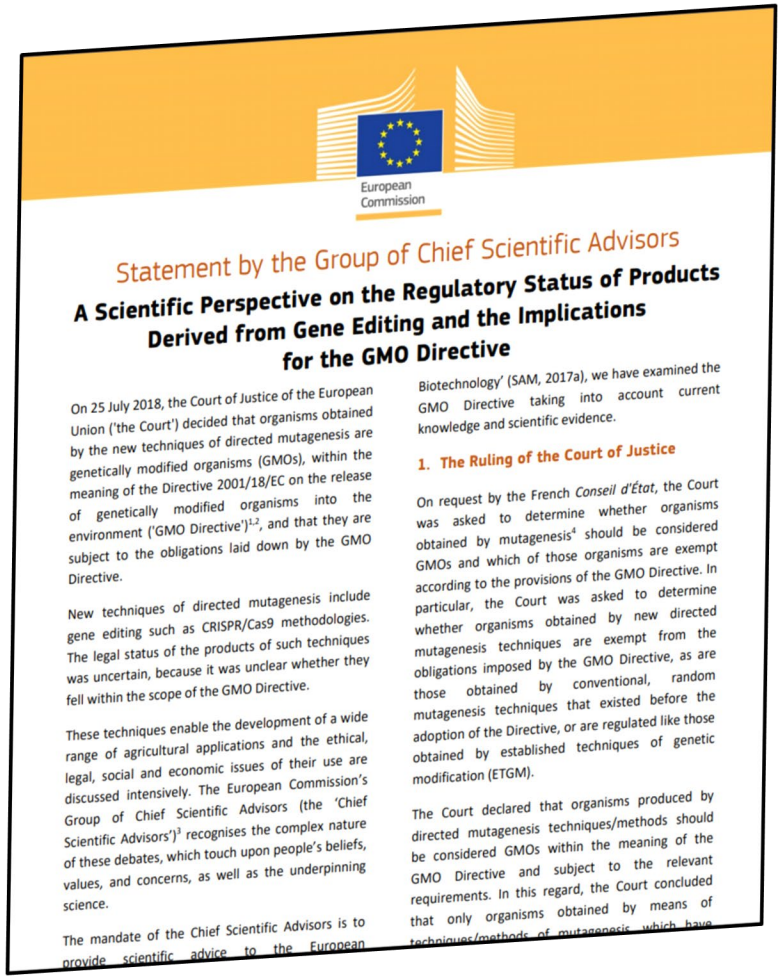
Europakommisjonen 25. juli 2018:

Organismer utviklet vha. genredigeringsteknikker er GMO



European Commission

Statement by the Group of Chief Scientific Advisors

A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive

On 25 July 2018, the Court of Justice of the European Union ('the Court') decided that organisms obtained by the new techniques of directed mutagenesis are genetically modified organisms (GMOs), within the meaning of the Directive 2001/18/EC on the release of genetically modified organisms into the environment ('GMO Directive')[1,2], and that they are subject to the obligations laid down by the GMO Directive.

New techniques of directed mutagenesis include gene editing such as CRISPR/Cas9 methodologies. The legal status of the products of such techniques was uncertain, because it was unclear whether they fell within the scope of the GMO Directive.

These techniques enable the development of a wide range of agricultural applications and the ethical, legal, social and economic issues of their use are discussed intensively. The European Commission's Group of Chief Scientific Advisors (the 'Chief Scientific Advisors')[3] recognises the complex nature of these debates, which touch upon people's beliefs, values, and concerns, as well as the underpinning science.

The mandate of the Chief Scientific Advisors is to provide scientific advice to the European

Biotechnology' (SAM, 2017a), we have examined the GMO Directive taking into account current knowledge and scientific evidence.

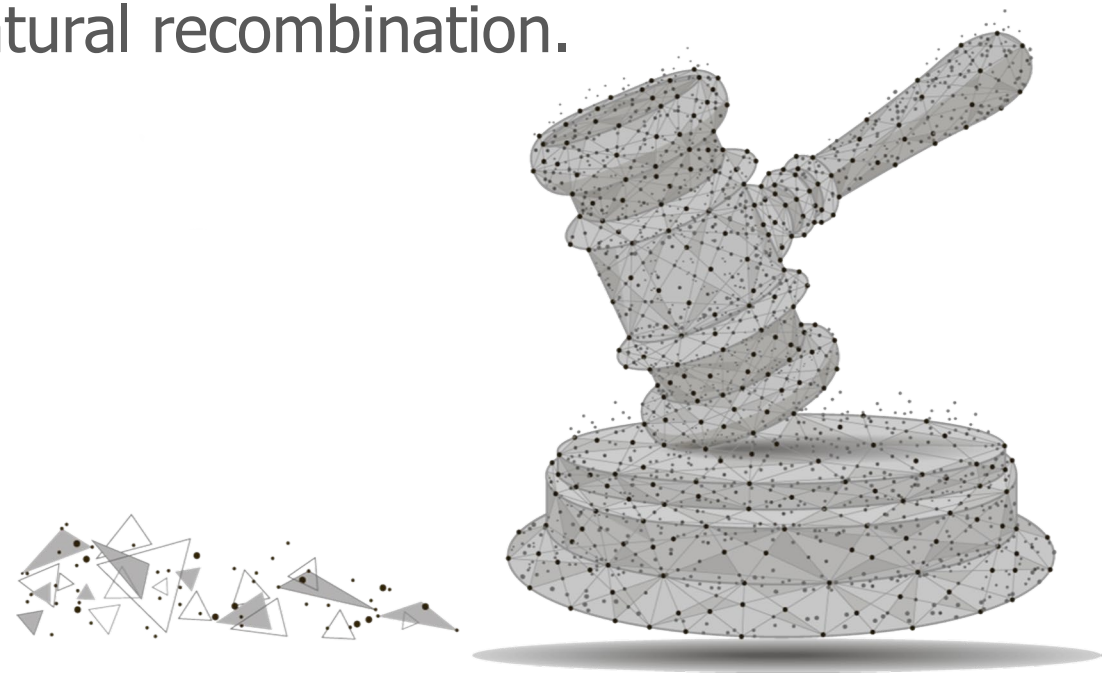
1. The Ruling of the Court of Justice

On request by the French *Conseil d'État*, the Court was asked to determine whether organisms obtained by mutagenesis[4] should be considered GMOs and which of those organisms are exempt according to the provisions of the GMO Directive. In particular, the Court was asked to determine whether organisms obtained by new directed mutagenesis techniques are exempt from the obligations imposed by the GMO Directive, as are those obtained by conventional, random mutagenesis techniques that existed before the adoption of the Directive, or are regulated like those obtained by established techniques of genetic modification (ETGM).

The Court declared that organisms produced by directed mutagenesis techniques/methods should be considered GMOs within the meaning of the GMO Directive and subject to the relevant requirements. In this regard, the Court concluded that only organisms obtained by means of techniques/methods of mutagenesis which have

GMO - is the acronym for Genetically Modified Organism.

According to EU legislation, it 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.



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Hva med risikovurdering av genomredigerte organismer?

Er EFSA sine veiledninger gode nok?

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Vitenskapskomiteen for mat og miljø

Norwegian Scientific Committee for Food and Environment

Genome editing in food and feed production – implications for risk assessment

Opinion of the Steering Committee of the Norwegian Scientific Committee for Food and Environment

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Takk for oppmerksomheten

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Vitenskapskomiteen for mat og miljø

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