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GM and gene-editing - how to distinguish the hype from reality

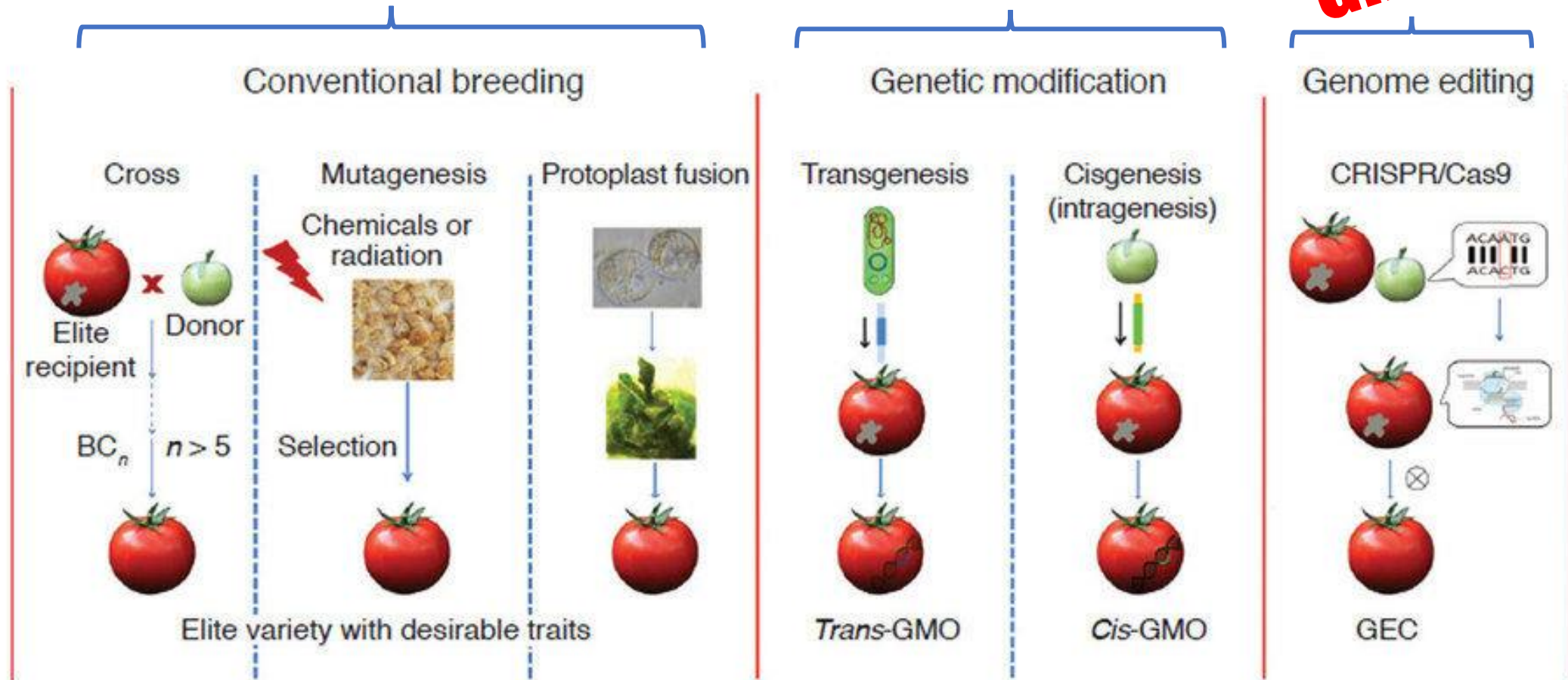
Or: How GM and Gene Editing can help deliver improved crops for better nutrition

The different approaches that can be used for crop genetic improvement

Not subject to GM regulation

Always subject to GM regulation

GM in EU



IP retained by Plant Breeding Rights

100's of years old

IP retained by patents

Since 1990s

IP retained by patents

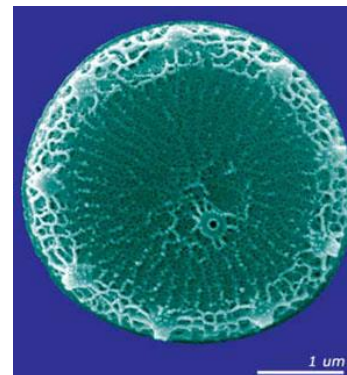
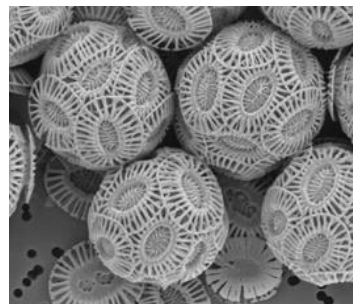
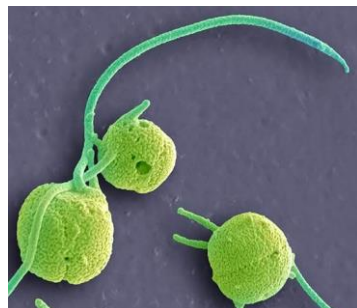
Since 2010s

A GM example – making omega-3 fish oils in plants

- Beneficial for human health
- A limited natural resource
- No known plant sources available
- Valuable and important ingredient of aquafeed diets
 - Aquaculture consumes 80% of all the fish oils we take from the oceans.
 - Aquaculture is central to feeding the global population – but needs to be sustainable



Making omega-3 LC-PUFAs in a heterologous host



The sources of genes for omega-3 LC-PUFA biosynthesis are marine microalgae, diatoms etc

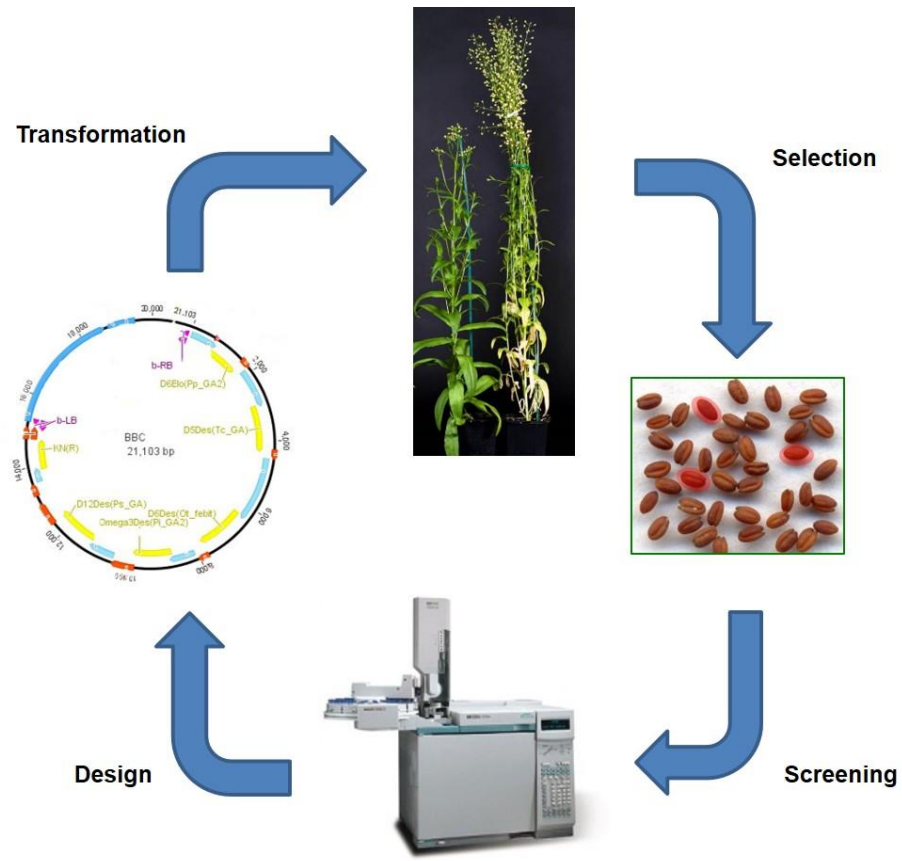


Identify algal genes for the synthesis of omega-3 LC-PUFAs & transfer them to oilseeds

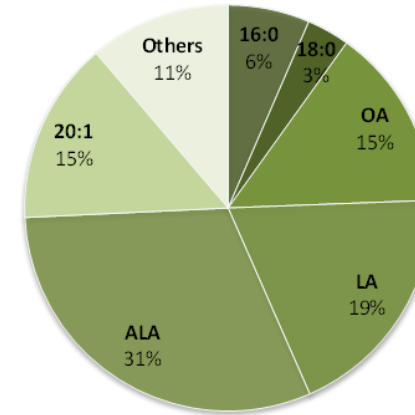


Express algal genes in seeds = transgenic plants with novel fatty acid traits

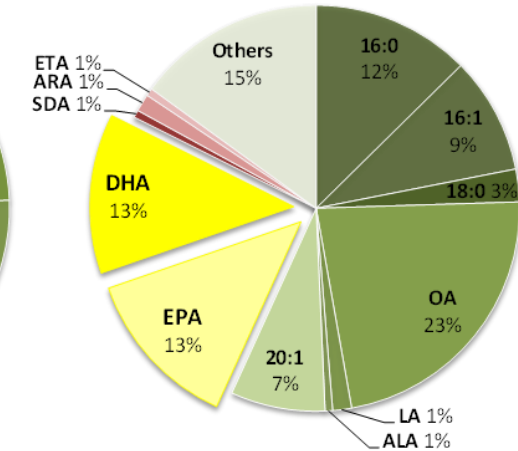
Using GM to deliver enhanced nutrition



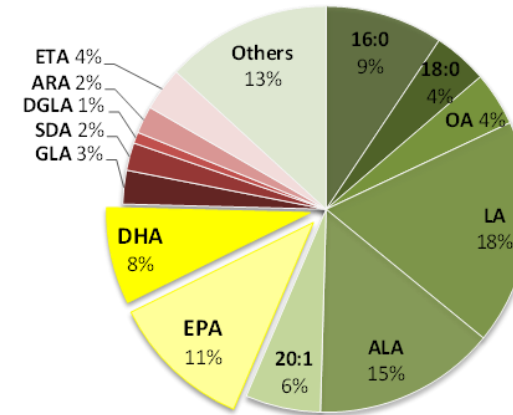
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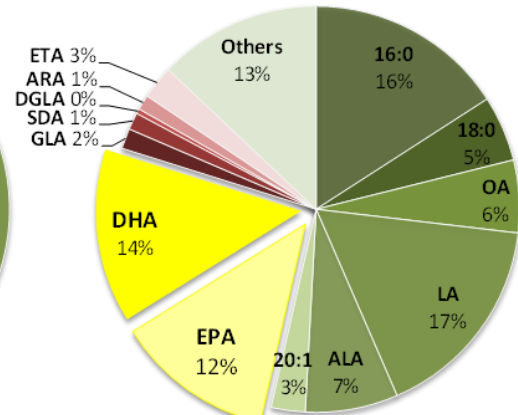
Bulk fish oil



DHA line



Highest DHA seed



GM Camelina Field Trials at Rothamsted- 2014 onwards



ROTHAMSTED
RESEARCH



The UK's only continuous GM field trials.. And all that entails

The conversion of an idea into a product takes time and money



Creating a value chain which delivers better nutrition to the consumer and helps aquaculture to reduce its reliance on oceanic sources of fish oils

*Hurdles: (GM) Regulation, IP/FTO, Business development, Commercialisation
[many skills & experience absent in academia]*



Homepage > Omega-3 Canola

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First land-based omega-3 canola

Since 2011, Nuseed has collaborated with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) in Australia to develop canola seed with a unique profile that includes long chain omega-3 fatty acids that provide the building blocks essential for both human health and fish of fish oil.

RESEARCH AND DEVELOPMENT

Australian regulators have granted approval for the production and use in aquaculture feed applications in other markets that recognise Australia as a reference source of long chain omega-3 fatty acids. The US Department of Agriculture (USDA) notification and Nuseed received US approval for the production and use in aquaculture feed applications.

Nuseed's omega-3 oil will be used as an ingredient in aquaculture feed as a new and sustainable source of long-chain omega-3 for improved health, as they are uniquely rich in DHA, a vital building block of good nutrition.



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Cargill launches Latitude™, a sustainable, plant-based alternative source of Omega-3 for fish feed applications

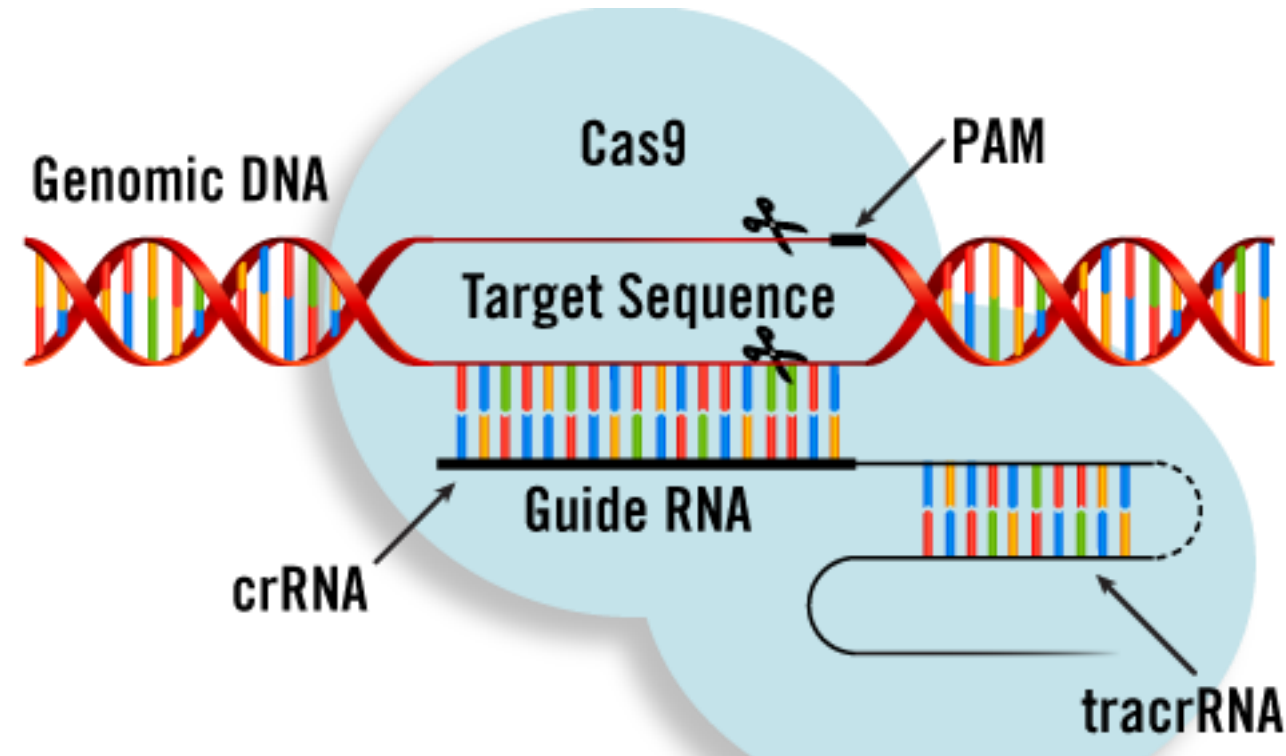
Fish oil alternative relieves harvesting pressure on wild fish populations, while delivering on market need for a reliable, fully traceable supply of Omega-3s

(PUERTO MONTT, CHILE) October 16, 2018 – Cargill has announced the launch of Latitude™, a plant-based fish oil alternative that provides long chain Omega-3 fatty acids for aquafeed. Latitude is 100 percent traceable since Cargill manages the supply chain from the canola seed to crop cultivation and oil production—and industry-first for a product of this kind.

Gene-editing is transforming how we do life sciences

- CRISPR-Cas9 and related tools are a disruptive technique with which to edit DNA
- Incredibly precise, easy to use, “democratising” research.
- BUT – Use in EU has effectively been blocked by ECJ ruling of July 2018 (GE \equiv GM)
- Commercial use is covered by patents
- New technology largely untested at scale

Irrespective of that, it is widely expected that GE will transform plant and animal breeding, decreasing susceptibility to diseases, enhancing nutrition and decreasing environmental impact.



NEWS · 25 JULY 2018 · UPDATE 25 JULY 2018

CRISPR plants now subject to tough GM laws in European Union

Top court's ruling threatens research on gene-edited crops in the bloc.

Ewen Callaway

Home / News / Agrifood / Innovation in agriculture / Industry shocked by EU Court decision to put gene editing technique under GM law

Industry shocked by EU Court decision to put gene editing technique under GM law

By Sarantis Michalopoulos | EURACTIV.com

25 Jul 2018 (updated: 09 Aug 2018)



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Gene editing is GM, says European Court

By Paul Rincon
Science editor, BBC News website

25 July 2018

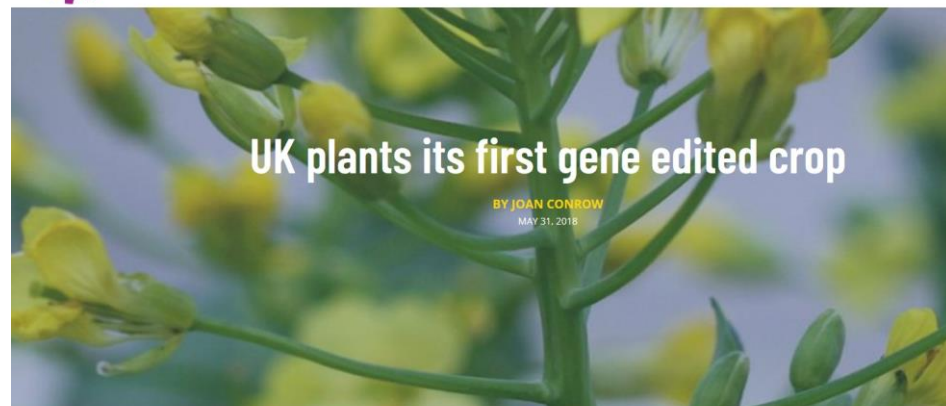


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The European Court of Justice has ruled that altering living things using the relatively new technique of genome editing counts as genetic engineering.

Until now, gene editing, involving the precise replacement of one DNA sequence with another, has been a grey area.



UK plants its first gene edited crop

BY JOAN CONROW
MAY 31, 2018

SHARE Scientists at **Rothamsted Research** have sown one of the world's first experimental field trials of a genome edited crop in an effort to develop more nutritious plants that

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EU verdict on CRISPR crops dismays scientists

Decision to tightly regulate gene-edited plants is a blow to biotech and science, critics say

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of what the European Commission is trying to do, which is to try and have impact and translatable research."

The U.S. government, which has allowed some gene-edited plants on the market with no regulation, voiced its displeasure as well. "Government policies should encourage scientific innovation without creating unnecessary barriers or unjustifiably stigmatizing new technologies," U.S. Secretary of Agriculture Sonny Perdue said in a written statement that called the 2001 regulations "regressive and outdated." But the decision could benefit U.S. science if European researchers decide to seek a more welcoming home for their studies, Napier says. "It just means that we are going to export good ideas and good people to go and work in more favorable territories."

Napier is one of the scientists whose work is now in limbo. At Rothamsted, he has been growing *Camelina*, an oil-seed crop, edited to lack an enzyme that converts oleic acid into linoleic acid. It's a possible step in the creation of plants that churn out omega-3 fatty acids, which have human health benefits. Created by French scientists, the plants were growing at Rothamsted because the U.K. Department for Environment, Food and Rural Affairs (DEFRA) had given field trials a green light. Now, "We're sort of sitting and waiting for DEFRA to provide advice," Napier says. (Whether the United Kingdom might become more welcoming to gene editing after Brexit remains to be seen; the U.K. government's most recent position paper makes the case for complete alignment with the European Union in agriculture.)

Basic plant science may suffer, however. Detlef Weigel, director at the Max Planck Institute for Developmental Biology in Tübingen, Germany, is studying how various genetic changes can help plants adapt to climate change—and he needs to grow them outside, he says. "Again and again we have seen that there are big differences between the results we get in a greenhouse and in a field, even if we use the same earth and sprinkle the plants with rainwater." Weigel tested some edited plants in a field in Sweden this year. "Luckily we harvested the plants a few weeks ago," because the cumbersome permitting process will now make such research impractical, he says. "If we want to test a single mutant in the field, it will cost us about €500 to create that plant, and then about €250,000 to get the permit to grow it in a field."

Joyce Tait, who directs the Institute for Innovation Generation in the Life Sciences at The University of Edinburgh, says she understands scientists' frustration. "But I also feel the current gene-editing technology does enable you to make changes that are so significant that to claim 'this must be safe because it is natural' is stretching the evidence-based risk analysis," she says. She thinks Europe's regulatory system should focus on evaluating the risks of individual plants rather than the method that produced them. "If Europe sticks with the current system and the way it has operated the past 20, 30 years, I think it will become increasingly separated from the rest of the world," Tait says.

But the European ruling could also affect the rest of the world, she adds. The Carta-

"I find the decision depressing, a huge step backwards."

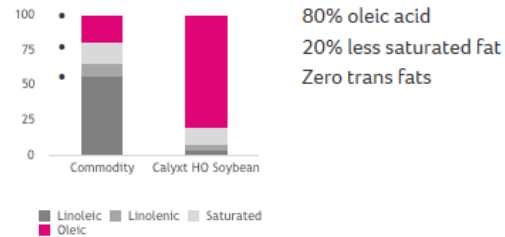
Johnathan Napier,
Rothamsted Research

THE FIRST GENE-EDITED FOOD IS NOW BEING SERVED



TALENS, not CRISPR

High oleic acid soybean oil



calyxt™

The banana is dying. The race is on to reinvent it before it's too late

The world's most popular fruit is facing extinction, and scientists are racing to use gene-editing to save it. To succeed, they'll need to overcome an even bigger problem: opposition to GMO crops



Other targets for gene-editing

- Allergy-free peanuts
- Gluten-free wheat
- Caffeine-free coffee
- Reduced spoilage
- Reduced disease susceptibility

Gene-editing is the perfect tool for removing negative genes

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REGULATION

USDA greenlights gene-edited crops

Agency says techniques like CRISPR are equivalent to traditional plant-breeding methods

by *Melody M. Bongardner*
APRIL 9, 2018 | APPEARED IN **VOLUME 96, ISSUE 15**

The U.S. Department of Agriculture says it will not regulate most crops modified with gene-editing techniques such as CRISPR. In a [statement](#) released March 28, USDA Secretary Sonny Purdue said that gene editing is equivalent to techniques traditionally used by plant breeders to generate beneficial traits and does not carry additional risks that require oversight.

Until now, companies developing gene-edited crops had to request clarification via letter to find out if the agency would regulate their product. In each case, USDA responded that it would not.

The agency outlined the [gene-editing methods](#) it considers equivalent to common plant-breeding techniques, such as hybridization and mutagenesis via chemicals or radiation. The equivalent methods include DNA deletions of any size, single-base-pair substitutions, and insertions of DNA from plant relatives. The agency will continue to regulate genetically modified crops that



Credit: Forbes/Wikimedia Commons

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Of course, not everyone recognizes the advances offered by gene editing as positive






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New research confirms GM causes massive off-target damage to plant genomes

Published: 28 January 2019

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GMWatch concludes scalpel and scissors metaphors used to describe GM methods must be replaced by child with chainsaw





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New study claimed to show safety of CRISPR shows the opposite

Published: 29 January 2019

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Confirms process-based regulation is necessary

A new [study](#)[1] by Chinese researchers has been hailed in a [lobbying post](#) as showing that plant gene editing via CRISPR is precise, predictable, and controllable.

In fact, however, it shows the opposite - that the CRISPR process, taken as a whole, causes large numbers of

...although many of the suggested “problems” are not well-founded

- **GM** is proven technology, well-established and working at scale.
- **Mainly about adding foreign DNA to a host**
- Has further potential to deliver a “second generation” of crops with enhanced nutrition traits

- **GE** is a new and disruptive technology
- It is not the same as GM (although EU says it is) and some of the things GM can do can't be done by GE (and vice versa)
- **Mainly about removing host DNA/genes**

- If we are serious about feeding 9 billion people, we need to use every available tool and approach

However, without societal consent and consumer acceptance, these new genetic technologies will be restricted in the potential impact, at least in agriculture and food.

Also, variation in regulatory standards will act as a barrier to trade and also further restrict investment in these new technologies

Some other examples of modified crops with consumer benefit traits

GM 2010s



CRISPR 2014



GM 2005

GM 1990s



Some took a very long to advance, some less so.
Some are likely to have a big impact, some less so



Herbicide tolerance – 17 years

Average time for
agricultural innovation
- 28 years



Golden Rice >35 years



DHA-Canola – 21 years

Slow magic: Agricultural R&D a century
after Mendel (2000)

Persistence pays: US agricultural
productivity growth and the benefits
from public R&D spending (2009)

*Professor Philip Pardey (Department of
Applied Economics, University of
Minnesota)*

Innovation in Agriculture – Time is not on your side!

A key question for the public: Who is paying and who is benefiting?



In our experience, a lot of opposition is focused against globalisation and its impact on the food chain, rather than GM *per se*.

Thanks for your attention – Questions?

