HSE

Department for Environment Food & Rural Affairs

Llywodraeth Cymru
Welsh Government

England and Wales

Genetically Modified Organisms (Contained Use) Regulations 2014

Competent Authority Policy Statement

EU Regulation 2020/1043 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 (COVID-19)

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EU Regulation 2020/1043 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 (COVID-19)

1. EU Regulation 2020/1043 came into force in July 2020. This Policy Statement is intended to help stakeholders in scope of the EU Regulation understand how it impacts on the obligations contained in The Genetically Modified Organisms (Contained Use) Regulations 2014, which implements EU Directive 2009/41 - on the contained use of genetically modified micro-organisms.

2. This Policy Statement does not address areas outside the remit of the Genetically Modified Organisms (Contained Use) Regulations 2014, such as the Deliberate Release of Genetically Modified Organisms (GMOs).

Clinical trials

3. Article 2 of Regulation 2020/1043 states that:

> 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 or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC when these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

4. For the purposes of the GMO (Contained Use) Regulations 2014, HSE interprets Article 2 to mean the following:
   a. All operations related to the conduct of a clinical trial on a human medicine containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the human medicine, shall be exempt from certain requirements of the GMO (Contained Use) Regulations 2014, as long as the clinical trial has been authorised under the Medicines for Human Use (Clinical Trials) Regulations 2004.

5. Annex 1 lists the requirements that a clinical trial authorised under the Medicines for Human Use (Clinical Trials) Regulations 2004 is exempt from. The Annex contains details of the specific GMO (Contained Use) Regulations 2014 that are exempted and the corresponding EU Directive 2009/41 requirements referred to in this EU Regulation. Users affected by this EU Regulation will be able to use this table to determine what they are currently exempted from with regards to their work with genetically modified micro-organisms and the GMO (Contained Use) Regulations 2014.

6. Users affected by this exemption should be reminded that:
   a. the Competent Authority expects the requirements of the GMO (Contained Use) Regulations 2014 not listed in Annex 1 to continue to be followed.
   b. broader health and safety and environmental requirements are still in place.

Authorisation of human medicines

7. Article 3 pertains to the disapplication of certain requirements of the GMO (Contained Use) Directive 2009/41 if the human medicine in question has the requisite authorisation in place to be used as a human medicine.

8. As Regulation 3(2)(b)(i) of the GMO (Contained Use) Regulations 2014 already exempts human medicines with the requisite authorisation in place, no further action is required by those with the requisite authorisations to deliver compliance with EU Regulation 2020/1043 with regards to the contained use of GMOs.

Period of time the EU Regulation will apply

9. Article 4 of EU Regulation 2020/1043 states that the Regulation shall apply either:
   a. as long as the World Health Organisation has declared COVID-19 to be a pandemic; or
   b. as long as an implementing act by which the Commission recognises 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 applies.

10. The England & Wales Genetically Modified Organisms (Contained Use) Regulations 2014 Competent Authority shall take steps to keep this situation under review, and are committed to keeping stakeholders appropriately informed.

Annex 1a

Regulatory Requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 within scope of the exemptions referred to in Article 2(1) of the EU Regulation (Articles 4-13 of EU Directive 2009/41 - on the contained use of genetically modified micro-organisms)

GMO (Contained Use) Regulations 2014	Relevant 2009/41 Article	Purpose of 2009/41 Article
Regulation 5	Article 4.2	Requires the user to carry out a risk assessment.
	Article 4.3	Risk assessment to result in a final classification.
Regulation 7	Article 4.6	Requirements as to the record of the risk assessment.
	Article 5.2	Requirements to periodically review the protective measures.
	Article 7	Requirements for Class 1 contained use.
Regulation 9	Article 6	Requirements for use of premises for the first time.
	Article 7	Requirements for Class 1 contained use.
Regulation 10	Article 8.1	Requirements for first and subsequent Class 2 contained use.
	Article 8.2	Requirements for Class 2 or higher contained use where previous consent has been given.
	Article 8.3	Provision to proceed with Class 2 contained use where previous consent has not been given.
Regulation 11	Article 9.1	Requirements for first and subsequent Class 3 & 4 contained uses.
	Article 9.2	Provisions controlling the start of Class 3 & 4 contained uses.
	Article 13.1	Requirement that an emergency plan is drawn up and made available to others.

Regulation 15	Article 11.1	Requires the user to notify the competent authority of any new information or modifications likely to have significant consequences in terms of risk posed.
Regulation 16	Article 10.3	Provisions relating to what the competent authority may require from the user.
Regulation 18(1)-(2)	Article 4.1	Requires measures to be taken to avoid adverse effects which might arise from the contained use of GMMs.
	Article 4.5	Risk assessment must take into account the disposal of waste and effluents and safety measures to be put into effect.
	Article 5.1	Requirements to apply the general principles and appropriate protective measures.
Regulation 19	Article 4.4	Where there is doubt, the more stringent protective measures shall be applied unless agreed otherwise with competent authority.
	Article 4.5	Risk assessment must take into account the disposal of waste and effluents and safety measures to be put into effect.
	Article 5.1	Requirements to apply the general principles and appropriate protective measures.
Regulation 21(1), (3) & (4)	Article 13.1	Requirement that an emergency plan is drawn up and made available to others.
Regulation 23	Article 10.2	Required the competent authority to examine the accuracy and correctness of the notification.
	Article 13.1	Requirement that an emergency plan is drawn up and made available to others.
Regulation 24	Article 10.3	Provisions relating to what the competent authority may require from the user.
	Article 10.4	Exemptions when calculating time periods for when Class 2-4 contained uses may start.
Regulation 25	Article 10.3	Provisions relating to what the competent authority may require from the user.
	Article 11.2	Further to Article 11.1, the competent authority may require the user to modify, suspend or terminate the contained use.

Annex 1b

Regulatory Requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 that are exempted as a consequence of Article 2(1) of EU Regulation 2020/1043

There are certain requirements contained within the Genetically Modified Organisms (Contained Use) Regulations 2014, that rely upon the outputs of other regulatory requirements that have been exempted by Article 2(1) of EU Regulation 2020/1043, for example – risk assessments and notifications.

The following GMO (Contained Use) Regulations are therefore also exempted:

GMO (Contained Use) Regulations 2014	**Title**	**Reason for exemption**
Regulation 8	Advice from a genetic modification safety committee	The advice pertains to the risk assessment, which is exempted. There would be nothing to advise on.
Regulation 13	Single notifications to the joint competent authority and for connected programmes of work	Notifications are exempted, so any work captured under this exemption would not need to be notified under a single notification for connected programme
Regulation 14	Changes of circumstances relating to notifications	Notifications are exempted, so there is no need to submit a change of circumstances.
Regulation 17	Withdrawal of notification	Notifications are exempted, so there would be no need to withdraw a notification.
Regulation 28	Register of notifications	Notifications are exempted, so there would be no notification to add to the register of notifications.
Regulation 29	Information not to be included in the register	Notifications are exempted, so there would be no notification information to exclude from the register of notifications.