EXPLANATORY MEMORANDUM TO

THE HEALTH SECURITY (EU EXIT) REGULATIONS 2021

2021 No. 0000

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument addresses failures of retained European Union (EU) law on health security so that it operates effectively and establishes a standalone regime which will ensure that the four nations of the United Kingdom (UK) coordinate on data sharing, epidemiological surveillance and their approach to the prevention and control of serious cross-border health threats.

2.2 It also implements the UK-EU Trade and Cooperation Agreement[1] (TCA) in so far as it relates to health security.

Explanations

What did any relevant EU law do before exit day?

2.3 EU law on health security, including disease prevention and control, sets rules on epidemiological surveillance, monitoring, and for the early warning and combating of serious cross-border health threats. This includes rules on preparedness and response planning related to those activities in order to coordinate and complement member States' responses to such threats. Its objective is to support cooperation and coordination between member States to improve the prevention and control of severe human disease across the borders of member States and to combat other serious cross-border threats to health. In doing so it aims to contribute to a high level of public health protection in the EU.

Why is it being changed?

2.4 The EU law no longer operates effectively to coordinate functions or set rules for those purposes in the UK. Therefore, to ensure that these coordination functions and rules continue to support a high level of health protection across the UK, the functions previously exercised by the EU on behalf of the member States have been modified and transferred to a new UK Health Protection Committee ("the Committee") and to the UK Health Security Agency (UKHSA)[2], acting in cooperation with the public health agencies for the other parts of the UK. The changes are set out in Section 7 and

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948119/EU-UK_Trade_and_Cooperation_Agreement_24.12.2020.pdf

[2] This role will be carried out by Public Health England until such time as it transfers to UKHSA

they enable the UK to operate a standalone system and cooperate with the EU on health security on the terms agreed in the TCA.

What will it now do?

2.5 By transferring the coordination functions previously carried out by the EU to the Committee and UKHSA, the UK will maintain its ability to detect, prepare for and respond to serious cross-border health threats. The implementation of the health security part of the TCA supports effective future working and information sharing between the UK and the EU in the event of a serious cross-border health threat affecting the UK and an EU member State.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Under Part 2 of the Regulations the UK public health agencies must, for the part of the UK for which they are responsible, undertake epidemiological surveillance on the communicable diseases and related special health matters listed in the Schedule. For the time being, the list of communicable diseases and related special health matters in the retained EU law are adopted for this purpose. However, there is a regulation making power (regulation 6(7)-(8)) allowing the Secretary of State, on the advice of the Committee, and with the consent of the Ministers in the devolved administrations, to revise the list of communicable diseases or related special health matters for which surveillance must be undertaken, including scope to add new ones.

3.2 Part 3 of the Regulations creates procedures for addressing serious cross-border health threats. In particular, it includes provision for the UK public health agencies to communicate with each other in giving alerts and sharing relevant information about such threats in accordance with a Communications Protocol. The Communications Protocol, as defined in regulation 8, details the operational arrangements by which the UK public health agencies are to communicate with each other so as to ensure that they are able to meet the requirements of regulation 10, for example by providing a template for alert notification. Regulation 8 also allows the Communications Protocol to be amended by the Committee from time to time. The responsibility to update the Communication Protocol is delegated administratively to the Committee because those with operational responsibility for carrying out the necessary communications required by regulation 10 are uniquely placed to determine the most effective and efficient procedures for doing so, with flexibility to amend the document from time to time to reflect technical or organisational developments as necessary. We consider that section 8(5) of EUWA allows the Regulations to make such provision and that this is a suitable delegation to the Committee.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.3 The territorial application of this instrument includes Scotland and Northern Ireland.

3.4 The powers under which this instrument is made (section 8 of EUWA) and section 31 of the European Union (Future Relationship) Act 2020 (EUFRA)) extend to the entire United Kingdom and the territorial application of this instrument is not limited either by those Acts or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is all of the United Kingdom.

4.2 The territorial application of this instrument is all of the United Kingdom.

5. European Convention on Human Rights

5.1 The Minister of State for Health, Edward Argar, has made the following statement regarding Human Rights:

"In my view the provisions of the Health Security (EU Exit) Regulations 2021 are compatible with the Convention rights."

6. Legislative Context

6.1 Section 3 of EUWA provides that direct EU legislation namely EU regulations, decisions and tertiary legislation form part of domestic law on and after the transition period ending on 31 December 2020.

6.2 The direct EU legislation on health security is:

- Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (Decision 1082/2013);
- Regulation EC No. 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control;
- Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision 1082/2013; and
- Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

6.3 The approach taken in this instrument is to revoke and restate, with modifications, direct EU legislation on health security in one domestic instrument. This is in reliance on the power in paragraph 21(b) of Schedule 7 to EUWA to make provision re-stating retained EU law in a clearer or more accessible way.

6.4 Section 8 of EUWA provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate (a) any failure of retained EU law to operate effectively; or (b) any other deficiency in retained EU law arising from the withdrawal of the UK from the EU.

6.5 This instrument relies on the power at section 8 of EUWA to ensure that all aspects of retained EU law on health security operate effectively and are not deficient.

6.6 Section 29 (general implementation of agreements) of EUFRA is currently being relied on, in conjunction with operational guidance to the UK's public health agencies, to ensure the UK meets its TCA obligations for health security, including informing the EU and sharing with them information about serious cross-border health threats affecting the UK and at least one member State. This instrument relies

on the power in section 31 of the EUFRA to provide more specific implementation and prescribe a UK-wide approach for addressing serious cross-border health threats.

7. Policy background

What is being done and why?

7.1 The UK's capability to prevent, prepare for, detect and respond to serious cross-border health threats, such as infectious diseases and non-infectious disease threats, is enhanced by the ability to share information and coordinate health protection activity between all four UK nations and internationally.

7.2 Whilst the UK was a member State, the four UK nations coordinated and shared information on public health protection with Public Health England (PHE), the UK's national competent authority and focal point for communications with the EU. This included sharing information on serious cross-border health threats, new and emerging threats, and surveillance, and response coordination. The EU's system also supported the UK's compliance with the International Health Regulations[3] (2005) (IHR).

7.3 In a UK Government (UKG) common frameworks exercise held in August 2017, public health protection was identified as an area where there was considerable existing coordination between England, Scotland, Wales and Northern Ireland that was, in part, underpinned by the UK's relationship with the EU and its agencies, including the European Centre for Disease Prevention and Control (ECDC).

7.4 UKG, the devolved administrations and the UK's public health agencies all agreed that a common framework was necessary to ensure that cooperation on serious cross-border health threats continued following the end of the Transition Period, acknowledging the importance of such cooperation in providing a high level of UK-wide human health protection. It was also assessed as necessary to ensure that the UK can best meet its international obligations under the IHR.

7.5 The Public Health Protection and Health Security Common Framework ("Common Framework") is a non-legislative agreement between the UKG, devolved administrations and the public health agencies of England, Scotland, Wales and Northern Ireland. The framework strengthens cooperation and governance arrangements between the parties on serious cross-border health threats. The Common Framework is in the process of being formally agreed by all four UK nations after which it will be shared with legislatures for formal scrutiny.

7.6 These Regulations, which support and are aligned to the Common Framework, revoke and restate with modifications retained EU law on health security. The Regulations ensure that EU law continues to function effectively following the end of the Transition Period and provides a legislative regime for epidemiological surveillance and response to serious cross border health threats whether at risk of extending beyond the UK to an EU member State or as may otherwise necessitate a coordinated response within the UK to ensure a high level of human health protection.

[3] https://www.who.int/publications/i/item/9789241580496

7.7 The arrangements set out in the Regulations are based on existing strong collaborative working between England, Scotland, Wales and Northern Ireland and will support continued health security for the whole of the UK.

7.8 Both the Common Framework and these Regulations take an "all hazards" approach to health protection and health security. In particular, they address biological threats, including communicable diseases, as well as non-infectious threats of chemical, environmental, or unknown origin. This is in line with existing national policies, the IHR and EU law.

7.9 The Regulations also implement the health security arrangements agreed between the UK and the EU under the TCA.

7.10 In the TCA at article 702 (Cooperation on health security) the UK and the EU agreed to inform each other of any serious cross-border health threats in a timely manner via designated focal points. The UK has designated PHE as its focal point and we expect to pass this function later in 2021 to the UKHSA. The UK focal point will work alongside the UK's other public health agencies in this role, in line with the existing collaborative arrangements that are in place.

7.11 Where there is such a threat, the UK may request access to the EU's Early Warning and Response System (EWRS). EWRS access would allow the UK, the Commission and the member States to exchange information, assess public health risks and coordinate measures to protect public health in relation to that threat.

7.12 In addition, the EU may invite the UK to participate in a committee established to support the exchange of information and facilitate coordination in relation to the threat. Currently this committee is the EU Health Security Committee (HSC), which the UK attends in relation to the Covid-19 response.

7.13 The TCA also makes provision for cooperation on scientific and technical matters between the ECDC and the UK body responsible for surveillance, epidemic intelligence and scientific advice on infectious disease. Such cooperation may include concluding a memorandum of understanding.

7.14 These Regulations provide specific implementation of the health security provisions of the TCA as follows:

- Where the UK's designated focal point, working in collaboration with the other UK public health agencies, is satisfied that there is a serious cross-border health threat which spreads or entails a significant risk of spreading across the borders of the UK and at least one member State, it must notify the European Commission (designated by the EU as its focal point) of that threat.
- Where the UK is granted access to the EU's EWRS for a particular threat, the UK's focal point must share on EWRS any available information which may be used to assess public health risks or coordinate public health measures in relation to the threat.
- A notification from the EU's focal point of a serious cross-border health threat to the UK must get passed on by the UK's focal point to all four of the UK's public health agencies.

7.15 The Regulations provide for epidemiological surveillance to be undertaken and make arrangements for coordination and information sharing between the UK's four nations in the planning and response to serious cross border health threats. These also support the arrangements with the EU under the TCA. The Regulations accordingly:

- Identify, for the purposes of the Regulations, the UK public health agencies responsible for health security in the respective parts of the UK.
- Require the UK's four public health agencies to conduct epidemiological surveillance on the list of communicable diseases and related special health matters, using applicable case definitions, and to share comparable and compatible data arising from their surveillance with each other.
- Place obligations on the UK's public health agencies to notify the UK's focal point of any newly identified serious cross-border health threats without delay and in any event no later than 24 hours from the time when they first become aware of the threat, and for the duration of the threat to share information that may be useful for coordinating the response.
- Require UKG, the devolved administrations and the UK's public health agencies to consult each other with a view to coordinating their efforts to develop, strengthen and maintain their respective capacities for monitoring, early warning and assessment of, and response to, serious cross border health threats and to inform each other of any substantial revisions to preparedness and response planning.
- Establish the UK Health Protection Committee which will consist of one member for each of England, Scotland, Wales and Northern Ireland representing a relevant Minister and one member representing each of the four UK public health agencies. The Committee, which will support collaboration between all parts of the UK and can only make decisions with the agreement of all permanent members, will function to:
    - review and provide advice to the Secretary of State on the list of communicable diseases and related special health matters that are subject to UK-wide surveillance;
    - maintain the list of case definitions to be used when the UK public health agencies share information with each other collected as part of their epidemiological surveillance. Case definitions contained within the Commission Implementing Decision 2018/945[4] ("the Implementing Decision") are part of retained EU law, and as such would otherwise require the UK public health agencies to use these case definitions when sharing information. However, the Regulations change this requirement, with the Committee given responsibility for a list drawn from the case definitions in that Implementing Decision and which the Committee may amend from time to time as necessary. The Committee may also adopt case definitions for any additional communicable diseases and related special health matters added by regulations, as well as for Covid-19 where no case definition has as yet been adopted in the Implementing Decision;
    - establish and review procedures for the collection of surveillance data; and
    - maintain the Focal Point Communications Protocol.

[4] COMMISSION IMPLEMENTING DECISION (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions

- Give the Secretary of State a regulation making power to revise the list of communicable diseases and related special health matters on the basis of advice from the Committee and with the consent of the Ministers in the devolved administrations. UKHSA will be responsible, in cooperation with the devolved administrations, for maintaining databases on the UK-wide surveillance undertaken and for providing quality assurance.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of EUWA in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the EU. The instrument is also made under paragraph 21 of Schedule 7 to EUWA to restate retained EU law in a clearer or more accessible way. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

8.2 Alongside EUWA powers, the instrument is also being made under section 31 of EUFRA to implement the health security part of the TCA (see section 6.6).

9. Consolidation

9.1 This SI does not amend another instrument.

10. Consultation outcome

10.1 There has been no public consultation in relation to this instrument. However, extensive consultation of, and engagement with, the devolved administrations and the UK public health agencies has taken place in the development of both the Common Framework and these Regulations. The Four Nations Health Protection EU Transition Group, which consisted of representatives from UKG, devolved administrations and the UK public health agencies, was used as the main forum to discuss policy development. This included through three one-day workshops held in London, Cardiff and Belfast, as well as fortnightly meetings to progress work on both the Common Framework and these Regulations throughout 2020 and early 2021.

10.2 The Minister of State for Health, Edward Argar, wrote to the Cabinet Secretary for Health and Sport in Scotland, the Minister of Health for Northern Ireland and the Minister of Health for Wales on the proposed Regulations in February 2021.

11. Guidance

11.1 The UK Focal Point Communications Protocol on serious cross-border health threats was published on 27 May and can be found at International Health Regulations 2005: UK National Focal Point - GOV.UK (www.gov.uk)

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the instrument maintains existing public health standards.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation will be kept under regular review.

14.2 As this instrument is made under EUWA, no review clause is required.

15. Contact

15.1 Nicholas Gunning at the Department of Health and Social Care Telephone: 02079725715 or email: Nicholas.gunning@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Morwenna Carrington, Deputy Director for UK Health Security, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister of State for Health, Edward Argar at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018 and the European Union (Future Relationship) Act 2020

Part 1A

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the

		made a political commitment to include these statements alongside all EUWA SIs	EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees

Part 2

Statements required under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister of State for Health, Edward Argar at the Department of Health and Social Care has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Health Security (EU Exit) Regulations 2021 do no more than is appropriate".

1.2 This is the case because they remedy failures of retained EU law on health security to operate effectively, define ways of working between the four nations, support effective future working and information sharing between the United Kingdom and the EU and maintain the United Kingdom's ability to detect, prepare for and respond to serious cross-border health threats.

2. Good reasons

2.1 The Minister of State for Health, Edward Argar at the Department of Health and Social Care has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are to provide specific implementation of the health security provisions of TCA (see 7.12) and to maintain intra-UK coordination and information sharing on serious cross-border health threats (see 7.13).

3. Equalities

3.1 The Minister of State for Health, Edward Argar, has made the following statement(s):

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006, or the Equality Act 2010 or subordinate legislation made under those Acts".

3.2 The Minister of State for Health, Edward Argar, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Edward Argar, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.".

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.