

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 and paragraph 6(3) of Schedule 5 to the European Union (Future Relationship) Act 2020 for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2021 No.

**EXITING THE EUROPEAN UNION
PUBLIC HEALTH**

The Health Security (EU Exit) Regulations 2021

*Made - - - - 2021
Coming into force - - 1st September 2021*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018⁽¹⁾ (“the 2018 Act”) and section 31 of the European Union (Future Relationship) Act 2020⁽²⁾ (“the 2020 Act”).

In accordance with paragraph 1(1) of Schedule 7 to the 2018 Act and paragraph 6(3) of Schedule 5 to the 2020 Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

PRELIMINARY

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Health Security (EU Exit) Regulations 2021 and come into force on 1st September 2021.

(2) These Regulations extend to the whole of the United Kingdom.

(3) These Regulations apply to the whole of the United Kingdom.

(1) 2018 c. 16. Paragraph 21 of Schedule 7 was amended by paragraph 53 of Schedule 5 to the European Union (Withdrawal Agreement) Act 2020 (c. 1).
(2) 2020 c. 29.

Interpretation

2. In these Regulations—

“the Committee” means the UK Health Protection Committee established under regulation 4(1);

“communicable disease” means any infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid which is contaminated with the contagious agent;

“health threat” means a condition, agent or incident which may cause, directly or indirectly, ill health;

“IHR” means the International Health Regulations (2005) of the World Health Organisation adopted by the fifty-eighth World Health Assembly on 23rd May 2005(3);

“monitoring” means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data and analysis on specified indicators relating to serious cross-border health threats;

“part of the United Kingdom” means England, Scotland, Wales or Northern Ireland;

“related special health matters” means antimicrobial resistance and healthcare associated infections related to communicable diseases;

“relevant Minister” means—

- (a) in England, the Secretary of State;
- (b) in Scotland, the Scottish Ministers;
- (c) in Wales, the Welsh Ministers;
- (d) in Northern Ireland, a Minister within the meaning of the Northern Ireland Act 1998(4) or a Northern Ireland department;

“serious cross-border health threat” has the meaning given in regulation 5;

“TCA” means the Trade and Cooperation Agreement within the meaning in section 37(1) of the European Union (Future Relationship) Act 2020;

“UK authority” means in respect of a part of the United Kingdom—

- (a) the UK public health agency for that part; and
- (b) the relevant Minister for that part;

“UK focal point” means the national focal point for the United Kingdom designated by the Secretary of State for the purposes of Title 1 of Part 4 of the TCA and notified to the European Union(5).

UK public health agency

3.—(1) For the purposes of these Regulations, “UK public health agency” means—

- (a) in relation to England, Public Health England(6);
- (b) in relation to Scotland, Public Health Scotland(7);

(3) <https://www.who.int/ihr/publications/9789241596664/en>. The World Health Organization is a specialised agency within the terms of Article 57 of the Charter of the United Nations. A hard copy can be obtained from the Department of Health and Social Care, UK Health Security Team, 39 Victoria Street, London SW1H 0EU.

(4) 1998 c. 47.

(5) This is entitled “Thematic Cooperation Title I: Health Security Article 702: Cooperation on health security”. Public Health England is currently designated as the UK focal point. See paragraph 4 of that Part about designation of a focal point.

(6) An executive agency of the Department of Health and Social Care.

(7) Public Health Scotland was constituted as a Special Health Board by S.S.I. 2019/336.

- (c) in relation to Wales, the Public Health Wales National Health Service Trust⁽⁸⁾;
- (d) in relation to Northern Ireland, the Regional Agency for Public Health and Social Well-being⁽⁹⁾,

or such other person or body in relation to a part of the United Kingdom as the relevant Minister for that part designates.

(2) Where a UK public health agency is also the UK focal point, the obligations in regulations 10 and 12 on a UK public health agency to notify and provide information to the UK focal point are satisfied if the notification is made or the information is provided by the persons responsible for the exercise of its functions as a UK public health agency to the persons responsible for the exercise of its functions as the UK focal point.

UK Health Protection Committee

4.—(1) The Secretary of State must establish a committee to be known as the UK Health Protection Committee.

(2) The membership of the Committee is to be as follows—

- (a) one person representing each relevant Minister;
- (b) one person representing each UK public health agency.

(3) The chair of the Committee must be one of the persons representing a relevant Minister, to be elected, from time to time, by the members of the Committee.

Serious cross-border health threats

5.—(1) For the purposes of these Regulations, “serious cross-border health threat” means a life-threatening or otherwise serious health threat specified in paragraph (2) which—

- (a) spreads or entails a significant risk of spreading across the borders of the United Kingdom and at least one member State; or
- (b) may necessitate a coordinated response by the UK authorities in order to ensure a high level of human health protection.

(2) The following are specified for the purposes of paragraph (1)—

- (a) threats of biological origin consisting of—
 - (i) communicable diseases;
 - (ii) related special health matters;
- (b) biotoxins or other harmful biological agents not related to communicable diseases;
- (c) threats of chemical origin;
- (d) threats of environmental origin;
- (e) threats of unknown origin;
- (f) events which may constitute public health emergencies of international concern under the IHR provided that they fall under one of the categories of threats set out in sub-paragraphs (a) to (d).

⁽⁸⁾ Public Health Wales National Health Service Trust was established by Welsh S.I. 2009 No. 2058 (W. 177).

⁽⁹⁾ The Regional Agency for Public Health and Social Well-being was established by section 12(1) of the Health and Social Care (Reform) (Northern Ireland) Act 2009 (c. 1) and is commonly known as the Public Health Agency for Northern Ireland.

PART 2

EPIDEMIOLOGICAL SURVEILLANCE IN THE UNITED KINGDOM

Epidemiological surveillance and sharing of information

6.—(1) For the purposes of this Part, “epidemiological surveillance” means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on the communicable diseases and related special health matters listed in the Schedule.

(2) Each UK public health agency must undertake epidemiological surveillance in relation to the part of the United Kingdom for which it is responsible.

(3) Each UK public health agency must collect the following information arising from the epidemiological surveillance—

- (a) comparable and compatible data and information in relation to the epidemiological surveillance of those communicable diseases and related special health matters;
- (b) information concerning the progression of any epidemic situations;
- (c) information concerning unusual epidemic phenomena or new communicable diseases of unknown origin.

(4) The information in paragraph (3)(c) includes any information which comes to the attention of the UK public health agency relating to unusual epidemic phenomena or new communicable diseases of unknown origin originating or occurring outside the United Kingdom.

(5) The information specified in paragraph (3) must be shared with the other UK public health agencies in accordance with the procedures established by the Committee under regulation 7(1)(a).

(6) When sharing information under paragraph (5), the UK public health agency must, where available, use the relevant case definition for each communicable disease and related special health matter specified on a list kept by the Committee for that purpose (“the case definitions list”).

(7) The Secretary of State may, on the advice of the Committee, by regulations—

- (a) add a communicable disease to the list in Part 1 of the Schedule;
- (b) amend the name of a disease on that list; or
- (c) remove a disease from that list.

(8) The Secretary of State may, on the advice of the Committee, by regulations—

- (a) add a related special health matter to the list in Part 2 of the Schedule;
- (b) amend the name of a related special health matter on that list; or
- (c) remove a related special health matter from that list.

(9) In giving advice for the purposes of paragraph (7) or (8), the Committee must have regard to—

- (a) the potential of the communicable disease or related special health matter to cause significant morbidity or mortality, or both, across the United Kingdom, especially where the prevention of that disease or related special health matter requires a United Kingdom-wide approach to coordination;
- (b) the desirability of exchange of information between the UK authorities about the communicable disease or related special health matter in order to provide early warning of the threats to public health;
- (c) whether in the case of a rare and serious communicable disease or related special health matter the pooling of data would allow hypothesis generation from a wider knowledge base;

- (d) whether effective preventive measures relating to the communicable disease or related special health matter are available with a protective health gain; and
 - (e) whether United Kingdom-wide comparison would aid evaluation of programmes aimed at preventing the communicable disease or related special health matter in question.
- (10) The case definitions list means the list of case definitions for each communicable disease and related special health matter as specified in Annex 2 of the Implementing Decision—
- (a) subject to any variation to any of the case definitions as the Committee may, from time to time, consider appropriate; and
 - (b) including any additional case definitions added by the Committee under paragraph (11).
- (11) The Committee, in order to ensure the comparability and compatibility of the data collected from across the United Kingdom from epidemiological surveillance, must add to the case definitions list any case definitions adopted by the Committee to apply—
- (a) to Covid-19;
 - (b) to any additional communicable diseases and related special health matters added by regulations under paragraph (7) or (8); and
 - (c) to any serious cross-border health threat to which regulation 12 applies.
- (12) Each UK public health agency must publish —
- (a) the case definitions list;
 - (b) any variation or addition to the case definitions list under paragraph (10) or (11).
- (13) In paragraph (10), “the Implementing Decision” means 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.

Surveillance procedures and methodologies

- 7.—(1) The Committee must—
- (a) establish procedures for the collection and sharing of information from the epidemiological surveillance undertaken under this Part; and
 - (b) endeavour to harmonise and rationalise operating methodologies for such surveillance.
- (2) The Committee may update the procedures established under paragraph (1)(a) from time to time.
- (3) The UK public health agency in relation to England, in cooperation with the other UK public health agencies, must—
- (a) provide quality assurance by monitoring and evaluating epidemiological surveillance activities to ensure optimal operation of the surveillance; and
 - (b) maintain databases for any epidemiological surveillance undertaken.
- (4) Where the UK public health agency in relation to England—
- (a) has received data from another UK public health agency relating to epidemiological surveillance undertaken by that agency under regulation 6(2); and
 - (b) has analysed that data,
- the UK public health agency in relation to England must communicate the results of the analysis to all the UK public health agencies.

PART 3

PROCEDURES FOR ADDRESSING SERIOUS CROSS-BORDER HEALTH THREATS

Interpretation

8. In this Part—

“the Communications Protocol” means the UK Focal Point Communications Protocol, being the protocol for bringing the UK public health agencies into permanent communication with one another in order to facilitate the prevention and control of serious cross-border health threats⁽¹⁰⁾ as amended by the Committee from time to time;

“public health measure” means a decision or an action taken which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health.

Preparedness and response planning

9.—(1) The UK authorities must 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 (“preparedness and response planning”).

(2) Any consultation under paragraph (1) must aim to—

- (a) enable the sharing of best practice and experience in preparedness and response planning;
- (b) promote the interoperability of preparedness and response planning across the United Kingdom;
- (c) address the intersectoral dimension of preparedness and response planning across the United Kingdom; and
- (d) support the implementation of core capacity requirements for surveillance and response as referred to in Articles 5 and 13 of the IHR.

(3) Where a relevant Minister or a UK public health agency is substantially revising preparedness and response planning within the part of the United Kingdom for which it is responsible, it must inform the other UK authorities in a timely manner of the main aspects of their revisions that are relevant to the objectives referred to in paragraph (1).

Alert notification

10.—(1) Each UK public health agency must, in accordance with the Communications Protocol, alert the UK focal point of any serious cross-border health threat.

(2) The alert notified under paragraph (1) must—

- (a) specify whether the threat—
 - (i) is unusual or unexpected for the given place and time;
 - (ii) causes or may cause significant morbidity or mortality in humans;
 - (iii) is growing rapidly or may grow rapidly in scale; or
 - (iv) exceeds or may exceed national response capacity; and

⁽¹⁰⁾ <https://www.gov.uk/government/publications/international-health-regulations-2005-uk-national-focal-point-communications-protocol>. A hard copy can be obtained from the Department of Health and Social Care, UK Health Security Team, 39 Victoria Street, London SW1H 0EU.

- (b) be notified without delay and in any event no later than 24 hours from the time when the UK public health agency concerned first became aware of that threat.
- (3) When notifying an alert under paragraph (1), the UK public health agency concerned must provide the UK focal point with any available relevant information in their possession that may be useful for coordinating the response including—
 - (a) the type and origin of the agent;
 - (b) the date and place of the incident or outbreak;
 - (c) the means of transmission or dissemination;
 - (d) toxicological data;
 - (e) detection and confirmation methods;
 - (f) public health risks;
 - (g) public health measures implemented or intended to be adopted by the UK authority in the part of the United Kingdom concerned;
 - (h) any measures other than public health measures adopted or intended to be adopted in the part of the United Kingdom concerned; and
 - (i) any personal data necessary for the purpose of contact tracing.
- (4) Following the notification of an alert under paragraph (1) or a notification from the UK focal point under regulation 13(2), each UK public health agency must, in accordance with the Communications Protocol and for the duration of the threat, share with the UK focal point all relevant and available information relating to that threat which it has obtained from its monitoring activities.
- (5) Where an alert is notified under paragraph (1), the UK public health agency notifying the alert may produce jointly with the UK focal point a risk assessment of the potential severity of the health threat, including possible public health measures.
- (6) Any risk assessment produced under paragraph (5) must, for the purpose of coordinating a response from across the United Kingdom, be made promptly available to the other UK public health agencies.
- (7) Where a UK public health agency is also the UK focal point, the power in paragraph (5) may be exercised by the risk assessment being produced jointly by the persons responsible for the exercise of its functions as a UK public health agency and the persons responsible for the exercise of its functions as the UK focal point.
- (8) In paragraph (3)(i), “contact tracing” means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border health threat and who are in danger of developing, or have developed, a disease arising from that threat.

Coordination of response

- 11.**—(1) Following the notification of an alert under regulation 10(1) or a notification from the UK focal point under regulation 13(2), the UK authorities must, where requested by a relevant Minister or a UK public health agency, consult each other with a view to—
- (a) coordinating efforts to make appropriate responses within the United Kingdom to any serious cross-border health threat;
 - (b) developing the nature of the response by the Secretary of State to the serious cross-border health threat—
 - (i) for the purposes of regulation 13; or
 - (ii) where there is an event which may constitute a public health emergency of international concern under the IHR;

(c) developing appropriate risk and crisis communication, to be adapted to the needs and circumstances of the relevant part of the United Kingdom, aimed at providing consistent and coordinated information to the public and to healthcare professionals.

(2) Where the UK authorities consult each other under paragraph (1), they must do so on the basis of the available information, including the information referred to in regulation 10(3) and (4) and any risk assessment referred to in regulation 10(5), and in accordance with the Communications Protocol.

(3) Where a relevant Minister or a UK public health agency intends to adopt in the part of the United Kingdom for which it is responsible public health measures to combat a serious cross-border health threat, it must, before adopting those measures, inform and consult the other UK authorities on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

(4) Where a relevant Minister or a UK public health agency adopts as a matter of urgency public health measures in the part of the United Kingdom for which it is responsible in response to a serious cross-border health threat, it must, immediately upon adoption, inform the other UK authorities of the nature, purpose and scope of those measures.

Information about other serious cross-border health threats

12.—(1) This regulation applies where a UK public health agency has notified the UK focal point, in accordance with regulation 10, of a serious cross-border health threat which is not a communicable disease or a related special health matter listed in the Schedule.

(2) Following the notification of the alert, each UK public health agency must, in accordance with the Communications Protocol and for the duration of the threat, share with the UK focal point all relevant and available information relating to that threat which it has obtained from its monitoring activities.

(3) The information shared under paragraph (2) must, if available, include in particular any change—

- (a) in the geographical distribution, spread and severity of the threat concerned; and
- (b) in the means of detection of that threat.

Arrangements with the European Union under the Health Security chapter of the TCA

13.—(1) Where the UK focal point has been notified of an alert under regulation 10(1) it must, upon being satisfied that there exists a relevant threat, notify the EU focal point of that threat.

(2) Where the EU focal point has notified the UK focal point that there is a relevant threat, the UK focal point, upon being satisfied as to its existence as a relevant threat, must from that time notify each UK public health agency of that threat without delay and in any event within 24 hours.

(3) Where the UK focal point—

- (a) has notified the EU focal point of a relevant threat under paragraph (1); or
- (b) is satisfied as to the existence of a relevant threat of which notification has been given by the EU focal point under paragraph (2),

the Secretary of State may make a written request to the European Commission for access to the EWRS.

(4) Where the request in paragraph (3) is accepted, the UK focal point must provide through the EWRS any available information which may be used to assess public health risks and to coordinate public health measures in relation to the relevant threat.

(5) Where invited by the European Commission, the Secretary of State may participate in any committee (“the European Committee”) established within the European Union and composed of representatives of member States for the purposes of supporting the exchange of information and of coordination in relation to the relevant threat.

(6) The arrangements in paragraphs (4) and (5), where applicable, apply on a temporary basis, and in any event for no longer than the period that the Secretary of State or the European Commission, having consulted each other, consider necessary for the purposes of dealing with the relevant threat.

(7) If there is a change in the identity of the person designated as the UK focal point, the Secretary of State must notify the European Commission of the identity of the new UK focal point.

(8) The Secretary of State and the UK focal point must observe all applicable conditions for the use of the EWRS and the rules of procedure of the European Committee for the period of access granted in respect of the relevant threat.

(9) If the Secretary of State considers that the conditions or rules of procedure cannot be accepted, the Secretary of State may withdraw the United Kingdom’s participation in the EWRS or its participation in the European Committee, as the case may be, in respect of the relevant threat.

(10) The Secretary of State must cooperate with the European Centre for Disease Prevention and Control⁽¹¹⁾ on technical and scientific matters of mutual interest to the United Kingdom and the European Union and, to that end, may conclude a memorandum of understanding.

(11) In this regulation—

“European Commission” means the institution of the European Union with that name⁽¹²⁾ and references in this regulation to the European Commission include such person or persons as the European Commission may specify by written notice to the Secretary of State;

“EU focal point” means the focal point for the European Union designated by the European Union for the purposes of Title 1 of Part 4 of the TCA and notified to the United Kingdom⁽¹³⁾;

“EWRS” means the Early Warning and Response System operated by the European Union in respect of serious cross-border health threats affecting the European Union⁽¹⁴⁾;

“relevant threat” means a serious cross-border health threat referred to in regulation 5(1)(a).

PART 4

REGULATIONS

Regulations

14.—(1) The Secretary of State may make regulations under regulation 6(7) or (8) (“the regulations”) in relation to the whole of the United Kingdom.

(2) The Secretary of State may not make the regulations without the consent of—

(a) in relation to Wales, the Welsh Ministers;

(b) in relation to Scotland, the Scottish Ministers;

(c) in relation to Northern Ireland, a Minister within the meaning of the Northern Ireland Act 1998 or a Northern Ireland department.

⁽¹¹⁾ The European Centre for Disease Prevention and Control is established by Regulation (EU) 851/2004.

⁽¹²⁾ See Article 13 of the Treaty on European Union (OJ N C 326, 26.10.2012, p13).

⁽¹³⁾ This is entitled “Thematic Cooperation Title I: Health Security Article 702: Cooperation on health security”. The European Commission is currently designated as the EU focal point.

⁽¹⁴⁾ See Article 8 of Regulation (EC) 851/2004.

- (3) Where any of the parties mentioned in paragraph (2)(a) to (c) requests that the Secretary of State make the regulations, the Secretary of State must have regard to that request.
- (4) The regulations are to be made by statutory instrument.
- (5) The power to make the regulations includes power to make—
 - (a) different provision for different purposes;
 - (b) consequential, supplementary, incidental, transitional, transitory or saving provision.
- (6) A statutory instrument containing the regulations is subject to annulment in pursuance of a resolution of either House of Parliament.

PART 5

REVOCATIONS

Revocations

- 15. The following retained direct EU legislation is revoked—
 - (a) 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;
 - (b) 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;
 - (c) 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 No 1082/2013/EU of the European Parliament and of the Council.

Date

Name
Secretary of State
Department of Health and Social Care

SCHEDULE

Regulation 6(1)

COMMUNICABLE DISEASES AND RELATED SPECIAL HEALTH MATTERS

PART 1

COMMUNICABLE DISEASES

Acute hepatitis A
Acute poliomyelitis
Anthrax
Botulism
Brucellosis
Campylobacter enteritis
Chikungunya virus disease
Chlamydial infection, including Chlamydial lymphogranuloma (venereum) (LGV)
Cholera
Congenital rubella syndrome
Congenital syphilis
Congenital toxoplasmosis
Congenital Zika virus disease
Covid-19
Creutzfeldt-Jakob disease
Cryptosporidiosis
Dengue
Diphtheria
Echinococcosis
Enteritis due to *Yersinia enterocolitica* or *Yersinia pseudotuberculosis*
Giardiasis (lambliasis)
Gonococcal infection
Haemophilus influenzae infection, invasive disease
Hepatitis B
Hepatitis C
Human immunodeficiency virus (HIV) infection and Acquired immunodeficiency syndrome (AIDS)
Influenza
Influenza A/H5N1
Legionnaires' disease
Leptospirosis
Listeriosis
Lyme neuroborreliosis
Malaria

Measles
Meningococcal infection, invasive disease
Mumps
Pertussis
Plague
Q fever
Rabies
Rubella
Salmonella enteritis
Severe acute respiratory syndrome (SARS)
Shiga toxin/verocytotoxin-producing *E. coli* infection (STEC/VTEC), including Haemolytic-
uraemic syndrome (HUS)
Shigellosis
Smallpox
Streptococcus pneumoniae infection, invasive disease
Syphilis
Tetanus
Tick-borne viral encephalitis
Trichinellosis
Tuberculosis
Tularaemia
Typhoid and paratyphoid fevers
Viral haemorrhagic fevers (VHF)
West Nile virus infection
Yellow fever
Zika virus disease

PART 2

RELATED SPECIAL HEALTH MATTERS

Antimicrobial resistance
Nosocomial infections

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in part in exercise of the powers in section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) and (g) of that Act) arising from the withdrawal of the United Kingdom from the European Union. The retained direct EU law concerned relates to health security.

Part 1 (starting with regulation 2) defines terms used in the Regulations. Regulation 3 identifies the bodies which are UK public health agencies for the purposes of the Regulations and makes provision about satisfying obligations under the Regulations where such an agency is also the UK focal point. Regulation 4 establishes a UK Health Protection Committee (“the Committee”). Regulation 5 sets out what constitutes a “serious cross-border health threat”.

Part 2 (starting with regulation 6) imposes an obligation on the UK public health agencies to carry out epidemiological surveillance on the communicable diseases and related special health matters listed in the Schedule in relation to their respective part of the United Kingdom. Regulation 6 also contains a power to allow the Secretary of State by regulations to amend the list of communicable diseases and related special health matters in the Schedule or to add or remove communicable diseases or related special health matters in respect of which epidemiological surveillance is to be undertaken. Regulation 6 adopts the case definitions for those diseases as contained in retained direct EU law on IP completion day. It also allows the Committee to create case definitions for new communicable diseases or related special health matters and to revise case definitions. Regulation 7 requires the Committee to establish procedures for collecting and sharing of information arising from epidemiological surveillance undertaken under this Part in order to harmonise and rationalise methodologies for such surveillance. It also requires the UK public health agency for England to provide quality assurance and to maintain databases in respect of such surveillance.

Part 3 (starting with regulation 8) relates to procedures for dealing with serious cross-border health threats across the United Kingdom and liaison with the European Union. Regulation 9 requires the UK authorities to consult each other about preparedness and response planning for such threats. Regulation 10 requires UK public health agencies to notify alerts to the UK focal point immediately when such threats arise. Regulation 11 makes provision for coordinating responses to such threats. Regulation 12 relates to the sharing of information where there are alerts about serious cross-border health threats which are not communicable diseases or related special health matters. Regulation 13 is made under powers in section 31 of the European Union (Future Relationship) Act 2020 (c. 29) in order to implement the Trade and Cooperation Agreement between the United Kingdom and the European Union in so far as it relates to health security.

Part 4 (regulation 14) makes provision about the regulations to be made under regulation 6(7) and (8). Part 5 (regulation 15) revokes the relevant retained direct EU law.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.