Genetic Engineering in agriculture - clarity on challenges & solutions

Introduction

Currently in a UK commercial context we are yet to see marketable food products containing PBOs. However, there is a case to suggest that the likelihood is that food and feed products will be market ready in the next 6-12 months. The Genetic Technology (PB) Act was promoted by and comes under the responsibility of Defra and pertains to England only, although there is also relevance to all of the Devolved Administrations due to both the UK Internal Markets Act and the Windsor Framework. The Genetic Technology (PB) Act refers to a range of genetic technologies which includes genetic technologies that are as yet unproven in the field here in the UK, though they may have been seen in medical applications under the authority of the Medicines & Healthcare products Regulatory Agency, e.g. CRISPR-Cas.

GMOs and the Organic regulations

We understand that the UK Government is not amending UK organic regulations as a consequence of this Act and as such 'Precision Bred' crops will be considered as GMOs for the purposes of UK organic regulations. Therefore, 'Precision Bred' material, crops and livestock, cannot be classed as organic and must be kept out of organic food and feed supply lines.

Organic in the Devolved Administrations

UK organic regulations come under statutory law with a mandated inspection and certification regime and operating across England, Northern Ireland, Scotland and Wales. Organic Control Bodies working in Northern Ireland are legally obliged to operate to European Union organic regulations. EU regulations do not recognise 'Precision Bred' material. All genetically 'edited' material and any products containing such would therefore come under EU GMO legislation.

PBOs in the Devolved Administrations

From the Food Standards Agency:

- *Under the UKIMA market access principles, PBO food and feed authorised in England (produced in or imported into England) can be sold lawfully in Wales and Scotland.*
- *The scope of the UKIMA does not, however, extend to processing after sale.*
- *If the PBO is subject to a final significant and regulated production step in Scotland or Wales, under UKIMA it would be considered to be produced in that nation and relevant domestic regulations would apply.*
- *In this scenario, currently, the final product can only be placed on the local market if it is authorised as a genetically modified organism (GMO) in that nation and satisfies the conditions of authorisation applicable to its placing on the market.*

This interpretation of UK law would suggest a clear conflict with EU and UK organic regulations where supply chain integrity runs across England and the Devolved Administrations and into the EU.

Definitions

The definitions that some organisations have described are not entirely accurate.

This from the FSA:

Gene-editing uses specialised enzymes to cut DNA at specific points. These changes must be equivalent to those that could have been made using traditional plant or animal breeding methods.

Genetic editing can replace or remove key parts of or entire sequences of DNA that would not necessarily be seen in so-called traditional breeding. The government have not, neither Defra nor the FSA, made clear proposals for monitoring and therefore would not be able to determine which genetic editing of genetic material would come under the new law and which would potentially fall outside of it.

Responsibilities

Defra are obliged to enable relevant bodies, such as the Food Standards Agency, Local Authority Trading Standards, the National Food Crime Unit and Organic Control Bodies, to maintain and protect the safety and therefore the integrity of food and feed supply lines, including seed production and distribution.

The genetic modification of food crops and livestock by means of the so-called 'editing' of the genome may have potential for good but also for ill (FDA calves).

Any discussion on PBO merits or otherwise can develop as production develops. Effective governance requires monitoring and application of all relevant regulations sufficient to maintain supply chain integrity and thereby continuity of delivery.

Solving the problem

Whilst the Genetic Technology (PB) Act does not clearly state that labelling will be mandatory neither does it necessarily prohibit some form of identification. The Act states that there will be a register of PBO events *.

For the Genetic Technology Act to remain in line with both the Environmental Protection Act and UK Organic Regulations relevant agencies including the Environment Agency, Organic Control Bodies, and Local Authorities, will require full disclosure, including any material otherwise deemed to be commercially confidential, in order to properly carry out all obligations under UK law.

—-

* *Section 18 Precision breeding register*

1. *The Secretary of State must establish and maintain a register ("the register") containing prescribed information*
2. *The Secretary of State must not include information in the register if, on request by a person, the Secretary of State determines that the information is for the time being commercially confidential in relation to that person.*

Section 19 ***Inspectors***

1. *The Secretary of State may appoint inspectors for the purposes of this Part.*

———————

(3) Regulations under this section —

(d) must contain provision to prohibit information obtained by inspectors under the regulations being used or disclosed otherwise than—

(i) for the purposes of this Part or Part 6 of the Environmental Protection Act 1990, or

(ii) for prescribed purposes relating to safeguarding the health and welfare of animals.

(4) Regulations under this section are subject to the affirmative procedure.

Detection

The FSA commissioned a literature review which was carried out by molecular biologists, Malcom Burns and Gavin Nixon. In the review Burns and Nixon concluded that detection is possible:

https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/literature-review-on-analytical-methods-for-the-detection-of-precision-bred-products#main-recommendations-for-providing-an-infrastructure-towards-the-design-development-and-implementation-of-analytical-met

Excerpt from literature review on analytical methods for the detection of precision bred products

...

It is therefore recommended that each PBO be treated on a case-by-case basis in order to evaluate the likely success of a method providing unequivocal detection of a particular PBO.

...

This report recommends additional work be conducted, in parallel with UK and international authorities, to monitor those PBOs potentially destined for authorisation, and actively assess the extent of the genetic variability and mutations, in order to make an informed decision on the type and complexity of detection methods that may be effective. This could be further informed as part of the official authorisation process and results on sequence information be held in a publicly available database or register.

...

Should sufficient information be known regarding the sequence alteration and confidence can be attributed to that sequence alteration being specific to a PBO, then detection, identification and quantification can potentially be achieved.

...

If you have any comments or questions about any of the issues raised please contact OF&G's business development manager, Steven Jacobs.