

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

| Key players | | | |
|--|--|-------------------|------------------|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | <div style="border: 1px solid red; display: inline-block; padding: 2px;">ENVI</div> Environment, Public Health and Food Safety | | |
| Council of the European Union | | | |
| European Economic and Social Committee | | | |
| European Committee of the Regions | | | |

| Key events | | | |
|------------|---|--|---------|
| Date | Event | Reference | Summary |
| 17/06/2020 | Legislative proposal published | COM(2020)0261  | Summary |
| 19/06/2020 | Committee referral announced in Parliament, 1st reading | | |
| 08/07/2020 | Results of vote in Parliament |  | |
| 10/07/2020 | Decision by Parliament, 1st reading | 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) |

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| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| Legal basis | Rules of Procedure EP 170 Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 114-p1 |
| 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 | | | | |
|--|---|--|------------|-------------------------|
| European Parliament | | | | |
| Document type | Committee | Reference | Date | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T9-0203/2020 | 10/07/2020 | Summary |
| Council of the EU | | | | |
| Document type | | Reference | Date | Summary |
| Draft final act | | 00028/2020/LEX | 15/07/2020 | |
| European Commission | | | | |
| Document type | | Reference | Date | Summary |
| Legislative proposal | | COM(2020)0261  | 17/06/2020 | Summary |
| National parliaments | | | | |
| Document type | Parliament /Chamber | Reference | Date | Summary |
| Contribution | PT_PARLIAMENT | COM(2020)0261 | 06/08/2020 | |

| Additional information | | |
|------------------------|----------|------|
| Source | Document | Date |
| European Commission | EUR-Lex | |

| Final act |
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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

2020/0128(COD) - 10/07/2020 - Text adopted by Parliament, 1st reading/single reading

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 Parliament's 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.

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

2020/0128(COD) - 17/06/2020 - Legislative proposal

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.