This response was submitted to the Call for Evidence held by the Nuffield Council on Bioethics on Genome editing between 27 November 2015 and 1 February 2016. The views expressed are solely those of the respondent(s) and not those of the Council.

NBT Platform's contribution to the Nuffield Council on Bioethics's 'Open call for evidence'

FROM DATE NBT Platform 1 February 2016

NBT Platform's contribution to the 'Open call for evidence - Genome editing in plant science'

• What is the current state of the art in the field? What are the current technical limitations and constraints/ bottlenecks?

The NBT Platfrom believes that at this moment, the most relevant technical limitation comes from the unclear regulatory framework provided by the Directive 2001/18/EC.

More specifically, the European Commission is reviewing if NBTs should fall into the scope of Directive 2001/18/EC. Until regulatory clarity is provided, the commercial application of these innovative solutions is hampered. However, many organisations worldwide use NBTs in their research and first commercial products have already reached the market, for instance in North America.

• What are the main directions of travel? What are the envisaged endpoints/ applications?

New breeding techniques for plants can provide solutions for societal problems that are linked to our food supply, for instance decreasing the need for natural resources and reducing dependence on chemical crop protection.

Also, the whole agrofood chain, and ultimately consumers, will benefit by the development of NBTs as they help producers to design higher quality products (e.g. improved resistance, longer shelf life, ease of processing, etc.), more diversity in products (e.g. market robustness, changing demand, etc.) and improved nutritional contents (e.g. more vitamins and less allergens).

The innovative nature of this industry, however, is seriously threatened by the fact that NBTs are drawn into the EU-debate on GMOs. While plant products resulting from the application of NBTs differ from GMOs in various ways, the EU institutions have not been able to decide whether or not they fall within the scope of GMO legislation.

• What is the rate of travel? What are the expected timescales for realising the envisaged endpoints?

The NBT Platform does not have a particular position on this argument.

• Are gene drives an area of particular interest or concern and, if so, why?

The NBT Platform does not have a particular position on this argument.

Conditions of research and innovation

• What are the main 'drivers' and 'obstacles' for plant genome editing in relation to envisaged endpoints?

We are of the opinion that NBTs offer a clear benefit to the plant breeding sector, to consumers and to society as a whole; especially in Europe.

The knowledge generated through the research on NBTs, and the product innovations that are derived from their use, are already applied for commercial products in countries outside Europe. Prolonged absence of regulatory clarity for products derived from NBTs in the EU will hamper plant-related innovation in the EU and will mean a competitive disadvantage for EU-based plant breeders.

• What direct or indirect influence does historical public discussion surrounding genetic modification of plants have? What is (and what should be) the current level and focus of public debate?

Most of the current level of public discussion, is on whether NBTs lead to GMO or not.

However, based on the legal analysis performed by the NBT Platform, it can be concluded that most products derived through the use of NBTs do not satisfy the criteria of the Directive 2001/18. Nonetheless, depending on the alteration that is made by the plant breeder, some NBTs can also lead to products which would *a priori* be covered by the GMO legislation.

Outcomes

 What are the main anticipated benefits and costs (including safety and other risks) of genome-edited plants? In what ways, if any, are they significantly different from alternative GM technologies?

New breeding techniques allow the plant breeding industry to develop new plant varieties in a similar—but faster and more precise—manner compared to conventional breeding techniques, and to effectively overcome a number of limitations of conventional breeding. Conventional plant breeding generally relies on techniques of which the outcome is difficult to predict, requiring between seven and twenty five years, depending on the species, to generate the desired characteristics and to introduce these into stable and uniform new plant varieties.

NBTs are crucial for seed and plant breeders in Europe, as they provide them with a 'toolbox' of innovative plant breeding methods alongside the traditional methods, which allow them to remain globally competitive. Most of the world's research on NBTs was done in Europe, totalling to almost 46% of research published up to 2012.

• Are there particular issues raised by genome editing in relation to ecological stability, biological diversity, technology transfer between countries, and equitable sharing of the benefits of research?

Apart from the normal competitive advantage that using new techniques (such as NBTs) may give certain companies in the sector, there is no disadvantage for the seed sector as a whole.

Outside Europe, several products have been developed and have already been approved by the relevant national authority, which means that they can be placed on the market. One example is the herbicide tolerant canola obtained through the use of ODM, for which developer Cibus received market approval in the US and Canada, and is expected for other countries worldwide in 2018.

• To what extent, and in what way, does and should the distribution of anticipated benefits and costs of using genome editing in plants influence research and innovation?

The NBT Platform does not have a particular position on this argument.

• To what extent are public and commercial interests in genome editing in plants complementary? In what circumstances might they come into conflict?

The NBT Platform does not have a particular position on this argument.

• What other important questions should or might we have asked in this section?

The NBT Platform does not have a particular position on this argument.