WELSH STATUTORY INSTRUMENTS

2023 No. 678 (W. 100)

AGRICULTURE, WALES

The Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023

Made	20 June 2023
Laid before Senedd Cymru	22 June 2023
Coming into force	14 July 2023

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 15 and 18A(3)(b) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(1).

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(2).

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023.

- (2) These Regulations—
 - (a) extend to England and Wales;
 - (b) apply in relation to Wales;
 - (c) come into force on 14 July 2023.

Interpretation

2.—(1) Expressions used in these Regulations and in Regulation 1831/2003 or Regulation 767/2009 have the same meaning as in Regulation 1831/2003 or Regulation 767/2009, respectively.

(2) In paragraph (1)—

⁽¹⁾ EUR 2003/1831, amended by S.I. 2019/654, 2022/377 and 2022/1351. S.I. 2019/654 was amended by S.I. 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 2 of EUR 2003/1831.

⁽²⁾ EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant. S.I. 2019/641 was amended by S.I. 2020/1504.

"Regulation 1831/2003" ("*Rheoliad 1831/2003*") means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;

"Regulation 767/2009" ("*Rheoliad 767/2009*") means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(**3**).

Form of provisional authorisations

3.—(1) Paragraphs (2) to (5) prescribe the forms of provisional authorisations for certain feed additives(4).

(2) The prescribed form of provisional authorisation of cobalt(II) acetate tetrahydrate (identification number 3b301) is set out in Schedule 1.

(3) The prescribed form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) is set out in Schedule 2.

(4) The prescribed form of provisional authorisation of cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303) is set out in Schedule 3.

(5) The prescribed form of provisional authorisation of cobalt(II) sulphate heptahydrate (identification number 3b305) is set out in Schedule 4.

Lynne Neagle Deputy Minister for Mental Health and Wellbeing, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

20 June 2023

⁽³⁾ EUR 2009/767, amended by S.I. 2019/654; there is another amending instrument not relevant to these Regulations. S.I. 2019/654 was amended by S.I. 2020/1504.

⁽⁴⁾ The feed additives were provisionally authorised, in relation to Wales, by administrative decision of the Welsh Ministers dated 20 June 2023, pursuant to Article 15 of EUR 2003/1831.

SCHEDULE 1

Regulation 3(2)

Form of provisional authorisation of cobalt(II) acetate tetrahydrate (identification number 3b301) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) acetate tetrahydrate, belonging to the additive category "nutritional additives" and to the functional group "compounds of trace elements", is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	Cobalt(II) acetate tetrahydrate
Identification number of the additive	3b301
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	 Cobalt(II) acetate tetrahydrate Crystals/granules, containing a minimum of 23% cobalt Particles < 50 μm: below 1%
Characterisation of the active substance(s)	Cobalt(II) acetate tetrahydrate • $Co(CH_3COO)_2 \times 4H_2O$ • CAS number ⁽¹⁾ : 6147-53-1
Analytical methods ⁽²⁾	For the identification of acetate in the additive: • European Pharmacopoeia monograph 20301 ⁽³⁾
	For the crystallographic characterisation of the additive: • X-ray diffraction
	 For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	 For determination of particle size distribution: Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
Species or category of animal	 Ruminants with a functional rumen Equidae Lagomorphs Rodents Herbivore reptiles Zoo mammals
Maximum age	None
Minimum content ⁽⁷⁾	None

Maximum content ⁽⁷⁾	1 (total)
Other provisions	1. The additive must be incorporated into compound feed in the form of a premixture.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.
	 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: In English: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." In Welsh: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
	 4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed: In English: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." In Welsh: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
Start of provisional authorisation period	15 July 2023
End of provisional authorisation period	End of 14 July 2028

- (1) CAS Registry Number® assigned to this substance by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.
- (2) Details of the analytical methods are set out in the document referenced "JRC.D.5/FSQ/CvH/PRO/ag/ARES(2012)214390" dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (3) Monograph 20301: 2.3.1. "Identification reactions of ions and functional groups". European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online https://pheur.edqm.eu/home.
- (4) Under reference BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (5) Under reference BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (6) Under reference BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (7) Content of element (cobalt) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 2

Regulation 3(3)

Form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) carbonate, belonging to the additive category "nutritional additives" and to the functional group "compounds of trace elements", is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	Cobalt(II) carbonate
Identification number of the additive	3b302
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	 Cobalt(II) carbonate Powder, containing a minimum of 46% cobalt Cobalt carbonate: minimum 75% Cobalt hydroxide: 3% - 15% Water: maximum 6% Particles < 11 μm: below 90%
Characterisation of the active substance(s)	Cobalt(II) carbonate • CoCO ₃ • CAS number ⁽¹⁾ : 513-79-1
Analytical methods ⁽²⁾	For the identification of carbonate in the additive: • European Pharmacopoeia monograph 20301 ⁽³⁾
	For the crystallographic characterisation of the additive:X-ray diffraction
	 For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	 For determination of particle size distribution: Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
Species or category of animal	 Ruminants with a functional rumen Equidae Lagomorphs Rodents Herbivore reptiles Zoo mammals
Maximum age	None

Minimum content ⁽⁷⁾	None
Maximum content ⁽⁷⁾	1 (total)
Other provisions	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.
	 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: In English: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." In Welsh: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
	 4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed: In English: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." In Welsh: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
Start of provisional authorisation period	15 July 2023
<i>End of provisional authorisation period</i>	End of 14 July 2028

(1) CAS Registry Number® assigned to this substance by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

- (2) Details of the analytical methods are set out in the document referenced "JRC.D.5/FSQ/CvH/PRO/ag/ARES(2012)214390" dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.
- (3) Monograph 20301: 2.3.1. "Identification reactions of ions and functional groups". European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online https://pheur.edqm.eu/home.
- (4) Under reference BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (5) Under reference BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (6) Under reference BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.

⁽⁷⁾ Content of element (cobalt) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 3

Regulation 3(4)

Form of provisional authorisation of cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) carbonate hydroxide (2:3) monohydrate, belonging to the additive category "nutritional additives" and to the functional group "compounds of trace elements", is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	Cobalt(II) carbonate hydroxide (2:3) monohydrate
Identification number of the additive	3b303
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	 Cobalt(II) carbonate hydroxide (2:3) monohydrate Powder, containing a minimum of 50% cobalt Particles < 50 μm: below 98%
Characterisation of the active substance(s)	Cobalt(II) carbonate hydroxide (2:3) monohydrate • 2CoCO ₃ × 3Co(OH) ₂ × H ₂ O • CAS number ⁽¹⁾ : 51839-24-8
Analytical methods ⁽²⁾	For the identification of carbonate in the additive: • European Pharmacopoeia monograph 20301 ⁽³⁾
	For the crystallographic characterisation of the additive: • X-ray diffraction
	 For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	 For determination of particle size distribution: Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
Species or category of animal	 Ruminants with a functional rumen Equidae Lagomorphs Rodents Herbivore reptiles Zoo mammals
Maximum age	None
Minimum content ⁽⁷⁾	None

<i>Maximum content</i> ⁽⁷⁾	1 (total)
Other provisions	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.
	 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: In English: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." In Welsh: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
	 4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed: In English: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." In Welsh: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
Start of provisiona authorisation period	l 15 July 2023
<i>End of provisiona authorisation period</i>	l End of 14 July 2028

(1) CAS Registry Number® assigned to this substance by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

(2) Details of the analytical methods are set out in the document referenced "JRC.D.5/FSQ/CvH/PRO/ag/ARES(2012)214390" dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://jointresearch-centre.ec.europa.eu/publications/fad-cobalt-group_en.

- (3) Monograph 20301: 2.3.1. "Identification reactions of ions and functional groups". European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online https://pheur.edqm.eu/home.
- (4) Under reference BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (5) Under reference BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (6) Under reference BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.

(7) Content of element (cobalt) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 4

Regulation 3(5)

Form of provisional authorisation of cobalt(II) sulphate heptahydrate (identification number 3b305) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) sulphate heptahydrate, belonging to the additive category "nutritional additives" and to the functional group "compounds of trace elements", is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

Additive	Cobalt(II) sulphate heptahydrate
<i>Identification number of the additive</i>	3b305
Authorisation holder	None specified
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	 Cobalt(II) sulphate heptahydrate Powder, containing a minimum of 20% cobalt Particles < 50 μm: below 95%
Characterisation of the active substance(s)	Cobalt(II) sulphate heptahydrate • CoSO ₄ × 7H ₂ O • CAS number ⁽¹⁾ : 10026-24-1
Analytical methods ⁽²⁾	For the identification of sulphate in the additive: • European Pharmacopoeia monograph 20301 ⁽³⁾
	For the crystallographic characterisation of the additive: • X-ray diffraction
	 For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	 For determination of particle size distribution: Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
Species or category of animal	 Ruminants with a functional rumen Equidae Lagomorphs Rodents Herbivore reptiles Zoo mammals
Maximum age	None
Minimum content ⁽⁷⁾	None

<i>Maximum content</i> ⁽⁷⁾	1 (total)
Other provisions	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.
	 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: In English: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." In Welsh: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
 on the instructions of use of the compound feed: In English: "Protective measures to avoid exposure wide by inhalation or by dermal route should be taken." In Welsh: "Dylid cymryd mesurau diogelu i osgoi dod 	 In English: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." In Welsh: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr
Start of provision authorisation period	<i>al</i> 15 July 2023
End of provision	al End of 14 July 2028

authorisation period

- (3) Monograph 20301: 2.3.1. "Identification reactions of ions and functional groups". European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online https://pheur.edqm.eu/home.
- (4) Under reference BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum, and lead by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (5) Under reference BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (6) Under reference BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (7) Content of element (cobalt) in mg/kg of complete feed with a moisture content of 12%.

⁽¹⁾ CAS Registry Number® assigned to this substance by the Chemical Abstracts Service https://www.cas.org/cas-data/cas-registry.

⁽²⁾ Details of the analytical methods are set out in the document referenced "JRC.D.5/FSQ/CvH/PRO/ag/ARES(2012)214390" dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision as regards the provisional authorisation, in relation to Wales, of certain feed additives under Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition.

Regulation 3, and Schedules 1 to 4, prescribe the forms of the provisional authorisations, in relation to Wales, of four feed additives.

- Schedule 1 contains the prescribed form of provisional authorisation for cobalt(II) acetate tetrahydrate (identification number 3b301).
- Schedule 2 contains the prescribed form of provisional authorisation for cobalt(II) carbonate (identification number 3b302).
- Schedule 3 contains the prescribed form of provisional authorisation for cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303).
- Schedule 4 contains the prescribed form of provisional authorisation for cobalt(II) sulphate heptahydrate (identification number 3b305).

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW or by writing to regulated.products.wales@food.gov.uk.

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