

Why the regulation of gene editing will not hurt small and medium size companies (SMEs)

Michael Antoniou, PhD
King's College London

Claire Robinson, MPhil
Editor, GMWatch.org



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The push for de-regulation

- Proponents of new genetic modification techniques such as gene editing are trying to weaken or abolish the EU's GMO regulations to allow easier market access for gene-edited crops and foods.
- They say de-regulation will open the market to small and medium size enterprises (SMEs), which will democratise GM and end the monopolistic domination of big agrochemical companies like Monsanto/Bayer.
- **This is highly doubtful because ...**

Most startups fail – and not because of regulation

- Only 10% of all startups succeed (Forbes, 2015)
 - Biotech startups have it harder – even smaller percentage succeed
 - Why? According to article on biotech industry platform Labiotech.eu (2020), reasons are:
 - ✧ Flawed financial strategy (failure to attract right investment)
 - ✧ Inexperienced management
 - ✧ Mediocre science
- “Excessive regulation” doesn’t come into it

Gene-edited crops won't be easier to generate or cheaper to market

- With first-generation GM crops, the cost of bringing a GM trait to market between 2008 and 2012 was US\$136 million.
- Only 25% of that cost went to meeting regulatory requirements – the rest was research and development costs.
- Gene editing won't change that because the generation of candidate edited plants will take a similar input of resources and time.
- Additional costs are massive licensing and royalty fees paid to the CRISPR base patent holders – Dr Antoniou will talk about this.

Gene editing won't change the biotech business model

- Dr Antoniou has years of experience of developing biotech products in medical research with SMEs and larger companies, and holds inventor status on patents.
- Same gene-editing technology used in medical applications is also used in plant/livestock animal applications.
- He will explain why gene editing won't change the biotech business model.

Sample of Potential Licensing Needs for CRISPR-Cas9 in Eukaryotes

University of California/Charpentier

The Broad Institute/MIT/Harvard

Vilnius University

In vitro Cas9-guide RNA complex (“RNP complex”)

General Hospital Corporation (Partners Healthcare)

SpyCas9 gRNAs with increased specificity; dCas9-Fok1 fusion proteins; other SpyCas9 and SaCas9 variants

MilliporeSigma

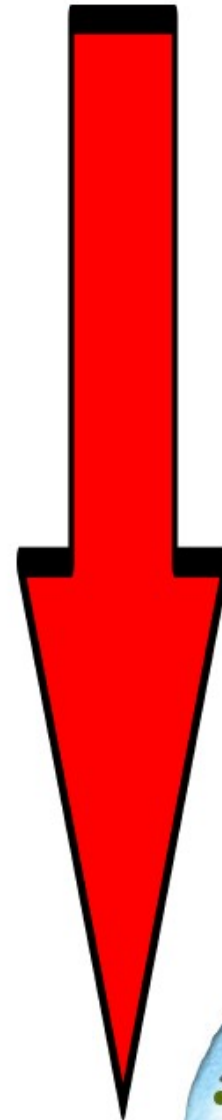
Methods for integrating a donor sequence in a chromosome

Sangamo Therapeutics, Inc.

SpyCas9/sgRNA complex with increased binding specificity; CRISPR Cas/sgRNAs for cleavage and inactivation of T cell receptor (TCR) and/or HLA genes

Collectis

Method of preparing genetically modified T cells for immunotherapy using an RNA-guided endonuclease (expressed from transfected mRNA) and a specific guide RNA (expressed as a transcript from a DNA vector)



Who controls CRISPR in agbiotech?

- According to Testbiotech, agribiz giant DowDupont controls large parts of the seed market through a patent cartel on CRISPR gene-editing technology.
- DowDupont (with its agribiotech sector Corteva) has allegedly signed contracts with all the important owners of base patents on CRISPR/Cas technology.
- DowDuPont has combined 48 patents on the most basic tools in one patent pool. According to DowDupont, access to such a high number of patents is necessary in order to apply the technology in plant breeding to its full extent.

