Amendment 1
Kateřina Konečná
on behalf of the GUE/NGL Group
Bas Eickhout
VEon behalf of the Verts/ALE Group

– **C9-0185/2020**
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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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

Proposal for a regulation
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
1. All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational ***medicinal products*** for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational ***medicinal products***, shall not require a prior environmental risk assessment and/or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 6 to 13 of Directive 2009/41/EC when these activities relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.	1. All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational ***vaccines*** for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational ***vaccines***, shall not require a prior environmental risk assessment and/or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 6 to 13 of Directive 2009/41/EC when these activities relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

Or. en

Justification

The derogations on the environmental impact assessment at the time of clinical trials relating to COVID-19 are far reaching and should be limited to only the necessary applications. There are some promising candidates for vaccines which might require these derogations, but there are no treatments known or directly foreseen for which these derogations would be necessary. It is therefore proportionate to limit the waiving of the obligation to perform a prior environmental risk assessment and/or consent to the clinical trials of vaccines containing or consisting of GMOs, in order to eliminate the chance of misuse of these derogations as much as possible.

Amendment 2
Kateřina Konečná
on behalf of the GUE/NGL Group
Bas Eickhout
on behalf of the Verts/ALE Group

– **C9-0185/2020**
–

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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Where feasible,*** Member States shall implement appropriate measures to minimize foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.	2. Member States shall implement appropriate measures to minimize foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment. ***Member States shall provide information to the public about all clinical trials of medicinal products containing or consisting of GMOs taking place within their territory***.

Or. en

Justification

In accordance with the Aarhus Convention, the public has the right to information relating to environmental matters. Member States should inform the public with information on clinical trials which involve genetically modified organisms, even if the full environmental impact assessment is not yet available at the time of the trials.

Amendment 3
Kateřina Konečná
on behalf of the GUE/NGL Group
Bas Eickhout
on behalf of the Verts/ALE Group

– **C9-0185/2020**
–

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 (COM(2020)0261 – C9-0185/2020 – 2020/0128(COD))

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation ***applies as long as COVID-19 is regarded as a pandemic by the World Health Organisation or as long as a Commission decision recognising a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision No 1082/2013/EU of the European Parliament and of the Council[7] applies.***	1. This Regulation ***shall expire on 31 December 2020.***
	However, if at that expiry date the public health emergency due to COVID-19 still necessitates the derogations provided for in this Regulation, the Commission may propose an extension of these provisions for three months.

Or. en

Justification

The derogations are very broad in scope and should not remain in place indefinitely. It is proporionate to limit the derogations in time, and at the same time allow for an extension if that proves to be needed by the end of this year.