Opinion

Rebecca Nesbit
Scientific programme manager
at Nobel Media

It's time for rational regulation

Post-Brexit, the UK can lead on developing a sound regulatory system for emerging agricultural techniques

To many people, herbicide-resistant crops are synonymous with genetic modification and Monsanto. In reality, however, the market is more complex. For example, Bayer has used conventional breeding techniques to create genes conferring herbicide resistance to crops such as canola, cotton and soya. More recently, the American company Cibus developed a herbicide-resistant canola which was developed using gene editing, not GM.

This highlights a mismatch in the EU's regulatory system: from a farmer's perspective these crops differ only in the particular herbicide they are resistant to. To an EU regulator, however, their similarities are irrelevant – what matters is the techniques used to develop them.

GM crops face extensive testing before they are approved for import or cultivation, in complete contrast to crops produced through conventional breeding, which aren't subject to any regulatory approval at all. New breeding techniques, particularly genome-editing tools such as CRISPR, don't fall neatly into either camp, and the result is a regulatory vacuum.

Unlike herbicide-resistant crops created through traditional genetic modification, Cibus's genome-edited canola contains just two mutations, in known locations – it doesn't have a new gene 'inserted' into its genome. Does this make it genetically modified? That depends where you are.

Argentina and the USA are among the countries that have ruled that genome-edited crops aren't subject to the same regulation as GMOs. Europe, however, remains undecided.

The European Commission's analysis of whether new plant-breeding techniques should be considered GMOs was expected in 2015, yet the decision has been repeatedly delayed. With an increasing number of public and private institutions using genome-editing techniques on livestock and crops legal guidance on regulation is urgently needed.

As the UK negotiates the terms of its departure from the EU now is the time to discuss a regulatory system which supports innovation while protecting health and the environment.

Predictably, there are calls to regulate all genome-edited crops under existing GMO regulation, with anti-GMO lobby groups being particularly vocal. For the scientists exploring the potential benefits of genome editing to agriculture, however, this would be a disaster.

The effect of the EU's GMO regulatory system has effectively been to prevent the cultivation of GM crops in Europe. If this regulation is applied to genome-edited crops they would no doubt be doomed to the same fate. Many scientists are instead calling for the trait and product to be regulated, not the technology or technique. This would be far more logical for herbicide-tolerant crops, which can create both benefits and challenges to farmers and ecosystems no matter how they were developed.

Regulators should consider environmental challenges – such as the emergence of herbicide-resistant weeds – when deciding whether to authorise a crop, not how it was made.

Genome editing has great potential in agriculture, with research ranging from drought-resistant wheat to hypoallergenic eggs. But this potential will only be realised if genome-edited crops and animals are subject to a sound regulatory system.

When designing regulations we need to learn from the GMO debate, including the importance of listening to public concerns. However, it is important not to let loud voices block the development of rational, evidence-based policy.

Regulation as a GMO will do nothing to ensure that genome editing is used to support sustainable agriculture. In fact, it will probably do the opposite – the cost of current regulatory approvals mean that they are restricted to the largest agribusinesses. Humanitarian projects are unlikely to get a look-in.

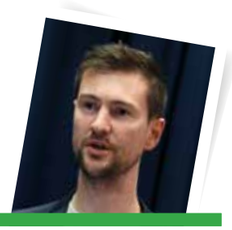
As with all the scientific challenges and opportunities that accompany Brexit it is important that voices are heard. Starting an open, clear and respectful debate can help ensure that our society is comfortable in adopting a regulatory system that is based on evidence not fear.

Rebecca Nesbit's book on GMOs, Is that Fish in Your Tomato? *is out now from Ockham Publishing*

Herbicide-resistant crops can create both benefits and challenges no matter how they are developed

Opinion

Jon Tennant
Founder of paleorXiv



Preprints and best practice

Scholars should cite literature based on relevance and quality, not just because it has been published in a journal

In 1990 the ambitious CERN computer scientist Tim Berners-Lee [redacted] the web as a way of rapidly sharing [redacted]rmation between researchers.

Just a few months later, arXiv (pronounced 'archive') was developed as a centralised web-based network for the maths, computer science and physics communities. Nearly 30 years on more than 8,000 'preprints' – academic articles that have not yet been formally peer reviewed – are submitted to arXiv every month.

In the life sciences around 1,000 papers are submitted as preprints every month. Several developments have catalysed the use of preprints in the biosciences, including bioRxiv, an arXiv mimic, and the community-led ASAPbio initiative that encourages the productive use of preprints. Large research bodies including the NIH, MRC and BBSRC now both allow and encourage the use of preprints in grant submissions.

In spite of this growth there is still resistance to preprints. One major barrier is the question of their citation as scholarly works. Some researchers have claimed that it constitutes bad scholarship and that preprints, due to their preliminary nature, are no different to other 'grey literature', such as non-peer-reviewed reports, articles, correspondence etc.

This is part of our academic culture where typically only research that has been explicitly peer reviewed, and therefore has a stamp of certification, is cited.

This is actually quite different from other fields. According to Google Scholar, four of the most highly cited 'journals' of all time in maths and physics are arXiv subsections. In these communities, a preprint is considered to be an establishment of priority for that research, a starting point for further discussion or investigation. In the life sciences, preprints have not yet gained this status.

Attempts to close this value gap have largely focused on making preprints more citable from a technical perspective – for example, provision of better metadata, persistent identifiers (DOIs), and even the look and feel of a traditional journal article. However, researchers don't avoid citing preprints because it's technically difficult. They don't cite them because they are not deemed worthy of citation.

Some researchers have claimed that preprints are no different to other 'grey literature'

What researchers rely on are journals (and peer review) to take on the responsibility of telling them what is citable. Preprints tell us that the responsibility of the citation lies with the citer, and for some researchers this is scary. However, evaluating the quality and context of research is part of our job. There are good and bad preprints, just as there are good and bad papers. As research communities we should not be using journals as an excuse to absolve ourselves of the ability to think critically.

I recently established paleorXiv, a community-led preprint server for palaeontology research. It didn't take long for this to spark a lot of discussion, and I even received an email from a senior researcher emphasising fears that it might be used by creationists to 'get one over' on real science. Yikes.

We are still just at the beginning, and there is a long way to go. The biosciences are incredibly diverse, with many subdisciplines – each with its own set of community norms and values. It is understandable that a 'one size fits all' model for preprints will never work across the entire life sciences.

For paleorXiv, we decided to create community-oriented submission guidelines to engage with researchers and help address many of their concerns, particularly regarding preprint citations. To me, the most important is: "Please exercise the same care and judgement you would use for any research output when it comes to the citation and re-use of preprints." That's just good scholarly practice.