Bees

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In February 2016, the UN released a report about pollinator species that are at risk of global extinction, which includes nearly 2,000 species of bees. Bees are an important part of ecosystems all over the world. They play a critical role in agriculture, with 35% of global crops depending on animal pollinators like bees. Over the last 10 years, more and more bees have been lost.

Possible Gene Editing Solution:

It is not clear yet what is causing so many bees to die, but possibilities include disease, parasites, and pesticides. Scientists have been studying the genomes of 'hygienic' bees, which obsessively clean their hives and remove sick and infested bee larvae. Hygienic colonies are less likely to die out from disease or parasites. If scientists can identify the hygienic genes, they can use CRISPR to copy them to other types of bees to help the bees survive.

SUCCESSES:

New option to save bees: Many people, including scientists, the Environmental Protection Agency, and the Department of Agriculture, as well as their counterparts all over the world, have been trying for years to combat the loss of bees with little success. Modification with CRISPR may give the bees a way to survive.

CHALLENGES:

Complex genetics: No genes associated with hygiene have been definitively identified. The combination of genes driving the behavior may turn out to be complex. It is not clear whether changing the hygienic genes might cause other behavior changes in the bees.

Conventional breeding may be enough: If hygiene-associated genes are identified, conventional breeding may be enough to spread resistance to new populations, potentially making CRISPR unnecessary.

More Details: Bees

Scientific Overview
Honey bees can be bred to be more "hiveproud," which means that they take better care of their hive. Hiveproud bees kept their hives clear of mites without pesticides. New research indicates that bees that detect and remove the parasites now harming many of the world's hives might be a cheaper, greener alternative to using pesticides.

Industry
Honey bees contribute to pollinating crops such as apples, berries, melons and almonds. Plants that depend on pollination make up 35% of global crop production volume with a value of as much as $577 billion a year. Many farmers rent out their bees to put near these crops to boost yields. The agricultural system, for which pollinators play a key role, creates millions of jobs worldwide.

Costs
Canadian scientists are preparing to breed honey bees to make them resistant to disease and harsh winter conditions with a $7.3 million (Canadian dollars) budget. The research is expected to provide economic gains of $8 to $15 million (Canadian dollars) annually, particularly to beekeepers and the food and agricultural industries.

External Effects
Without an international effort, increasing numbers of bees face extinction. However, releasing genetically modified bees presents risks, such as the spread of the modified gene to other bees, unintended effects on bees and other animals, and possible impacts on human health. The exact potential risks depend on the specific changes to the bees.

Regulation
In January 2009, the Food and Drug Administration (FDA) issued a final guidance for industry on the regulation of genetically engineered (GE) animals. The regulation states that GE animals contain DNA that is intended to alter the structure or function of the animal. Therefore, they are considered to contain a new animal drug. GE animals therefore require pre-market approval by the FDA prior to their introduction to the marketplace. The framework for biotechnology is now being reviewed.

Biofuels

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Fossil fuel reserves are being depleted, and people are looking for new reliable sources of fuel. Every day in 2015, the world used 93 million barrels of petroleum-based fuel. That number has gone up almost every year since 1980.

Possible Gene Editing Solution:

Scientists have come up with a way that they could engineer yeast to produce liquid biofuels, which could be used for transportation, including jet fuel. This could quickly and cleanly make renewable resources to meet the world's transportation needs.

SUCCESSES:

Reduction in risk: Currently, fuel is produced from non-renewable raw materials derived from petroleum in processes that are inefficient and pose safety risks. Biofuels from yeast would be cheaper and remove those safety risks.

Better method to work with yeast: The type of yeast that may be used to make biofuels has historically been difficult to work with. However, scientists were able to show that CRISPR could make the types of changes necessary to produce biofuels.

CHALLENGES:

May be more complicated than expected: This research is in its very early stages, and it may turn out to be more complicated than expected to use CRISPR to make yeast that produces usable biofuels.

Energy inefficient: In most cases, producing biofuels consumes more energy than they ultimately produce.

More Details: Biofuels

Scientific Overview

When using corn as the source for biofuels, scientists found that it took about 1.3 times as much energy to produce the biofuels as they provided when they were used. Now, scientists have adapted CRISPR for use in a yeast strain *(Yarrowia lipolytica)* that can produce useful precursors for biofuels. Until now, this yeast has been hard to manipulate at the genetic level, but now CRISPR allows scientists to tap into its bio-manufacturing potential. Yeast may be more efficient than corn at converting energy for fuel, but it will still take more energy to produce than it provides. In addition to yeast, researchers are also pursuing other methods of producing biofuels, such as genetically engineered algae that could be used as fuel.

Industry

Biofuels now meet about 3% of the global transport fuel demand, and are produced using 2-3% of the global farmable land. The two main biofuels are bioethanol and biodiesel, with roughly 80% and 20% of the market, respectively. The market for biofuels was expected to reach $99 billion by 2014. Major companies are partnering with startups to develop new biofuel technologies.

Costs

Ethanol and biodiesel tend to cost slightly more at the pump than gasoline or regular diesel for the same mileage at current prices, though this could change in the future. However, the full costs of production are hidden in varying subsidies for each type of fuel.

External Effects

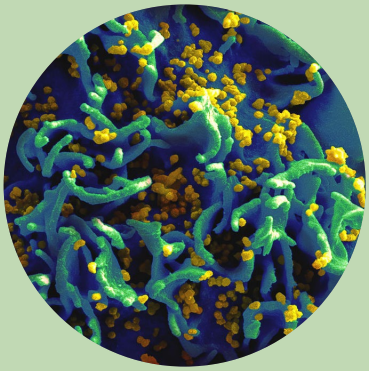
Biofuels are one of few fuel options available to potentially reduce CO_2 emissions from road transportation over the coming decades, especially for heavy-duty vehicles, marine vessels, and aircraft.

The food the yeast requires to produce biofuels can affect the availability of food for humans. If biofuels are produced from crops that would have been used for food, then biofuels directly reduce potential food supplies. Even if a crop is not directly used to produce biofuels, it can still affect food supplies if it is grown on land that would otherwise be planted with a food crop.

Regulation

The Renewable Fuel Standard (RFS) is a federal program that requires transportation fuel sold in the United States to contain a minimum volume of renewable fuels. The RFS originated with the Energy Policy Act of 2005 and was expanded and extended by the Energy Independence and Security Act of 2007. The RFS requires renewable fuel to be blended into transportation fuel in increasing amounts each year, escalating to 36 billion gallons by 2022. Each renewable fuel category in the RFS program must emit lower levels of greenhouse gases relative to the petroleum fuel it replaces.

HIV



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Over 35 million people are living with HIV globally, and about 2 million people are infected every year. Of this number, only about 16 million are receiving the treatment necessary to keep the condition under control. People around the world are working on many methods for reducing the transmission of HIV, with some success, so that between 2000 and 2015, new HIV infections fell by 35%. However, over a million people still died in 2014 due to HIV-related causes.

Possible Gene Editing Solution:

Scientists have developed a way to use CRISPR to make human cells immune to HIV by making the virus unable to enter the cells. This could be a way of treating HIV without the need for ongoing drugs.

SUCCESSES:

No toxic side effects: The experiment showed that the technology is safe for the cells, with no toxic effects.

Promising for treatment: Early results suggest that this method could be used as a new method of treatment in the future.

No reinfection: Cells that went through this process could not be reinfected with HIV.

CHALLENGES:

Still in early stages of development: Currently, this is only a study in a petri dish. It is still many years away from being available as a treatment for people with HIV.

May be more complicated than expected: HIV is constantly mutating, which makes it difficult to treat. It's possible that HIV could evolve resistance to edits made with CRISPR.

More Details: HIV

Scientific Overview

While drugs can help control HIV infection, once patients stop taking them, the virus starts copying itself again from copies of its DNA in other cells. HIV enters a cell through a specific receptor in the cell. Some people have cells with a version of this receptor that does not allow HIV to enter. These people are immune to HIV. CRISPR could be used to alter the receptors in non-immune people so that HIV would not be able to enter their cells. The use of CRISPR will not permanently cure HIV, but it could prevent AIDS without needing drugs.

Industry

Experts predict that sales of HIV treatments will rise from $15.5 billion in 2015 to $22.6 billion in 2024.

Costs

This treatment for HIV is not yet on the market. A similar treatment, the first gene therapy drug that has been approved by European regulators, was set to launch in Germany in early 2015 with a US $1.4 million price tag for patients. This drug is for a rare genetic protein deficiency disorder, not HIV, but gene therapy is the same type of treatment that would likely be used for HIV.

Regulation

HIV treatments are overseen by the Food and Drug Administration (FDA). The FDA is a regulatory agency that enforces the Food, Drug, and Cosmetic Act and the Public Health Service Act, assuring that drugs and biologics are safe and effective for their intended uses, and properly labeled. The agency primarily serves a review and oversight function in areas related to drugs, biologics, and medical devices for the prevention and treatment of HIV/AIDS, and AIDS-related conditions. The FDA works with developers of new products to assure that clinical trials are well designed, scientifically sound, ethically conducted, and appropriately analyzed.

Mosquitoes

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Mosquitoes are the deadliest animal on the planet. Mosquitoes carry malaria, yellow fever, dengue fever, Zika virus and West Nile virus. Traditional methods for controlling mosquito populations, such as insecticide spraying and bed nets, as well as drugs used for treatment of diseases like malaria, are becoming less effective over time.

Possible Gene Editing Solution:

Scientists are considering several approaches for reducing or eliminating disease-carrying mosquitoes. One approach would be to make offspring more likely to be male, which would reduce future populations. Another possibility involves knocking out genes that are important for fertility. Then the infertility-causing genetic change would spread through the population and cause a population crash. Both of these options depend on gene drive technology, which introduces new environmental risks. Other options exist that don't require gene drives but instead depend on repeated releases of GE mosquitoes.

SUCCESSES:

Reduces disease transmission: Fewer mosquitoes in an area means less transmission of diseases. If the mosquito population gets low enough, it becomes practically impossible to transmit diseases, even if the population isn't zero.

Reduces the need for insecticides, bed nets, and drugs: Genetically engineered mosquitoes reduce the need for insecticides, bed nets, and treatment drugs, which are becoming less effective as mosquitoes and the viruses or parasites that cause the diseases adapt to them.

CHALLENGES:

Could spread: Scientists do not know whether the altered gene might spread to other related species of mosquitoes.

Could completely wipe out a species: It is unclear how eliminating a species of mosquito would affect the environment.

More Details: Mosquitoes

Scientific Overview

Mosquito-borne diseases cause half a million deaths and hundreds of millions of cases every year. Malaria is widespread in 95 countries, with over 40% of the world's population at risk. This risk is closely linked to poverty and social and economic development. Over 200 million cases of malaria occur every year, 90% of them in Africa, and there are over 400,000 deaths annually.

Gene drives have been tested in a lab in the main mosquito species that transmits malaria, and they were found to be over 90% effective in transmitting female sterility genes to offspring.

The same gene editing techniques that have been tested for malaria have also been used for dengue fever, though without the gene drives. The techniques should work for a wide variety of mosquito-borne diseases, including Zika. Recent releases of sterile male mosquitoes have successfully reduced local populations of the mosquito that spreads dengue.

Industry

There is currently only one established company working on GE mosquitoes, called Oxitec. Oxitec, a British biotech company, received $10 million in funding in 2014 for its work and was acquired by Intrexon in 2015 for $160 million. The Chinese government is also working on and releasing its own GE mosquitoes.

Costs

A proposed project in the Florida Keys has been constrained to cost no more than their current chemical-intensive methods, which cost approximately $1.1 million per year.

Oxitec has not said how much the mosquitoes cost, but Brazil expected to pay about 30 Brazilian reals, or $7.50 a year, per person protected. Protecting the city of Piracicaba, with a population of 390,000, would cost $2.7 million a year.

External Effects

The consequences of escape and survival of Oxitec's mosquitoes in the environment have been extensively studied. Data and information from those studies indicate that there are unlikely to be any negative effects on other species, including humans, or on other countries. The status of the environment is restored when releases are stopped (the released mosquitoes all die, and the environment goes back to the pre-trial status). Because in many places these mosquitoes are an invasive species, removing them should have little effect on the food chain.

Regulation

In January 2009, the FDA issued a final guidance for industry on the regulation of GE animals. The regulation states that GE animals contain DNA that is intended to alter the structure or function of the animal and are considered to contain a new animal drug. GE animals therefore require pre-market approval by the FDA prior to their introduction to the marketplace.

The FDA's Center for Veterinary Medicine is reviewing an Investigational New Animal Drug file from Oxitec, about their GE mosquitoes. As part of the review, the FDA published for public comment a draft environmental assessment submitted by Oxitec that assesses the potential environmental impacts of conducting a field trial in Key Haven, Florida and a preliminary finding of no significant impact. The FDA is reviewing information on the Oxitec mosquito with government experts from other agencies, including CDC and EPA. The FDA will not complete its evaluation until it has had the opportunity to review public comments on the draft environmental assessment and subsequently issue either a final environmental assessment and finding of no significant impact or an environmental impact statement.

Spider Silk

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Spider silk is a very useful biomaterial because it is so strong and elastic, but using spiders isn't practical as their silk becomes a more in-demand biomaterial. Spider silk has an especially promising future in medicine. It is biocompatible, meaning it can be used in the human body without adverse reactions. It could be used for applications ranging from body armor to replacement hearts.

Possible Gene Editing Solution:

Scientists have developed a way to engineer bacteria to make synthetic spider silk. This could make spider silk a practical option for many medical and non-medical applications.

SUCCESSES:

Even better silk in the future: Now that a basic technique has been established for making synthetic spider silk, it should be possible to refine the genetic edits and improve the silk's strength. CRISPR will allow scientists to do this faster and more easily.

Many applications: Synthetic spider silk could be used for a wide variety of applications, including artificial tendons, ligaments, skin, and bone, as well as safer airbags and lighter, impact-resistant and fuel-efficient vehicle parts.

CHALLENGES:

Not as strong: This lab-grown silk isn't yet quite as strong as the spider-spun variety.

More Details: Spider Silk

Scientific Overview

Spider silk is five times stronger than steel and three times stronger than Kevlar by weight, with excellent heat-conducting properties. Companies working on synthetic spider silk have copied genes from spiders and inserted them into other organisms, such as the bacteria *E. coli*. In this way, they were able to generate silk proteins in a wide variety of materials, including fibers, gels and coatings, absorbent sponges, adhesives that grip both wood and plastics, and transparent films that are possible to read through. Spider silk has potential applications in everything from bullet proof vests to computer electronics.

Industry

Several small biotechnology companies are working on commercializing synthetic spider silk. One company, AMSilk, anticipates products generating annual sales in the next couple of years of more than $10 million. It is targeting sales of more than $100 million once large-scale production of synthetic fibers is under way. Another, Bolt Threads, has raised $90 million in funding and has recently signed a deal with Patagonia to further develop their fabric.

Costs

One company is aiming to provide a hybrid spider-and-silkworm silk for textile applications that is superior to silkworm silk but costs the same.

Regulation

GMOs are regulated in the United States under the Coordinated Framework for Regulation of Biotechnology, published in 1986, with a focus on the nature of the products rather than the process in which they are produced. GMOs in food, drugs, and biological products are regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. The form of regulation varies depending on the application of GMO involved.

Wheat

flickr / International Maize and Wheat Improvement Center

Wheat is vulnerable to a variety of diseases, including a fungal disease called powdery mildew that reduces its yield and quality. Wheat is the most widely grown cereal crop in the world, with an ever increasing demand. It plays a fundamental role in food security, and meeting increasing requirements for it is a major challenge.

Possible Gene Editing Solution:

Scientists have created a strain of wheat that is resistant to powdery mildew using CRISPR, and are considering adding other features, such as drought resistance, as well.

SUCCESSES:

Interest is growing: Companies are interested in spending money on this type of product. They are working with scientists and hoping to bring drought- and fungus-resistant wheat to market in the next 5-10 years, and field trials are scheduled to begin in 2016. This is much faster than changes can happen with traditional selective breeding.

CHALLENGES:

May be more complicated than expected: Traits such as drought tolerance involve many genes, and are subject to complex environmental interactions, including precipitation, heat, and soils. This might mean that the modified wheat would not be as drought tolerant as intended.

Perception of risk: Some consumers prefer non-GMO products, despite studies showing that they are safe to eat.

More Details: Wheat

Scientific Overview
Scientists have successfully created powdery-mildew-resistant wheat and have shown that the trait is passed on from generation to generation. CRISPR could also be critical in helping scientists keep up with the constantly evolving microbes that attack crops. Scientists are trying to engineer resistance to blights or to low rainfall by introducing beneficial genes found in other varieties of the same species. Using conventional breeding to do the same thing can take many years.

Industry
A large biotech company is trying to grow drought-resistant corn and wheat that can breed like a hybrid rather than self-pollinate. If the tests are a success, the new GE wheat can increase yield by 10-15%. They will join crops that have already been edited with CRISPR, like soybeans, rice, and potatoes. The company plans to bring the products to market in 5-10 years. They will have exclusive rights to the patents once approved. Thanks to biotechnology, the seed business has grown to about $40 billion a year, dominated by large companies.

Costs
GE wheat is not yet available on the market, but seeds for other genetically engineered crops tend to be more expensive than traditional crops. For example, seeds for an acre of GE corn cost around $114, while seeds for traditional corn cost around $65. However, the cost is more than recovered by the increased yield of the GE corn. Farmers would not be required to use GE wheat.

External Effects
CRISPR-edited wheat could potentially yield more food with less pressure on water and land.

Regulation
The FDA regulates the safety of food for humans and animals, including foods produced from GE plants. Foods from GE plants must meet the same food safety requirements as foods derived from traditional plants. Existing FDA safety requirements impose a legal duty on everyone in the farm to table continuum to market safe foods to consumers, regardless of the process by which such foods are created. It is unlawful to produce, process, store, ship, or sell unsafe foods to consumers. The FDA created the Plant Biotechnology Consultation Program in the 1990's to work with GE plant developers to help them ensure foods made from their new GE plant varieties are safe and lawful. Although the consultation program is voluntary, GE plant developers routinely participate in it before bringing a new GE plant to market.

To U.S. regulators, most organisms currently under development may not be considered genetic modification. This is because U.S. policy is product-based, and with many types of CRISPR edits, the product will not include foreign genetic material. In cases where editing introduces genes from close crop relatives, the product might even be genetically indistinguishable from the results of conventional crossbreeding and could even qualify as organic. Companies hope gene-edited crops could be largely exempted from regulation. The USDA has told several companies that it will not regulate these plants because they don't contain genes from other species.