ACADÉMIE d'AGRICULTURE de FRANCE

AGRICULTURE ■ ALIMENTATION ■ ENVIRONNEMENT

POSITION PAPER
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GENOME EDITING, ETHICS AND TRUST

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Here are only translated the recommendations of this Position Paper. To read the full Paper (in French) please refer to :
https://www.academie-agriculture.fr/publications/publications-academie/avis/reecriture-du-genome-ethique-et-confiance (+ *pdf available*)

By a mission letter of March 20, 2017, the Perpetual Secretary of the French Academy of Agriculture (AAF) set up a working group of 34 members, bringing together the various fields of expertise, scientific disciplines and schools of thought represented within the AAF, to develop the theme "Genome Editing[1], ethics and trust" in the context of cultivated plants, forests and farm animals. Presented in the fall of 2019, then modified in sections, this opinion was approved by the Plenary Assembly on January 8, 2020 by 85 votes to 7 against with 12 abstentions (80% in favor).

Recommendations

37. The French Academy of Agriculture simultaneously wants to act responsibly and respect the principle of precaution. Aware that rapid scientific and societal developments must lead to regular reassessments, the Academy wishes that a debate be organized over time and extended far beyond the circles of experts.
The French Academy of Agriculture makes eight recommendations and one suggestion.

I.- Act responsibly

38 **R1.1 Consider that each operation, for purposes other than research, aimed at the release of plants or animals having had their genome edited is a particular case; the objective sought must be defined and made known, and the choice of editing the genome in this case must serve the general interest and be legitimate, therefore argued**. It is hence about reasoning on a case-by-case basis, with a given species of plant or a given animal species or breed, in a precise ecological and socio-economic context.

[1] *The French Academy has used the word "réécriture" which is literally translated as "re-writing", for matter of convenience "Réécriture du génome" will be here translated through by Genome Editing (note of the translator).*

39 In particular, **encourage studies on diversified plant or animal** species (including those neglected by research)**, adapted to differentiated ecological and socio-economic contexts**, including for the benefit of farming communities in developed and developing countries; public research should have its place.

40 **Each choice should be debatable and justified a priori by contradictory evaluations and by a benefit-risk analysis as part of a general comparison of the various possible strategies to meet the desired objective**, taking into account the scientific, technical, ecological, economic, health and societal aspect

41. Genome editing is based on two pillars, the first, obvious, refers to the knowledge of the DNA sequences of genomes, and the second to the functional knowledge of genes. If the first pillar is contingent to such or such genotype, the second is built throughout the whole plant or animal world: the mechanisms which operate for flowering are universal, and its actors, the genes, can play different scenarios depending on the species or group of species. This is the reason why a large part of plant molecular physiology derives from the work carried out on two model species, Thale cress (*Arabidopsis thaliana*) or rice (Oryza sativa). The same holds true, for animals, with worm (nematode *Caenorhabditis elegans)*, Drosophila, chicken or mouse.
In short, there is no identity mark of the genes that would attribute them to such or such species. There are no wheat, tomato or goldfish genes!
For example, if one wishes to modify the earliness of a corn by modifying some of its genes, it will be necessary to use the information on the mechanisms and genes identified in *Arabidopsis*, rice, or sugar cane, without being limited to the corn species. If one wishes to modify the fatty acid composition of a soybean, it will be necessary to use the knowledge of the enzymes and genes discovered more than 30 years ago in *Arabidopsis*, and present in other plants.

Hence the following recommendation

42 R1.2 **In Genome Editing operations care should be taken so as to preserve the identity of the species**.
For this, **one will limit oneself to the cases** of plants or production animals **in which any allele editing would be so that the function of the resulting gene proceeds from that of another allele or of an orthologous gene and of the same function.**
Such a choice is intended to be prudent and pragmatic

II.- Respect the principle of precaution

43 R2.1 **Maintain the principle of an authorization prior to any release after editing the genome, but with better calibrated dossiers, proportionate to the hazards of each particular case. In addition, institute systematic monitoring with authorizations limited in time and revocable in view of the information provided by this monitoring**. In other words, promote a regulation **that allows progressive and accompanied experimentation**.
This would make it possible to considerably reduce the initial dossier to be supplied at present, these products being classified as GMOs, a dossier so heavy and costly that it effectively excludes all SMEs and public laboratories.

44 R2.2 For this, **ensure in each case that if a temporary authorization was granted, it could be terminated** legally, ecologically, technically and economically, **without irreversibility**.

45 There are many environmental hazards (increased use of pesticides in response to the development of resistance among crop pests, indirect effects on the diversification of species, even on the reduction of the diversity of landscapes, etc.). In addition, many of the impacts of the "off-target" effects are little known or ignored and the environmental assessment methods relating to them are still little identified and tested. And yet, it is the responsibility of scientists to highlight and characterize emerging hazards of different kinds, to research and define the uncertainties associated with innovations introduced in these fields, including in the long term.

Consequently, the academy recommends:
- a powerful public research including in the environmental field, in particular in terms of impacts;
- comparative assessments including time dimensions and geographic scales in order to give content to the concept of reversibility, on time scales compatible with ecological temporality;
- a systemic and interdisciplinary assessment of environmental risks, in addition to case-by-case approaches, **in order to better respond to the recommendation of "better calibrated dossiers, proportioned to the hazards".**

III.- Engage the public. Inform the Society. Act transparently

46 **R3.1 Imagine new means, methods and places of debate to:**
- train and inform the public in a transparent manner,
- and associate them with authorization decisions. To do this, draw inspiration from other institutions, such as the National Consultative Ethics Council (CCNE).

47 **R3.2 Carry out periodic public assessments, on a plant or an animal, as well as on a given ecosystem or area, taking into account possible changes**. Environmental disturbances are rapid (climate, erosion of biodiversity, invasive species, anthropogenic activities). Have there been changes, are others possible, if so which ones, why and at what pace? How to be protected against possible collateral damage? Vigilance is essential, far beyond genome editing, and public research has a major role to play here. **Again, transparency is a must and so is the involvement of the public.**

IV.- Re-evaluate regularly

48 **R4.1 Apply to the cases mentioned here above in R1.2, the differentiated procedure of article 7 of the "Directive 2001/18 / EC on the deliberate release into the environment of genetically modified organisms".**
The simplest is to use for the gene editing's defined in R1.2 above - the only cases referred to in this Position Paper- the differentiated procedure detailed in article 7 of the directive. Annex V to the directive lists the conditions to be met in order to fall into this category, conditions which the organizations referred to in R1.2 above seem to fulfill. It is expected that the competent authority of the Member State will make the request; once seized, the European Commission has 90 days to receive comments from the competent authorities of other Member States, the public and the opinion of the competent scientific committee (s), plus an additional 90 days to render its decision.
Would this procedure be found difficult to use in practice, the directive would then have to be partially modified, but without control of the result or of the timetable.

49 **Suggestion 1: The French competent authority could rely on the advice of an agency like ANSES[2],** provided that the committee or committees concerned include researchers in genetics, agronomy, zootechnics, toxicology, in plant health and human and veterinary medicine, as well as in economic and social sciences.
It can be noted that all of the above proposals comply with the Cartagena protocol on biosafety (art. 32 of the directive).

50 **R4.2 More generally, in the context of unprecedented scientific and technological leaps and strong societal expectations, provide for a revision every 7 years - as in the case of CCNE - of texts both at national and European level.** The AAF, for its part, wishes to contribute to this development and, to do this, is ready to solicit and support legislators, in conjunction with other French and European academies.

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[2] French Agency for Food, Environmental & Occupational Health Safety (ANSES)