

- Agriculture -

# Targeted modifications of living organisms: Time has come to change the European regulation

By Catherine Regnault Roger - 06.03.2023



*While a debate is in progress at the European level about the genetically edited products, it is time for the French government to revise its positions and to adopt a point of view relying on a sound scientific basis., as here explained by Catherine Regnault Roger, professor emeritus at the University of Pau and Pays de l'Adour (E2S UPPA), member of the French Academy of Agriculture and of the National Academy of Pharmacy.*

Genetically edited PLANT products and current review of European Regulations: WHAT SHOULD BE THE FRENCH POSITION?

# THE CONTEXT

The European Commission (EC) started in April 2021 a procedure to change European regulations on some of the New Genomic Techniques (NGTs) which edit genome. These new techniques modify very precisely targeted genome of organisms. NGTs represent the techniques of the second generation of genetic engineering. They are to replace transgenesis which is a very used technique by first-generation biotechnologies, those of the XX century, and whose products are regulated as GMOs.

These regulations applied to GMOs are very heavy and particularly in the European Union (EU). GMOs regulations were established in different countries that practiced the culture or the importation of transgenic products at a time when scientific knowledge on the associated risks with these genetic engineering organisms were poorly identified. The European regulation is costly in terms of approval of files (numerous preliminary tests including fictive extreme conditions projections) and post-marketing monitoring. Only large international consortia have the sufficient financial capabilities to assume them.

The very active research carried out with NGTs techniques opens immense perspectives in terms of human health, health, and welfare for animals and in agriculture, not only to improve diseases and crop pests' controls but also to face climate changes and global warming. The CRISPR technique, developed by Emmanuelle Charpentier and Jennifer Doudna who received the Nobel Prize in Chemistry in 2020 for this technological innovation, is the main technique developed in research the last ten years. Ongoing R&D projects concern more than 60% plants, animals and medical applications around respectively 15% and 20% (1).

## NGTS PRODUCTS ARE NOW WIDELY DEREGULATED IN MANY COUNTRIES

It is in this context that many countries of North and South America, and of the Asia-Pacific region have decided to modify their national GMOs regulations and to exempt from regulation numerous genetically edited products. This deregulation is in fact necessary when most of the products obtained by genome editing cannot be distinguished from organisms resulting from natural mutation. These edited products result from naturally repaired DNA without the addition of foreign DNA. They are called SDN1 (SDN for Site Directed Nuclease). Those which result by inserting homologous alleles (i.e., having a common evolutionary origin) are called SDN2. These SDN1 and SDN2 types of modifications are very common in nature because they occur spontaneously, thus giving us the biodiversity that we currently see, Does it then make sense, in such conditions, to regulate in a such a different frame these engineered products that are indistinguishable from natural products?

## A HIGHLY CRITICIZED CJEU JUDGMENT

Contrary to the conclusions of the General Advocate Bobek (18<sup>th</sup> January 2018), the European Court of Justice (CJEU) ruled otherwise in its decision of 25<sup>th</sup> July 2018, , which states that all the products obtained by post-directive NGTs techniques fall under Directive 2001/18 and so must be regulated like GMOs.

This legal position is not based on any sound scientific basis since the cornerstone of this decision is to distinguish the techniques prior to 2001 (date of the directive) and those which are posterior, in an appreciation coming from an amazing posture that can be summarized as follows: before we know and the regulations have taken into account the risks, but after 2001 it is *Terra incognita!*

While many countries notably in both Americas and in Asia have decided to lighten their national regulations applied to NGTs, this judgment of the CJEU has positioned the EU in the singularity.

Consequently, many negative reactions from various European agencies and personalities very early on came forward. The Group of Principal Scientific Advisers to the Commission European (or *SAM Scientific Advise Mechanism*) published in November 2018 a strong statement in which it claimed that the Directive 2001/18 was “now unsuitable”. It indicated that given the undetectability of genetic modifications mostly carried out by genome editing, it is necessary to evaluate the characteristics of the final product and not the method of obtaining it.

The French Parliamentary Office OPECST, which brings together senators and deputies, in its 2021 Report signed by the main author Senator Catherine Procaccia, reached the same conclusions, and proposed that the directive should be revised every five years to take into account the advances in techniques and the societal debate. Similarly, another Institution, namely the French Academy of Agriculture indicating, had issued the same proposition in its 2020 Opinion paper with a time step of 7 years, stressing the fact that that it would contribute to avoid a lag between science and law.

The same year, the European Union of Academies of Agriculture (UEAA) also urged the Commission to review and adjust the European regulation in its current draft (Directive 2001/18), and take into account both Crop Plant production and Farm Animal production In addition, many French and German political personalities (notably Members of Parliament *Grünen*), also Frans Timmermans, Vice-President of the European Commission (EC) and Stella Kyriakides, European Commissioner for Health and Safety food, underlined the great interest of genome editing in the sustainable development strategy of the Union. The French Ministers of Agriculture, Julien Denormandie and Marc Fesneau also pointed out the positive role of NGTs “to reclaim our food sovereignty”.

## **AN EUROPEAN STRATEGIC INITIATIVE IN PROGRESS**

In this context, a strategic initiative to review the regulation for NGTs has been initiated at the invitation of the European Council. The procedure is complex and includes several steps. The European Commission has instructed Joint Research Center (JRC) to draw up a state of the art on NGTs and examine progresses of R&D projects. JRC submitted two reports by 2021 Spring term. Following this step, an impact analysis step (road map) was initiated in September-October 2021. It was opened to the public and despite a cyberattack to which some MEPs from the Greens/EFA (Free Alliance Europe), those who led the campaign “*Let’s keep GMOs out of our fields and our plates*“, would not be stranger to, the results of this step authorized the continuation of the process. Consequently, a public consultation took place between April and July 2022 and its results were published in September 2022. Of the 2,300 validated responses, 80% were favourable to the revision of the EU regulations while 17% supported the maintain of current GMOs regulations to be applied to NGTs (2). Based on these results, the revision process of the EU regulations will be going to its end, and the European Commission should propose the terms of a new regulation to the European Parliament by 2023 Summer term.

## **“RE-WRITING THE GENOME, ETHICS AND SOCIETY” : PASSIONATE DEBATES AT THE FRENCH ACADEMY OF AGRICULTURE**

By 2020, the French Academy of Agriculture had published a public Opinion proposing new regulations to be applied to gene editing (3). Adopted by a majority of voting Academicians, this Opinion was very measured since it advocated “a prudent and pragmatic choice by setting limits allowing to preserve the identity of the species”. It emphasized the need for prior authorisation but with better calibrated files than now, and a monitoring based on revocable and time limited authorizations which is mentioned to be conceived without any ‘irreversibility’. Article 7 of Directive 2001-18 establishing a differentiated procedure – apparently never used

so far – could then provide a legal framework to be tested without changing the current legislation.

Fifteen Academicians (4) felt the need to write a divergent point of view that they wanted to attach to the main text, but which was filed in another section called the “points of view of Academicians”. Thereby this text has lost some of its impact of expressing nuanced amendments in addition to the main text of Opinion. These Academicians noted in this critical text that “to date, for none of the GMOs currently in use in all the world, there is no serious reason to assert the existence of a particular hazard, either for human health or the environment taken as a whole”. Because they found that the genome editing techniques were more precise and that NGTs considerably reduced the undesirable effects observed with the techniques of first generation (random mutagenesis and transgenesis), these 15 Academicians reiterated that “it would be absurd to take exaggerated precautions and unrelated to the magnitude of the potential risks in terms of the benefits they bring”. They worried about imports from abroad of large quantities of genetically modified or edited products regulated in a more flexible way, thus “in defiance to the rules of competition”. They pointed out that this situation would create conditions “likely to ruin our own producers”.

## **CAUTIOUS RECOMMENDATIONS TO THE FRENCH GOVERNMENT FROM THE ACADEMY OF TECHNOLOGIES**

Very recently, the French Academy of Technologies (AT) took up in turn the subject of NGTs applications to plants at the request of the French government who wishes to receive its recommendations before defining an official position. It thus published very recently its “Opinion on the New Genomic Techniques applied to plants” (February 15<sup>th</sup>, 2023) (5). This report is in the continuity of the 2020 French Academy of Agriculture’ Opinion which has not aged during these three last years.



This AT's Opinion paper underlines five general principles and twelve recommendations written under the chair of Bernard Chevassus-au-Louis, an Academician belonging both to the French Academy of Agriculture and to the French Academy of Technologies. It firmly reaffirms the following principles that (i) the precautionary principle (enshrined in the French Constitution) must be applied; (ii) it is necessary to overcome the “cleavage” between regulations based on the final characteristics of the product and the one considering the method of obtaining it ; (iii) “it is necessary to take pragmatically into account the context created by the controversy over GMOs which constitutes de facto a cultural framework ... in order to define public policies with regard to NGTs”.

The 12 recommendations relate to evaluate methods of assessment for discriminating “the cases where the modifications carried out are similar or not to those which may result from spontaneous or induced mutations”. They enjoin to “take into account in a differentiated way the varieties presenting a very favourable benefits/risk balance with positive impacts for the farmer, the consumer or the environment” (recommendation 2), and advocate to set up biomonitoring systems in the fields and a network considering the people's opinion named “biovigilance”. The recommendations also indicate that the areas in which NGTs plants would be grown should be limited at the beginning in order to survey what will happen in these fields. At least, recommendation n°12 is considering the legal level. It specifies that NGTs have to be regulated within the framework of Directive 2001/18, either through Article 7 that mentions “differentiated procedures”, or by “a new appendix, specific to NGT”.

Because it proposes to have a differentiated assessment procedure based on a case-by-case basis for the SDN1 and SDN2 modifications, this AT's Opinion may be considered to request a lighter regulatory framework for NGTs compared to the present regulation of GMOs (transgenic products). But nevertheless, it also falls into a precautionary approach comforting the frame of Directive 2001/18 and its associated regulations and directives: a regulatory body which is acknowledged to govern the authorizations of

cultivation of GMOs “among the most restrictive manners in the whole world ” as it underlined. This is this regulatory body that has strongly slowed down, and for many years in the UE, the development of innovative genetic solutions and also braked fast plant varietal improvement to give a fair answer to parasitic and climatic emergencies. The case of the French sugar beet industry which has to deal now with epidemics of yellow virus carried by an aphid with no alternative to neonicotinoid insecticide treatments (today all are prohibited in France, but some authorized in other UE Member States), sadly illustrates this situation.

Among the many questions raised by this Opinion paper, one can also be surprised by this affirmation of wanting to go beyond the existing “cleavage” between regulations based on the final product characteristics and those considering the method of obtaining. Several countries have indeed abandoned the second option because it appears difficult to regulate differently a genetically edited final product that cannot be discerned genetically from a natural product. Why should one discriminate between two products totally identical which consequently have rigorously the same level of assumed risks? And how could one discriminate them on the method by which they were obtained, method which is moreover in most cases unidentifiable? What scientific logic obeys this desire to overcome this “cleavage”?

It must also be noted that Directive 2001/18 should be reviewed in correcting GMOs definition in order to take into account the recent scientific advances. These advances demonstrate that there are naturally not only many organisms issued from very many spontaneous mutations but also natural transgenic organisms such as sweet potato. But here too, the report is silent on this point and prefers to refer to the existing Directive 2001/18 without asking for any rectification.

## **A STRATEGIC INITIATIVE BELOW THE STAKES**

In 2021, the European Commission published an initiative entitled “Legislation for plants produced by certain new genomic techniques”. This



initiative intends to propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. These genetic modifications can also be obtained by natural mutation or classical selection. Micro-organisms and animals are not concerned, nor are concerned genetic modification techniques which are neither cisgenesis nor targeted mutagenesis. In these conditions, the European Commission has therefore restricted the scope of the upcoming revision of the regulations.

This decision to exclude the animal kingdom from the scope of the revision is contested by the French Veterinary Academy, which has publicly stressed that research on gene editing of farmed animals would contribute to improve not only animal health for crucial epizootic diseases but also for animal welfare. This position is fully shared by the European Union of Academies of Agriculture (UEAA) which underlines that, in these times of zoonoses (monkey pox, Covid-19 and others), European research work on animal diseases will be hampered by this exclusion.

## WHAT SHOULD BE THE FRENCH POSITION?

The French position which will be expressed in Brussels should therefore indicate that NGTs need new and adapted European regulatory texts. All these new techniques must be considered in the range of their full applications and not be restricted to plants. The French government must also reaffirm that our country, the country of the XVIII<sup>th</sup> century's Enlightenment, strongly condemns unjustified regulatory restrictions but encourages scientific and technological innovations in which genome editing is a part of the development of sustainable agriculture, an agriculture which concerns both plant production and livestock farming.

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## FURTHER READING

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