

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



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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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