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To the Minister of
Infrastructure and Water Management
Cora van Nieuwenhuizen-Wijbenga
P.O. Box 2090
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DATE 24 June 2020

REFERENCE CGM/200624-01

SUBJECT COGEM advice concerning the proposal by the EC to suspend the environmental risk assessment of clinical trials for the treatment or prevention of COVID-19

Dear Mrs Van Nieuwenhuizen,

COGEM was asked to advise on the European Commission's proposal to amend the rules on clinical trials with genetically modified organisms (GMOs) intended to treat or prevent COVID-19.[1] COGEM is a strong proponent of shortening and relaxing procedures as long as human and environmental safety is not put at risk, but is of the opinion that a generic setting aside of the GMO legislation and the authorisation of GMOs without a prior environmental risk assessment is irresponsible and disproportional.

Given the urgent need to develop treatments and vaccines for COVID-19, the European Commission is of the opinion that protecting public health and the health of individual patients and the benefits of the availability of an effective treatment or vaccine override other considerations, such as the environmental risks. Most medical directives contain provisions for making exceptions and suspending procedures in emergency situations, such as a pandemic. The GMO legislation[a] does not include such provisions. The European Commission therefore proposes that the environmental risk assessment required under the GMO legislation should be suspended for clinical trials of COVID-19 treatments or vaccines. The proposal is in the form of a Regulation that will apply equally to all Member States.

[a] Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Directive 2009/41/EC on the contained use of genetically modified microorganisms.

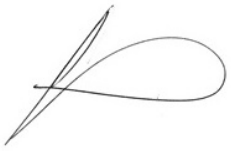
The Regulation concerns specific clinical trials with GMOs to test medicinal products and vaccines to treat or prevent COVID-19 and will remain in force as long as the pandemic lasts or there remains is a risk to human health. The production of GM medicines and vaccines does not fall under the Regulation and the placing on the market of these medical products remains subject to an environmental risk assessment. However, the European Commission also points out that individual Member States may authorise the application of a medical product in the absence of a formal marketing authorisation when there is a case for 'compassionate use' and in situations of urgency and need. In such situations the environmental risk assessment may be delayed for up to several years, during which time the potential risks to human health and the environment will remain.

COGEM applauds the shortening and relaxing of the procedures for the environmental risk assessment of GMOs, as long as human and environmental safety are not put at risk. With this in mind, COGEM has published various advisory reports in recent years proposing a generic environmental risk assessment for clinical trials with certain GMOs with the aim of speeding up the authorisation procedure.[2,3,4] In these cases it is sufficient to carry out an administrative check and this can effectively expedite the granting of a licence.

However, in its advisory report *Beoordeling van risico's voor derden bij gentherapiestudies* ('Assessment of risks to third parties of gene therapy studies', 23 January 2020)[5] COGEM indicated that some forms of gene therapy could involve risks to human health and the environment. In its proposal the European Commission refers to the intrinsic characteristics of the conduct of clinical trials in general (such as a limited number of patients, limited volumes of medicinal products and administration in a highly controlled environment) to support the argument that any potential environmental exposure is substantially limited. However, COGEM points out that many of the platforms used for the development of vaccines are based on GM viruses and that certain applications may involve risks to third parties and the environment. These risks are not necessarily covered by the general safety protocols to protect patients or test subjects/participants.

COGEM takes a positive view of the emergency procedure introduced in the Netherlands for speeding up the authorisation of COVID-19 clinical trials to within 28 days.[6] According to COGEM this is sufficient to prevent any significant hold-ups to the development of a GM vaccine or medicine. COGEM therefore sees no reason to take drastic measures such as those proposed by the European Commission. COGEM is of the opinion that from the viewpoint of human and environmental safety a generic setting aside of the GMO legislation and the authorisation of GMOs without a prior environmental risk assessment is irresponsible and disproportional.

Yours sincerely,



Professor Sybe Schaap
Chair of COGEM

c.c. Dr J. Westra, Head of the GMO Office
Ministry of Infrastructure and Water Management, Environmental Safety and Risks Directorate
Directorate-General for the Environment and International Affairs

1. European Commission (2020). 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. COM(2020) 261, 17 Juni, Brussels. URL: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=COM:2020:261:FIN&from=EN (Bezocht 24 juni 2020)
2. COGEM (2019). Generieke milieurisicobeoordeling van klinische studies met ex-vivo retro- en lentiviraal getransduceerde cellen. COGEM advies CGM/190729-01
3. COGEM (2019). Generieke milieurisicobeoordeling van klinische studies met AAV-vectoren. COGEM advies CGM190905-01
4. COGEM (2020). Generiek advies over de milieurisicobeoordeling van klinische studies met ex vivo lentiviraal getransduceerde cellen: aanwezigheid van vrije vectordeeltjes in het medisch product. COGEM advies CGM/200507-01
5. COGEM (2020). Beoordeling van risico's voor derden bij gentherapiestudies. COGEM advies CGM/200123-01
6. IenW (2020). Regeling Tijdelijke regeling afwijkende behandeling vergunningaanvragen gentherapie in verband met bestrijding COVID-19. URL: https://www.rijksoverheid.nl/documenten/regelingen/2020/03/30/bijlage-1-spoedregeling-ggo-i-v-m-coronavirus (Bezocht 24 juni 2020)