université de Caen Basse-Normandie

Caen
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# Lacks and possible improvements in European Union law concerning GMOs


**Marie-Pierre BAUDIN-MAURIN**
marie-pierre.baudin-maurin@unicaen.fr

Private Law Research Center

Law Department

**Jean-Michel PANOFF**
jean-michel.panoff@unicaen.fr

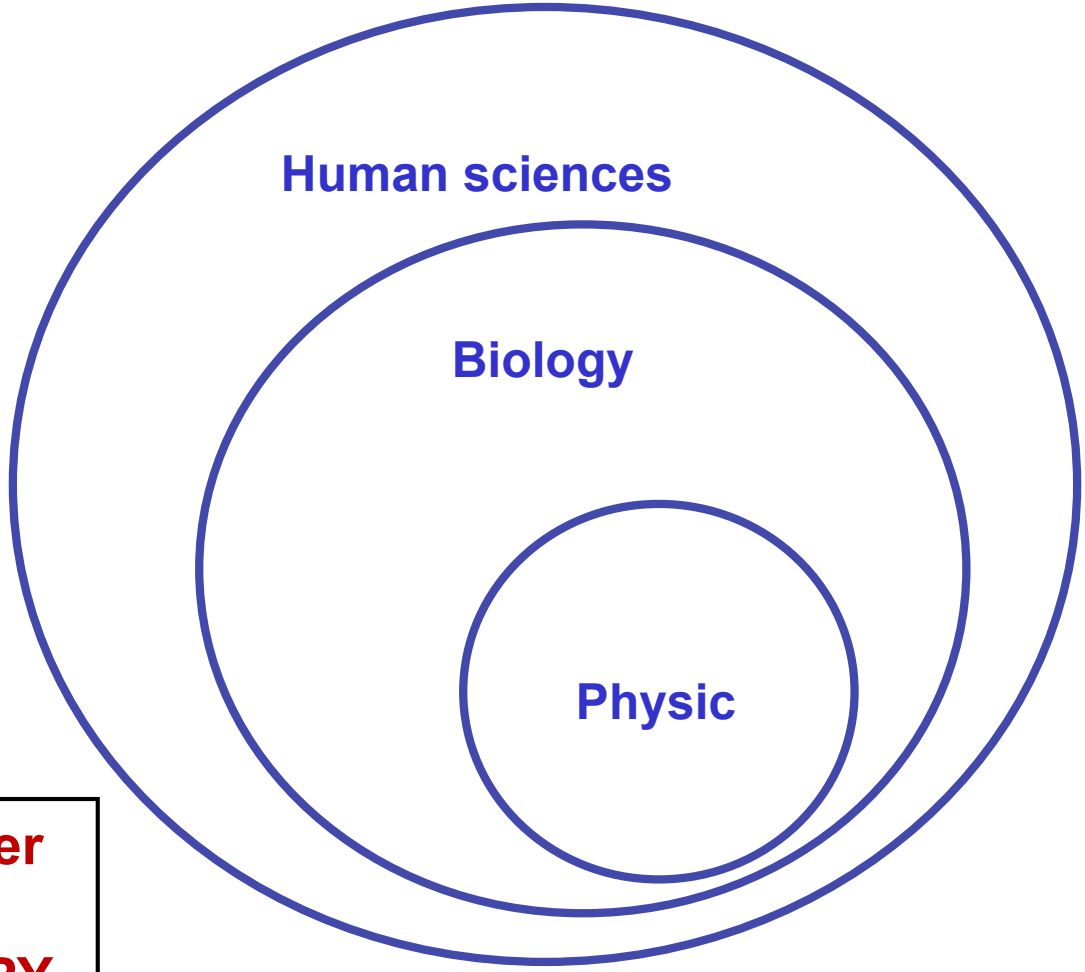
Dairy and Food Microorganisms Laboratory

Institute of Biology - IFR 146 ICORE

Multidisciplinary Center on Risks, Human Sciences Institute

CRIIGEN Committee for Research and Independent Information on Genetic Engineering

# A global approach of knowledge (from Morin, 1990)




**We can probably reach a better sustainable environment by increasing MULTIDISCIPLINARY or even TRANSDISCIPLINARY assessment of the European Union laws**

**Directive 2001/18/EC**
**of the European Parliament and of the Council of 12 March 2001**
**on the deliberate release into the environment of genetically modified organisms**
**Repealing Council Directive 90/220/EEC**
***OJ L 106, 17.4.2001, p. 1–39***

**Directive 2009/41/EC**
**of the European Parliament and of the Council of 6 May 2009**
**on the contained use of genetically modified micro-organisms**
**Recasting Directive 90/219/EEC**
***OJ L 125, 21.5.2009, p. 75–97***

# Analyze and suggest improvements

1. **Comparative approach :**

**Evolution of some major definitions**

**2. Specific approach :**

**Necessity to notice some major exemptions**

**The Annex II, Part A, Section 4 from the Directive 2009/41/EC**

# What is a genetically modified organism (GMO) ?

**(90/220) Article 2 For the purposes of this Directive:**

**"genetically modified organism (GMO) :**

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

**(2001/18) Article 2 For the purposes of this Directive:**

**"genetically modified organism (GMO) :**

**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".**

# What is a micro-organism ?

**(90/219)** **Article 2** **For the purposes of this Directive:**

**"micro-organism :**

**any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material".**

**(2009/41)** **Article 2** **For the purposes of this Directive:**

**micro-organism :**

**any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture.**

# Analyze and suggest improvements

1. Comparative approach :

Evolution of some major definitions

**2. Specific approach :**

**Necessity to notice some major exemptions**

**The Annex II, Part A, Section 4 from the Directive 2009/41/EC**

**Article 3**

**(…/…) this Directive shall not apply:**

**-where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A (…/…)**

**ANNEX II PART A**

**Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Directive (…/…)**

Section 1.

Section 2.

Section 3.

**Section 4**.

**ANNEX II PART A Section 4**

**Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.**

**Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.**

## ANNEX II PART A Section 4

**Self-cloning consisting in the removal of nucleic acid sequences from a cell (…/…) which may (…/…) be followed by reinsertion of (…/…) that nucleic acid (or a synthetic equivalent) (…/…) into cells of the same species or into cells of phylogenetically closely related species (…/…) where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.**

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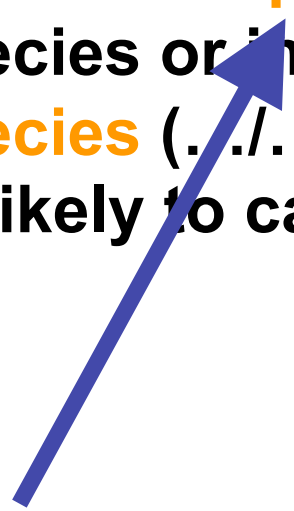

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## ANNEX II PART A Section 4

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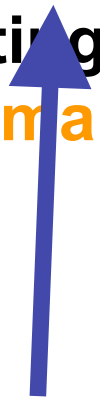
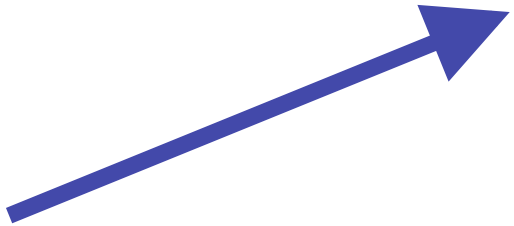


**Frederick M. Cohan (2002)**
**What are bacterial species ?**
***Annu Rev Microbiol* 56:457-487**

**« Bacterial systematic has not yet reached a consensus for defining the fundamental unit of biological diversity, the species »**

**ANNEX II PART A Section 4**

**Self-cloning consisting in the removal of nucleic acid sequences from a cell (…/…) which may (…/…) be followed by reinsertion of (…/…) that nucleic acid (or a synthetic equivalent) (…/…) into cells of the same species or into cells of phylogenetically closely related species (…/…) where the resulting micro-organism is *unlikely to cause disease* to humans, animals or plants.**



**Micro-organisms…**

## ANNEX II PART A Section 4

**Self-cloning may include the use of recombinant vectors with an *extended history of safe* use in the particular micro-organisms.**

***1.May / Can / Must biologists assess the juridic value of the European legislation related to genetic engineering***
***?***

***2. May / Can / Must lawyers assess the scientific value of the European legislation related to genetic engineering***
***?***

# CONCLUSION 1/3

**Some Genetically Modified Organisms can be excluded from the Directive 2009/41/EC and finally be used in open environments according to scientifically subjective and doubtful criteria**

# CONCLUSION 2/3

**Numerous scientific ambiguities in European Legislation raise the problem of the competence level and/or deontological behavior of the scientists who advised the lawyers in the drafting of the directives**

# CONCLUSION 3/3

**According to Directive 2001/18/EC, *"living organisms, […] released into the environment may reproduce […]. The effects of such releases on the environment may be irreversible."* *(introductory Whereas 4)***

**That's why *"the precautionary principle had been taken into account"*, pursuant to *this Directive.* (*introductory Whereas 8)***

**We really have to hope so, because according to Directive 2009/41/EC, *"the precise nature and scale of risks associated with […] GMMs are not yet fully known."* *(introductory Whereas 9)***

# ARKIVES

**Council Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms**

| | |
|---|---|
| 90/219/EEC | : Directive |
| 91/448/EEC | : Decision |
| 94/51/EC | : Decision |
| 96/134/EC | : Decision |
| 98/81/EC | : Directive |
| 2000/608/EC | : Decision |
| 2001/204/EC | : Decision |
| 2005/174/EC | : Decision |