Comparative Regulatory Approaches for new Plant Breeding Techniques

Abstract:
When the first transgenic plants reached the stage of commercialisation, the existing legislation was regarded as insufficient to regulate these new crops in many countries and governments introduced biotechnology or GMO (genetically modified organisms) legislation in the 1980s or 1990s. In the meantime new plant breeding techniques (NPBTs) which deploy biotechnology have been developed and in countries where GMOs are regulated under specific legislation the question arises if these NPBTs should be classified as techniques of genetic modification. In 2010 the Joint Research Centre (JRC) carried out a study on "New plant breeding techniques: state-of-the-art and prospects for commercial development" which covered the following techniques: zinc finger nuclease (ZFN) technology, oligonucleotide directed mutagenesis (ODM), cisgenesis, intragenesis, RNA-dependent DNA methylation (RdDM), grafting on GM rootstock, reverse breeding and agro-infiltration. From a survey which was carried out in the framework of this study, it appears that all seven NPBTs are already adopted by breeders and that the most advanced crops are close to commercialisation. Two of the fields covered by the JRC study are specifically relevant for the discussion of the classification of the techniques under the GMO legislation and for the risk assessment: An evaluation of the changes in the genome of crops obtained through NPBTs shows that besides the intended changes in the genome also unintended changes have to be expected. An investigation of the analytical possibilities for crops produced with NPBTs revealed that for most of the techniques identification of the genetic modification currently is not possible. As a follow-up of the 2010 study, the IPTS organised a workshop in September 2011 to discuss the regulatory approaches for biotechnology derived crops with specific focus on NPBTs in six countries/regions (Argentina, Australia, Canada, the European Union, Japan and South Africa). Whereas, in Canada products derived through biotechnology are treated as any other novel products (plants with novel traits, PNTs), specific biotechnology or GMO legislation was introduced in the other five countries/regions. The presentations and discussions during the workshop showed that also regulatory approaches for crops obtained by new plant breeding techniques differ from country to country. The Canadian regulatory process does not need to be changed or specifically adapted for crops derived through NPBTs. In the EU and Argentina groups of experts started to evaluate whether new techniques constitute genetic modification. In Australia, the Office of the Gene Technology Regulator encourages developers to contact them with specific cases where the regulatory status is not clear. The Office has given advice on a few occasions on the interpretation of legislative provisions relevant to NPBTs. In Japan, officials from several ministries responsible for regulating GMOs meet for the purposes of consulting and coordinating their activities under the national biotechnology legislation including issues relating to NPBTs. The South African participant in the workshop stated that initial considerations concerning NPBTs have started following
the invitation to the JRC workshop In the workshop, decisions and preliminary considerations were discussed for four groups of NPBTs: (i) mutagenesis, (ii) cisgenesis/intragenesis (iii) transgenic construct driven breeding and (iv) others (agro-infiltration and grafting on GM rootstock). Deviating decisions have to be expected in the countries represented in the workshop depending on the regulatory approaches and specifically on the different GMO definitions and their interpretation.

**URL:**

**Authors:**
LUSSER Maria

**Publication Year:**
2012

**Type:**
Contributions to Conferences

**Science Areas:**
- Agriculture and food security [1]
- Health and consumer protection [2]

**Keywords:**
- agriculture [3]
- GMO [4]
- innovation [5]

**Publisher:**
Eucarpia

**Citation:**
Proceedings - 19th Eucarpia General Congress

**Source URL:**

**Links**