

Erasmus  
School of  
Law

# The European Regulation of GEOS

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# EU-regulation on GMO's

## contained use

- Directive 2009/41/EG
- national regulations

## deliberate release/ field trials

- Directive 2001/18 part B
- national regulations

## placing on the market

- Directive 2001/18 part C
- Regulation 1829/2003
- Regulation 1830/2003 (traceability and labelling)

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# Placing on the market

- Directive 2001/18 part C
- Regulation 1829/2003, Regulation 1830/2003 (traceability and labelling)
- Directive 2015/412

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# GEOS= GMO?

## contained use

- Directive 2009/41/EG
- national regulations

## deliberate release/ field trials

- Directive 2001/18 part B
- national regulations

## placing on the market

- Directive 2001/18 part C
- Regulation 1829/2003
- Regulation 1830/2003 (traceability and labelling)

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# GMOs or not?

- Article D. 531-2 **French Environmental Code**:

The **techniques** referred to in Article L. 531-2, **which are not considered to give rise to genetic modification**, are the following: (...) 2 On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms:

(a) **mutagenesis**; (...)

- Annex I B **Directive 2001/18/EC**:

## **TECHNIQUES REFERRED TO IN ARTICLE 3**

**Techniques/methods of genetic modification yielding organisms to be excluded from the Directive**, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) **mutagenesis**,

(...).

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## Core of prejudicial questions

- Are products of mutagenesis GMOs within the meaning of Directive 2001/18 although they are exempt from the obligations of the Directive?
- (Or, alternatively, are they exempt *because* they are not GMOs?)
- Are products of all mutagenesis techniques, including directed mutagenesis techniques, exempt from the obligations of Directive 2001/18?

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## Answer EU Court

- Organisms obtained by mutagenesis are GMOs within the meaning of Directive 2001/18
- Only products of mutagenesis techniques '*which have conventionally been used in a number of applications and have a long safety record*' are exempt from obligations of Directive 2001/18



# Tight coupling ‘GMO’ and ‘genetic modification’

- Article 2(2) **Directive 2001/18/EC**:

“genetically modified organism (GMO)” 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.

Within the terms of this definition:

- (a) **genetic modification occurs at least** through the use of the techniques listed in Annex I A, part 1;
- (b) the techniques listed in Annex I A, part 2, are **not considered to result in genetic modification**;
- (...)

- Article 3(1) **Directive 2001/18/EC**:

This Directive shall not apply to organisms obtained through **the techniques of genetic modification** listed in Annex I B.

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## Three tastes (not two)

- Techniques that result in GMOs and are therefore subject to the obligations of Directive 2001/18
- Techniques that do not result in GMOs and are therefore not subject to the obligations of Directive 2001/18 (Annex I A part 2)
- Techniques that result in GMOs but are nevertheless exempt from the obligations of Directive 2001/18 (Annex I B)

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# Expectations of the Court-decision

- Do techniques of **directed mutagenesis** lead to GMOs?
- distinction between GMOs and GEOS

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## Options after Court ruling (I)

- Changing legislation; initiatives are being taken, will they receive sufficient support?
- Employing possibilities for research and development under contained use?
- Attempting to attain status of 'use in a number of applications and having a long safety record' through field trials under national legislation?
- Or escape route closed after new prejudicial questions about discrepancy between regulations and Directive 2001/18 (products of mutagenesis are GMOs)?

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