Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2020/0128(COD)	Procedure completed
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 Subject 3.10.09.06 Agro-genetics, GMOs 4.20.02.06 Clinical practice and experiments 4.20.04 Pharmaceutical products and industry Legislative priorities The EU?s response to the Covid-19 pandemic		

Key players

	Committee responsible	Rapporteur	Appointed
European Parliament	ENVI Environment, Public Health and Food Safety		
Council of the European Union			
European Economic and Social Committee			
European Committee of the Regions			

Key events

19/06/2020	?!oeil-ANPRO!?		
01/07/2020	Decision by committee, without report		
10/07/2020	?!oeil-DCPL!?	T9-0203/2020	Summary
15/07/2020	Act adopted by Council after Parliament's 1st reading		
15/07/2020	Final act signed		
15/07/2020	End of procedure in Parliament		
17/07/2020	Final act published in Official Journal		

Technical information

Procedure reference	2020/0128(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 114-p1; Rules of Procedure EP 163
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions

Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/03351

Documentation gateway

Legislative proposal		COM(2020)0261	17/06/2020	EC	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0203/2020	10/07/2020	EP	Summary
Draft final act		00028/2020/LEX	15/07/2020	CSL	

Final act

Regulation 2020/1043
OJ L 231 17.07.2020, p. 0012

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

PURPOSE: to provide a temporary derogation from EU legislation on GMOs in order to avoid delays in the conduct of clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: EU legislation requires that applications for marketing authorisation for a medicinal product, in a Member State or in the Union, be accompanied by a dossier containing the results of clinical trials carried out on the product. Sponsors are required, before the commencement of any clinical trial, to request authorisation from the competent authority of the Member State in which the clinical trial is to be conducted.

Clinical trials necessitate the performance of multiple operations which may fall within the scope of Directive 2001/18/EC (Directive on the deliberate release into the environment of genetically modified organisms) or Directive 2009/41/EC (Directive on the contained use of genetically modified micro-organisms) in cases where the investigational medicinal product contains or consists of GMOs.

Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental impact assessment and authorisation by the competent authority of a Member State is complex and may take a significant amount of time.

The complexity of that procedure increases greatly in the case of multi-centre clinical trials conducted in several Member States, as sponsors of clinical trials need to submit multiple requests for authorisation to multiple competent authorities in different Member States in parallel.

The Commission considers that it is of paramount importance that clinical trials with investigational medicinal products against COVID-19 containing or consisting of GMOs can be conducted within the Union, that they can begin as soon as possible, and that they are not delayed due to the complexity of differing national procedures put in place by Member States in implementation of Directives 2001/18/EC and 2009/41/EC.

CONTENT: in the public health emergency created by the COVID-19 pandemic, the proposed Regulation aims to ensure that clinical trials with medicinal products for human use containing or consisting of GMOs to treat or prevent COVID-19 can start swiftly and without a prior environmental risk assessment and/or prior consent under Directive 2001/18/EC or Directive 2009/41/EC.

The Regulation shall apply for as long as COVID-19 is considered a pandemic by the World Health Organisation (WHO) or declared an emergency situation in accordance with Decision No 1082/2013/EU and remains so.

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

The European Parliament adopted by 507 votes to 67, with 9 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council 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.

The European Parliaments position adopted at first reading in accordance with the ordinary legislative procedure supported the Commission proposal.

The proposal aims to ensure that clinical trials with medicinal products for human use containing or consisting of GMOs to treat or prevent COVID-19 can start swiftly and without a prior environmental risk assessment and/or prior consent under Directive 2001/18/EC or Directive

2009/41/EC.

Under the proposed Regulation, no operations related to the conduct of clinical trials with medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19), with the exception of the manufacture of investigational medicinal products, shall require a prior environmental risk assessment or consent where these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

Sponsors shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.

This Regulation shall apply as long as World Health Organisation (WHO) has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 applies.