Nature Genetics to regulators: Treat crops made from conventional breeding, geneediting same

## The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis.

In a commentary in Nature Genetics, Chinese, German and US researchers make the case that many applications of gene-editing would lead to crops that would, at least in theory, be possible to produce by conventional methods, since gene-editing does not require insertion of foreign genes.

...President Obama reaffirmed that regulatory agencies shall "propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs." In agreement with these principles, we argue that there is no reason to regulate GECs with gene knockouts or nucleotide variants that either have been documented to exist within crop species or closely related wild species or that can reasonably be expected to arise by spontaneous mutation. Because such genetic stocks could in principle — although generally not in praxis — be generated by conventional breeding or random mutagenesis, they should be considered the same as those used in conventional breeding, which are not regulated. Importantly, wholegenome sequencing allows excellent documentation of the variation introduced by genome editing.

- 1. We recommend five steps as the primary guiding principles when considering the generation and regulation of GECs.
- 2. Minimize the risk of escape of GECs from laboratories and fields during the research and development phase.
- 3. Demonstrate the absence of foreign sequences, if genome engineering proteins were introduced as DNA constructs.
- 4. Document DNA sequence changes at the target sites. If new sequences were introduced by homologous recombination, identify the phylogenetic relationship between the donor and recipient, as a proxy for the likelihood of new interactions with genetic background. Sequences from distantly related species introduced into GECs by homologous recombination may have to be considered on a case-by-case basis.
- 5. Ensure that the primarily targeted site did not suffer unintended secondary editing events and consider the consequences of potential off-target events on the basis of available reference genome information and whole-genome resequencing technologies.
- 6. Include documentation of the above four points for cultivar registration. Beyond these four points, GECs should only be subject to rules and regulations that apply to products of conventional breeding before commercial release.

The opportunities that GECs offer for ensuring global food and nutrition security are at least on the same order as those from GM crops and in many cases are more promising than those from conventional breeding. The world cannot afford to miss the opportunity of using the most relevant technologies to achieve the lofty targets stated in the recently released United Nations Sustainable Development Goals. The U.S. Department of Agriculture does not consider GECs to be GM organisms25 as long as GECs do

not contain DNA from plant pests. Similarly, German authorities recently confirmed that genome-edited canola generated with an older oligonucleotide method does not constitute a GM organism, as it is not distinguishable from the products of conventional mutagenesis. We urge other countries to follow suit.

Read full, original post: A proposed regulatory framework for genome-edited crops

I an accompanying editorial, the publication's editorial board also called for gene-edited crops to be subject to no more regulation than crops developed through conventional breeding.

Rapid, precise and appropriate breeding strategies are needed for the future of agriculture, not only to keep pace with the constantly evolving ecology of food and fodder production but also to meet increasing demand for more nutritious harvests (*Nat. Genet.* <u>47</u>, 561, 2015). In much of the world, most people subsist upon staple food crops that cannot keep up with the demands of the expanding human population and the drier and warmer field conditions imposed by climate change...

The technological revolution in genomics-based agriculture, if responsibly promoted, has the potential to meet and exceed our needs, equally for science and society. On 109, Sanwen Huang and colleagues propose a practical model for regulating the introduction of new genome-edited crops that would make it possible to achieve some of these goals while building popular support for sustainable agriculture based on biological science. We fully endorse this proposal...

A distinction must be established, particularly in the public sphere, between 'genetically modified organisms' (GMOs) generated through the transgenic introduction of foreign DNA sequences and 'genome-edited crops' (GECs) generated through precise editing of an organism's native genome...

Central to the responsible application of genome editing to agriculture is the registration of GECs, which is directly comparable to the requirement that traditionally bred varieties be registered. No further regulation exists for varieties obtained by classical methods, so GECs likewise should not be subject to government oversight...

Read full, original post: Where genome editing is needed

GLP's sister site The Genetic Expert News Service carried several experts comments on the papers: Nature Genetics editorial: gene-edited crops 'should not be subject to government oversight'