



European Plant Science Organisation
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Opinion

Opinion on the SAM Explanatory Note on New Techniques in Agricultural Biotechnology

Brussels, 15.9.2017

The European Plant Science Organisation welcomes the Explanatory Note on New Techniques in Agricultural Biotechnology from the European Commission's High Level Scientific Advice Mechanism that was published in April 2017. The Explanatory Note provides scientific explanations and evidenced background on so-called "New Breeding Techniques" (NBTs) for agricultural purposes. It offers a dispassionate scientific view based on peer-reviewed publications and on applications as well as implications including potential risks and benefits. Essentially, the detailed comparative consideration of new (NBTs) and conventional breeding techniques (CBT) as well as established techniques of genetic modification (ETGM) enables a balanced and impartial science-based weighing of the impacts for each of them. Moreover, the Explanatory Note reconsiders NBTs independent from current regulatory and juridical discussions and any vested interests therein.

From the perspective of the plant science community EPSO acknowledges

- that the Explanatory Note analyses the quality and heterogeneity of the various methods and techniques summarized under the term NBTs in a science-based way;
- that the essential progress in the precision of plant breeding is portrayed, ranging from conventional crossing, mutation breeding, and genetic engineering to genome editing;
- that both the intended and the possible unintended changes in the genome resulting from the application of the various established and new techniques are appropriately addressed, showing the comparatively low likelihood of unintended effects caused by genome editing;
- the notion that an "assessment of safety can only realistically be made on a case-by-case basis and depends on features of the end product" and the clarification that "genetically and phenotypically similar products deriving from the use of different techniques are not expected to present significantly different risks".

The Explanatory Note is in line with earlier considerations of EPSO, "to avoid overregulation whereby an unwarranted number of processes and products will have to undergo expensive and lengthy authorization procedures" (EPSO statement on *Crop Genetic Improvement Technologies*, 17.1.2017). It is an excellent starting point to implement a science-based policy on NBTs in Europe. It furthermore describes the impact of NBT on safety issues, efficacy and economic benefits as they pertain to conventional breeding or genetic engineering. It should be noted that future plant

breeding is expected to combine the application of conventional and new techniques rather than their cross substitution.

The Explanatory Note emphasizes that the common ground of all breeding techniques in agriculture is the “use of genetic diversity and change either naturally occurring or by intervention, in order to select or generate plants, animals or microorganisms that exhibit preferred characteristics”. The term *New Breeding Techniques* describes a heterogeneous set of methods and techniques that also comprise a broad range of applications. The approaches vary in their precision and extent, the presence or absence of modifications (inserted exogenous DNA) in the end product, and in the similarity of the derived products to conventionally bred or even “wild type” organisms.

In the opinion of EPSO, the multiple dimensions of the various NBTs techniques, their applications and socio-economic impacts, as well as their potential safety concerns each should be addressed explicitly rather than through an undifferentiated, but escalating discussion on regulatory issues. The current discussion raises the fundamental question of how regulations can be updated to accommodate new technical developments. The Explanatory Note suggests product-based and problem-oriented direction for regulation. This should guide further discussion and decision making, acknowledging, on one hand, familiarities of plant breeding products obtained by various techniques (e.g. genome editing and classical breeding), and on the other hand taking up the challenge of the identification and evaluation of novel traits. In this respect EPSO previously stated, “Current European legislation neither reflects the progress made in new crop genetic improvement approaches nor the positive economic, social or environmental impact of the resulting biological outcomes” (EPSO statement on *Crop Genetic Improvement Technologies*, 17.1.2017).

The Explanatory Note also discusses synthetic biology in its scientific interpretation: it is not a term synonymous with any particular NBT or for all together. What counts as synthetic organisms and products for regulatory purposes should be evaluated on a case-by-case basis. The wording in other regulatory frameworks at the European and international level – such as the Convention on Biological Diversity (CBD) - should not blur fundamental differences between NBTs and synthetic biology and should be used in a consistent and precise manner in order to prevent further ambiguities in legal interpretations (see also EPSO statement: *Synthetic Biology should not be confused with the application of new breeding techniques*, 30.8.2017).

For targeted plant breeding, the precision of genome editing, its minimization of unintended effects, as well as its positive impact on time-to-market and consequent economic advantages, have been elaborated clearly in the Explanatory Note. The broad benefits for agriculture rely on the increased accessibility of the techniques and resulting materials for both research purposes and breeding by both the public and private sector. Any unbalanced, expensive and lengthy authorization procedures will pose additional burdens on scientists and breeders, especially SMEs, hindering the progress of European bio-economy, its competitiveness, and its contribution to increasing varietal diversity in agriculture.

Attention should also be paid to the regulation and handling of intellectual property rights related to products derived from application of NBTs. EPSO emphasizes, in its statements on *Plant Breeder's Rights and Patent Rights* (2015), as well as *Implementing the Nagoya Protocol by national legislation in the countries of Europe* (2017), that varieties carrying beneficial traits generated by NBTs should also be available for further breeding programmes by both academic and commercial sectors in a way that grants rewards to the breeder and does not prevent progress in food and resource security.

The Explanatory Note proposed that available breeding techniques should be deployed as most appropriate and efficient to meet future challenges for agriculture. As a transparent and purely scientific (evidence-based) description, it provides a solid base for further discussions between scientists, the public, regulators, policy makers, and other stakeholders. It highlights the urgency to take next steps in the very near future to promote progress in plant science and commercial breeding in Europe as well as to meet future challenges for agriculture in due time. This could for instance include a second step by the European Commission, following the Explanatory Note, to develop options regarding the regulation of new techniques in agricultural biotechnology to be applicable to current and future developments and technical progress as appropriate. The options could include utilising existing rules such as Variety Registration for conventional varieties and the Seed Marketing Directive as applied to classical breeding.

This opinion was developed by Ralf Wilhelm, Frank Hartung and Peter Rogowsky and considered and approved by the EPSO Agricultural Technology Working Group and the EPSO Representatives in August - September 2017.

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Useful links

EC: Explanatory Note on New Techniques in Agricultural Biotechnology from EC's High Level Scientific Advice Mechanism, 28.4.2017
https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf#view=fit&pagemode=none

EC news alert Commission's top scientific advisers publish explanatory note on new techniques in agricultural biotechnology, 28.4.2017
<http://ec.europa.eu/research/index.cfm?pg=newsalert&year=2017&na=na-280417>

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EPSO WG on Agricultural Technologies: www.epsoweb.org/agricultural-technologies-wogr

Statements drafted by this group and approved by the EPSO representatives are for instance:

- EPSO: [Synthetic Biology should not be confused with the application of new breeding techniques](#), updated statement, 30.8.2017
- EPSO statement on [Implementing the Nagoya Protocol by national legislation in the countries of Europe](#), 3.7.2017,
- EPSO updated statement on [Crop Genetic Improvement Technologies](#), 12.01.2017
- EPSO statement on [Plant breeders' rights and patent rights](#), 26.2.2015

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