

Real World Applications of Synthetic Biology

Synthetic Biology Module 6
University of Rochester iGEM 2020

Module Overview

- Introduce the legal framework for safety review of commercial synthetic biology products.
- Introduce commercial synthetic biology products in the US market.



Should synthetic
biology products be
assumed safe until
proven harmful or vice
versa?



1) Should synthetic biology products be assumed safe until proven harmful or vice versa? *

Long answer text

Coordinated Framework for the Regulation of Biotechnology



Genetically Modified (GMO) Crops



Image source:
<https://edition.cnn.com/2015/02/16/health/apples-genetically-modified-usda/index.html>



Image source:
https://sites.google.com/a/cornell.edu/bee3299_sustainability-of-rice-production/home/golden-rice



Image source: <https://geneticliteracyproject.org/2019/02/22/drought-tolerant-corn-adoption-jumps-20-in-four-years-as-us-farmers-strive-to-protect-crop-yields/>

Proteins From Microbes



ANIMAL-FREE EGG WHITES TO DEBUT IN 2019

Article: <https://vegnews.com/2018/8/animal-free-egg-whites-to-debut-in-2019>

Animal-free dairy products move a step closer to market

San Francisco startup says its products taste identical but tackle guilty conscience of consumers concerned about large environmental footprint



Article: <https://www.theguardian.com/environment/2016/sep/13/animal-free-dairy-products-move-a-step-closer-to-market>



2) Do you think GMO food products are beneficial or harmful? *

Your answer

FDA: GMO Food Products

Manufacturers responsibility for premarket safety studies is determined on a case by case basis.

FDA is responsible for postmarket safety surveillance.



Will post market review policy need to change?

3) Should GMO food manufacturers be required to conduct post market safety surveillance instead of the FDA?

Your answer

GMO Animals

Manufacturer responsible for premarket and postmarket safety studies.

Genetic treatment must be safe for both animals and humans.

Source: <https://www.ncbi.nlm.nih.gov/books/NBK442204/>

Genetically Engineered Salmon Approved for Consumption



Article: <https://www.nytimes.com/2015/11/20/business/genetically-engineered-salmon-approved-for-consumption.html>

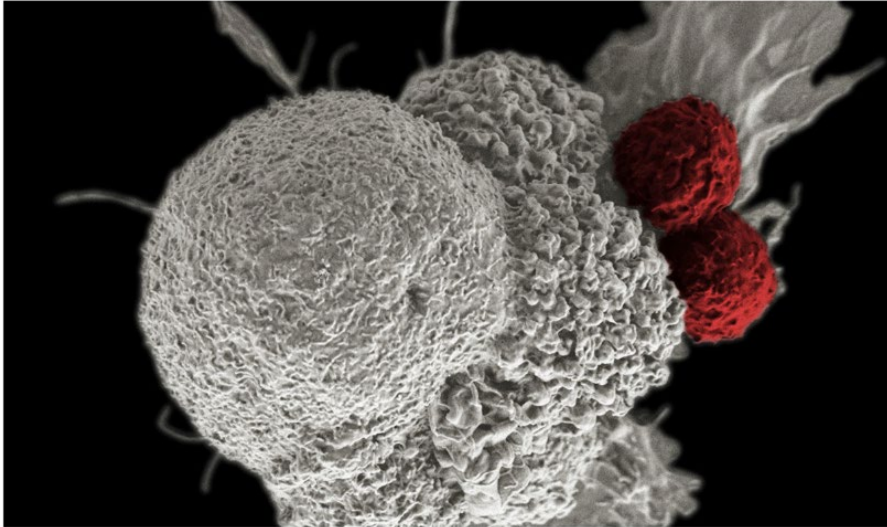


4) Synthetic biology can be used on animals for foods, such as the salmon we talked about, as well as for other purposes such as animal research, endangered species conservation, or exotic pets. What other applications of GMO animals can you think of? *

Your answer



Cellular & Gene Therapies



Immune cells called T cells attack a cancer cell. RITA ELENA SERDA, DUNCAN COMPREHENSIVE CANCER CENTER AT BAYLOR COLLEGE OF MEDICINE, NCI, NIH

Modified T cells that attack leukemia become first gene therapy approved in the United States

Article: <https://www.sciencemag.org/news/2017/08/modified-t-cells-attack-leukemia-become-first-gene-therapy-approved-united-states>

FDA NEWS RELEASE

FDA approves innovative gene therapy to treat pediatric patients with spinal muscular atrophy, a rare disease and leading genetic cause of infant mortality

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For Immediate Release: May 24, 2019

The U.S. Food and Drug Administration today approved Zolgensma (onasemnogene abeparvovec-xioi), the first gene therapy approved to treat children less than two years of age with spinal muscular atrophy (SMA), the most severe form of SMA and a leading genetic cause of infant mortality.

“Today’s approval marks another milestone in the transformational power of gene and cell therapies to treat a wide range of diseases,” said Acting FDA Commissioner Ned Sharpless, M.D. “With each new approval, we see this exciting area of science continue to move beyond the concept phase into reality. The potential for gene therapy products to change

Article: <https://www.fda.gov/news-events/press-announcements/fda-approves-innovative-gene-therapy-treat-pediatric-patients-spinal-muscular-atrophy-rare-disease#:~:text=The%20U.S.%20Food%20and%20Drug.genetic%20cause%20of%20infant%20mortality.>



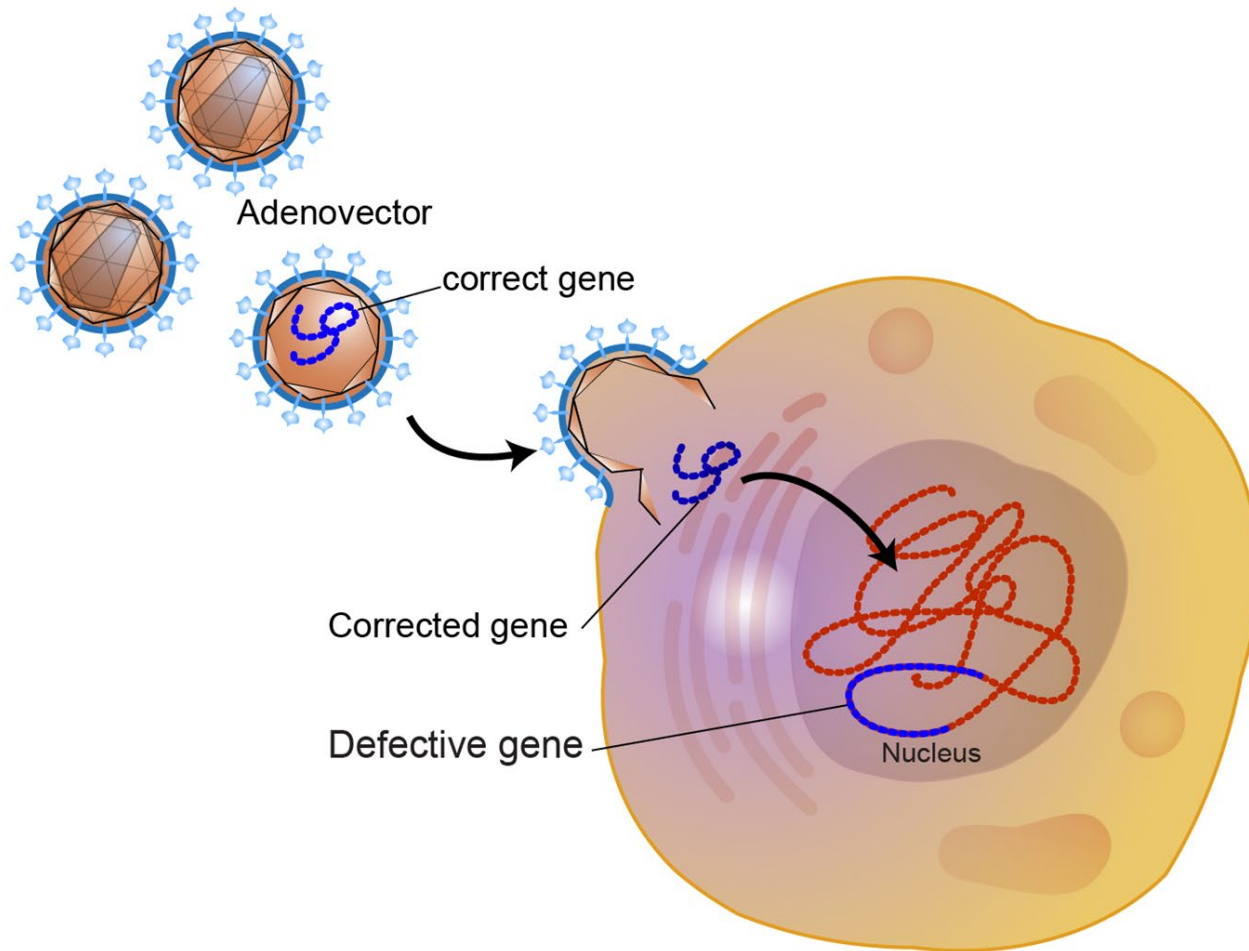
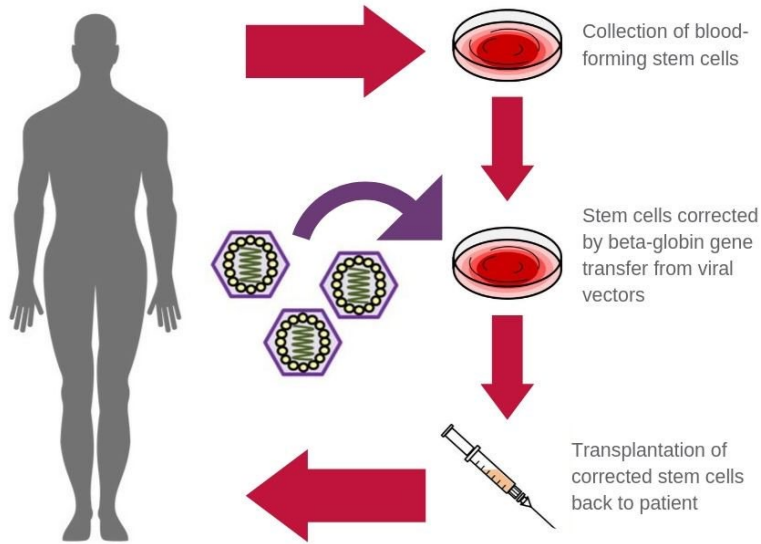


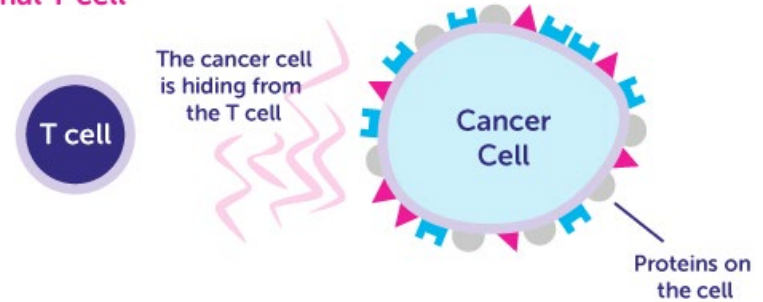
Image:
<https://www.genome.gov/genetics-glossary/Gene-Therapy>

Stem Cell Gene Therapies

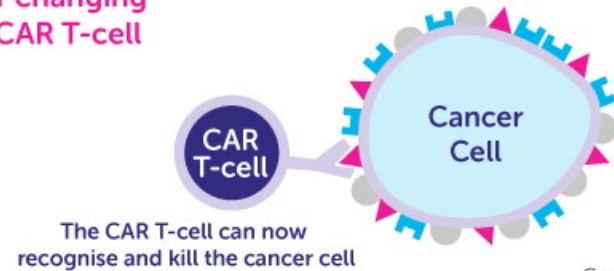
Gene therapy for sickle cell disease



1. Normal T cell



2. After changing into a CAR T-cell



Cancer Research UK

5) What do you know about the technical challenges and ethical concerns around gene therapy? *

Your answer



Pesticides from GMOs



Image: <https://www.agprofessional.com/article/insect-resistant-crops-hit-one-billion-acres-globally>



Image: <https://theconversation.com/virus-infested-fungus-could-help-cut-chemical-pesticides-110925>

Pesticides from GMOs: Safety Review

- Chemical properties and degradation times of new proteins
- Toxicity testing on target and non-target organisms
- Evaluate risks of gene transfer to wild plants

Pesticide resistance: Pests that have the genes to fight against pesticides will survive and produce offspring with the same genes. These offspring will become a species that are resistant to the pesticide.

Source: <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management>



6) Do GMO pesticides increase the risk of pesticide-resistant pest species? If yes, what can be done to avoid the risks?

Your answer

GMO for Insect Control

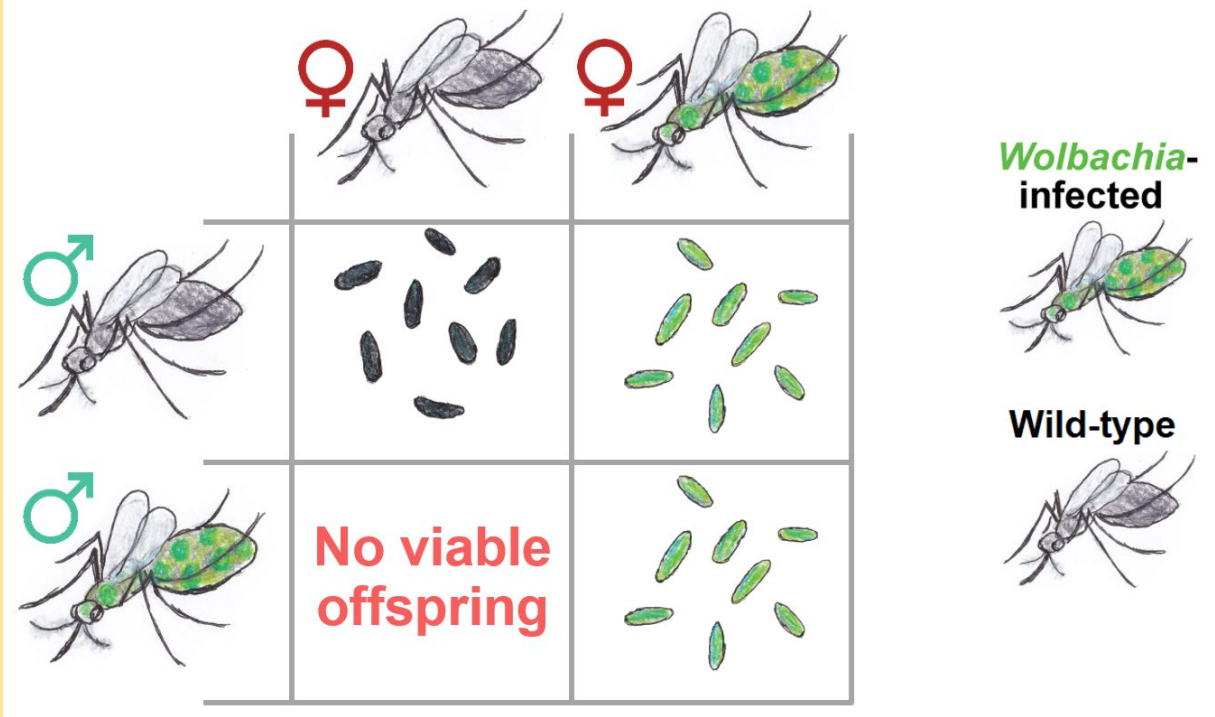


Image: <https://blogs.unimelb.edu.au/pearg/2018/04/13/wolbachia-bacteria-in-action-how-were-using-naturally-occurring-bacteria-to-stop-mosquitoes-from-spreading-disease/>

GMOs for Insect Control

Male moths genetically modified to kill females released in the wild



LIFE 29 January 2020

By Michael Le Page



Article: <https://www.newscientist.com/article/2231693-male-moths-genetically-modified-to-kill-females-released-in-the-wild/>



Genetically modifying mosquitoes to control the spread of disease carries unknown risks

October 2, 2019 8:11am AEST Updated October 4, 2019 6:02am AEST

Mosquitoes are one of the deadliest creatures because they are carriers for many lethal viruses. Shutterstock

Article: <https://theconversation.com/genetically-modifying-mosquitoes-to-control-the-spread-of-disease-carries-unknown-risks-123862>



Regulations should
provide safety without
inhibiting innovations.



7a) Please name three commercial synthetic biology products you know of, either through this module or from other sources. *

Your answer

8b) Do those three products require premarket or postmarket safety reviews? *

Your answer



Thank you!

Email us at uofr.igem@gmail.com



Sources

1. Board on Life Sciences et al, "The current biotechnology regulatory system," *Preparing for Future Products of Biotechnology* pp. 67-106, 2017. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK442204/>
2. Genetic Science Learning Center. (2012, December 1) Gene Therapy Successes. Retrieved from <https://learn.genetics.utah.edu/content/genetherapy/success/>
3. United States Environmental Protection Agency [EPA]. (2016). EPA's Regulation of Biotechnology for Use in Pest Management. Retrieved from <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management>

