Translation (non-official, original text in French) of the opinion of the French National Agency for Food, Environmental and Occupational Safety (ANSES) on the scientific analysis of Annex I to the proposal for a Regulation of the European Commission of 5 July 2023 on new genomic techniques (NTG) – Examination of the proposed equivalence criteria for defining NTG Category 1 plants

3.3. Conclusions of the Biotechnology Working Group (pp. 26-27)

The Biotechnology WG recalls the context of this self-referral:

The proposal for a regulation on NGTs adopted by the European Commission on 5 July 2023 proposes to exempt certain plants genetically modified with NGTs from GMO legislation on the grounds that they would be equivalent to conventional plants.

To this end, it is proposing equivalence criteria that would ensure that NGT plants meeting these criteria (category 1 NGT plants) could have been produced using conventional breeding techniques.

The Biotechnology WG recalls the key question of the self-referral: to what extent can plants defined in this way actually be considered equivalent to plants obtained using conventional techniques?

To answer this question, the Biotechnology Working Group first clarified the proposed equivalence criteria, explaining the terms and concepts needed to understand them and defining the different sets of techniques involved, capable of generating the genetic modifications under consideration. It then went into greater detail in its scientific analysis, criterion by criterion, and raised a number of questions, highlighting the associated limitations and examining their scientific basis more broadly.

At the end of its work, the "Biotechnology" WG identified the following points:

1) Lack of clarity:

- The equivalence criteria are singularly unclear, in particular because of the use of non-unambiguous terms (target site, similarity, gene, breeders' gene pool, contiguous DNA sequence);
- The criteria focus solely on genetic modifications localised in a "target site" and similar sequences. The "target site" and similar sequences are to be defined; their definition will condition the genetic modifications considered;
- The exclusion of intragenic plants from category 1 NGT plants is not explicitly stated in the criteria and should be clarified;
- The exclusion of plants obtained by non-targeted cisgenesis from category 1 NGT plants is not explicitly stated in the criteria and should be clarified.

2) Insufficient scientific justification for the equivalence sought between NGT plants meeting the proposed criteria and conventional plants:

- The maximum threshold of acceptable genetic modifications proposed is insufficiently justified;

- The possibility or likelihood of a given modification or combination of modifications being achieved by conventional techniques should be considered;
- On the basis of pan-genome analysis, the acceptance of deletions and inversions without size conditions is not scientifically justified;
- The failure to consider unintended genetic modifications potentially located outside the targeted sites and similar sequences (apart from transgenic elements) is not justified.

3) Failure to take account of the relationship of the proposed equivalence criteria to risk:

- The technical document states that categories of plants that would be equivalent in type, size and number of genetic variations or modifications would be equivalent in type of traits and level of risk. This assumption has no scientific justification;

- The proposal for a maximum threshold of acceptable genetic modifications is not scientifically based in terms of risk: the associated risk is not directly proportional to the number of modifications, whatever they may be;
- The proposal of a maximum threshold for the size of insertions or substitutions accepted makes no biological sense; the functional consequences and risks potentially associated with an insertion are not proportional to the length of its nucleotide sequence;
- Accepting any deletion or inversion without considering the functional consequences and potentially associated risks is not justified;
- The fact that unintentional genetic modifications, generated by a lack of specificity in sequences similar to the target, are included in the proposed count of genetic modifications without their possible negative effects being considered, is not justified.

Thus, analysis of the proposed criteria for equivalence between NGT plants and conventional plants has led the Biotechnology WG to consider the issue more broadly. The WG proposes that these equivalence criteria, which are based solely on molecular aspects and which, moreover, are insufficiently justified, should take account of the characteristics of the plants and their possible risks.