

## **Government Response: The Trade in Animals and Related Products (Amendment and Legislative Functions) and Animal Health (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2022**

### **Technical Scrutiny point 1**

Amendments introduced to the Trade in Animals and Related Products (Wales) Regulations 2011 will direct readers to the modifications introduced by these Regulations.

The Directives modified by Part 5 of the draft Regulations are implemented in relation to Wales by the Trade in Animals and Related Products (Wales) Regulations 2011. Therefore, any person wishing to consider the application of the Directives in relation to Wales would consider the 2011 Regulations. Amendments to the 2011 Regulations, within regulation 3(2) and (4) of the draft Regulations, require a reader to consider the draft Regulations.

### **Technical Scrutiny point 2**

Regulation 5(1) & (2) confer the role of appropriate authority on the Welsh Ministers.

### **Technical Scrutiny point 3**

The Government has considered and as the use of the term “British Isles” in this provision is consistent with its ordinarily understood meaning, reflect that the footnote is not necessary and will remove it on publication.

### **Technical Scrutiny point 4**

The Directives, as modified by Part 5 of the draft Regulations, acquire ongoing legal effect in relation to Wales, by virtue of the draft Regulations and the Trade in Animals and Related Products (Wales) Regulations 2011. Therefore, it is more appropriate to consider the Directives as part of these Regulations, rather than these Regulations as part of those Directives. The definition within regulation 8(2) is therefore effective.

A definition of the draft Regulations is introduced by amendment of the 2011 Regulations, by regulation 3(2).

### **Technical Scrutiny point 5**

We refer to our response to technical scrutiny point 2.

### **Technical Scrutiny point 6**

Directive 89/556 provides for animal health conditions applicable to trade in bovine embryos. Article 7 provides that only embryos from authorised third countries may be imported. Article 8 provides that in relation to those countries, embryos must have been collected, processed, stored, and transported in accordance with Chapter II of Annex A. The Welsh Ministers consider a power rather than a duty to legislate for a protocol is appropriate because there is

now an accepted protocol already in place based on international standards contained in the Manual of the International Embryo Transfer Society.

#### **Technical Scrutiny point 7**

The Government accepts the reporting point. The Government considers that, despite the minor translation error, the legislative intention is clear in both languages. The Government proposes to correct the error on making.

#### **Technical Scrutiny point 8**

The Government accepts the reporting point. The Government proposes to correct the error by an amending instrument at the next available opportunity. An amendment will be made early in 2023.

#### **Technical Scrutiny point 9**

The Government accepts the reporting point. The Government considers that, despite the minor translation error, the legislative intention is clear in both languages. The Government proposes to correct the error on making.

#### **Technical Scrutiny point 10**

Regulation 13(2) confirms Articles 2 and 6 of, and Annexes A, B, C and D to, this Directive only apply by virtue of these draft Regulations, and only for the purposes of references to those provisions in Directive 92/65 and Regulation (EU) No 206/2010. Neither “dealer” or “approved dealer’s premises” are used in those parts of Directive 91/68 that, by virtue of these Regulations will have ongoing legal effect, nor used in Regulation 206/2010.

#### **Technical Scrutiny point 11**

The Government accepts the first point reported, in relation to the use of the term “Directive 92/65/EEC” rather than “Directive 92/65” and propose correcting on making. Regulation (EC) No 853/2004 correctly refers to the defined term.

#### **Technical Scrutiny point 12**

The Government accepts the reporting point. This is a clear minor typographical error, and the Government will correct the error on making.

#### **Technical Scrutiny point 13**

“distribution” is removed from Article 1 of the Directive because, in the context of that provision, it refers to distribution, or movement within the European Union. The same rationale applies to Article 7. It is retained for the same rationale in in the heading of Chapter 1.

“distribution” is though retained in the definition of Articles 2 and 4 because it refers to the production process by which a food of animal origin is produced and reaches a further operator in the retail chain, or the consumer.

Article 3 applies to food business operators in third countries rather than in Wales, and therefore in that context distribution was not considered relevant.

In Article 4, the term “distribution” is relevant, in terms of what might be authorised within Wales under that derogation.

#### **Technical Scrutiny point 14**

The definition of “products of animal origin” in the Directive is deleted because it has been superseded by a definition within Regulation (EU) 2017/625, the Official Controls Regulation, which is retained EU law by virtue of the European Union (Withdrawal) Act 2018. Modifications made to the opening paragraph of Article 2 to the Directive confirm definitions in the Official Controls Regulations apply to the Directive.

The Trade in Animals and Related Products (Wales) Regulations 2011, the Official Controls Regulation, these draft Regulations and numerous individual direct principal EU Regulations across animal health, animal welfare, food and feed hygiene and food safety will all work in tandem. In particular, the Official Controls regime is the verification system by which compliance with the substantive standards set in retained direct EU law is verified.

#### **Technical Scrutiny point 15**

Regulation 16(6)(a)(i)(bb) maintains the wording “suspected of being infected” and is referred to locate new wording “may be authorised” immediately after it.

#### **Technical Scrutiny point 16**

The Directives modified by Part 5 are not currently part of the domestic statute book, because Directives were not retained by the European Union (Withdrawal) Act 2018.

It is correct that only the provisions modified will apply in relation to Wales, by virtue of their inclusion in these draft Regulations. The Directive provisions modified in Part 5 are enforced, in relation to Wales, by the Trade in Animals and Related Products (Wales) Regulations 2011 and amendments to those Regulations, in draft regulation 3(3) signpost readers to these Regulations, and the modified Directives.

#### **Technical Scrutiny point 17**

The Government accept the point and will correct the formatting error on making.

#### **Technical Scrutiny point 18**

The Government accept the point. This is a clear minor typographical error, and the Government will correct this error on making.

### **Technical Scrutiny point 19**

The amendments within regulation 17(8)(e)(i) and (ii) remove the requirement for animals to be accompanied by a veterinary certificate prepared in compliance by a European Union Committee in accordance with article 14 of the Directive.

The new provision provides for animals to be accompanied by a relevant health certificate, in the form published by the Welsh Ministers, as appropriate authority, from time to time. The Welsh Ministers can publish the certificate administratively, and we are content that this amendment is a technical operability amendment.

### **Technical Scrutiny point 20**

The Government accepts it would have been consistent with other similar modifications if the references to “the territory” had been replaced with a reference to Wales. However, we are content the effect of the provision is clear and there is no real risk of confusion.

### **Technical Scrutiny point 21**

The term "central veterinary authority" is used in relation to a third country's responsibility of approving an approved laboratory in Article 2 of Directive 2009/158. It is not “competent veterinary authority” but 'approved laboratory' which is defined in article 2(11).

The definition of approved laboratory is simply amended to exclude the notion an approved laboratory must be located in a Member State, as it would not make sense in the domestic context.

There is no definition of “competent veterinary authority” in the Directive therefore it is not being amended by the Regulations, and the term is used generically as it will apply in many different countries.

### **Technical Scrutiny point 22**

The Government accepts the reporting point. The Welsh text includes a clear typographical error, and the Government will seek to correct it on making.

### **Technical Scrutiny point 23**

The Government accepts the reporting point. The English text includes a clear typographical error, and the Government will seek to correct it on making.

### **Technical Scrutiny point 24**

The Government accepts the reporting point. The part heading for Part 6 is missing from the Welsh text. As this is not an operative part of the draft Regulations, we will seek to correct this formatting error on making.

## **Technical Scrutiny point 25**

In Directive 88/407, the purpose of listing the third sub-paragraph of Article 9(2), is because it is relevant to the Welsh Minister's regulation making power in Article 8(1).

In Directive 92/65, the purpose of listing the third subparagraph of Article 8(a) is because it contains the Welsh Ministers' regulation making power. Article 8(b) is relevant to a person wishing to import bumble bees under the requirements of the Trade in Animals and Related Products (Wales) Regulations 2011, rather than relevant to the exercise of the Welsh Ministers' regulation making powers.

In Directive 2002/99, paragraph 8(c) lists a Welsh Ministers' regulation making power set out in Article 4(3), and also the second sub paragraph, which relates to the need to maintain animal health protection standards, because it is relevant should the Welsh Minister's legislate under the paragraph 8(c) power. It is also separately listed in paragraph 8(c) as a free-standing or separate power.

In Directive 2002/99, in relation to Article 8(1) of Directive 2002/99, Article 8 has sub-paragraphs numbered 1, 3, 4 and 5, however there are no sub paragraphs 5-10.

In relation to all the provisions listed under bullet point number 5 under technical scrutiny point 25, the policy intention was to reference provisions together with the Welsh Minister's regulation making powers, because they are considered relevant to the exercise of those regulation making powers.

In relation to Articles 19(a) and 19(b) of Directive 92/65, in paragraph 6(s) and 6(t), it was not considered necessary to specifically reference any other provisions, they are separately listed to reflect the distinction in the policy intention between the two provisions. In relation to Articles 6(1), (2) and (3) of Directive 2004/68, the regulation making power is set out in Article 6(1), but Articles 6(2) & (3) are relevant to it.

In relation to the separate listing of the first and second sub-paragraphs of Article 4(6) of Directive 2009/156 in paragraphs 10(c) and 10(d), they are separately listed because the provisions contain two separate regulation making powers.

In relation to the references to Articles 19(a) – (d) in paragraphs 10(q) to (t) of the Schedule, we consider they could have been listed in a single paragraph, and it would not have altered the legal effect, but in separating them the different application in different circumstances is highlighted.

In Directive 2009/156, in relation to the query as to why Article 5(5)(a) is not listed, the Government have reviewed and confirm that it has been omitted by oversight and should be included in the list of functions in the Schedule. The Government proposes remedying this by amending statutory instrument early in 2023.

## **Technical Scrutiny point 26**

The Government accepts the reporting point. The Government considers that, despite the minor translation error, the legislative intention is clear in both languages. The Government proposes to correct on making.

### **Technical Scrutiny point 27**

The Government accepts the reporting point. The Government does not consider that this clear typographical error gives rise to a risk of confusion. The Government will seek for this error to be corrected on making.

### **Merits Scrutiny point 29**

It doesn't appear a government response is required to this reporting point.

### **Merits Scrutiny point 30**

Regulation 6(3) provides that Welsh Ministers' regulations made under functions listed in the Schedule to the draft Regulations may include consequential, incidental, supplementary transitional or saving provision, including provision amending, repealing or revoking *any* enactment. However, the extent of the power to amend, repeal or revoke *any* enactment is therefore limited to such consequential, incidental, supplementary transitional or saving provision as is included in Welsh Ministers' regulations, and so we consider the negative scrutiny procedure appropriate.

### **Merits Scrutiny point 31**

The policy intention is to provide the Welsh Ministers with regulation making functions that will enable them to make future modifications of the Directives to keep pace with future relevant policy, economic, scientific and technical developments. These new Welsh Ministers' functions replace such updating functions that were vested in EU bodies by the Directives.

### **Merits Scrutiny point 32**

The drafting approach is necessarily novel and complex in consequence of the existing legislative context. They will apply in a highly regulated policy area, and interact with a number of other lengthy and complex items of domestic and retained EU legislation. In particular the Official Controls regime and the Trade in Animals and Related Products (Wales) Regulations 2011.

In relation to copies of the Directives available publicly, you correctly note that the modifications made by these Regulations would not be read into those copies. However the Directives as a whole, as they exist outside of these draft Regulations, do not form part of the statute book. Part 5 modifies the Directives only for the purposes of the draft Regulations and the Trade in Animal and Related Products (Wales) Regulations 2011. In relation to the draft Regulations, the functions listed in the Schedule are functions of the draft Regulations, drafted by reference to the Directives. The Trade in Animals and Related Products (Wales) Regulations 2011 cross-refers to the draft Directives and so the application of the draft Regulations, and the incorporation of the modified Directive texts will be clear to the reader.

### **Merits Scrutiny point 33**

Noted. The preamble confirms that in so far as the Regulations utilise Articles 48(b) and 144(6) of Regulation (EU) 2017/625, the consultation requirement in Article 144(7) of Regulation (EU) 2017/625 has been met. Articles 48(b) and 144(6) apply in relation to regulation 3(8) only.

The consultation was done by the UK Government, with oversight of the Welsh Government, before the UKG then implemented this policy change in the Exemptions from Official Controls at Border Control Posts (Amendment) Regulations 2021.

At the time, the UK Government in agreement with Welsh Government, consulted all the relevant stakeholders from the life sciences industry sector and the response to the 2021 Regulations was positive.

Various industry bodies and leading organisations were engaged, representative of the sector as a whole across GB. These stakeholders operate at GB or UK-wide level, so it was not considered necessary for Welsh Ministers to consult the same stakeholders separately in Wales.