Council of the European Union
General Secretariat

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WRITTEN PROCEDURE

Contact:	javier.gomez-de-aguero-lopez@consilium.europa.eu codecision.adoption@consilium.europa.eu
Tel./Fax:	+32 2 281 72 02
Subject:	Draft 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 [2020/0128 (COD)] Outcome of the written procedure initiated by CM 3031/20: – Adoption of the legislative act, and – Derogation from the 8-week period provided for in Article 4 of Protocol 1 to the TFEU on the role of national parliaments in the EU

Delegations are informed that the written procedure, opened by CM 3031/20 of 13 July 2020 was completed on 14 July 2020:

1. all delegations voted in favour of, except for the Netherlands and the Czech Republic that abstained, the adoption of the draft 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, as set out in PE-CONS 28/20;

2. all delegations voted in favour of, except for the Czech Republic that abstained, the derogation, on the basis of the second subparagraph of Article 3(3) of the Council's Rules of Procedure, from the eight-week period referred to in the first subparagraph of that Article;

The required qualified majority has been reached. Therefore, the above Regulation is adopted.

The Council agreed to derogate, on the basis of the second subparagraph of Article 3(3) of the Council's Rules of Procedure, from the eight-week period referred to in the first subparagraph of that Article.

The statement by the Netherlands is reproduced in the Annex to this CM.

The above statement will be included in the summary of acts adopted by the written procedure as statements to be entered in the Council minutes, in accordance with the third subparagraph of Article 12(1) of the Council's Rules of Procedure.

Statement by the Netherlands

The Netherlands feels a strong sense of urgency to speed up the development of a vaccine or treatment against COVID-19. Facilitating this process as much as possible is a key priority for the Netherlands. This is exactly why Germany, France, Italy and the Netherlands established the Inclusive Vaccine Alliance and welcomed the EU Vaccine Strategy. The Netherlands appreciates the Commission proposal[1] for accelerating existing procedures for clinical trials with GMOs to facilitate quicker development of a vaccine or a cure for COVID-19.

However, the Netherlands' Commission on Genetic Modification[2] points out serious concerns with the proposal as it allows a derogation of the requirements for an environmental risk assessment (ERA) for clinical trials with GMOs, including clinical trials with unknown GMOs and unknown risks. In addition, the lack of an ERA brings forth questions on liability and responsibility, if an incident with negative effects would occur.

Although the Netherlands supports faster, more harmonised procedures in the EU regarding clinical trials involving GMOs, the Netherlands shares the concerns of its Commission on Genetic Modification with regard to ensuring safety for human health and the environment. An approach that simplifies and shortens the procedures for an ERA would be preferred above a generic derogation. However, amending this proposal in such a manner would significantly delay its adoption. In light of the current, unprecedented pandemic and the urgent need for a vaccine or medicine, such a delay can currently not be afforded.

The Netherlands urges sponsors of clinical trials, Member States and the European Commission to take full responsibility to seriously consider and prevent all possible negative impacts of GMOs for human health or the environment, when performing clinical trials with GMOs or administering medicinal products before a market authorisation is granted.

[1] COM(2020) 261

[2] The Netherlands Commission on Genetic Modification (COGEM) is an independent scientific advisory body that provides advice to the government on the risks to human health and the environment of the production and use of GMOs, and informs the government of ethical and societal issues linked to genetic modification.

If unforeseen negative impacts occur, the Netherlands urges all those involved to take all appropriate measures to prevent further escalation and immediately notify national authorities and the European Commission, so that coordinated efforts can be made to minimize newly identified risks.