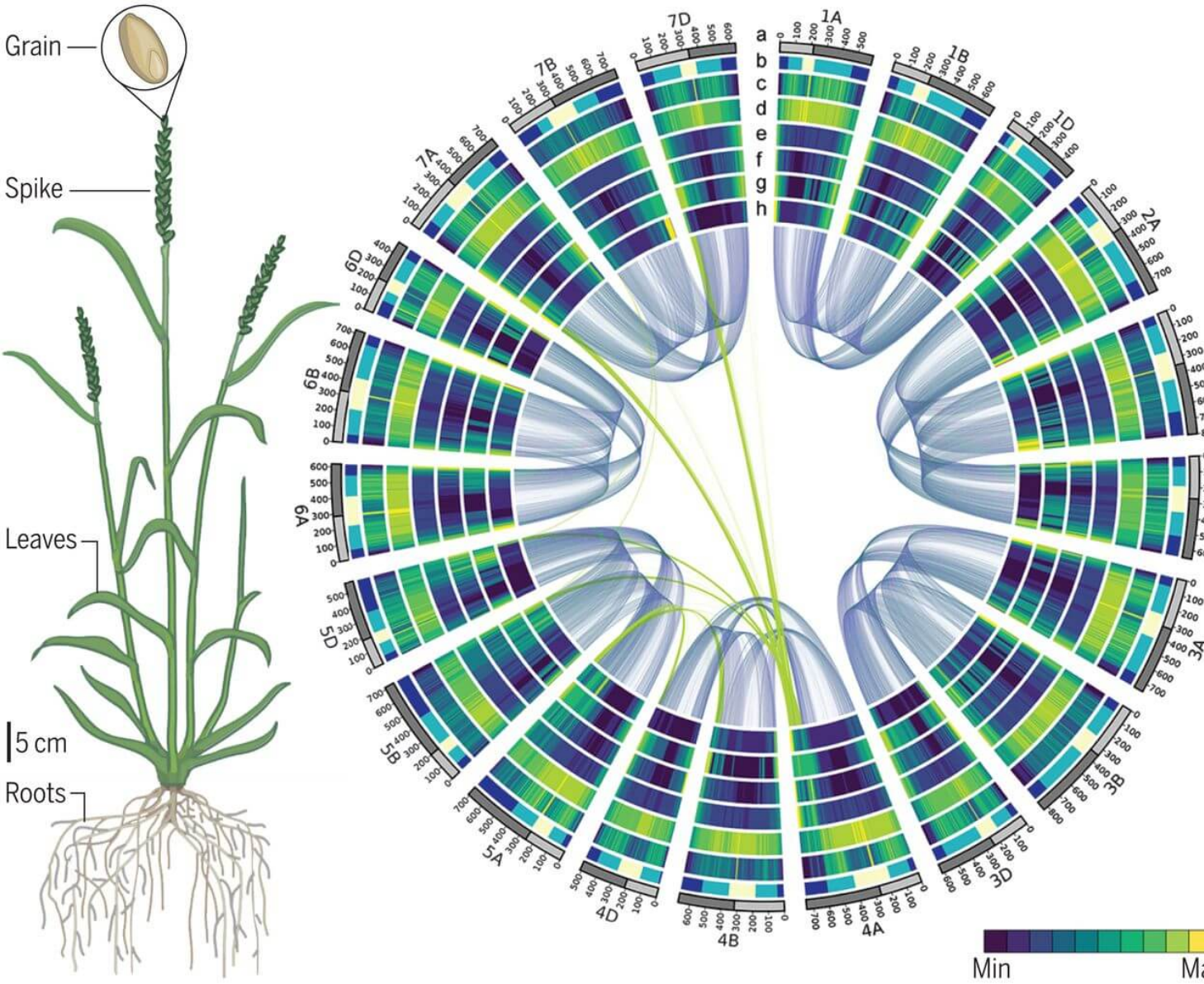
Viewpoint: Why gene editing is so much like ‘nature’ — and therefore should not be tightly regulated

At what point do regulatory experts possess sufficient knowledge on innovative technologies and their potential impacts, both beneficial and adverse, that they decide regulation is no longer required? Ideally, we would be able to have products seamlessly enter the market that required no regulatory oversight. The reality of this is quite unlikely, as one role of government is to ensure the safe provision of food to its citizens. Experts in risk assessment for the approval of new crops and foods are an important component of food safety systems, as they use science-based evidence to assess the potential risks of new food products. The risk from producing or consuming something can never be zero, so the production of all food products includes some degree of risk. It’s simply not possible to reach the point where the production of food contains zero risk. Raising the question, to what extent does food need to be regulated when its production will always include some level of measurable risk, no matter how tiny this might be?

Similar risks are approved, but new might not

When the risk of new products are similar to the risks of existing food products, the new product will be approved in Canada. This is a science-based process known as substantial equivalence. A subsequent and pertinent question is at what point is the change so tiny, that the resulting product is, for all purposes, identical to previous ones? I recently heard an excellent comparison that helps illustrate this concept. Take a book that has 20,000 words. If one word was changed, would the change result in the same book or a new one? Sure, if a word in the title was changed, this could change what we think the book is about, but would it change the book?

This aids in explaining how scientifically accurate genome editing (GEd) technologies can be. The advancements of GEd technologies are capable of removing one gene or changing it to express at higher, or lower, levels. In plants that have hundreds of thousands of genes, changing one gene is less than the number of genes that naturally mutation from one generation to the next. For instance, in wheat, there are only 21 chromosomes, but there are hundreds of thousands genes. When we look at natural rates of mutation in multicellular organisms, they range from 1 in 100,000 to 1 in 1,000,000 genes. The wheat genome ranges from 164,000 to 334,000 genes, that meaning that two or three genes will naturally mutate from one generation to the next, giving the plant slightly different trait characteristics. So what’s the difference between three natural, random mutations and one GEd targeted mutation?



Wheat reference genome. Credit: Science

Regulations that match the risk

It is impossible to regulate natural, random rates of genetic mutation. Those that are beneficial mutations will be passed along to future generations and can even be increased over time, such as how plants developed natural resistance to specific insect pests. Natural and random genomic mutations happen in all plant species from one generation to the next, all of which are completely unregulated with no risk assessments conducted. This fact raises the question of whether controlled mutation of a small number of genes through targeted mutagenic technologies, such as CRISPR-Cas9, require risk assessments and costly regulatory compliance?

Plants have amazing abilities to adapt to changing environments, such as improved drought resistance, seed production and insect resistance. Genome editing technologies have the precision to simply speed up what nature has been doing for millennia. Risk assessment is designed to ensure that transformative changes in products don't provide a greater level of risk to humans or the environment than existing products. Slightly changing two to three genes out of several hundred thousand, isn't a transformative change. Based on the safe consumption of plants for tens of thousands of years, humans have learned that mutation rates at this low level are safe.

Several countries, such as the USA, Brazil and Argentina, have said that if GEd technologies create a new plant variety that could have naturally occurred, additional regulatory oversight isn't required. For example, if drought tolerance already existed in a plant variety and GEd is used to enhance this trait, the resulting variety would not require additional regulation. Regulations need to be risk appropriate, there to be applied when there has been a significant genomic change in a plant variety. Some countries, such as those within the European Union, allow fear and uncertainty about all genomic technologies to drive their regulatory risk assessments. This has driven billions in research and development investments out of the EU, reducing the area's ability to ensure crop yields are sustained as the climate changes.

The future is unknown

We don't know what the future holds for us, but we are aware of the pressures climate change is placing on the agricultural world and food production. We cannot assume that natural mutations will be enough to ensure that improved crop and food varieties can sustain ever-growing food demands. That is why plant breeders are working so diligently to get approval for GEd crops, which address the growing concerns of climate change. However, we already know from previous blogs, that it takes years to get these crops to the point of approval, and years to receive approval, and in some jurisdictions, regulatory approval of genomic modifications takes 5-6 years or longer.

Is society prepared to stand by and watch the rates of food insecurity soar amongst the global population while technologies that could reduce this, languish in scientifically unjustified regulation? We are observing the effects of changing climates on crops in North America and elsewhere, where typically the resources to find solutions like changing crops, irrigating, and utilizing chemicals and fertilizers can be applied. However, these solutions may not be able to be applied in all crop producing regions. As the climate changes, improving food security depends on having risk appropriate regulations.

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