GENE EDITING AND NEW EU REGULATIONS URGENTLY NEEDED

Position Paper approved by the UEAA Steering Committee on 5 November 2020.

The UEAA (Union Européenne des Académies d'Agriculture, www.ueaa.info) claims that the Directive 2001/18 / EC has become unsuitable due to advances in scientific knowledge and recent technical advances such as genome editing and urges the E U Governance to review and adjust the European regulations on GMO's to recent scientific progress.

Today the European Union can be proud of the **Nobel Prize in Chemistry 2020** co-awarded to Emmanuelle Charpentier for the discovery of CRISPR-Cas9, a technological revolution which facilitates genome editing thanks to what is now commonly called "genetic scissors". This new tool is a precise technique, easy to implement and inexpensive compared to other genome editing techniques such as ZNF (Zinc finger nucleases) or TALEN (Transcription activator-like effector nucleases). Importantly, the changes of genetic information obtained by Site Directed Nucleases 1 and 2 (minor genome modifications) and induced by the CRISPR-Cas9 technology are indistinguishable from spontaneous mutations.

This invention is already successfully applied in human medicine for treatments of incurable genetic diseases (lymphoblastic leukemia) or potentially induce new therapeutic approaches such as for example β-hemoglobinemia. It provides genetic solutions in animal health with the generation of disease-resistant animals such as resistant pigs to Porcine Respiratory and Reproductive Syndrome virus (PRRSV) or to Classical swine fever already on the ground in the USA and in China respectively or to bovine tuberculosis or African swine fever, to the extent that it is now considered potentially as the prophylaxis measures of the 21st century to combat and prevent animal diseases. It can also enhance animal welfare through improved pig thermoregulation for example or else for the production of hornless cattle.

Similarly, it can be used in plant varietal breeding for the development of biotech plants that are more resistant to crop bio aggressors or drought, thus broadening the range of solutions to respond to global climate change. The method also allows rapid development of new cultivars with novel traits and improved food and feed quality. In addition, with restrictions on the use of these methods, we are closing the door on the development of crops with ecologically beneficial traits that will make it possible to reduce inputs of disease and pest spray, fertilizers, energy and greenhouse gas emissions during crop cultivation. The current regulation prevents breeding crops with efficient use of nutrients and sunlight, crops with higher levels of nitrogen fixation, disease and pest resistant crops, or crops with high water use efficiency. Thus, with this regulation, the European Union goes directly against the idea of a "Green deal", against sustainable agriculture and disdains the results of the research it so richly supports, but which offers solutions to the problems of today and the environmental crisis.

Already many countries have applied this technology and consider that for genome editing products obtained by Site Directed Nucleases 1 and 2 (minor genome modifications), there is no need to apply GMO regulations. This is notably the case of the United States, Canada, Argentina, Colombia, Chile and Brazil, Israel, Australia, Japan. The characteristics of the marketed product are evaluated on a case-by-case basis, regardless of the production technique. These regulatory provisions are already reflected in a wider range of new varieties of cultivated plants that are more efficient to adapt to climatic or environmental constraints, to better resist crop pest agents or to provide the desired nutritional contributions.

The judgment of July 25, 2018 of the Court of Justice of the European Union (CJEU) ruling that all cultivated varieties resulting from techniques of genetic modification are GMO's endangers the use in the European Union of new genome editing techniques. Only large international conglomerates that have a sufficient financial base can meet these regulatory requirements. Hence there is an urgent need to revise the European regulations on GMOs based on the Directive 2001/18 / EC and associated subsequent texts.

The situation of European genome editing research is also of major concern. More than 80% of the patents filed on applications of the CRISPR-Cas technique are American or Chinese and less than 10% European. This is a disastrous situation and would, if maintained, lead to a drastic decline in our global competitiveness and the loss of the EU's independence in the agri-food industries.

Voices have already been raised for the products obtained by genome editing to be subject to appropriate European regulations. This is the key point of the comments of the Scientific Advice Mechanism (SAM) which issued a statement entitled "A Scientific Perspective on the Regulatory Status of products derived from Gene Editing and the Implications for the GMO Directive" (EU 2018_11_gcsa_statement_gene_editing_1.pdf).

This committee points out that "it becomes evident that new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose" and is now inadequate, particularly in terms of the control and traceability of products obtained by such New Bio Technologies (NBTs).

This EU group of Chief Scientific Advisors (CSA) recommends that the characteristics of the final product be evaluated instead of legislating from the method of production. It stresses the need to take into account "current knowledge and scientific evidence, particularly on genomic editing and established genetic modification techniques" and to create a regulatory environment conducive to innovation so that "society can benefit from new science and technology." Finally, it calls for societal dialogue between all concerned and the general public.
This is further consistent with the European citizens' initiative entitled "Grow scientific progress :crops matter" launched in 2019 by a group of European students, calling for the revision of Directive 2001/18 and an amendment to the existing legislation to assess the final product rather than the technique "so that safety is guaranteed without the precious benefits of the new techniques being lost".

Today, it is clear that the European Union cannot do without genetic engineering and that European regulations must take into account these new scientific advances in human therapeutic fields, which are universally accepted, as well as in terms of animal or plant health in the context of sustainable agriculture.

Noting that current regulations hinder public and private research from being applied to agriculture and the marketing of new genome editing products, the U E A A stresses the need for new rules to give European public and private institutions the tools of innovation necessary to safeguard the interests of the European Union and its Member States, its independence and thus pave the way for a future of progress.