Nertila Kuraj, *PhD*
Postdoctoral Researcher, UC Berkeley Law
nkuraj@berkeley.edu

The Raise of Crispr in the Agritech Sector; Cutting Deeper in the EU-US Regulatory Divide.

Crispr, a primitive immune system common in prokaryotes, earned "the biggest biotech discovery of the century" status with the publication of Doudna and Charpentier's 2012 paper on how to harness its function as a genetic engineering technology to edit the genome of living organisms. Since then, Crispr has been combined with other emerging technologies, chiefly nanotechnology and DNA sequencing and synthetizing (including synthetic biology) to offer "*subtlety*, *speed* and a *high degree of control* over the outcome" in gene-editing.

But if the application of Crispr to the human genome is characterised by a cautionary approach and the weighting of attendant ethical and regulatory considerations (particularly in human germline genome editing), its use in the area of gene-editing for environmental purposes appears relatively unconstrained. This area encompasses primarily the *agritech sector*, where Crispr is used to obtain pest- and disease resistant or more nutrient crops. The FDA has signalled that it will not impose specific regulatory requirements on Crispr-edited plants (e.g. the white mushroom case), in line with the existing US *product-based* approach to GMOs. However, the EU, in line with its own *process-based* approach to GMO regulation, ruled in 2018 that plants edited with Crispr will have to comply with its GMO laws. Hence, the hopes that the EU would relax its highly precautionary approach to the approval of GMOs for Crispr'd crops dashed with the 2018 CJEU ruling, which indicates also that the old product-process divide is likely not only to remain but to intensify.

As it will be shown in this paper, the deepening of this divide will become even more pronounced in the case Crispr'd animals. While the only transgenic animal authorised for human consumption in the US, the AquAdvantage salmon (which the FDA regulates under the *animal-drug* category), produced by AquaBounty Inc., predates Crispr, the company was quick to applying Crispr to the production of *tilapia* fish in order to promote muscle growth that yield bigger fish filets. The case of the Crispr'd *tilapia* might be different, as no foreign DNA material is used to obtain the modified fish. This is precisely why it is currently being commercialised in Argentina, *without* special regulatory requirements.

Yet, in the EU, the transgenic salmon would need to undergo a safety assessment by EFSA, and, following the CJEU's ruling on Crispr'd plants, the tilapia too. Based on the EFSA assessment, the EU Commission can decide on whether to authorise the fish for human consumption.

Against this background, Crispr's use in the agritech sector is likely to cut deeper in the old divide between the two jurisdictions. This paper explores the evolution of the concepts of *risk*, *uncertainty* and *precaution* in regulatory science in the Crispr-era. It contends that if an unsurmountable polarisation between the EU and the US on Crispr use in the agritech sector is to be averted, dialogue about the role of such concepts in the regulatory approaches in both countries is imperative.