Regulation

The biotechnology industry argues that gene editing should not be classified as genetic modification and that the products should therefore be exempt from regulation.

Canada assesses the risks of genetically engineered organisms under regulations for "Novel Foods" and "Plants with Novel Traits". The Canadian government regulates products if they have a "novel" trait, regardless of the process used to make them. This means that most, but not necessarily all, gene edited products will be covered by these regulations.

The U.S. government is not conducting risk assessments before gene edited products are approved. In Europe, regulations for genetically modified organisms cover gene editing.

Gene Drives

Gene editing (CRISPR) is also being used to create so-called "gene drives". Gene drives force a specific trait to spread through generations of a wild species, overriding the process of natural selection. The intention is to engineer the genetics of entire populations of plants, insects or animals

Gene drives can be used to eradicate whole populations. Proposed uses include altering mosquitoes to prevent their reproduction, to reduce populations that carry diseases such as malaria. Companies are also experimenting to alter the genes of weeds and insect pests.

Once released, gene drive organisms cannot be recalled and any changes to wild populations would likely be irreversible. These could have far-reaching and unpredictable consequences for our society and the environment.

For more information

Gene edited organisms in agriculture (report), Friends of the Earth USA, 2018.

God's Red Pencil? CRISPR and The Three Myths of Precise Genome Editing (article), Jonathan Latham, Independent Science News, 2016.

www.cban.ca/gene-editing

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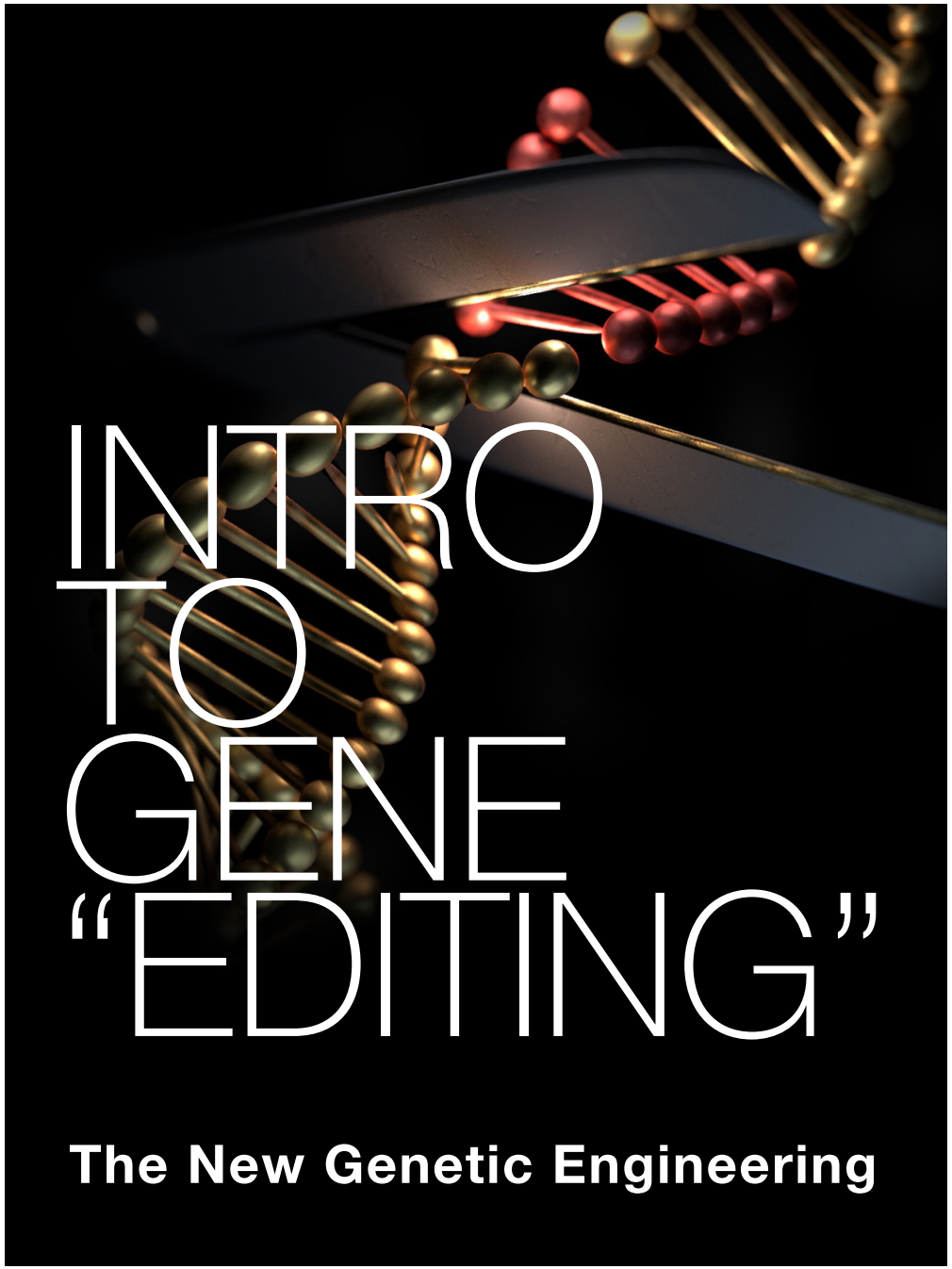

INTRO TO GENE "EDITING"

The New Genetic Engineering

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"Gene-editing" or "genome-editing" describes a range of new techniques to alter the genetic material of plants, animals, and microbes, such as bacteria. The most common of these techniques currently used in experiments is called CRISPR.

The new techniques can make it easier and faster to genetically engineer (genetically modify) a wider range of organisms, for more purposes. They are powerful research tools that are being used to better understand gene function and, in particular, to genetically modify mice and other research animals to study human diseases. They are also being used to develop new GM foods.

The biotechnology industry argues that gene editing should not even be classified as genetic modification, and should not be regulated or labelled. However, gene editing raises the same risk questions as earlier GM techniques, and the same environmental, social, economic and ethical concerns.

What is Gene "Editing"?

New gene editing techniques are attempts to target a specific site in the genome and damage that DNA by breaking it. This "cut" triggers the cell's own mechanisms to repair the site. We know that the repair mechanisms are imperfect and can generate mutations: **these mutations are the genetic changes that create new traits** that companies are looking for, to try to make new GM crops or other products.

In contrast, current genetic engineering methods randomly insert packages of genetic material from other organisms to create new DNA sequences.

The CRISPR-Cas9 system uses a **site-directed nuclease** (a DNA cutting enzyme) to create the break at a location chosen by a synthetic guide RNA. In short, the Cas9 RNA-guided nuclease is inserted into a cell and it breaks the DNA at the target site, to trigger the repair mechanism whose errors result in new changes to the organism. The break created by CRISPR can additionally be used to delete DNA or to add DNA from other species.

Oligonucleotide-directed mutagenesis (ODM) is a second "editing" method. It introduces a short strand of DNA that attaches itself to the organism's genome and causes a change to its DNA, also by triggering repair. This technique has already been used by the company Cibus to create a herbicide-tolerant canola, the only gene edited crop on the market in Canada.

Is Gene Editing Precise?

The term "editing" is misleading because it implies a level of precision that is not currently, and may never be possible. It suggests the ability to rewrite the genetic code and to simply cut and paste DNA but, in reality, the results are still determined by processes in the organism that we neither fully understand nor control.

It is commonly said that gene editing is capable of creating precise, accurate and specific alterations to DNA but this is **technically inaccurate**.

1) Gene editing can more efficiently target sites in the genome but the enzymes used in gene editing have been shown to **cut DNA in the wrong spots and create numerous off-target mutations**.

2) After a cut is made, the **cell's DNA repair mechanisms are in control of what happens next for the organism**. The results are alterations – such as deletions, insertions, and rearrangements.

Precise edits, even if possible, do not necessarily yield precise outcomes. Even a simple genetic "tweak" can have wide-ranging effects on an organism's . function and safety.

Unexpected Effects

Any attempt to alter genomes with such invasive methods can cause unexpected and unpredictable effects.

Unexpected large deletions or rearrangements of DNA can take place at the intended editing site or elsewhere, and can disrupt the function of non-target genes. Unwanted changes are likely to slip by undetected.

Even the intended alteration can inadvertently alter other important genes, causing changes in chemistry or protein production that can be important for food and environmental safety.

Gene editing may also have unintended impacts on an organism's ability to express or suppress other genes. The orchestration of gene function in an organism is part of a complex regulatory network that is poorly understood.