New breeding techniques – scientific potential and regulation

Agriculture in the EU faces some major challenges associated with the need to deliver food security worldwide at a time of increasing pressures from population growth, climate change and economic instability, and the continuing imperative to avoid further losses in biodiversity. Making better use of plant genetic resources is a very important part of the necessary response to the challenges for agriculture.

EASAC, the European Academies Science Advisory Council, has a longstanding interest in these issues. In 2004, we produced a report (1) describing the opportunities and challenges for using genomics research to support plant breeding and at the end of 2011 we published a detailed analysis of the steps necessary to improve efforts to identify, conserve, characterise and use plant genetic resources in improved breeding strategies (2). Conventional crop breeding has relied historically on lengthy and relatively imprecise techniques but application of modern biotechnology in various ways has the potential to transform the situation.

EASAC has recently initiated a new project, *Planting the future: opportunities and challenges for sustainable crop development*, continuing to address genetics and sustainable intensification of agriculture, covering science and technology in the context of EU food security and EU-global relationships (www.easac.eu). In initial Working Group discussions, it was emphasised how research on new breeding techniques has made considerable progress in the last decade (3) now bringing within range opportunities to introduce desired characteristics more precisely and efficiently into a variety of crops. However, at the EU level there is some confusion as to how these new breeding techniques should be regulated and until legal clarity is reached, application is hampered (4, 5). The registration costs are likely to be low if a technique or its products is classified as non-GMO but very high if classified as GMO and subjected to the same regulation as the previous generation transgenic approaches. This distinction will be of particular importance for small and medium sized enterprises, and classification as a GMO would limit application to traits for high-value crops.

Recent work (6, 7) from the European Commission's Joint Research Centre provides comprehensive analysis of the situation appertaining in R&D and commercialisation for a wide variety of new breeding techniques: Zinc finger nuclease technology; Oligonucleotide directed mutagenesis; Cisgenesis and intragenesis; RNA-dependent DNA methylation; Grafting (on GM rootstock); Reverse breeding; and Agro-infiltration, and there will be others. Currently, the EU has a research leadership position in several of these techniques. It should be noted that for several of these techniques, the commercialised crop would not contain an inserted transgene; that is it will be free of genes foreign to the species. One implication of this is that the genetic change in the product cannot be detected by current analytical methods and the changes cannot be distinguished from changes produced by conventional breeding techniques or by natural genetic variation.

Genetic engineering still attracts controversy and definitions vary worldwide. The European Commission's DG Environment has taken an important initiative in assembling a group of experts from the national regulatory agencies to evaluate whether certain new breeding techniques constitute genetic modification and, if so, whether the resulting organisms fall within the scope of the EU GMO legislation[1] (7). The recent detailed final report of this New Techniques Working Group (8) is most helpful in providing evidence-based perspectives on each of the novel approaches, clarifying and documenting where new breeding techniques fall outside the scope of current GMO legislation. Their conclusions are compatible with the emerging consensus in the scientific literature (9), which is beginning to bring about change in regulatory thinking in the USA. It should also be noted that in the first of the safety assessments – on cisgenesis - commissioned from EFSA on the new breeding techniques, the EFSA expert panel concluded that similar hazards can be associated with cisgenic and conventionally bred plants (10).

It is not our present purpose to discuss these scientific findings in detail, but rather to emphasise that they have important implications for the application of regulatory principles. We now urge the European Commission:
(i) To take account of this new evidence base in considering the regulatory options for managing the new breeding techniques arising from modern biotechnology; and
(ii) To ensure that the process of deciding the regulatory oversight is transparent and that the evidence base used for decision-making is accessible by the wider scientific community.

It is vital that the EU legislative position is fully informed by the advancing scientific evidence otherwise there is twin risk of becoming less competitive than those countries who have modernised their regulatory approaches and also of creating damaging knock-on effects for developing countries who may be dependent on the EU for export markets or look to the EU for leadership in managing bioscience innovation.

As has been emphasised by EASAC in other areas of innovation (11, 12), all risk assessment must be evidence based, focusing on the trait and product rather than the technology. Decisions on regulatory oversight need to be based on scientific principles and accumulated experience, and it is highly desirable to have consistent regulatory regimes worldwide. Given the political and trade problems in the EU associated with the regulation of GM crops, we ask that the regulation of the new breeding techniques should have a firm foundation in sound science, capitalising on the evidence and analysis available. If the EU can confirm that the products of new breeding techniques – when foreign DNA is absent – do not fall under the scope of GMO legislation, this will give strong impetus to the competitiveness of the EU plant breeding sector which, thus far, has been responsible for a significant proportion of the world's research (5) and facilitate the contribution by modern agriculture to tackling societal challenges.

[1] Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment and Directive 98/81/EC on the Contained Use of Genetically modified Micro-organisms.

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