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French agency for food, environmental and occupational health & safety
Investigate, evaluate, protect

Comments on the draft scientific opinion on genome editing

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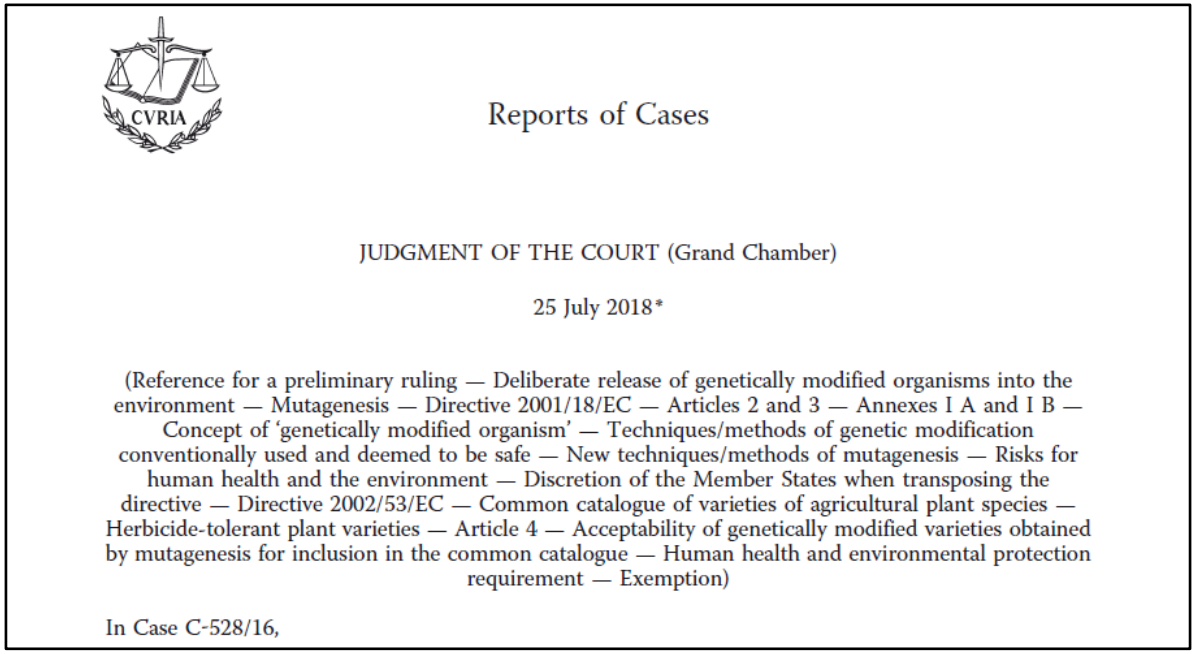
11th Meeting of the EFSA Scientific Network on Risk Assessment of GMOs
3 July 2020, tele-meeting

Scope



CVRIA

Reports of Cases

JUDGMENT OF THE COURT (Grand Chamber)

25 July 2018*

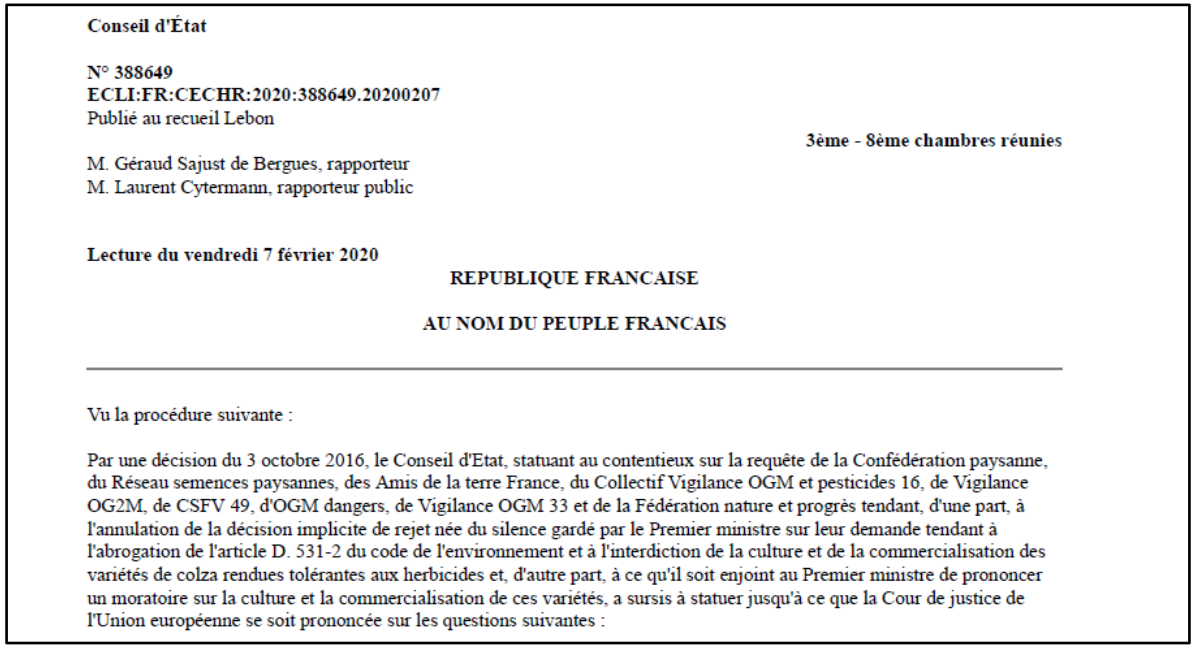
(Reference for a preliminary ruling — Deliberate release of genetically modified organisms into the environment — Mutagenesis — Directive 2001/18/EC — Articles 2 and 3 — Annexes I A and I B — Concept of 'genetically modified organism' — Techniques/methods of genetic modification conventionally used and deemed to be safe — New techniques/methods of mutagenesis — Risks for human health and the environment — Discretion of the Member States when transposing the directive — Directive 2002/53/EC — Common catalogue of varieties of agricultural plant species — Herbicide-tolerant plant varieties — Article 4 — Acceptability of genetically modified varieties obtained by mutagenesis for inclusion in the common catalogue — Human health and environmental protection requirement — Exemption)

In Case C-528/16,

Judgement of the Court of Justice of the European Union (case C-528/16):

- Paragraph 54: Only organisms obtained by means of techniques/methods of mutagenesis which have **conventionally been used** in a number of applications and have a **long safety record are excluded** from the scope of that directive.
- Paragraphs 47 and 51: Article 3(1) of Directive 2001/18 […] **cannot be interpreted as excluding** […] organisms obtained by means of new techniques/methods of mutagenesis **which have appeared or have been mostly developed since Directive 2001/18 was adopted**.

Scope



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3ème - 8ème chambres réunies

M. Géraud Sajust de Bergues, rapporteur
M. Laurent Cytermann, rapporteur public

Lecture du vendredi 7 février 2020

REPUBLIQUE FRANCAISE

AU NOM DU PEUPLE FRANCAIS

Vu la procédure suivante :

Par une décision du 3 octobre 2016, le Conseil d'Etat, statuant au contentieux sur la requête de la Confédération paysanne, du Réseau semences paysannes, des Amis de la terre France, du Collectif Vigilance OGM et pesticides 16, de Vigilance OG2M, de CSFV 49, d'OGM dangers, de Vigilance OGM 33 et de la Fédération nature et progrès tendant, d'une part, à l'annulation de la décision implicite de rejet née du silence gardé par le Premier ministre sur leur demande tendant à l'abrogation de l'article D. 531-2 du code de l'environnement et à l'interdiction de la culture et de la commercialisation des variétés de colza rendues tolérantes aux herbicides et, d'autre part, à ce qu'il soit enjoint au Premier ministre de prononcer un moratoire sur la culture et la commercialisation de ces variétés, a sursis à statuer jusqu'à ce que la Cour de justice de l'Union européenne se soit prononcée sur les questions suivantes :

⇨ Page 3, lines 73-76 of the draft scientific opinion, proposal to rephrase as follows: "The judgement of the Court of Justice [...] has clarified that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of Directive 2001/18/EC. The exact list of techniques that meet this criteria is not yet established, but it can be anticipated that SDN-1, SDN-2, and ODM techniques ("new mutagenesis techniques"), which have appeared or have been mostly developed since Directive 2001/18 was adopted, will come within the scope of that directive."

Presence or not of the SDN module in the final product

• “No new hazards as compared to both SDN-3 and conventional breeding”: this is true as long as the **absence of effectors** (DNA, RNA, protein) has been **demonstrated**.

• “Both transient and stable expression of the SDN can be used”: this doesn't take into account the cases where the **nuclease activity** is **introduced as mRNA or directly as protein**.

• “In the case of stable integration of the SDN genes, they can subsequently be removed by segregation.” […] “The SDN module can be removed by segregation. This step is not possible in case of non-sexually propagated crops.”: the **transient expression** of the SDN will have to be **demonstrated**, as well as the **removal of the SDN genes by segregation** in case of their stable integration. **When** this removal is **not feasible**, the associated **potential hazards need to be studied**.

Off-target effects: a question set aside too quickly

• Brief literature review: some techniques are poorly documented and even when studies exist, there is **not yet a scientific consensus**.

• "Whilst the SDN-3 technique can induce off-target changes in the genome of the recipient plant, these would be fewer than those occurring with most mutagenesis techniques. Furthermore, where such changes occur, they would be of the same types as those produced by conventional breeding techniques.":
References or analysis needed.
Not enough to exclude new hazards, which need to be studied.

• "In case of ODM, although very limited amount of information on the mechanisms and frequency of off-target effect is available in the literature, it is reasonable to assume that the same conclusions also apply since this technology is based on sequence-specific site recognition as for SDN-based methods.": **the lack of information available in the literature does not mean that off-target effect does not exist or that its occurrence is very low**.

Off-target effects:

- **Presence or not in the final product?**

"Backcrossing following the transformation process will remove these potential off-targets from the final product, except for those that are genetically linked to the intentionally modified locus":
Non-sexually propagated crops not considered.
Removal should be demonstrated.

- **How to characterise the final product?**

"The GMO Panel considers that the existing Guidance for risk assessment of food and feed from genetically modified plants (EFSA GMO Panel, 2011) and the Guidance on the environmental risk assessment of genetically modified plants (EFSA GMO Panel, 2010) are sufficient": this is **not true for the analysis of potential off-target effects**.

⇨ **Proposal to use whole genome sequencing (WGS)**, especially for the introduction of point mutations.

⇨ **Research efforts needed** to develop methods and tools for the identification of off-targets even in the most complex cases.