Position

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ESA is the voice of the European seed industry, representing those active in research, breeding, production and marketing of seeds of agricultural and ornamental plant species. It represents more than 30 national seed associations and more than 60 direct company members.

ESA's mission is to work for fair and proportionate regulation of the European seed industry, freedom of choice for customers in supplying seeds as a result of innovative, diverse technologies and produc - tion methods and for effective protection of intellectual property rights relating to plants and seed.

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Promoting and Enabling Innovation in Plant Breeding

ESA contribution to the OECD workshop on New Plant Breeding Techniques on 10.02.2014

(OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology)

Over the past 100 years, the world population has grown exponentially from 1.75 to today 7.2 billion creating an ever increasing demand for plant based raw materials for food and feed as well as industrial uses. Based on the discoveries of Mendel of the reproductive biology and inheritance of traits of plant species in the mid 19th century, a highly specialised plant breeding sector evolved. Plant breeders created new varieties based on crossing and selecting desired, valuable traits that increase yields, improve resistances against pests and diseases and that are adapted to new or adverse growing conditions. Together with a growing mechanization, professional use of fertilisers and crop protection and other innovations, this has allowed for a stunning increase of agricultural production that has increased global food security, spared wild habitats from being cleared for food production, and that contributes to social stability and societal development. Further discoveries and advanced understanding of the biology, physiology, genetics and chemistry of plants and their interaction with the environment continue to fuel the flow of plant breeding innovations.

Yet, while the achievements are impressive, in the light of continued rapid population growth and growing worldwide demand for a varied, high quality food supply, further progress in plant breeding innovation has unprecedented importance. Furthermore, this progress must not only deliver higher yields or nutritional values but is also expected to contribute to environmental protection, preservation of natural resources, and public health.

ESA is convinced that the continuous advances in science and technological development will provide the necessary new tools and techniques to plant breeders to further drive innovation and develop new varieties more quickly, more efficiently and for more diverse environments and uses than ever before. However, the future use of such new tools and techniques, developed and used by the public and private plant breeding sectors, and the in-

troduction of the resulting new plant varieties in commercial farming will strongly depend on an enabling regulatory environment and a supportive public policy.

Therefore, ESA is of the opinion that the following principles and procedures should be applied as regards the assessment, consequent regulatory approach and overall policy on New Plant Breeding Techniques (NPBTs):

- NPBTs are crucial for addressing the grand challenges of food security, sustainable intensification of farming, preservation of natural resources and improved public health. Their development and practical introduction into breeding programmes, variety development and commercial farming should be supported by a consistent, enabling political and regulatory approach.
- In view of the long research and product development cycles typical for the plant breeding sector, it is important that the breeding sector can rely on clear rules for variety registration and release and predictable processes well in advance of the market introduction of new varieties for which these techniques have been used as a step in the breeding process. The relevant authorities should provide guidance as early as possible to promote investment and safeguard the respective vital returns.
- A regulation of NPBTs beyond the existing, well-established rules for traditional breeding practices would create significant economic and administrative burden for the public and private plant breeding sector as well as potentially for the subsequent users of the resulting crops. This would seriously hamper the adoption of such techniques in a broad range of crops and create a factual financial threshold which would be prohibitive for the vast majority of small and medium sized breeding operations characterising the sector.
- In cases where an assessment of a NPBT or a resulting product is considered necessary, this must be science based and should take the following experience and principles into account:

    ◊ Plants developed by traditional breeding methods based on crossing and selection and involving random changes to genes or chromosomes (e.g. by chemical or radiation induced mutagenesis) have a proven safety record spanning more than a century.

    ◊ NPBTs generally allow breeders to exploit/deploy desired traits and to bring them into a wide (r) range of crops in a much more targeted and precise manner compared to traditional breeding of plants. They enable a targeted and exact genetic change at predefined locations in the plant DNA without necessitating other, undesired changes at the same time (precision breeding).

    ◊ Although these techniques are indeed new, the resulting plants are similar and often indistin-

guishable from (existing) plants developed by traditional methods. NPBTs are mainly refining existing breeding techniques by using innovative improvements that help to enhance and speed up the breeding process and that achieve the desired result in a shorter time and more precise manner.

◊ NPBTs are generally generic, allowing for the introduction of improvements into a wide range of plant species and helping to reduce breeding cycles and cut related costs.

◊ Where the application of a NPBT results in plants that are similar to existing plants or to plants obtained by traditional breeding methods, these should not trigger specific regulatory oversight or requirements.

- In cases where, following a science-based assessment, a NPBT (or a resulting product) is considered to require specific authorisation or other measures, these should be proportionate to the specific issues identified in the assessment. These measures should also be regularly reviewed to allow for reduction or abolition of conditions where practical experience and familiarity demonstrate safe use.
- Traceability and/or labelling requirements generally have a potential to hamper the free movement and trade of products across borders and place significant economic and administrative burden on operators. Such requirements should therefore be avoided where they are serving no demonstrable purpose related to scientifically established environmental safety or public health concerns. Where no specific risks are connected to a NPBT (or to the resulting product), there is no need to identify and track its use. This applies specifically to products that are indistinguishable from those resulting from traditional breeding or where the identification requires specific prior knowledge.

Based on these principal consideration, ESA calls upon the OECD and its members in view of the discussion of NPBTs at the Committee for Regulatory Oversight of Biotechnologies to promote an internationally harmonised and proportionate approach to both, the NPBTs currently under discussion as well as to the introduction of future NPBTs in the years to come.

Such approach needs to avoid undue regulation, acknowledge the history of safe use of new plant varieties developed with a large set of different plant breeding techniques, the simple refinement of many of these techniques brought about by growing scientific knowledge and increased precision enabled by the NPBTs, as well as the increasing familiarity with these techniques and with the resulting products. ESA stands ready to contribute its expertise and experience to this discussion and is committed to work for an approach that promotes further plant breeding innovation to meet the challenges of the future.