

Governance and regulation of genome editing for agriculture

Presentation by Roland Jackson (UK) to the G20-MACS meeting, 29 May 2018

It is both a privilege and a pleasure to be here to discuss the implications of genome editing for agriculture. I am particularly grateful to the organisers here in Argentina for extending an invitation to me to speak, and to the UK's Biotechnology and Biological Sciences Research Council for supporting my visit. Though I am a member of the Nuffield Council on Bioethics, which is effectively the UK's national bioethics institution, I should emphasise that my remarks here are my own. I am not representing any particular UK organisation, or the UK Government. However, I should mention that the Nuffield Council on Bioethics published in 2016 what we call a 'platform' report on genome editing, called *Genome editing: an ethical review*, which explores the issues in general. The Council will soon publish a detailed report on genome editing in human reproduction. Following that, the Council is setting up a working group to produce a report on genome editing and livestock. I hope that report in may, in time, be of particular interest to people here.

In the next few years, and decades, through genome editing, we may be able to make major changes, quickly, at scale, and in a targeted manner, to the genetic endowment of bacteria, plants, insects, and animals. Those changes could have significant implications for agriculture and the environment, and for people's lives and livelihoods. But just because we *may* be able to do something now does not mean that we always *should* do it now.

What I want to do in this presentation, is to raise some questions for discussion about the governance and regulation of genome editing for agriculture. I want to suggest some ways by which we should look at genome editing for agriculture, in the context of all the other ways by which we might seek to meet the challenges posed by feeding the world's population equitably and sustainably.

Biotechnologies were defined at the 2018 Davos meeting as 'conjunctions of knowledges, practices and applications'. They therefore come with strong ethical, social, and political dimensions. The theme of that Davos meeting was 'Creating a shared future in a fractured world'. It is that creation of a shared future on which I want to concentrate.

In a report on *Emerging Biotechnologies* in 2012, the Nuffield Council on Bioethics recommended that ‘commitments to particular technological pathways should be evaluated not only in terms of their expected future impacts but also by comparison to possible *alternative* pathways’. In other words, we should not assume that any given technology is the best solution to any given problem. This does not mean that the pursuit of particular outcomes is unethical; indeed, it is indispensable. But it points to two possible errors. First, we should not imagine that meeting social ‘challenges’ require particular technological solutions and therefore limit our exploration of other kinds of response. Second, we should not focus the development of biotechnologies too tightly on solutions to *particular* challenges and therefore fail to be sensitive to the range of possible benefits they might bring, perhaps in very different contexts.

This is why concentrating too much on *regulatory* hurdles, which so many scientists and others complain about, is often to miss the point, important though regulatory issues are.

Regulation is what we might call a downstream activity. It happens late in the process of discovery and development. Regulation is concerned with ensuring safety to humans and the environment, not with those choices about a shared future. If there is nowhere else for effective discussions about shared futures to take place, it is not surprising that people’s concerns surface at the point of regulation. There is nowhere else for their hopes, priorities, or concerns to be raised. That is one reason why there has been so much opposition to GMOs in the regulatory process in many countries. GM effectively becomes a proxy for other issues, including corporate control of the food system, which is not of course limited to GMOs. You may see that as scientifically illiterate, but that’s not the point. It becomes a question of public values, and beliefs about nature, not just a scientific question.

So, I’m not going to go into whether specific examples of genome editing should or should not come under GM regulations in, for example, Europe or America. Nor will I go into concepts of precaution, though we may want to discuss both in the plenary.

Instead I want to outline five brief examples of current or emerging practice, and then highlight their implications, from my perspective, for the governance and regulation of genome editing.

First. The case of artemisinin, the antimalarial agent, **highlights the complexity of economic systems.** The production of semi-synthetic artemisinin through synthetic biology has been hailed by some as ‘a biotechnology solution to the global problem of access to affordable antimalarial drugs’. Yet the initial price was similar to the agricultural product obtained from plants, despite Sanofi selling it on a ‘no-profit, no-loss’ basis, more than 50 million US dollars of research and development funding for the project from the Bill & Melinda Gates Foundation, and not having to pay patent royalties to Amyris and Berkeley. The price of artemisinin has been quite unstable over the past decade and the availability of the synthetic version does not seem to have substantially stabilised it. In my view, over-promising a technological solution to a complex issue of economics and community health practices is dangerous. Is this alternative really better, or even needed? Remember that the current controversy around GM crops developed partly as a result of similar, overblown promises, made in the late 1990s, about their prospects for ‘feeding the poor’ that proved out of step with what was actually delivered. This is not a regulatory question. Nevertheless, we should note that it has recently been announced that a version of *Artemisia annua*, producing up to three times the wild-type level, has been engineered in China. As far as I am aware, there are currently no GM approved *Artemisia annua* anywhere in the world, and it will be interesting to see the response in China, where the crop is grown and where the plant is a high-profile example of Chinese Traditional Medicine.

My **second** example **highlights the need to work closely with agricultural communities**, which won’t be a surprise to anyone here. For reasons of confidentiality I will not give the precise details, but I was quite shocked recently to hear a proposal by researchers, that had been funded through philanthropic source, to engineer a plant, whose root is used as a starch crop in certain developing countries, to flower and produce fruit. At no point in the development of this idea had the researchers thought to consult and engage with the farming practices, dietary preferences, and economies of the communities that might be affected. Again, that is a question of anticipatory and participatory governance, not initially of regulation.

Third. Issues with gene drives. Gene drives are seen as a potential way to eradicate insect pests, for example. But they require huge forethought. It is interesting that Kevin Esvelt, working on a long-range plan to create a gene drive in white-footed mice to fight Lyme disease in the eastern US, called for patents to require scientists to disclose their experiments *before* they do them. He said: 'It's essential we don't develop ecological technologies behind closed doors'. I think we need to ask if we're really sure, in any particular case, that gene drives are the solution. Do we really understand organisms and ecosystems that well? Gene drives must surely be looked at in the context of all the alternatives, and their targets identified by societal discourse, not driven by what happens to be a particular research or commercial interest.

Fourth. The massive potential of genome editing in livestock. Certainly genome-edited livestock are easier to manage and contain than crops. All sorts of possibilities lie ahead, from creating resistance to disease, to increasing muscle, faster growth, and larger size. We heard the fascinating example yesterday from INRA of the development in Argentina of a transgenic cow producing milk with an anti-rotavirus agent. Given the long breeding cycle of livestock animals, genome editing is a potential game-changer. But it raises huge questions about human relationships to animals, and the ethical issues involved. What impact could it have on animal husbandry? What impact could it have on preservation or reduction of genetic diversity? And what will consumers think of particular applications in different countries? We should also not forget that livestock are dominant greenhouse gas producers and key drivers of changes of land use. How, for example, might genome editing in livestock contribute to combating those challenges?

Fifth, and finally, I will just mention **bacteria**. Some research groups are exploring engineering bacteria, for example to create nitrogen-fixing cereal crops, or otherwise to affect plant signalling pathways. Genetic engineering of bacteria is generally done in contained systems, through industrial biotechnology, when chances of release can be minimised. Deliberately engineering soil bacteria, such a complex and partially understood world, certainly requires some care.

What I take from these examples, which will not be news to anyone here, is the complexity of organisms, ecosystems, and economies. We know that genome editing increases the potential scale, scope, and speed of genetic modification, whether of bacteria, plants, insects, or animals, all of which may have agricultural implications. We know the techniques can be used for good as well as for deliberate or accidental harm; the concept of dual use. We know that early technology choice matters, through technological lock-in, preventing other or better solutions from emerging later. So, what is technically achievable *now* should not necessarily be attempted *now*. We appreciate the speed of evolutionary resistance to introduced genetic changes, especially for bacteria, insects, and plants. It is wise to be humble around biological organisms and ecosystems. One major environmental disaster from a genome-edited product, or serious example of public resistance, could greatly increase public scrutiny for this whole field of genome editing. We need to proceed with care and caution, in step with public values and beliefs.

If we want to create a shared future in a fractured world, regulation should not be the focus, important though it is. We need a much better public debate about visions and values for agriculture and its impact on our societies and agricultural communities. We need to talk about the role genome editing could play, *compared with* all the other means of addressing particular problems, both political and technological, including for example techniques like data-driven artificial intelligence and image recognition. It would be quite wrong to look at genome editing in isolation.

This is where MACS-G20 could play a major role. You already have several concrete initiatives to promote cooperation. You might consider a further initiative to examine the potential of genome editing, in the context of other means of addressing the same problems, and *explicitly* with wide stakeholder and citizen dialogue and participation.

Three key policy drivers for agriculture are to increase production sustainably, often in marginal environments affected by climate change, to reduce waste, and to provide equitable access to people of the benefits of agriculture.

National Agricultural Institutions have a major part to play here. To my mind, research priorities and agendas need to be influenced by farmers and citizens,

though discourse. Institutions often engage extensively with farmers, but perhaps less with consumers and citizens. Capacity building should include the skills to do that. And if researchers are making claims about social and economic impact, then those claims need to be explored and evidenced as rigorously as the science itself. That means, in terms of capacity building, that the development of capabilities in economics, social, and political science, in developed as well as developing countries, needs supporting just as much as those in the natural and environmental sciences. It is interesting in this respect, for example, that the US Department of Agriculture and National Institute of Food and Agriculture have just announced grants to advance research on public engagement and the implications of gene drives and other gene editing technologies. Aims include determining effective ways to educate consumers, and identifying key inducements and impediments to public trust of gene-edited foods and their governance. This is all welcome, though I do have one concern. That is that citizens are being seen here purely as research subjects to be influenced and manipulated. I would rather see a systemic process of genuine citizen involvement.

These issues are all tied up with food system sustainability, and there are differing views about how this might be achieved, whether through focusing on efficiency and increased production, demand restraint, or food system transformation (and these are not mutually exclusive). Whatever your own orientation, and governments tend towards a technologically-driven efficiency orientation, it will greatly influence the ways in which you think genome editing should be applied. As Tara Garnett said in an important paper in 2013, more work is needed to understand the values underlying different approaches to the food sustainability problem. I think those discussions about values, people's views of the role of technology, their relationship to nature, and their definition of a 'good life', need to be brought into public discourse that can influence policy. My own view is that only a considered food system transformation can simultaneously address the problems of excess in some places and insufficiency in others. Focusing on increasing efficiency (including of reducing waste) or demand reduction, will be inadequate on their own. Our major challenges are socio-economic, and indeed political, not just technological. So I hope, when we consider genome editing, that we will think of it in a systems way, and in a coordinated way across the G20, recognising the very different situation in

different countries, especially for people with poor diets and limited access to food.

With respect to genome editing, if the MACS-G20 community sees the problem as simply persuading the public that particular genome-edited organisms are safe and acceptable, we will probably find ourselves in the same situation as with earlier GMOs. The setting of priorities, to which genome editing might be part of the solution, *must* be opened up to wider discourse. That means public bodies, charitable and philanthropic organisations, as well as the private sector, need to take wider engagement more seriously.

Using biotechnology deliberately and strategically to support biodiversity, reduce waste, and increase production sustainably, is a noble challenge. Indeed, I think we have an ethical duty to explore it. With genome editing we have the possibility of hugely increased speed, scale, and, potentially, precision. We also have a massively increased choice of targets or traits to choose between. Those choices cannot be left simply to market forces or to the interests of individual researchers. That did not work with GMOs, and it probably won't work now.

Regulatory criteria are always going to be significant, not least when they differ between different countries, as they do at the moment, whether in relation to plants or livestock, for example. But regulation is a *second order* question. It is the *governance* that matters. We need to think from the outset about priorities that carry public enthusiasm and support. If our vision builds on international cooperation, rather than competition between individual countries or private corporations, and if we built it on a deep understanding of what is valued and acceptable to citizens, consumers, and farmers, the rest will follow more easily.

So, to end I would highlight four main suggestions I have made, that might, among others, be a useful focus for our discussion. You, I am sure will have others.

1. We should not look at genome editing in any specific case, or as a general set of techniques, without considering all the other possible means of addressing the same problems.
2. With respect to capacity-building for genome editing, the development of capabilities in economics, social, and political science, needs supporting just as much as those in the natural and environmental sciences.
3. Discussions about values, people's views of the role of technology, their relationship to nature, and their definition of a 'good life', need to be brought into public discourse that can influence policy. This is regardless of whether you take an approach that focuses on efficiency and increased production, on demand restraint, or on food system transformation (or a combination of the three). However, it does depend on your view of the relationship between humans and nature. My view, and my ethical stance is derived from it, is that humans are an integral part of nature.
4. MACS-G20 could play a major role, through a coordinated initiative to examine the potential of genome editing, in the context of other means of addressing the same problems. I think the G20 Agriculture Ministers draft declaration offers a way of thinking about this. rather than *pushing* research-driven possibilities from genome editing onto agriculture, we might look at the proposed Ministerial priorities and ask in each case how genome editing might contribute, alongside other approaches (technological and non-technological). A policy pull approach, rather than technology push. You might do this explicitly with wide stakeholder and citizen dialogue and participation. It is not a case of telling people what's good for them, or that they are stupid if they don't understand the science. My contention is that if the consultation and dialogue were done meaningfully, problems at the regulatory stage, of introducing innovations, could be greatly reduced.