Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19) (Text with EEA relevance)

Article 3

1 Articles 6 to 11 and 13 to 24 of Directive 2001/18/EC as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and use of medicinal products containing or consisting of GMOs that are intended to treat or prevent COVID-19, including packaging and labelling, storage, transport, destruction, disposal, distribution or administration, with the exception of the manufacturing of the medicinal products, in any of the following cases:

a where such medicinal products have been excluded from the provisions of Directive 2001/83/EC by a Member State pursuant to Article 5(1) of that Directive;

b where such medicinal products have been temporarily authorised by a Member State pursuant to Article 5(2) of Directive 2001/83/EC; or

c where such medicinal products are made available by a Member State pursuant to Article 83(1) of Regulation (EC) No 726/2004.

2 Where feasible, Member States shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal product into the environment.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2020/1043 of the European Parliament and of the Council, Article 3.