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FIZ Karlsruhe at a Seminar on the New EU Regulation on NGT Plants

27.08.2026 — **Who owns a plant whose genetic blueprint comes from a database? How do you regulate a product that can no longer be distinguished analytically from a conventional one? And what role do public registries, databases, and reliable information infrastructures play as plant breeding, innovation, and the law become increasingly intertwined?**

New genetic engineering techniques such as CRISPR/Cas allow for targeted interventions in the genetic material of plants that are fast, precise, and carried out at a fraction of the previous cost. This brings traits such as drought tolerance, disease resistance, or reduced need for pesticides within reach even for smaller breeding companies and public research institutions. At the same time, the starting point of value creation is shifting, because breeders now work primarily with genomic information.

Legally, this raised two issues. First, such plants were previously considered genetically modified organisms (GMOs) without exception and had to undergo a complex and costly approval process, even though the result is often indistinguishable from a conventionally bred or naturally occurring plant. For smaller companies and public research institutions, this hurdle was often prohibitive and hindered innovation. Second, even interventions affecting only a few base pairs can be patented, even though the same change can also occur naturally. This raises the question of how far exclusive rights should extend and what that means for access to seeds.

Against this backdrop, **Regulation (EU) 2026/1388 on plants derived from new genomic techniques (NGT)** was adopted a few weeks ago. It distinguishes between two categories. NGT-1 plants are considered equivalent to conventional plants and undergo only a simplified verification procedure involving entry into a public database. They are not specially labeled for end consumers. NGT-2 plants, which exhibit more extensive modifications, remain subject to the stricter authorization procedure under genetic engineering law, including risk assessment, traceability, and labeling.

When it comes to patents, the regulation emphasizes transparency. Anyone applying for the classification of an NGT-1 plant must disclose which patents and published patent applications are involved, and this information is made available through the public database. Additionally, applicants may declare their willingness to license the protected subject matter under fair and reasonable terms. The database thus serves as a clearinghouse.

But what exactly does the new regulation govern? What are its strengths and weaknesses for the agricultural and food industries and for agricultural innovation? How does Europe's approach compare to NGT regulations in other countries? These questions were discussed on July 27 at the **Universitat Politècnica de València** (Spain) during **a seminar on the new regulation** organized by Prof. Dr. Felipe Palau Ramírez of the Universitat Politècnica de València and Prof. Dr. Juan Antonio Vives Vallés of the Universitat de les Illes Balears.

Our research fellow, **Dr. Pedro Henrique D. Batista**, participated in the conference as a commentator on the individual panels and summarized the event's conclusions at the end. His assessment is nuanced. In addition to adjustments to the GMO authorization procedure, the regulation largely governs information—specifically, public registries, transparency requirements regarding patents, and traceability along the supply chain. Freedom of action does not begin with the patent, but rather with lawful access to genetic information. However, it remains unclear exactly where the line between the two categories lies, what binding effect the commitment to fair and reasonable licensing terms has, and how requirements can be enforced if NGT-1 plants are not analytically detectable. This does not speak against the regulation, but it does show how much will depend on its implementation.

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