

To the Minister for Infrastructure and Water Management
Ms A.W.H. Bertram
P.O. Box 20901
2500 EX The Hague

DATE 22 July 2026
REFERENCE CGM/260722-01
SUBJECT Policy letter regarding AI and GMO legislation

Dear Ms Bertram,

Recently, it has become possible to design new organisms using artificial intelligence (AI, generative design) and then create these organisms in a laboratory.^a However, the definition of a genetically modified organism (GMO) in the legislation appears to be based on the modification of an existing organism. This prompts the question of whether these newly created organisms fall within the scope of GMO legislation and will be assessed for their safety for humans and the environment.

AI makes the creation of new organisms possible

In the Trend Analysis Biotechnology 2023, COGEM already noted that the development of new AI language models, combined with the availability of countless sequences of organisms and viruses and the ever-increasing automation in laboratories,^b would in future make it possible to synthesise new viruses.^c It was recently announced that researchers in the United States of America have actually succeeded in designing bacteriophages (viruses that infect bacteria) using an AI application (the Evo 2 genome language model). These researchers synthesised sixteen new bacteriophages that were capable of infecting the bacterium *E. coli*.

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- a. King SH et al. (2025). Generative design of novel bacteriophages with genome language models. <https://www.biorxiv.org/content/10.1101/2025.09.12.675911v1>
 - b. Viruses are not organisms, but in GMO legislation they are defined as micro-organisms: Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, Article 2; Decree on Genetically Modified Organisms (Environmental Management) 2013, Article 1.5
 - c. COGEM & Health Council of the Netherlands (2023). Biotechnology Trend Analysis 2023. A call for vision, decision and direction. CGM/230321-02



This development may have far-reaching societal, ethical and legal implications. Due to biosecurity concerns, the researchers chose to create viruses that can only infect bacteria (bacteriophages). However, the approach used could also be applied to design viruses capable of infecting humans or animals. As a precaution, the researchers therefore disabled this capability in the Evo-2 model they developed and used. The researchers also state that rapid developments in generative design and other innovations in biotechnology are bringing the creation of complete living organisms closer.

Concerns about the scope of the GMO legislation

In Article 1.1(1) of the Genetically Modified Organisms (Environmental Management) Decree (GMO Decree), a GMO is defined as “an organism, other than human beings, whose genetic material has been altered in a way that does not occur naturally through reproduction or natural recombination.” The GMO Decree implements Directive 2001/18/EC, which contains essentially the same definition in Article 2(2).^d

However, when a virus or other organism is designed, there is no existing organism that is modified. Despite the Directive’s broad objective of protecting human health and the environment, it is unclear exactly what the scope of the term “altered” is in the definition of a genetically modified organism, and whether this also includes organisms that have not been altered but created. The preparatory documentation for the Directive and its predecessor, Directive 90/220/EEC, does not appear to have taken into account the possibility that humans might, in the long term, be able to create new organisms.

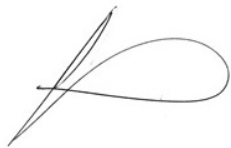
It is therefore unclear whether newly designed viruses and other organisms fall within the scope of the GMO legislation and must therefore undergo an environmental risk assessment. If meeting the definition requires the modification of an existing organism, the GMO legislation does not apply to created organisms. In that case, there would be no need to comply with the requirements for authorisation, such as an environmental risk assessment, while no other legislation appears to apply either.

Need for consultation at EU level

COGEM points out that the safety of humans and the environment may be compromised if newly created organisms fall outside the scope of regulations covering, among other things, safety and health. COGEM notes that the debate over whether newly created organisms fall within the scope of GMO legislation is not a national matter, but must be conducted at EU level. This applies equally to the question of how to safeguard human and environmental safety if GMO legislation does not apply.

d. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. <https://eur-lex.europa.eu/legal-content/NL/TXT/HTML/?uri=CELEX:32001L0018>

Yours sincerely,

A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke.

Professor Sybe Schaap,
Chair of COGEM

c.c.

- Ministry of Infrastructure and Water Management, Environmental Safety and Risks
Directorate, Directorate-General for the Environment and International Affairs