

NTBs in EU food law; possible interpretations and consequence of the EU court case

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Overview

- NBTs in EU food legal requirements
 - Novel Foods Regulation
 - GMO package
 - Pending preliminary procedure

Novel Foods (Reg. 2283/2015, Art. 3)

Novel food: not used for human consumption to a significant degree within EU before 15 May 1997 that falls under one of the following categories:

(iv) food consisting of, isolated from or **produced from plants** or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

— traditional propagating practices which have been used for food production within the Union before 15 May 1997; or

— **non-traditional propagating practices** which have not been used for food production within the Union before 15 May 1997, where those practices do **not give rise to significant changes** in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

Propagating?

- Previous text: foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional **propagating or breeding** practices and having a history of safe food use
- Logic: propagating does not create anything new → read 'breeding'

Novel foods

- Require authorisation
 - Criteria; safety, not misleading, not nutritionally disadvantageous
- Dossier by applicant
- Risk assessment by EFSA
- Authorisation is generic
 - → for the product, not (just) the applicant)

In between conclusion

- Products derived from NBTs need authorisation as novel foods
 - Except: when there are no **significant changes** in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances
- Or, are under GMO legislation

Authorisation requirements

- Novel foods
 - Burden but less politicised
 - Possible alleyway to open discussion in legal status
- GMO
 - Burden
 - Heavily politicised
 - Limited chance on authorisation
 - No chance on public acceptance

Art. 2(2) NFR

- This Regulation does not apply to: (a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003

- Do NBTs give rise to GMOs?

GMO

- Reg. 1829/2003, Art. 2(5): 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC

Dir. 2001/18 Art. 2(2)

'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;

Dir. 2001/18 Art. 3(1) & Annex

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

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**

Case C-528/16

- Preliminary question lodged by conseil `d état 17-10-2016
- Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre France, Collectif vigilance OGM et Pesticides 16, Vigilance OG2M, CSFV 49, OGM : dangers, Vigilance OGM 33, Fédération Nature et Progrès v. Premier ministre, Ministre de l'agriculture, de l'agroalimentaire et de la forêt
- → No parties engaged in NBTs involved in formulating the questions

4 questions, among which

1) Do organisms obtained by mutagenesis constitute genetically modified organisms within the meaning of Article 2 (...) although they are exempt under Article 3 of and Annex IB (...) from the obligations laid down for release and placing on the market of genetically modified organisms? In particular, may mutagenesis techniques, in particular new directed mutagenesis techniques implementing genetic engineering processes, be regarded as techniques listed in Annex IA, (...) Consequently, must Articles 2 and 3 of and Annexes IA and IB to Directive 2001/18 of 12 March 2001 be interpreted as meaning that they **exempt** from precautionary, impact assessment and traceability measures all organisms and seeds obtained by mutagenesis, or **only organisms obtained by conventional random mutagenesis methods** by ionising radiation or exposure to mutagenic chemical agents existing before those measures were adopted?

- I.e. is targeted mutagenesis **hidden GMO**?

Missing question

- Does mutagenesis (do NBTs) create organisms in which the genetic material has been **altered in a way that does not occur naturally** by mating and/or natural recombination?
- I.e. to what refers '**altered in a way that does not occur naturally**'
 - To the result?
 - To the process?

Relevance of the missing question

- The answer is not obvious, but very important
- When criterion applies to the process: all current NBTs legally result in GMOs (that may be exempted)
- When the product criterion applies for many cases of NBT is can be argued that legally they do result in GMOs
 - Directive no applicable → exemptions not applicable

What happens next?

- Member State can take a position
- Court grants parties opportunity to plead their case
- Court decides about asking opinion of Advocate-General
 - AG researches the issue
 - AG publishes opinion
- Court considers the case & answer questions to Conseil d'état
- Ruling is published
- Conseil decides underlying case

The way forward

- Can the Court still answer the missing question?
 - Reading into the first sentence: 'Do organisms obtained by mutagenesis constitute genetically modified organisms'
 - Derive from logic
- Can the Court be convinced to do it?
- Publish!
 - Describe the issue in a clear and accessible way
 - Add to the body of knowledge the AG analyses

Thank you for your
kind attention

Q&A

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