Dear Madam, Sir

Thank you for your letter of 8 February addressed to Commissioner Sinkevičius, Commissioner Wojciechowski and myself¹, concerning the Commission’s announced policy initiative on new genomic techniques and the ongoing proceedings before the European Court of Justice in a case concerning certain techniques of mutagenesis.

The Commission is aware of the ongoing proceedings in Case C-688/21, which refer to a reference for a preliminary ruling by the French Conseil d’État regarding the interpretation of the exemption under Article 3(1) of Directive 2001/18/EC in conjunction with the first point of Annex IB to that directive.

On 29 April 2021, together with the publication of its study on the status of new genomic techniques under Union law², the Commission announced a policy initiative on plants obtained by certain new genomic techniques. Based on the information gathered, the analysis and the outcome of that study, the Commission concluded there is sufficient evidence and scientific basis to initiate a policy action on plants derived from targeted mutagenesis and cisgenesis. That announcement was followed by the publication, on 24 September 2021, of an inception impact assessment, in which the Commission’s objectives and plans were presented in order to allow citizens and stakeholders to provide feedback on the intended initiative.

¹ This open letter is also addressed to the Members of the European Parliament and to the Member States. This reply only reflects the views of the Commissioners referred to above.

² SWD(2021) 92 final
The questions put by the French Conseil d’État to the European Court of Justice in the above-mentioned preliminary ruling case do not concern the techniques under the scope of the announced Commission policy initiative. That case concerns the status of products obtained by in vitro random mutagenesis techniques under Directive 2001/18/EC, namely whether those techniques are exempted in accordance with Article 3(1) of that Directive read in conjunction with the first point in Annex IB and recital 17 of the Directive. By contrast, the announced Commission initiative on new genomic techniques covers products obtained by two other groups of genetic modification techniques (targeted mutagenesis and cisgenesis) on which, following the interpretation of the European Court of Justice in its judgment of 25 July 2018, there is no doubt that they are not exempted from the Directive.

In your letter, you consider that the European Court of Justice is about to rule in Case C-688/21 on how the EU Treaty’s precautionary principle is to be interpreted. In fact, the question to the Court rather concerns the status of products obtained by in vitro random mutagenesis techniques under Directive 2001/18/EC, also in the light of the precautionary principle.

In view of the above, since the policy initiative announced by the Commission on plant products obtained by targeted mutagenesis and cisgenesis is unrelated to the questions pending before the Court of Justice, the Commission considers that there is no objective reason impeding the continuation of the preparation of this initiative.

Yours sincerely,

[Signature]

Cc: Janusz Wojciechowski, Member of the European Commission for Agriculture
    Virginijus Sinkevičius, Member of the European Commission for Environment, Oceans and Fisheries
    Members of the European Parliament
    Representatives of the Member States to the European Union