WELSH STATUTORY INSTRUMENTS

2021 No. 915 (W. 208)

PUBLIC HEALTH, WALES

The Health Protection (Coronavirus, International Travel and Operator Liability) (Wales) (Miscellaneous Amendments) (No. 3) Regulations 2021

	at 1.38 p.m. on 30
Made	July 2021
	at 6.00 p.m. on 30
Laid before Senedd Cymru	July 2021
	at 4.00 a.m. on 2
Coming into force	August 2021

The Welsh Ministers, in exercise of the powers conferred on them by sections 45B, 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984(1), make the following Regulations.

Title and coming into force

1.—(1) The title of these Regulations is the Health Protection (Coronavirus, International Travel and Operator Liability) (Wales) (Miscellaneous Amendments) (No. 3) Regulations 2021.

(2) These Regulations come into force at 4.00 a.m. on 2 August 2021.

Amendments to the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020

2. The Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020(**2**) are amended as follows.

^{(1) 1984} c. 22. Part 2A was inserted by section 129 of the Health and Social Care Act 2008 (c. 14). The function of making regulations under Part 2A is conferred on "the appropriate Minister". Under section 45T(6) of the 1984 Act the appropriate Minister as respects Wales, is the Welsh Ministers.

⁽²⁾ S.I. 2020/574 (W. 132), amended by S.I. 2020/595 (W. 136), S.I. 2020/714 (W. 160), S.I. 2020/726 (W. 163), S.I. 2020/804 (W. 177), S.I. 2020/817 (W. 179), S.I. 2020/840 (W. 185), S.I. 2020/868 (W. 190), S.I. 2020/866 (W. 196), S.I. 2020/917 (W. 205), S.I. 2020/942, S.I. 2020/944 (W. 210), S.I. 2020/962 (W. 216), S.I. 2020/981 (W. 220), S.I. 2020/1015 (W. 226), S.I. 2020/1042 (W. 231), S.I. 2020/1080 (W. 243), S.I. 2020/1098 (W. 249), S.I. 2020/133 (W. 258), S.I. 2020/1165 (W. 263), S.I. 2020/1191 (W. 269), S.I. 2020/1223 (W. 277), S.I. 2020/1232 (W. 278), S.I. 2020/1237 (W. 279), S.I. 2020/1288 (W. 286), S.I. 2020/1329 (W. 295), S.I. 2020/1362 (W. 301), S.I. 2020/1232 (W. 278), S.I. 2020/1521 (W. 325), S.I. 2020/1288 (W. 332), S.I. 2020/1645 (W. 345), S.I. 2021/20 (W. 7), S.I. 2021/24 (W. 8), S.I. 2021/46 (W. 10), S.I. 2021/48 (W. 11), S.I. 2021/20 (W. 7), S.I. 2021/24 (W. 8), S.I. 2021/154 (W. 38), S.I. 2021/48 (W. 11), S.I. 2021/50 (W. 12), S.I. 2021/46 (W. 15), S.I. 2021/72 (W. 18), S.I. 2021/50 (W. 149), S.I. 2021/568 (W. 156), S.I. 2021/364 (W. 161), S.I. 2021/669 (W. 170), S.I. 2021/765 (W. 187), S.I. 2021/826 (W. 193) and S.I. 2021/867 (W. 203).

Amendments to regulation 2A

- **3.**—(1) Regulation 2A (exemptions for vaccinated travellers and others) is amended as follows.
- (2) In paragraph (3)—
 - (a) in sub-paragraph (b), after "United Kingdom" insert "or a relevant country";
 - (b) after sub-paragraph (b) insert—
 - "(ba) if the course of doses was received in the United States of America, is ordinarily resident in the United States of America.";
 - (c) in sub-paragraph (c)—
 - (i) after "immigration officer" insert "or the operator of a commercial service on which P travels to Wales from outside the common travel area";
 - (ii) for "through the NHS COVID pass" to the end substitute-

"through-

- (i) the NHS COVID pass, or equivalent from NHS Scotland, NHS Wales or the Department of Health in Northern Ireland,
- (ii) the EU Digital COVID certificate, or
- (iii) the Centers for Disease Control and Prevention vaccination card,";
- (d) after sub-paragraph (c), insert—
 - "(ca) is able to provide proof if required by an immigration officer or the operator of a commercial service on which P travels to Wales from outside the common travel area of meeting the requirement in sub-paragraph (ba), and".

(3) In paragraph (4)(b), after "participation" insert "if required by an immigration officer or the operator of a commercial service on which P travels to Wales from outside the common travel area".

(4) After paragraph (4) insert—

"(4A) P—

- (a) has participated or is participating in a clinical trial in the United States of America by the Food and Drugs Administration of a vaccine for vaccination against coronavirus;
- (b) is able to provide proof of such participation through the Centers for Disease Control and Prevention vaccination card if required by an immigration officer or the operator of a commercial service on which P travels to Wales from outside the common travel area;
- (c) has declared that P meets the COVID-19 vaccination eligibility criteria for reduced isolation and testing requirements using a facility referred to in regulation 4(1); and
- (d) is ordinarily resident in the United States of America and is able to provide proof of that residence if required by an immigration officer or the operator of a commercial service on which P travels to Wales from outside the common travel area.".
- (5) In paragraph (5)(a), after "United Kingdom" insert "or a relevant country".
- (6) In paragraph (10)—
 - (a) for the definition of "authorised vaccine" substitute—

""authorised vaccine" ("*brechlyn awdurdodedig*") means a medicinal product for vaccination against coronavirus authorised—

(a) in relation to doses received in the United Kingdom—

- (i) for supply in the United Kingdom in accordance with a marketing authorisation, or
- (ii) by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012;
- (b) in relation to doses received in a relevant country, for supply in that country following evaluation by the relevant regulator for the country;";
- (b) for the definition of "marketing authorisation" substitute-

"marketing authorisation" ("awdurdodiad marchnata")-

- (a) in relation to a vaccine authorised for supply in the United Kingdom or in a member State, has the meaning given in regulation 8(1) (general interpretation) of the Human Medicines Regulations 2012;
- (b) in relation to a vaccine authorised for supply in a relevant country other than a member State, means a marketing authorisation granted by the relevant regulator for the country;";
- (c) after the definition of "NHS Wales" insert-

""relevant country" ("gwlad berthnasol") means a country listed in the first column of the table in paragraph (11);

"relevant regulator" ("*rheoleiddiwr perthnasol*"), in relation to a relevant country, means the regulator identified in the corresponding row of the second column of the table in paragraph (11), and a reference to a regulator in that table is a reference to the regulatory authority of that name designated as a Stringent Regulatory Authority by the World Health Organization pursuant to the operation of the COVAX Facility(**3**);";

(d) after paragraph (10) insert—

"(11) The table referred to in the definitions of "relevant country" and "relevant regulator" follows—

Relevant country	Relevant regulator
a member State	European Medicines Agency
Andorra	European Medicines Agency
Iceland	European Medicines Agency
Liechtenstein	European Medicines Agency
Monaco	European Medicines Agency
Norway	European Medicines Agency
San Marino	European Medicines Agency
Switzerland	Swissmedic
the United States o America	f United States Food and Drug Administration
Vatican City State	European Medicines Agency".

⁽³⁾ A list of the national regulatory authorities designated as Stringent Regulatory Authorities has been published by the World Health Organization and is available online athttps://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

Amendments to the Health Protection (Coronavirus, International Travel, Pre-Departure Testing and Operator Liability) (Wales) (Amendment) Regulations 2021

4. The Health Protection (Coronavirus, International Travel, Pre-Departure Testing and Operator Liability) (Wales) (Amendment) Regulations 2021(4) are amended as follows.

Amendment to regulation 4

5. In regulation 4 (interpretation), in the appropriate place insert, ""Schedule 3A passenger" ("*teithiwr Atodlen 3A*") means a person who has been in a country or territory listed in Schedule 3A to the International Travel Regulations and who is not a person to whom regulation 12E(2) and (3) of those regulations applies;".

Amendment to regulation 5B

6. In regulation 5B(3) (requirement to ensure passengers possess notification of post arrival testing arrangements), omit the definition of "Schedule 3A passenger".

New regulations 5C and 5D

7. After regulation 5B insert—

"Requirement to check vaccination status

5C.—(1) An operator must ensure that a passenger, other than a Schedule 3A passenger, ("P")—

- (a) who is on an international passenger service; and
- (b) has, using a facility referred to in regulation 4(1) of the International Travel Regulations (requirement to provide passenger information), indicated that P meets the COVID-19 vaccination eligibility criteria for reduced isolation and testing requirements,

is in possession of the required evidence when P arrives in a port in Wales.

(2) In paragraph (1) "the required evidence" means—

- (a) evidence of the description in regulation 2A(3)(c), (3)(ca), (4)(b), (4A)(b) and (d) or (6)(a)(ii) of the International Travel Regulations; or
- (b) where P intends to take advantage of the exemption in regulation 2A(5) or (6)(b) of those regulations (P aged under 18 years and 3 months), evidence of P's age.

(3) An operator must implement and maintain processes and systems to ensure that the requirement in paragraph (1) is complied with.

(4) This regulation does not apply in the case of the operator of an international passenger service which commences in Metropolitan France.

Requirement to check exemptions

5D.—(1) Where, using a facility referred to in regulation 4(1) of the International Travel Regulations, a passenger who arrives in Wales on an international passenger service indicates that they are a person referred to in a paragraph of Schedule 2 to those Regulations (exemptions), an operator must ensure that the passenger possesses evidence that they are such a person.

⁽⁴⁾ S.I. 2021/48 (W. 11), amended by S.I. 2021/72 (W. 18), S.I. 2021/171 (W. 39), S.I. 2021/305 (W. 78), S.I. 2021/584 (W. 161), S.I. 2021/646 (W. 166) and S.I. 2021/826 (W. 193).

(2) Paragraph (1) does not apply in relation to a person described in paragraph 6(2)(d) (i) of Schedule 2 to the International Travel Regulations (road haulage worker), who is the driver of a goods vehicle that has been or will be conveyed to Wales on an international passenger service."

Amendments to regulation 6

- 8. In regulation 6 (offences)—
 - (a) in paragraph (1)—
 - (i) in sub-paragraph (b) omit "or";
 - (ii) after sub-paragraph (c) insert-
 - "(d) regulation 5C(1),
 - (e) regulation 5C(3), or
 - (f) regulation 5D,";

(b) after paragraph (5) insert—

"(6) In relation to an offence in paragraph (1)(d), it is a defence for the operator to show that the relevant passenger presented a document purporting to be the required evidence which the operator, or a person acting on behalf of the operator, could not reasonably have been expected to know was not the required evidence.

(7) In relation to an offence in paragraph (1)(e), it is a defence for the operator to show that it was not reasonably practicable to have the processes and systems in place at the relevant time.

(8) In relation to an offence in paragraph (1)(f), it is a defence for an operator to show that the passenger presented a document purporting to be appropriate evidence which the operator, or a person acting on behalf of the operator, could not reasonably have been expected to know was not the appropriate evidence."

Amendment to regulation 10

9. In regulation 10 (review), for "5A and 5B", substitute "5A, 5B, 5C and 5D".

Eluned Morgan Minister for Health and Social Services, one of the Welsh Ministers

At 1.38 p.m. on 30 July 2021

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020 (S.I. 2020/574 (W. 132)) (the "International Travel Regulations") and the Health Protection (Coronavirus, International Travel, Pre-Departure Testing and Operator Liability) (Wales) (Amendment) Regulations 2021 (S.I. 2021/48 (W. 11)) (the "Operator Liability Regulations").

The International Travel Regulations impose requirements on persons entering Wales after having been abroad. They include a requirement for persons arriving in Wales from non-exempt countries or territories to isolate for a period determined in accordance with those Regulations.

Regulation 3 amends regulation 2A of the International Travel Regulations to introduce exemptions for certain travellers, primarily those who have received a full course of an authorised vaccine in, or who are under 18 and ordinarily resident in, a relevant country. Such travellers are exempted from the requirement to isolate on return from a non-exempt country or territory (except one specified in Schedule 3A to the International Travel Regulations), and are only required to take a day 2 test. These exemptions therefore apply in relation to relevant arrivals from what are commonly known as the 'amber list' countries.

The Operator Liability Regulations impose requirements on persons operating international passenger services ("operators") arriving into Wales from outside the common travel area. In accordance with those requirements operators must, for example, ensure that passengers travelling on such services possess notification of a negative test result and have made arrangements to take further tests following their arrival.

Regulations 4 to 9 of these Regulations amend the Operator Liability Regulations to place duties on operators of international passenger services to check, (i) that a person who has declared that they are an eligible vaccinated arrival within the meaning of regulation 2A of the International Travel Regulations has the evidence required to support that declaration; and (ii) that passengers seeking to rely on an exemption in Schedule 2 to the International Travel Regulations possess evidence that they are eligible for the exemption.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has not been prepared as to the likely costs and benefits of complying with these Regulations.