

Societal expectations and challenges linked to *new genomic techniques*

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New genomic techniques (NTGs) make it possible to carry out genetic modifications that could, in theory, have occurred naturally and spontaneously. They have a very wide range of applications, including plant and animal breeding. The European Union is considering a legislative initiative to regulate their use on cultivated plants. It was against this backdrop that the Prime Minister referred the matter to the ESEC, which she asked to clarify the Government's position on the subject of NTGs applied to cultivated plants.

What is the regulatory framework for new genomic techniques?

NTGs can be an additional tool to help meet the challenges facing agriculture (scarcity of arable land, need to use fewer inputs, pest control, etc.). They can help meet environmental challenges and maintain the excellence of the French seed industry.

However, more needs to be known about the impact of these technologies on health and the environment.

By recommending systematic risk assessment, both *before* and *after* the product is launched, and by recommending systematic traceability and labelling, the ESEC wishes to guarantee freedom of choice and preserve the confidence of all stakeholders.



DEFINITION

WHAT ARE NEW GENOMIC TECHNIQUES?

NTGs involve the targeted modification of an organism's genetic information by adding, deleting or exchanging part of the genome sequence. NTGs can therefore achieve the desired changes more quickly and at a lower cost.

- 1 Risk assessment and management: defining an appropriate framework to ensure the safety of health and the environment**
- Before any authorisation of products derived from NTGs, carry out, *a priori*, an assessment of the risks, in particular for health and the environment.
 - Provide for risk monitoring *a posteriori*, which could take the form of biovigilance and sociovigilance networks as well as “review clauses”, in order to adapt authorisations over time, in the light of the effects observed.

- 2 Traceability and labelling: guaranteeing transparency**
- Make marketing authorisation conditional on the traceability of the techniques used, as well as the modifications resulting from them.
 - Guarantee users and consumers access to sufficient comprehensible information through labelling.

- 3 Taking sustainability criteria into account**
- Treat the issue of risk assessment independently from that of sustainability.
 - Use sustainability criteria to guide research and stakeholders, structure public policies, target incentives, enhance the value of a variety, etc.

- 4 Strengthening research**
- Controlling the scientific advance represented by NTGs in order to understand their possibilities and limits, by significantly boosting public research resources for assessing the risks and effects on health and the environment of these technologies.

- 5 Redefining an intellectual property regime that does not stifle innovation and supports the SME ecosystem**
- Do not privatise living matter by maintaining the non-patentability of plant material.
 - Set up a system of compulsory licences at reasonable cost to encourage innovation and support SMEs.
 - Mobilise innovation aid to enable small businesses to finance risk assessments.
 - Subject products from NTGs that are imported into the European Union to the same obligations (“mirror clauses”).

THE RAPPORTEURS

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