The European Coordination Via Campesina (ECVC) would like to detail, in this annex to our open letter to the European Commission, why we consider that the public consultation on new genomic techniques is not a real tool for stakeholders to express their opinion on the initiative proposed by the Commission. Indeed, only the first two questions of the questionnaire allow to ask for a retention of the current regulation; answering the rest of the questionnaire means accepting a deregulation of these techniques. Furthermore, ECVC considers that the introduction and the questions contain a lot of misinformation, inaccurate information and statements which represents the Commission’s opinions rather than factual data, which we detail below:

(1) Incorrect legal context and definitions

First of all, the European Commission's initiative to propose a "proportionate" regulatory framework for new genomic techniques is based on a first supposed mistake, namely the alleged "legal uncertainties of Directive 2001/18/EC". However, the Court of Justice of the European Union (CJEU) has more than clearly confirmed in its ruling of July 2018 (case C-528/16), that the Directive 2001/18 cannot be interpreted as excluding, from the scope of the directive, organisms obtained by means of new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted. There is no uncertainty, but simply a refusal by the Commission to apply the current legislation. In consequence, the Commission needs to distort the legal context to fit its deregulatory plans.

Indeed, in the introduction to this consultation, we read: "In recent decades, advances in biotechnology have led to the development of new genomic techniques (NGTs), i.e. techniques capable of altering the genetic material of an organism that have emerged or have been developed since 2001, when Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted". However, the CJEU has clearly emphasised that "techniques which appeared or have been mostly developed after 2001 cannot be excluded from the scope of the Directive". The omission of the word "mostly" by the European Commission is not insignificant, since it allows the exclusion from the scope of the Directive of "random in vitro mutagenesis, consisting in subjecting plant cells to chemical or physical mutagenic agents". However, this technique was only developed before 2001 to a very limited extent, on the same dates and on far fewer hectares than transgenesis. Transgenesis is not excluded by the Directive, which does not consider it to be mostly developed before 2001, so the same should apply to random in vitro mutagenesis. Admittedly, the Commission is contesting this finding before the Court of Justice of the European Union (CJEU), which has not yet given a ruling: it doesn’t mean that the Commission has the right to anticipate hypothetical conclusions in its favour.

The introduction then mentions that, "in 2018, the Court of Justice of the European Union clarified that organisms obtained by targeted mutagenesis techniques are GMOs subject to the requirements of the EU GMO legislation. Targeted mutagenesis techniques are new genomic techniques, as opposed to random

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1 This term is used by the European Commission to refer to new techniques of genetic modification, as defined by Directive 2001/18/EC as amended by 2018/350.
2 The questionnaire can be consulted on the Commission’s website, or it can be consulted in pdf on our website: https://www.eurovia.org/wp-content/uploads/2022/06/Public-consultation-NGTs-EN.pdf
mutagenesis techniques. This is again a misinformation, as all mutagenesis techniques that emerged or were mostly developed after 2001 are subject to GMO legislation, not only targeted mutagenesis. Furthermore, the CJEU does not mention random or targeted mutagenesis in the conclusions of its judgment (cited above).

(2) Unsubstantiated claims about the development, value and sustainability of NGTs

The consultation also includes several unsubstantiated claims about the development of new genomic techniques and their potential to contribute to the sustainability of food systems, which are based on the Commission staff working paper published in April 2021 by DG SANTE, whose incorrect conclusions ECVC had already criticised. DG SANTE states in the consultation that "NGTs have developed rapidly in many parts of the world", whereas currently less than a dozen plant or animal products derived from NGTs have been developed worldwide, in small areas and too recently to have any idea of their real interest and safety. All the others are only promises that have been the subject of various research and laboratory experiments, but have not been developed to date.

It is also mentioned that "there is considerable interest in the application of NGTs to plants in the EU", which is true if we limit this statement to the interests of the industry wishing to use these techniques, and of the research centres working for this industry, but untrue if we take into account the interest and opinion of the public: European citizens are overwhelmingly opposed to the use of these techniques in agriculture, and made this known during the previous public consultation on this subject, with more than 67,000 contributions demanding to see NGTs strictly regulated and labelled, or in national petitions such as the French petition which received almost 160 000 signatures.

This is followed by a series of statements on the potential of these techniques to contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy, which are not supported by any factual data, and also ignore several studies that have shown that NGTs are in fact associated with an industrial model of agriculture that is particularly harmful to the environment, especially in terms of pesticide use.

Moreover, these statements indicate an extremely narrow view of sustainability: it is not the varieties that should be sustainable, but the farming systems. Sustainable varieties in a peasant agro-ecological system, for example, will not be sustainable if used in an industrial agricultural system, nor will insecticide or herbicide tolerant GMOs be sustainable in a peasant agro-ecological system. Yet, all the questions concerning sustainability in this consultation propose various ways of making NGTs sustainable without undermining the principle of sustainable use of pesticides set out in Directive 2009/128/EC which sets out the Commission's understanding of the application of sustainability. This is the directive that allows glyphosate and many other endocrine disrupting, mutagenic and/or reprotoxic pesticides to continue to be authorised in the EU.

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7 https://ogm-jeneuuxpas.agirpourlenvironnement.org/
8 See for example a recent study by Friends of the Earth Europe (2022) which demonstrates on the basis of evidence that NGTs do not reduce pesticide use, and in some cases are even associated with an increase in pesticide use: https://friendsoftheearth.eu/publication/new-gmos-and-pesticides-reduction-fast-track-to-failure/
(3) **Intellectual property rights are nowhere to be found in this consultation**

Intellectual property rights, and in particular biotechnology patents, are the most important fear of the agricultural sector in the event of deregulation: if traceability and labelling obligations for certain new modification techniques are weakened or disappear, farmers will have no guarantee that:

- the seeds they buy do not contain GMOs;
- that their crops will not be contaminated by GMOs;
- that their own peasants’ seeds and varieties will not be confiscated on the grounds that they contain a trait covered by a patent on one of these NTGs that allegedly do the same thing as traditional breeding.

Apart from the fact that such practices would be a clear violation of peasants’ rights to seeds, the economic impact of such deregulation would be immense: **any weakening of the rules governing these techniques and the intellectual property rights that protect them would directly threaten the organic farming sector, but also the GMO-free farming sector, which concerns a large number of EU Member States, as well as small and medium-sized farmers who select and produce their own seeds.** If their seeds are contaminated or assimilated into patented varieties, they will lose their seed autonomy and will not have the financial capacity to pay royalties to the multinationals holding these patents. In all countries that have accepted GMOs, the price of seeds has more than doubled in a few years.

Deregulation would seriously weaken small-scale agriculture, which today provides the bulk of European food security, particularly in times of health or international trade crises such as those we have experienced since 2020. It would also contribute to reinforcing the concentration of the seed market and the control of the food chain by a few multinational companies.

For ECVC, the impact assessment and the consultation currently carried out by the European Commission are severely flawed as they exclude, without any justification, the consideration of this issue of intellectual property rights, although patents on biotechnology are the main driver of this Commission initiative. In this respect, collaboration between the Directorate-General for Health and Food Safety (DG SANTE) and the Directorate-General for the Internal Market (DG GROW) is imperative before any proposal for regulatory change.

(4) **Misleading statements concerning the traceability of these techniques**

The ‘Information for operators and consumers’ section of the questionnaire starts by recalling the traceability requirements of the current legislation, before stating that "in some cases of plants obtained by targeted mutagenesis or cisgenesis, analytical methods may be able to detect the product, but not to differentiate it from similar plants obtained by conventional non-GMO breeding techniques or by conventional mutagenesis". This statement is incorrect, as there is no technical barrier to developing differentiation processes. The problem is a lack of investment in research into these differentiation methods. The European Commission has not fulfilled its role by refusing, despite repeated requests, to fund research to define reliable identification and differentiation protocols for these new genetic modification techniques.

All the questions in this section assume that the traceability of the products of these techniques is impossible because of technical obstacles, when it is simply a lack of political will. Furthermore, as all these techniques are patented, all the information that allows their products to be detected and differentiated from other plant products is well known to the industrial firms that developed them in order to defend their patents, but will be covered by industrial secrecy if the GMO regulation does not make their publication mandatory.

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11 See question 16 of the consultation.