



Introduction Workshop: Genetic Engineering

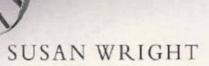
Angelika Hilbeck, ENSSER Board and Founding Member

MOLECULAR POLITICS

Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982

Mid 70s:

Lederberg and Stanley Cohen, duly emphasized the promise of the new gene-splicing techniques for medicine, industry, and agriculture. The techniques could revolutionize the pharmaceutical industry, according to the San Francisco Chronicle. 44 The new methods will "meet some of the most fundamental needs of both medicine and agriculture such as supplies of now scarce hormones and nitrogen-fixing microorganisms," according to the New York Times.

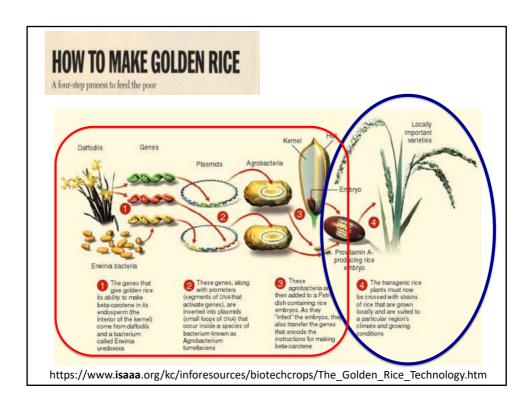


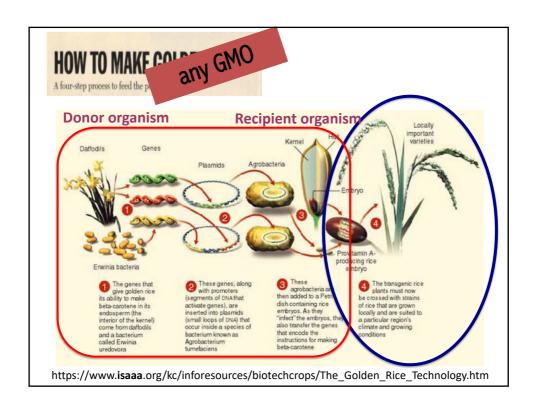
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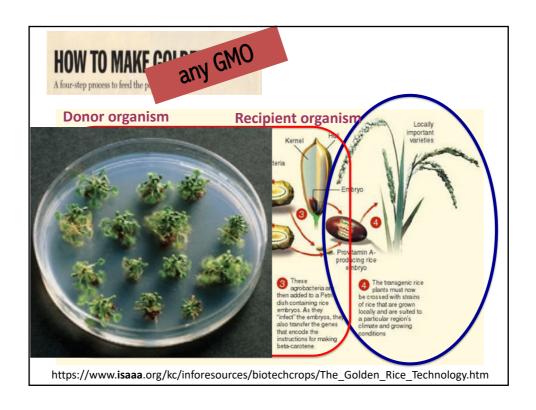
Assumption:

 reductionistic concept: Organisms are the sum of it's 'coded' parts.

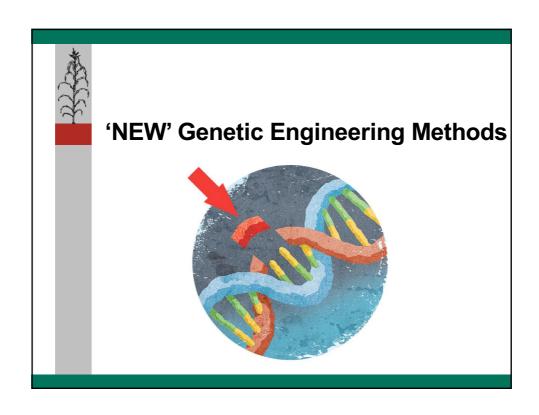


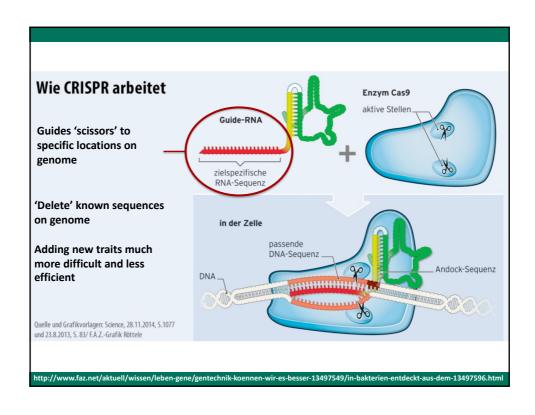


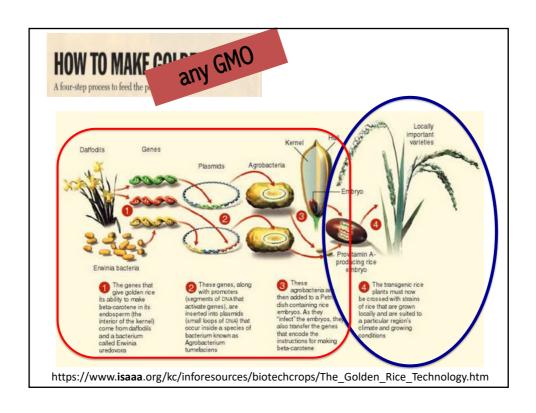


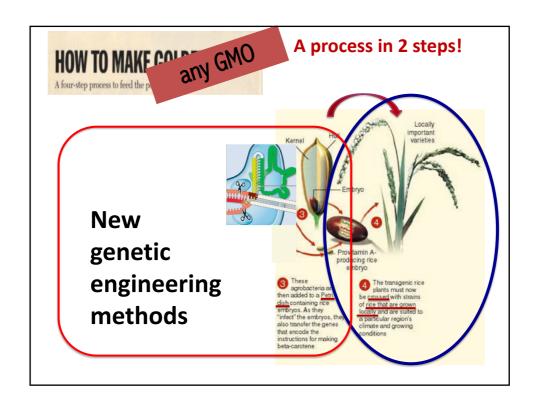


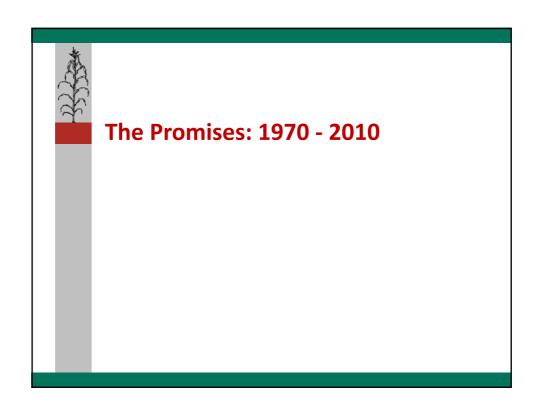














Sweeping safety claims – total disregard for risks

Prominent example:

Robert May (Chief Scientific Advisor to UK Government), **2000**:

"On the one hand so-called GM techniques which in **the precise and targeted way bring in a couple of genes** that you know what they do and you know where they are is **vastly safer**, **vast, vastly more controlled** than this so-called conventional breeding that reshuffles about a tenth of the genome."

'Is GM safe?' - https://www.bbc.co.uk/science/horizon/1999/gmfood_script.shtml



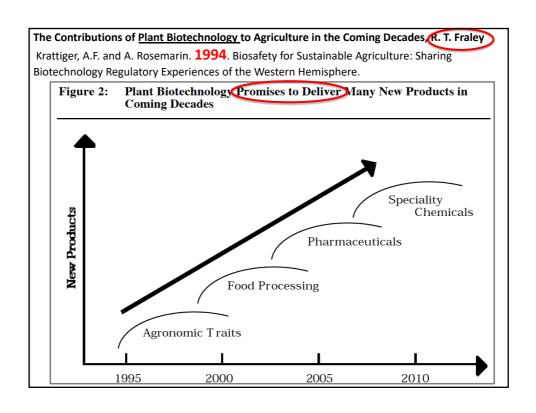


Grains Of Hope

By SIMON ROBINSON/NAIROBI; J. MADELEINE NASH/ZURICH Monday, Jul. 31, 2000

31. Juli 2000





Editor's Choice

Plant Physiol. Vol. 124, 2000

Ending World Hunger. The Promise of Biotechnology ...

Norman E. Borlaug Nobel Prize Laureate for Peace, 1970

Versprechen der neuen Gentechnik

GM CROPS

GM crops help fight hunger

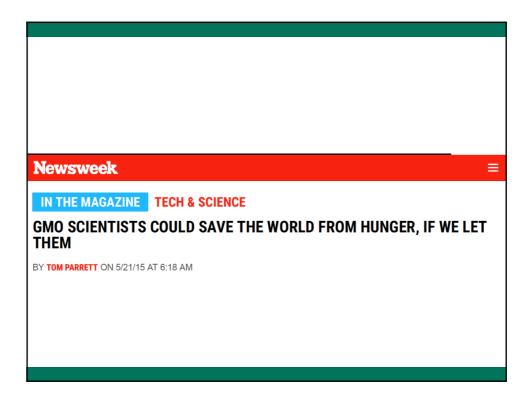
In the light of new European legislation, **Sterling Crew**, Head of Technical at Kolak Snack Foods, reviews the essential role of GM crops in safeguarding the security of our food supply, protecting the environment and improving our quality of life.





IFST International Food Science & Technology Journal. Vol 28 Issue 1 March

2015





Re-newed efforts of semantic engineering:

Not calling it what it is: genetic engineering

Gene/genome EDITING, CODING, WRITING, SPELLING,... New BREEDING techniques (although the aim is to overcome 'breeding') etc.

One example: "So what is gene editing? Scientists liken it to the find and replace feature used to correct misspelling in documents written on a computer. Instead of fixing words, gene editing rewrites DNA, the biological code that makes up the instruction manuals of living organisms."

 $lan \ Sample, \ the \ Guardian, \ 2018 \ \textit{https://www.theguardian.com/science/2018/jan/15/geneediting-and-what-it-really-means-to-rewrite-the-code-of-life}$

"The end product is what matters"

Detlef Weigel, Director at the Max Planck Institute for Developmental Biology, explains why genome **editing** offers a targeted way of **breeding** better crops

... together with colleagues from the USA and China, is asking for genome-edited plant varieties of this kind not to be classified as genetically modified plants.

- no regulation, no safety testing (sweeping claims)
- no oversight
- no responsibility
- no knowledge outside of insider developer circles

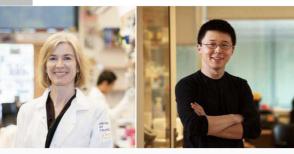
https://www.mpg.de/10444274/genome-editing-breeding-better-crops



Persisting CONTRADICTION:

'Product' only matters regarding safety and regulations

It is all about 'process' when it comes to profiting from patents and property rights!



enroller Doutse (top. left) at the University of California, Berkeley, USA, and Feng Zhang (be njett) at the Brand Institute of the Massachusetts stitute of Technology (MIT) and Harvard University, have each undertaken pioneering work in relation to CRISPIR-Case). They and others are urrently embroiled in a legal frestorm over who owns commercial or IP right in the technology. (Photos: Keegan Houser/UC Berkeley and Justin

THE BATTLE FOR OWNERSHIP

"Whoever owns the commercial or IP rights to CRISPR-Cas9 has the potential to generate huge financial returns and to decide who gets to use it."

https://www.wipo.int/wipo_magazine/en/2017/02/article_0005.html



Sweeping, unsupported, arbitrary safety claims PREVAILING 'DOGMA':

Control over DNA = Precision = Safety = predicted outcomes

Science & Society

Trends in Biotechnology May 2014, Vol. 32, No. 5

Caution required for handling genome editing technology

Motoko Araki¹, Kumie Nojima², and Tetsuya Ishii¹

¹ Office of Health and Safety, Hokkaido University, Sapporo 060-0808, Japan ² Molecular Imaging Center, National Institute of Radiological Sciences, Chiba 263-8555, Japan

Nucleic Acids Research, 2013, 1-9 doi:10.1093/nar/gkt714

CRISPR/Cas9 systems targeting β -globin and CCR5 genes have substantial off-target activity

Thomas J. Cradick, Eli J. Fine, Christopher J. Antico and Gang Bao*

Department of Biomedical Engineering, Georgia Institute of Technology and Emory University, Atlanta, GA 30332, USA

Nucleic Acids Research, 2014 1 doi: 10.1093/nar/gku402

CRISPR/Cas9 systems have off-target activity with insertions or deletions between target DNA and guide RNA sequences

Yanni Lin¹, Thomas J. Cradick¹, Matthew T. Brown¹, Harshavardhan Deshmukh¹, Piyush Ranjan², Neha Sarode², Brian M. Wile¹, Paula M. Vertino³, Frank J. Stewart² and Gang Bao¹.˙

High-frequency off-target mutagenesis induced by CRISPR-Cas nucleases in human cells

Yanfang Fu $^{1-4}$, Jennifer A Foden $^{1-3}$, Cyd Khayter $^{1-3}$, Morgan L Maeder $^{1-3,5}$, Deepak Reyon $^{1-4}$, J Keith Joune $^{1-5}$ & Jeffry D Sander $^{1-4}$

Gelinsky and Hilbeck Environ Sci Eur (2018) 30:52 https://doi.org/10.1186/s12302-018-0182-9 Environmental Sciences Europe

COMMENTARY

Open Access

European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling

Eva Gelinsky^{1,2} and Angelika Hilbeck^{3,4*}

<u>Challenge</u>: "... whether organisms obtained by mutagenesis are GMOs and whether they are subject to the obligations laid down by the GMO Directive?"



Ruling: "... the Court of Justice takes the view, first of all, that organisms obtained by mutagenesis are GMOs within the meaning of the GMO Directive, in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally. It follows that those organisms come, in principle, within the scope of the GMO Directive and are subject to the obligations laid down by that directive."



"... the Court considers that the <u>risks</u> linked to the use of these new mutagenesis techniques <u>might prove to be similar to</u> those that result from the production and release of a GMO through <u>transgenesis</u>, since the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into the organism (transgenesis) and those new techniques make it possible to produce genetically modified varieties <u>at a rate out of all proportion to those resulting from the application of conventional methods of mutagenesis."</u>

Prof Nick Talbot, Deputy Vice Chancellor, and Professor of Molecular Genetics, University of Exeter, said:

"This ruling by the CJEU is a mis-guided and retrograde step that is not based on any scientific evidence. **Mutation occurs all the time in all organisms**."

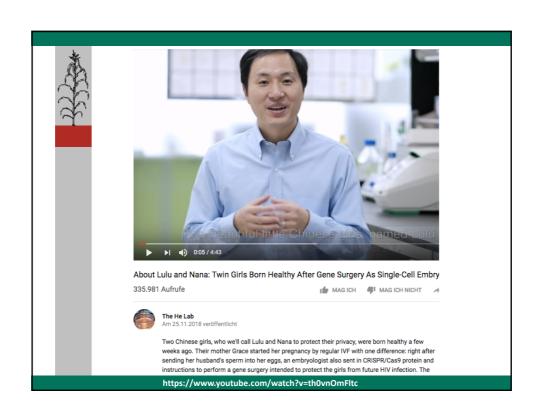
Dr Nicola Patron, Head of Synthetic Biology, Earlham Institute, said:

"This is not an approach based on scientific evidence. Mutagenesis is a natural phenomenon responsible for the genetic diversity that can been seen in all living organisms. Humans have used different technologies to induce mutations in plants to increase genetic diversity and improve the agronomic qualities of crops for almost a century; the same outcomes can now be achieved using **faster**, **more efficient and precise** mutagenesis methods."

http://www.sciencemediacentre.org/expert-reaction-to-court-of-justice-of-the-european-union-ruling-that-gmo-rules-should-cover-plant-genome-editing-techniques/



Now it's safe - now it's not!





"This kind of gene editing [Crispr/Cas9] ... is still experimental and DNA changes can pass to future generations, potentially with unforeseen side-effects. ... Many mainstream scientists think it is too unsafe to try..."

Julian Savulescu, a professor of practical ethics at the University of Oxford. "... Gene editing itself is experimental and is still associated with off-target mutations, capable of causing genetic problems early and later in life,"

https://www.theguardian.com/science/2018/nov/26/worlds-first-gene-edited-babies-created-in-china-claims-scientist

New Scientist

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ANALYSIS 15 November 2017, updated 16 November 2017

Biohackers are using CRISPR on their DNA and we can't stop it

People are starting to alter their own DNA with cheap, easy gene-editing technology. Is it time to regulate CRISPR?



Former Nasa biochemist Josiah Zayner became an online sensation by conducting DIY gene therapy on himself. He explains why he did it



▲ Josiah Zayner with his Crispr gene-editing kit. Photograph: Courtesy Josiah Zayner / The ODI

osiah Zayner, 36, recently made headlines by becoming the first person to use the revolutionary gene-editing tool Crispr to try to change their own genes. Part way through a talk on genetic engineering, Zayner pulled out a syringe apparently containing DNA and other chemicals designed to trigger a genetic change in his cells associated with dramatically increased muscle mass. He injected the DIY gene therapy into his left arm, live-streaming the procedure on the internet.

The former Nasa biochemist, based in California, has become a leading figure in the growing "biohacker" movement, which involves loose collectives of scientists, engineers, artists, designers, and activists experimenting with biotechnology outside of conventional institutions and laboratories.



A Biohacker Regrets Publicly Injecting Himself With CRISPR

"There's no doubt in my mind that somebody is going to end up hurt eventually."

SARAH ZHANG | FEB 20, 2018 | SCIENCE





A biotech CEO explains why he injected himself with a DIY herpes treatment on Facebook Live

He says he wants everyone to have access to affordable gene treatments.



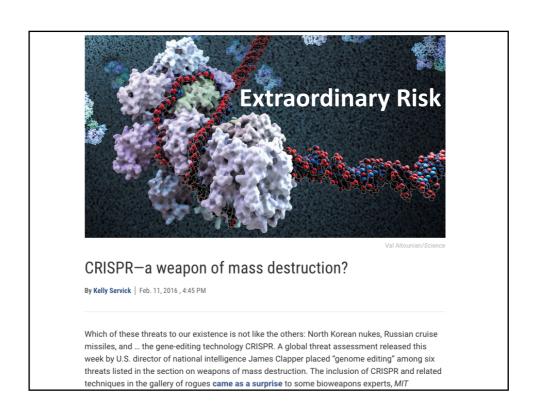
experimental gene therapy into his stomach fat, he was sitting on a leather couch in his friend-slash-yoga instructor's living room, not on a doctor's examining table.

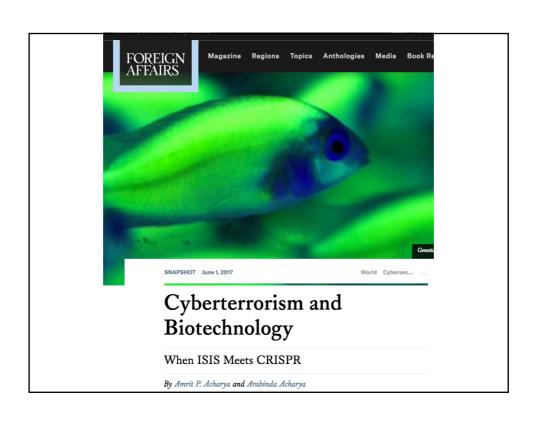
A serious new hurdle for CRISPR: Edited cells might cause cancer, two studies find

By SHARON BEGLEY @sxbegle / JUNE 11, 2018

"Another leading CRISPR scientist, who asked not to be named because of involvement with genome-editing companies, called the new data "pretty striking," and raised concerns that a potential fatal flaw in some uses of CRISPR had "been missed."

https://www.statnews.com/2018/06/11/crispr-hurdle-edited-cells-might-cause-cancer/









CONCLUSIONS:

The field is riddled with scientific contradictions and logical misfits (safe in plants/animals, unsafe in humans)

- 'Product' for regulation but 'process' of property rights
- 'Natural' to avoid regulation but 'non-natural human invention' for IP rights
- Hyping promises to maintain massive (public) cash flow into (privatized) underdelivering on promised science-fiction techno-fixes
- Science falls by the wayside to maintain/rescue the DNAcentered world view that forms the root of power structure

