Norwegian Committee set up to review advances in gene technology calls for "softening" of regulation

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June 2023
Science for Sustainable Agriculture

A report from the public committee advising the Norwegian Government on the future regulation of genetic technologies in food was published earlier this week. It concludes that current regulation of precision breeding techniques such as gene editing in Norway and the EU is disproportionately high, and calls for products that are comparable to conventionally bred products to be regulated as such, mirroring a similar approach recently announced by the Canadian authorities. As the EU Commission prepares to unveil its proposals for future regulation of new genomic techniques, and as Defra and the Food Standards Agency develop more detailed plans to implement the Genetic Technology Act in England, the Committee's report presents a compelling case for proportionate and enabling regulation of these vital technologies, writes science communicator Dr Julian Little.

The Genetic Technology Committee in Norway was set up by Royal decree in 2020 to "update the knowledge base in Norway in the area of genetic technology and genetically modified organisms (GMOs)", essentially updating a previous viewpoint published in 2000.

Led by Head of Research at the Institute of Marine Research, Anna Wargelius, the committee comprises 12 members with "expertise in molecular biology, synthetic biology, microbiology, aquaculture, medicine and health, law and ethics".

Its report into advances in biotechnology in the food system, published earlier this week, calls for a significant softening of current regulations "to realise the potential of genetic technology".

An accompanying press statement (English can be set) explains that "The entire committee believes that genetic technology can play a significant role in meeting future challenges related to food production, climate change and health."

The report itself warns that unnecessarily strict regulations, which are not justified by scientific evidence of risk, will stifle innovation that can help tackle these societal challenges, and concludes that current regulation of genetic technologies such as gene editing in Norway and the EU is disproportionately high for products that are comparable to conventional products.

Critically, Anna Wargelius, in her presentation of the committee's findings to the Ministry of Climate and Environment, points out that it is now "... more risky to maintain a strict regulation than to soften it".

The report provides a fascinating review of the regulatory landscape, noting that EU classification of gene edited products as GMOs was "due to a legal definition that was created before the existence of new breeding techniques such as gene editing". Notably, the report uses the term "precision breeding" throughout to describe gene editing, in a nod to recent UK legislation in this area. It also sends a very clear economic and innovation warning to the whole of the European Union.

"If Norway and the EU are to have significantly stricter requirements than the rest of the world, it will particularly weaken the competitiveness of companies exporting to the international market. It could also result in international developers, who have better access to the technologies, delivering sustainable and useful innovations to the Norwegian/EU market more efficiently than local developers can. Not least, it hinders innovation outside of capital-intensive businesses and industrialized sectors and contributes to monopolization in key areas. Continuation of the current GMO regulations for new breeding techniques would hinder Norwegian/EU competitiveness both domestically and internationally."

Likewise it points out that Norway's and the EU's highly restrictive policy on gene technology "contributes to creating general skepticism and mistrust of genetic technology in the population, because it suggests that there must be something inherently problematic or risky about the technology, even though the scientific evidence indicates otherwise."

However, the report does not call for a regulatory free-for-all, but makes a clear case for regulations that differentiate between GMOs and gene-edited products, along the lines of "the UK and many other countries in the world."

The committee also proposes a risk assessment approach that anyone following the UK model would recognise, ranging from a "no risk assessment needed" to a standard GMO assessment, with two options in between. Description of the proposed regulatory regime is quite detailed, with great examples to illustrate different applications, including salmon resistant to sea lice, sterile garden plants, gene-edited bacteria that fix nitrogen, hornlessness in cattle, wheat stem shortness and disease resistance in food crops.

Table 1: Conceptual distribution of organisms and products in accordance with three main parameters related to risk

A) Are genetic changes within the species gene pool? *(Targeted mutagenesis, cis-/intragenesis)*	Yes ✓	Yes ✓	No ✗	No ✗
B) Are the intended genetic changes as planned, and are there no unintended changes that give cause for concern?	Yes ✓	Yes ✓	Yes ✓	Yes ✓
C) Can we be reasonably sure that the product is safe and has no other significant negative impacts based on existing, transferrable knowledge? *(History of safe use / familiarity and/or known structure and function)*	Yes ✓	No ✗	Yes ✓	No ✗
Assessed at level:	**1** No risk assessment	**2** Simplified assessment tailored to PB	**3** Simplified assessment tailored to GMO	**4** Standard assessment

The committee also "propose that products that meet particularly large unmet needs, especially related to sustainable development, can be granted conditional approval based on less documentation than usual."

On labelling, the report is equally clear:

"We believe that labelling PB products as GMOs would be misleading for consumers and would itself hinder innovation in the field due to reputational risks for producers. It would undermine the potential of the technology for sustainable transformation. Furthermore, requiring GMO labelling and separate production lines for PB products would entail such significant practical and economic consequences for many producers and companies in the value chain that it would not be feasible in practice."

Likewise, on traceability, the committee argues that precision bred "products should be subject to the current general, but strict, traceability requirements that apply to conventional products."

In conclusion, therefore, this report provides a comprehensive review of many of the issues that the UK regulatory authorities are grappling with, and that the European Union is about to confront, with some very clear and constructive pointers of what should be done, and critically, why.

A Fellow of the Royal Society of Biology, Dr Julian Little has worked in plant science and food production for over thirty years. He holds a first degree in biochemistry and a PhD in molecular plant pathology. After a successful career in a number of crop protection and seed companies,

he now helps a range of individuals and organisations improve their communications and public affairs activities in relation to scientific research and innovation in agriculture. He is a member of the Science for Sustainable Agriculture advisory group.