CropLife International New Plant Breeding Working Group

Position Document on

Regulatory Oversight of Products Developed Through New Breeding Techniques (NBTs)

CropLife International recognizes the importance of new techniques in plant breeding. In most cases, NBTs are innovative improvements and refinements of traditional breeding methods used to optimize plant health, nutritional quality and yield. They are key in enabling farmers to meet our planet's future food demands by contributing towards efficient and sustainable agricultural practices which preserve our environment's natural resources and stimulate further innovation in plant breeding. CropLife International is concerned about the unnecessary regulation of products developed using NBTs simply based on the breeding technique employed and not the characteristics of the final products. In many cases, NBTs result in products which are similar or indistinguishable from products developed through traditional breeding methods. Adding regulatory burdens based on the method used to develop a product bears the risk of stalling innovative solutions without enhancing product safety.

General Policy on New Breeding Techniques

- CropLife International encourages all governments to adopt a globally harmonized approach towards NBTs, and avoid unnecessary regulation of products developed through NBTs.

- Government policies should aim to foster innovation in vital sectors such as plant breeding to increase food and feed production in a sustainable way.

- Regulations, if needed, should be based on sound scientific principles and proportional to the degree to which the product is creating new potential safety concerns to the environment or food chain, and not on the process by which it was produced. Small changes to plant genomes need to be viewed in light of inherent natural variability of plant genomes.

- Governments should provide timely guidance to product developers on the regulation of NBTs. The regulation of plants produced by NBTs should be predictable in order for industry and public research institutes to foresee appropriate investments and planning for the development and commercialization of any regulated NBT products in a reasonable time frame.

- Governments should avoid regulating products developed through NBTs that are similar or indistinguishable from products resulting from traditional breeding methods, since such products do not differ in their safety.

NBTs foster further innovation in plant breeding

Innovation is crucial in supporting continued developments in plant breeding. As more food, feed, fiber and fuel are needed to meet our global population demands, farmers are being

required to produce more on the same land area, under ever-changing environmental conditions. To meet these needs, innovations in plant breeding, including NBTs, continue to evolve to complement and enhance existing breeding techniques, allowing breeders and researchers in the public and private sectors to increase the efficiency and specificity of plant breeding. NBTs offer positive benefits to food security, environmental protection and global agricultural sustainability by virtue of trait advancements which improve the agronomy, production and value of the crop for both the farmer and consumer.

Plant breeding has a long history of safe use

Plant breeding has been practiced since the beginning of human civilization. For several millennia, farmers have domesticated crops through the selection of desirable plant traits with the goal of developing crops for agricultural purposes and, ultimately, for increasing the production of quality food. Modern day maize, wheat and rice are dramatic examples of the effect of human selection on agricultural crops. Through thousands of years of domestication and selection of desirable agronomic and yield enhancing traits, today's maize, wheat and rice are safe, robust, staple food crops capable of growing under a wide range of environmental conditions and relied upon to feed a majority of the world's population.

Plant breeding makes use of variations in plant genomes to develop new crop varieties to meet the demand of farmers and consumers. Changes and variation in plant genomes are ubiquitous and essential drivers for plants to adapt to their environment (Weber et al 2012[1], Winkler 2008[2]) and have resulted in a wide variety of crops with a long history of safe use. For example, over the past century, mutagenesis applications (radiation and chemical mutagenesis) have resulted in over 3,200[3] improved crop varieties which have been planted and safely consumed in over 175 plant species including rice, maize, wheat, tomato, squash and soybean. As a result of the long history and contribution to improved crop varieties, mutagenesis is globally considered to contribute to the production of safe, reliable and sustainable crops.

Advancing agriculture through precision breeding

NBTs are currently used in plant breeding of major row crops such as maize and soybean, vegetables, commodity and specialty crops by both the private and public sectors. Compared to traditional methods of inducing genomic changes (*e.g. gene and chromosome rearrangement,* chemicals, radiation) that have a long history of safe use, but are random, NBTs provide a high level of accuracy and precision to generate targeted changes at predefined locations in plant DNA.

Currently NBTs include, among others, Oligonucleotide Directed Mutagenesis (ODM) and Site-Directed Nuclease (SDN) applications to make targeted DNA mutations which are more precise and predictable compared to traditional mutational applications; RNA dependent DNA Methylation (RdDM) which results in epigenetic modifications allowing for precision gene regulation and expression without changing the DNA sequence of the plant genome; and the

[1] Plant Physiol. 2012 160: 1842-1853.doi:10.1104/pp.112.204271. Natalie Weber, Claire Halpin, L. CurtisHannah, Joseph M. Jez, John Kough, and Wayne Parrott http://www.ilsi.org/FoodBioTech/Publications/Plant%20Physiol.-2012-Weber-1842-53.pdf

[2] Trends Plant Sci. 2008 Dec;13(12):640-6. doi: 10.1016/j.tplants.2008.09.004. Epub 2008 Oct 22. Wijnker E, de Jong H. http://www.ncbi.nlm.nih.gov/pubmed/18948054

[3] http://www-infocris.iaea.org/MVD/default.htm

selective and efficient transfer of existing plant genes from wild relatives into modern agricultural plant varieties (cisgenesis).

As science continues to progress, new plant breeding techniques will continue to evolve and emerge. Although these techniques may be considered new, the products developed through them are similar or indistinguishable (including at a molecular level) from existing products developed using traditional breeding techniques. NBTs are simply innovative improvements and refinements of existing breeding methods; designed to enhance the speed and efficiency of breeding, with more knowledge and understanding than ever before.

NBT safety and regulatory perspective

As witnessed by the long history of safe use of plant varieties produced through human domestication and breeding, the techniques used to develop new plant varieties do not pose a specific safety hazard; it is the characteristics of the plant that determines its safety. Thus, the need to regulate plants developed through NBTs should be driven by the characteristics of the product (*i.e.*, whether it is materially different from existing products present in food, feed or the environment) rather than by the production method or process used to produce that product.

An increasing number of plant varieties are being developed using NBTs in countries all around the world by both the private and public sectors. As a result, NBT products may be subject to different regulatory requirements leading to differences in the regulation among trading partners, and may result in potential trade issues and enforcement problems globally. It is well understood that regulatory approaches have the potential to influence perceptions of the hazard of technologies and products, unduly raise public concern and negatively impact the global trade of goods produced through such technologies.

Like the private sector, public sector breeders and scientists have significant opportunities to employ NBTs in their breeding programs, especially for minor crops, such as trees and vegetables. However, the adoption of these technologies by both sectors is highly dependent on the regulatory requirements for products developed using NBTs.

Unnecessary regulation and oversight of such products, based on the method of development, would result in undue, costly regulatory burdens, stifle innovation and prevent the uptake of scientifically advanced, innovative breeding applications by the public and private sectors. In addition, the regulatory status of NBTs will impact trade not only in seeds but also in agricultural commodities derived from these seeds. Different government approaches risk disrupting international commodity trade flows, particularly in a scenario where various levels of regulation are applied to the same type of product, with asynchronous pre-market approvals.