EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Acting Director

Brussels
SANTE/E3/FSX/gk (2022)2439122

Dear Ms Volling and Mr Then,

Subject: Your letter of 1 March 2022 calling for no deregulation of CRISPR/Cas organisms in the EU through the backdoor

Thank you for your above-mentioned letter[1] to Executive Vice-President Timmermans and Commissioner Kyriakides, who have asked me to reply on their behalf.

We agree with the statement in your letter that the legal requirements in Articles 3(1) and 15(1) of Regulation (EC) No 1829/2003 apply to genetically modified organisms (GMOs) for food or feed use, to food and feed containing or consisting of GMOs, and to food, food ingredients and feed produced from GMOs.

In this context, you consider in your letter that a descendant of a GMO automatically is a GMO. Article 2(2) of Directive 2001/18/EC defines a GMO as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*". However, in our view, in case an organism does not feature the alteration of genetic material, which was present in its ancestor, this organism does not fulfil the definition of GMO in this Article. The same applies to the products produced by that organism.

This is in line with the objective pursued by the EU legislators in Directive 2001/18, which is the protection of human, animal health and the environment from potential risks associated with organisms presenting a genetic material altered in a way that does not occur naturally by mating or natural recombination. In this regard, a decisive element for the inclusion of an organism in the definition of GMO legislation is the presence of a genetic alteration in the organism at the moment of the placing on the market.

[1] Registered under our reference Ares(2022)1538758

Ms Annemarie Volling,
Arbeitsgemeinschaft bäuerliche Landwirtschaft, AbL
Heiligengeiststr. 28
21335 Lüneburg, Germany
volling@abl-ev.de

Mr Christoph Then, Testbiotech, Executive Director
Testbiotech
Frohschammerstraße 14,
80807 Munich, Germany
info@testbiotech.org

The letter sent by DG SANTE to the authorities of a Member State, to which you refer to in your letter, is based on the considerations above, and based on the information provided. It expresses the view of the Commission services and does not commit the European Commission. The European Court of Justice has the ultimate prerogative for the interpretation of EU law.

More generally, you emphasise in your letter that CRISPR/Cas is known to produce both intended and unintended genetic changes and the latter create new and specific risks. The available evidence in the scientific literature confirms that the off-target mutations potentially induced by site directed nuclease (SDN)-based technologies, such as CRISPR/Cas, are of the same type as and less numerous than those mutations induced in conventional breeding, including spontaneous mutations and those produced by physical and chemical mutagenesis. More importantly, based on the available scientific evidence and contrary to the conclusion in your letter, such unintended modifications do not entail new and specific hazards compared to mutations that occur in conventional breeding or by physical and chemical mutagenesis. The articles you have referred to do not contradict this.

With reference to the conclusions of your letter, let me emphasise that, with the ongoing policy initiative on plants produced by targeted mutagenesis and cisgenesis, the Commission is not proposing a deregulation or lowering of safety standards. On the contrary, the Commission is aiming at a proportionate regulatory oversight that combines high levels of safety with clear benefits to society and the environment. As clearly indicated in the inception impact assessment, meeting the safety requirements is to remain a prerequisite for the deliberate release or placing on the market.

Yours sincerely,

[e-signed]
Klaus Berend