

ECJ ruling: will 'GMO 2.0' be introduced to Europe's fields through the back door?

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When and what is the ruling, and why does it matter?

On July 25 the European Court of Justice (ECJ) will rule whether a new generation of genetically modified seeds and foods – so-called 'GMO 2.0' – should be fully regulated as GMOs (C 528/2016).[1]

<u>The case</u> was referred to the ECJ by the French Conseil d'État, after French organisations including Les Amis de la Terre/Friends of the Earth France filed it at the national level.

If the court's ruling follows its Advocate General's opinion as expected, it is likely to suggest that most food and crops derived from these new genetic engineering techniques would be classified under the EU legal definition of GMOs. [2]

However, this doesn't automatically mean that they will be subject to the same safety laws that cover most existing GMOs – potentially allowing GMO 2.0 crops and food to be grown and consumed without safety checks or consumer labelling in the EU.

What are these new GMO 2.0 techniques?

The new genetic engineering techniques modify genetic material in plant or animal cells in a way that does not occur naturally with conventional plant breeding. These modifications of the genome can result in the same unintended changes in cells as existing GM techniques, raising the same questions about risks to the environment and human health. Some of these techniques are relatively well-known such as CRISPR, but the ruling also covers others such as TALEN and ZFNs.

At the moment the only crop grown with these new techniques is cultivated in the USA: a strain of herbicide-resistant oil-seed rape. Soybean, maize and potato strains are in the pipeline. The USA does not regulate GM plants on the basis that they are genetically modified. While often developed by start-ups and universities, the six largest biotech companies own more than 70% of GMO 2.0 patents and licenses.

What is the court likely to rule?

At present, some older seed breeding techniques are exempt from EU GMO laws. These older 'mutagenesis' techniques – where plants are subjected to chemical or radiation stress – have been exempt since the EU's main GMO law was passed in 2001. [3]

The court ruling will mainly be about the scope of the exemptions: will some or all of the new GMO 2.0 techniques be exempt, or will only older mutagenesis techniques continue to be left unregulated?

Depending on the ruling, there are three possible scenarios.

- a) **Full regulation.** The ECJ rules that new GMO 2.0 techniques must be fully regulated under existing law. This means safety checks, labelling and traceability across the board.
- b) Changing the definition of GMOs. The ECJ rules that the current definition of GMOs in EU law has gaps and needs updating, and recommends that the European Commission does so. This would mean an interim period where it is vital that the European Commission and national regulators ensure that import controls and authorisations of GMO 2.0 should be prohibited or dealt with under current GMO laws, to avoid hidden dissemination of seed supplies, food and the wider environment.
- c) Some GMO 2.0 exemptions. The ECJ rules that some (but not all) of the new GM techniques are classified as producing GMOs, but would be exempted from the GMO safety law. This would mean GMO 2.0 would be able to be grown in the EU without labelling, traceability and authorisation processes.

What will each mean for the future of the food and farming sector?

Scenario a) all GMO 2.0 must be fully regulated under existing GMO law. The EU's food safety and traceability standards are maintained.

Scenario b) the European Commission and national regulators must speak up immediately after the ruling and make it clear that GMO 2.0 crops will be regulated under existing GMO law. Not doing so would mean regulatory chaos in the food sector.

If they are fully regulated they can be tested for their safety, monitored, and, in an emergency, withdrawn from the food chain. Authorities need full GM traceability to fulfil their role to implement food laws. Any lack of regulation would result in market distortions for conventional and organic food markets and undermine the established market for GM-free food and agriculture in the EU. If they were to escape EU regulations, any potential negative effects on food, feed or environmental safety would go unchecked. European consumers, farmers and breeders would have difficulties avoiding GMOs.

After over a decade of investment to avoid GM ingredients in supply chains and providing full transparency on GMOs, inaction would put the entire food sector in the EU at risk.

Scenario (c) the European Commission and national regulators must clarify immediately after the ruling the steps they will take to ensure that GMO 2.0 crops will be regulated under existing GMO law. Not doing so would mean regulatory chaos in the food sector (see above under b).

Friends of the Earth Europe calls for:

 Sensible safety checks in the public interest: these new GM 2.0 techniques should be subject to the same safety checks as existing GMOs to ensure public health and the environment are protected. EU GM rules are process-based, meaning that even if a specific GMO cannot be detected in a food product, it must still be defined as GM food. Safety tests must take into account that these techniques are still imprecise and the outcomes are not completely predictable or controllable.

- Protecting nature and non-GM food and farming: sustainable food and farming, as well as biodiversity and natural resources, must be protected from any possible contamination from unproven and possibly irrecoverable technologies such as GM 2.0. Our countryside and food should not be a place for agribusiness to experiment.
- **Applying the rules:** The EU has clear science-based policy to regulate GMO safety. These laws generally work, and we should apply them to the crops produced using the new GM techniques.

Notes

- [1] Case C-528/16 on the European Court of Justice website >> http://bit.ly/gmo20case
- [2] http://www.foeeurope.org/ecj-opens-back-door-new-gmos-180118
- (3) Article 3 (annex 1 B) of the EU GMO safety law defines which existing techniques are exempted https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001L0018



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