Julian Gillespie LLB, BJuris

.. first

And to be very clear

These GMOs Were Never Needed

RNA dependent RNA polymerase
@BCdrainoty

so, integrate DNA and then disable p53. Yeah, all innocent. I've yet to see a reason why spike wasn't created in vitro then injected. Why was gaining access to the cellular machinery SO important.

7:43 AM · Nov 13, 2023 · **635** Views

2 6 25 2

Post your reply

Reply

Kevin McKernan @Kevin_McKernan · Nov 13

Bingo!
They should have used nasal peptides. Not transfection

4 1 25

Cell Res. 2020 Apr;30(4):343-355. doi: 10.1038/s41422-020-0305-x. Epub 2020 Mar 30.

Inhibition of SARS-CoV-2 (previously 2019-nCoV) infection by a highly potent pan-coronavirus fusion inhibitor targeting its spike protein that harbors a high capacity to mediate membrane fusion

Shuai Xia [#1], Meiqin Liu [#2,3], Chao Wang [#4], Wei Xu [#1], Qiaoshuai Lan [1], Siliang Feng [4], Feifei Qi [5], Linlin Bao [5], Lanying Du [6], Shuwen Liu [7], Chuan Qin [5], Fei Sun [8], Zhengli Shi [2], Yun Zhu [9], Shibo Jiang [10,11], Lu Lu [12]

Affiliations + expand

PMID: 32231345 PMCID: PMC7104723 DOI: 10.1038/s41422-020-0305-x

Free PMC article

Abstract

The recent outbreak of coronavirus disease (COVID-19) caused by SARS-CoV-2 infection in Wuhan, China has posed a serious threat to global public health. To develop specific anti-coronavirus therapeutics and prophylactics, the molecular mechanism that underlies viral infection must first be defined. Therefore, we herein established a SARS-CoV-2 spike (S) protein-mediated cell-cell fusion assay and found that SARS-CoV-2 showed a superior plasma membrane fusion capacity compared to that of SARS-CoV. We solved the X-ray crystal structure of six-helical bundle (6-HB) core of the HR1 and HR2 domains in the SARS-CoV-2 S protein S2 subunit, revealing that several mutated amino acid residues in the HR1 domain may be associated with enhanced interactions with the HR2 domain. We previously developed a pan-coronavirus fusion inhibitor, EK1, which targeted the HR1 domain and could inhibit infection by divergent human coronaviruses tested, including SARS-CoV and MERS-CoV. Here we generated a series of lipopeptides derived from EK1 and found that EK1C4 was the most potent fusion inhibitor against SARS-CoV-2 S protein-mediated membrane fusion and pseudovirus infection with IC50s of 1.3 and 15.8 nM, about 241- and 149-fold more potent than the original EK1 peptide, respectively. EK1C4 was also highly effective against membrane fusion and infection of other human coronavirus pseudoviruses tested, including SARS-CoV and MERS-CoV, as well as SARSr-CoVs, and potently inhibited the replication of 5 live human coronaviruses examined, including SARS-CoV-2. Intranasal application of EK1C4 before or after challenge with HCoV-OC43 protected mice from infection, suggesting that EK1C4 could be used for prevention and treatment of infection by the currently circulating SARS-CoV-2 and other emerging SARSr-CoVs.

Similar GMO legal Definitions in the UK

Environmental Protection Act 1990

See Section 106

Environmental Protection Act 1990

What Version

Latest available (Revised)

Original (As enacted)

Advanced Features

Show Geographical Extent

(e.g. England, Wales, Scotland and Northern Ireland)

Show Timeline of Changes

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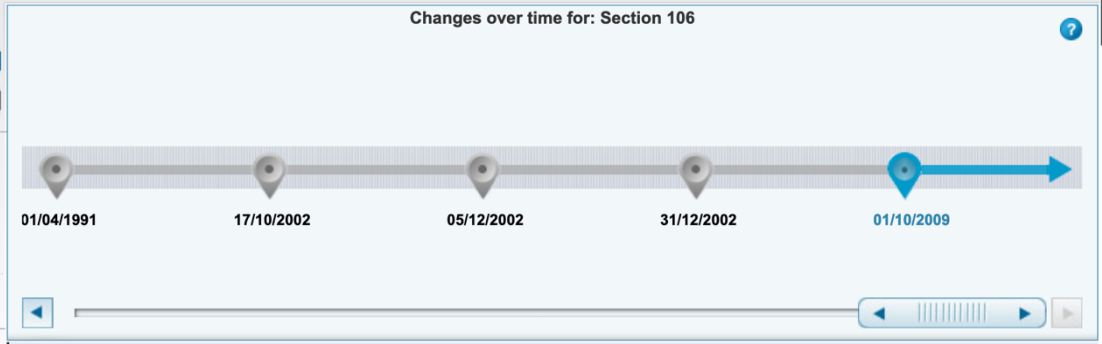


Status: There are multiple versions of this provision on screen. These apply to different geographical extents.

Skip to: E+W - England and Wales extent S - Scotland extent

Changes to legislation: Environmental Protection Act 1990, Section 106 is up to date with all changes known to be in force on or before 25 November 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

View outstanding changes

106 Purpose of Part VI and meaning of "genetically modified organisms" and related expressions. E+W

[F1 (1) This Part has effect for the purpose of ensuring that all appropriate measures are taken to avoid damage to the environment which may arise from the escape or release from human control of genetically modified organisms.]

(2) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form), other than humans [F2, human embryos or human admixed embryos] ; and, unless the context otherwise requires, the term also includes any article or substance consisting of or including biological matter.

(3) For the purpose of subsection (2) above "biological matter" means anything (other than an entity mentioned in that subsection) which consists of or includes—

(a) tissue or cells (including gametes or propagules) or subcellular entities, of any kind, capable of replication or of transferring genetic material, or

(b) genes or other genetic material, in any form, which are so capable,

and it is immaterial, in determining if something is or is not an organism or biological matter, whether it is the product of natural or artificial processes of reproduction and, in the case of biological matter, whether it has ever been part of a whole organism.

.. relevantly

(2) In this Part the term "organism" means any acellular, unicellular or multicellular entity (in any form) .. the term also includes any article or substance consisting of or including biological matter.

The LNP-modRNA complexes satisfy being an entity of ***any*** form, that are acellular.

(3) .. "biological matter" means anything .. which consists of or includes —

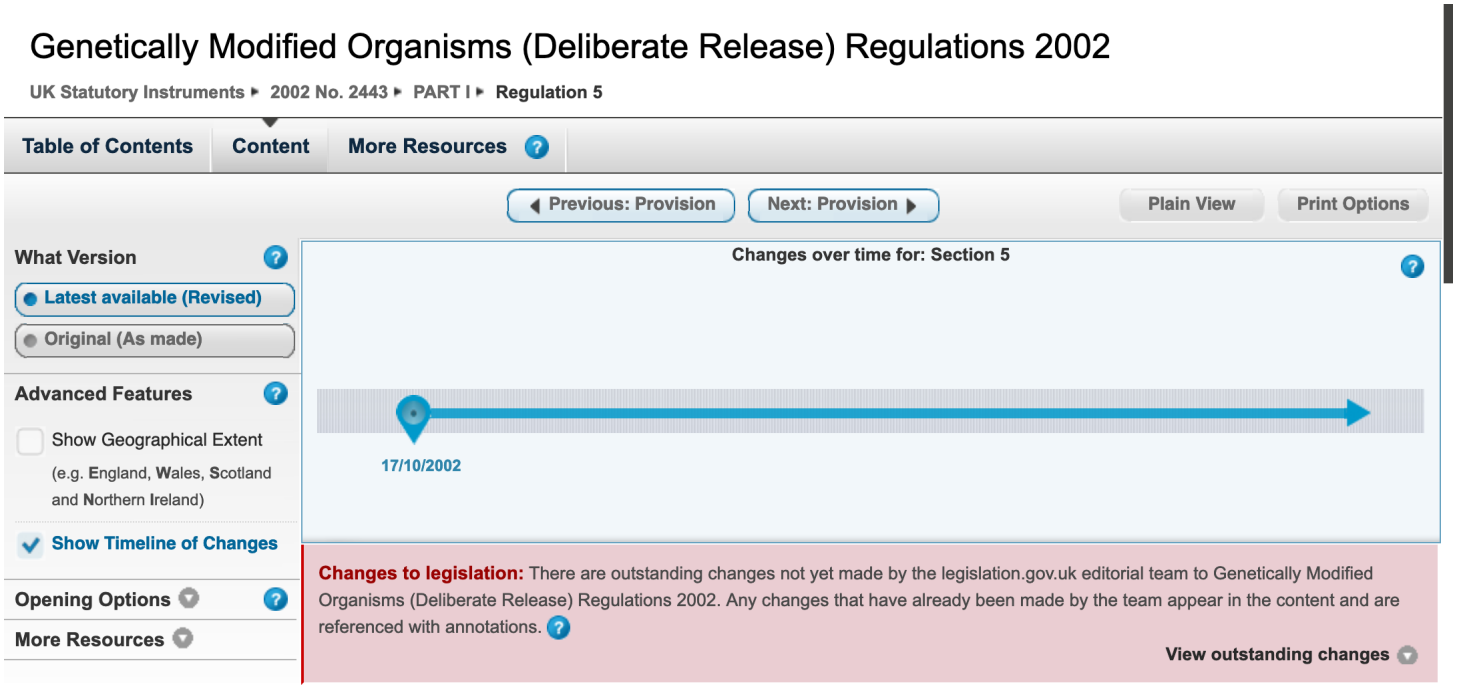
(b) genes or other genetic material, in any form, which are so capable [of transferring genetic material: see ss3(a)]

The LNP-modRNA complexes contain genetic material (modRNA) where the LNP part of the complexes ***transfers the genetic material*** (modRNA) throughout the human body (bio-distribution) and ***transfers the genetic material*** across/through the cell membrane (transfection) of all cell types in the human body.

(4) For the purposes of this Part an organism is "genetically modified" if any of the genes or other genetic material in the organism—

(a) have been artificially modified, or

artificially modified genes are defined under



Genetically Modified Organisms (Deliberate Release) Regulations 2002

UK Statutory Instruments ▸ 2002 No. 2443 ▸ PART I ▸ Regulation 5

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Changes over time for: Section 5

17/10/2002

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.

View outstanding changes

Techniques of genetic modification

5.—(1) Until the coming into force of the first regulations under section 106(4B)(a) **M1** of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

.. a closer look

5.—(1) Until the coming into force of the first regulations under section 106(4B)(a) F1 of the Act, genes or other genetic material shall be taken, for the purposes of subsection (4) of that section, to be artificially modified if they are altered using any of the following techniques:

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

under the Environmental Protection Act 1990

GMOs proposed to be marketed must undergo an extensive Risk Assessment and seek a separate Consent from the Secretary of State

108(1) Subject to subsections (2) and (7) below, **no person shall import or acquire, release or market any genetically modified organisms** unless, before doing that act—

(a) **he has carried out an assessment of any risks there are** (by reference to the nature of the organisms and the manner in which he intends to keep them after their importation or acquisition or, as the case may be, to release or market them) **of damage to the environment being caused as a result of doing that act**; and

111(1) Subject to subsection (7) below, **no person shall import or acquire, release or market any genetically modified organisms** —

(a) in such cases or circumstances as may be prescribed in relation to that act,

except in pursuance of a consent granted by the Secretary of State and in accordance with any limitations and conditions to which the consent is subject.

BUT sub Sections 108(7) and 111(7) allow for an Exemption under the UK GMO Regulations

Genetically Modified Organisms (Deliberate Release) Regulations 2002

UK Statutory Instruments ▸ 2002 No. 2443 ▸ PART III ▸ Regulation 15

Exempt activities

15(1) The cases and circumstances prescribed for the purposes of sections 108(7) and 111(7) of the Act in which persons are exempt from the requirements of section 108(1)(a) of the Act (to carry out a risk assessment) and of section 111(1)(a) of the Act (to obtain consent), respectively, insofar as they relate to marketing genetically modified organisms, are all cases and circumstances in which:

(e) a genetically modified organism is marketed which is contained in a medicinal product authorised under the Human Medicines Regulations 2012

And Yes

.. both Pfizer and Moderna did make applications for marketing approval under the Human Medicines Regulations 2012:

(a) Pfizer under regulation 174: see MHRA Public Assessment Report, page 5.

(b) Moderna under regulation 50: see MHRA Public Assessment Report (summary), page 6.

.. in Europe almost the same legal definitions

BUT No exemptions from having to submit extensive Risk Assessments and undertake Public Consultation prior to marketing approval

This was all ignored intentionally by the EMA

.. for details see

International Journal of Vaccine Theory, Practice, and Research

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The Canaries in the Human DNA Mine

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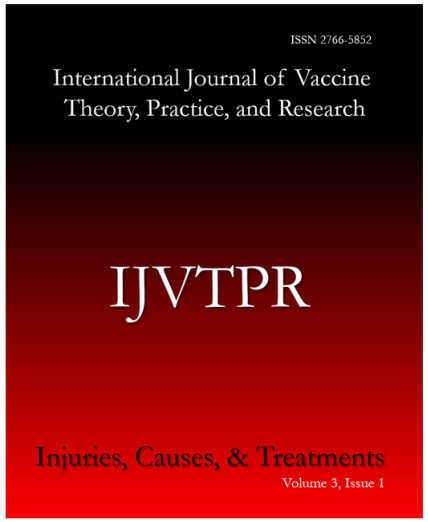
DOI: https://doi.org/10.56098/ijvtpr.v3i1.83

Keywords: genetically modified organisms, GMO, Moderna, modified RNA, modRNA, Pfizer, retroposition, reverse transcription, SARS-CoV-2



Abstract

.. specifically

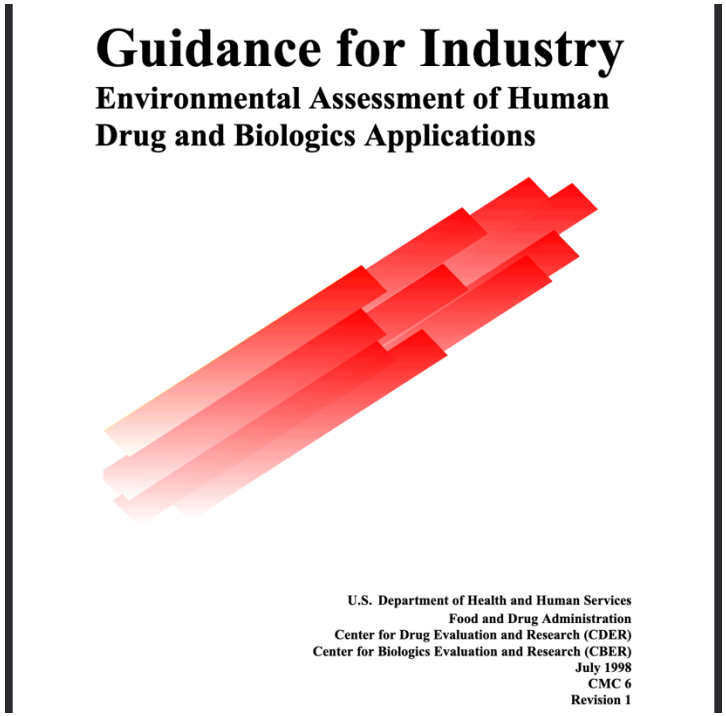
Directive 2001/18/EC Notification Information Required before the Deliberate Release of GMOs into the Environment or when seeking Authorisation for GMO products to Enter the Market

The definition for what constitutes a GMO is found at Article 2 (emphasis shown in italics is added):

> For the purposes of this Directive:
>
> (1) "organism" means any biological entity *capable* of replication or of *transferring genetic material*;
>
> (2) "*genetically modified organism (GMO)*" means an organism, with the exception of human beings, *in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*;

.. in the US, Environmental Assessments (EA) were required in respect of the GMO nature and consequent risk these GMOs posed

Guidelines:



.. relevantly an EA is required for any

New molecular entity: An active moiety (present as the unmodified base [parent] compound, or an ester or a salt, clathrate, or other noncovalent derivative of the base [parent] compound) that has not been previously approved or marketed as the active moiety in the United States for use in a drug product, either as a single ingredient or as part of a combination product, or as part of a mixture of stereoisomers.

.. But .. in lay terms

the FDA granted Pfizer and Moderna an exemption/exclusion from having to prepare Environmental Assessments, on the false basis the active molecules (modRNA) had previously been approved

.. for clarity

In pharmacology, an active moiety is the part of a molecule or ion – excluding appended inactive portions – that is responsible for the physiological or pharmacological action of a drug substance.

.. the FDA cited the exemption/exclusion found here

CFR - Code of Federal Regulations Title 21

FDA Home › Medical Devices › Databases

The information on this page is current as of Oct 17, 2023.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).

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[Code of Federal Regulations]
[Title 21, Volume 1]
[CITE: 21CFR25.31]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A - GENERAL

PART 25 -- ENVIRONMENTAL IMPACT CONSIDERATIONS

Subpart C - Categorical Exclusions

Sec. 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

.. specifically

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(a) Action on an NDA, abbreviated application, application for marketing approval of a
biologic product, or a supplement to such applications, or action on an OTC monograph, if
the action does not increase the use of the active moiety.
```

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

The End

.. but Not the end