#### SCHEDULE 1

Regulation 7(4)(b), (27), (50), (53), (55)

and (60)

Regulation (EU) No 1151/2012 of the European Parliament and of the Council: new provisions

# PART 1

#### Article 3: new definitions

- "(9) 'the EUWA' means the European Union (Withdrawal) Act 2018;
- (10) 'EU Regulation 1151/2012' means Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs as it had effect in EU law immediately before exit day;
- (11) 'Regulation 1308/2013' means Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products;
- (12) 'Regulation 664/2014' means Commission Delegated Regulation (EU) No 664/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules;
- (13) 'the Quality Schemes Regulations' means the Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018;
- (14) 'the competent authority', in relation to the United Kingdom, means the person specified in regulation 3(1) of the Quality Schemes Regulations;
  - (15) 'the designated authority' means:
    - (a) unless point (b) or (c) applies, the person specified in regulation 3(2) of the Quality Schemes Regulations as the person responsible for carrying out the relevant function;
    - (b) in a case where an official control has been delegated to a control body in accordance with Article 39, the control body to which the function has been delegated;
    - (c) in a case where an enforcement authority has been appointed to carry out the function under regulation 6 of the Quality Schemes Regulations, the appointed enforcement authority;
- (16) 'domestic law' means the means the law of England and Wales, Scotland and Northern Ireland;
  - (17) 'enactment' includes:
    - (a) enactments of the type specified in paragraphs (a) to (f) of the definition of "enactment" in section 20(1) of the EUWA, and
    - (b) except in Article 28, retained direct EU legislation;
- (18) 'established protected designation of origin' means a designation of origin shown as a United Kingdom registered designation of origin on the register maintained by the European Commission pursuant to Article 11 of EU Regulation 1151/2012 as that register stood immediately before exit day;
- (19) 'established protected geographical indication' means a geographical indication shown as a registered United Kingdom geographical indication on the register maintained by the European Commission pursuant to Article 11 of EU Regulation 1151/2012 as that register stood immediately before exit day;
- (20) 'established protected traditional speciality guaranteed' means a traditional speciality guaranteed shown as a registered United Kingdom traditional speciality guaranteed on the register

maintained by the European Commission pursuant to Article 22 of EU Regulation 1151/2012 as that register stood immediately before exit day;

- (21) 'FTT' means the First-tier Tribunal;
- (22) 'third country' means any country, other than the United Kingdom, and includes:
  - (a) the Bailiwick of Guernsey;
  - (b) the Bailiwick of Jersey;
  - (c) the Isle of Man."

# PART 2

#### Article 28: new Article

#### "Article 28

#### Existing enactments

- 1. Nothing in this Regulation prevents the maintenance of enactments on optional quality terms that are not covered by this Regulation and are in force immediately before exit day, provided that they comply with retained EU law.
- **2.** In paragraph 1, 'maintenance' includes repeal and replacement, and revocation and replacement, without, in both cases, any substantive modification."

#### PART 3

#### New Article 52a

## "Article 52a

#### Applications pending on exit day

- 1. An application made under EU Regulation 1151/2012 before exit day to which paragraph 2 applies is deemed to be an application made under Article 49(1) of this Regulation for which scrutiny under Article 50(1) of this Regulation has not been commenced. Unless requested not to do so in writing by the applicant who submitted the application, the Secretary of State must scrutinise the application under Article 50(1) of this Regulation. The six month period specified in Article 50(1) starts from the day on which exit day falls.
- **2.** This paragraph applies to an application submitted to the Secretary of State on or after 1st January 2019 or the Secretary of State or the Department for Environment Food and Rural Affairs before that date:
  - (a) to register:
    - (i) a name of a geographical area in, or partly in, the United Kingdom as a designation of origin,
    - (ii) a name of a geographical area in, or partly in, the United Kingdom as a geographical indication, or
    - (iii) a name as a traditional speciality guaranteed, and
  - (b) that has not been scrutinised under Article 49(2) of EU Regulation 1151/2012 before exit day or has been subject to scrutiny under Article 49(2) before exit day but for

which no decision has been taken as to whether it meets the relevant conditions of EU Regulation 1151/2012 or is justified.

**3.** An application made under EU Regulation 1151/2012 before exit day to which paragraph 4 applies is deemed to be an application made under Article 49(1) of this Regulation that has been found by the Secretary of State, for the purpose of Article 50(2), to fulfil the conditions laid down in this Regulation but for which the documents specified in Article 50(2) have not been published.

In the case of an application to register the name of a designation of origin or geographical indication, the Secretary of State must, unless requested not to do so in writing by the applicant who submitted the application, publish the single document and product specification submitted with the application made under EU Regulation 1151/2012 as soon as reasonably practicable after exit day.

In the case of an application to register the name of a traditional speciality guaranteed, the Secretary of State must, unless requested not to do so in writing by the applicant who submitted the application, publish the product specification submitted with the application made under EU Regulation 1151/2012 as soon as reasonably practicable after exit day.

The publication of the documents specified in the second or third subparagraph by the Secretary of State initiates the opposition procedure to which Article 51 of this Regulation applies in relation to the application.

- **4.** This paragraph applies to an application submitted to the Secretary of State on or after 1st January 2019 or the Secretary of State or the Department for Environment Food and Rural Affairs before that date:
  - (a) to register:
    - (i) the name of a geographical area in, or partly in, the United Kingdom as a designation of origin,
    - (ii) the name of a geographical area in, or partly in, the United Kingdom as a geographical indication, or
    - (iii) a name as a traditional speciality guaranteed, and
  - (b) that has been scrutinised under Article 49(2) of EU Regulation 1151/2012 and been found by the Secretary of State to meet the conditions of, and to be justified under, EU Regulation 1151/2012 before exit day but for which the Commission has not adopted an implementing act under Article 52 of EU Regulation 1151/2012 before exit day."

#### New Title 5A

# "TITLE 5A

#### **APPEALS**

#### Article 54a

Appeals: general

- 1. An appeal may be made to the FTT against a decision of the Secretary of State specified in the first column of the table in Annex 3.
  - 2. Such an appeal may be made:
    - (a) in all cases, by a person specified in the corresponding entry in the second column of the table in Annex 3;
    - (b) in the case of a decision affecting an application submitted by the authorities of a third country, the authorities of that third country.
  - **3.** In determining such an appeal the FTT:
    - (a) must consider the decision appealed against afresh, and
    - (b) may take into account evidence that was not available to the Secretary of State.
  - **4.** The FTT may:
    - (a) dismiss the appeal, or
    - (b) if it allows the appeal, exercise any power specified in the corresponding entry in the third column of the table in Annex 3.
- **5.** The Secretary of State may consider a decision specified in the first column of the table in Annex 3 afresh if evidence becomes available to the Secretary of State after making the original decision that was not available to the Secretary of State at the time of the original decision.
- **6.** Paragraph 5 applies even though an appeal has been made to the FTT in respect of the original decision.
- 7. Where the Secretary of State decides to consider an original decision afresh in a case where an appeal has been made to the FTT in respect of that decision, the appeal to the FTT is suspended until such time as the Secretary of State has made a fresh decision in relation to the matter.
- **8.** If the Secretary of State makes the same decision again, the appeal to the FTT restarts. If the Secretary of State makes a different decision, the appeal to the FTT ceases unless the FTT directs otherwise.

#### Article 54b

Appeals: applications to register designations of origin, geographical indications and traditional specialities guaranteed

1. Where an appeal is made to the FTT relating to a decision to approve an application to register a designation of origin, geographical indication or traditional speciality guaranteed,

and the Secretary of State has made an entry in the relevant register pursuant to Article 52 relating to that registration, the entry in the register is to be maintained but is in suspense and must be marked to indicate that it is in suspense until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.

**2.** Where an appeal is made to the FTT relating to a decision to approve an application to register a designation of origin, geographical indication or traditional speciality guaranteed, and the Secretary of State has not made an entry in the register, the Secretary of State must not make an entry in the register until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.

#### Article 54c

Appeals: applications to amend product specifications

- 1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 53(2) to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has not updated the entry in the relevant register relating to it pursuant to Article 14(3) of Commission Implementing Regulation (EU) 668/2014 by replacing the copy of the product specification attached to the relevant register with the amended version of the product specification.
- 2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed applies without amendment but the entry in the relevant register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
- **3.** Paragraph 4 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 53(2) in relation to the amendment of a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has updated the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed by replacing the copy of the product specification with the approved amended version.
- **4.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the previous copy of the product specification attached to the entry in the relevant register is to be restored but the entry in the relevant register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
- **5.** Paragraph 6 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application of the type specified in Article 53(2) to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed.
- **6.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register is to be maintained but the entry in the register must be marked to indicate that an appeal relating to an application to amend the product specification is pending.
- 7. Paragraph 8 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 6(4) and (4)(a) of

Regulation 664/2014 to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed on a temporary basis and the Secretary of State has not included an entry in the relevant register relating to the temporary amendment of the product specification pursuant to Article 14(3b) of Commission Implementing Regulation (EU) 668/2014.

- **8.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register applies without amendment but the entry in the register must be marked to indicate that an appeal relating to the temporary amendment of the product specification is pending.
- **9.** Paragraph 10 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 6(4) of Regulation 664/2014 in relation to the temporary amendment of a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has updated the entry in the relevant register by including an entry relating to the temporary amendment of the product specification.
- 10. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the copy of the product specification attached to the entry in the relevant register applies and the entry in the relevant register relating to the temporary amendment must be marked to indicate that an appeal relating to the temporary amendment of the product specification is pending.
- 11. Paragraph 12 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application of the type specified in Article 6(4) and (4)(a) of Regulation 664/2014 to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed on a temporary basis.
- 12. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the copy of the product specification attached to the entry in the relevant register applies but the entry in the register must be marked to indicate that an appeal relating to an application to amend the product specification on a temporary basis is pending.

#### Article 54d

Appeals: applications to cancel registered designations of origin, geographical indications and traditional specialities guaranteed

- 1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed under Article 54 and the Secretary of State has not removed the entry in the relevant register.
- **2.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the relevant register is to be maintained but must be marked to indicate that an appeal relating to its cancellation is pending.
- **3.** Paragraph 4 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has removed the entry in the relevant register.

- **4.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register must be restored but must be marked to indicate that an appeal relating to its cancellation is pending.
- **5.** Paragraph 6 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State not to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed.
- **6.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed must be marked to indicate that an appeal relating to the cancellation of the entry is pending."

#### New Article 56

#### "Article 56

#### Regulations

- **1.** Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.
  - **2.** Such regulations may:
    - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments);
    - (b) make different provision for different purposes.
- **3.** Except as specified in paragraph 4, a statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.
- **4.** A statutory instrument containing regulations made under the second subparagraph of Article 2(1) or Article 18(5), 30(1) or 41(3) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
- **5.** Before making any regulations under this Regulation, the Secretary of State must consult:
  - (a) such bodies or persons as appear to the Secretary of State to be representative of the interests likely to be substantially affected by the regulations;
  - (b) such other bodies or persons as the Secretary of State may consider appropriate."

# New Annex 3

# "ANNEX 3

# **APPEALS**

Decision	Persons who may appeal against the decision	FTT powers
Decision of the Secretary of State to approve an application		Power to:
made under Article 49 to register a designation of	<ul><li>(a) a person who submitted a reasoned statement of opposition under Article 51(2);</li><li>(b) a person marketing a product that is, or may be,</li></ul>	(a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register;
	affected by the registration of the designation of origin, geographical indication or traditional speciality guaranteed.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of	The persons are:	Power to:
origin, geographical indication	the application to register	(a) quash the decision and direct the Secretary of State to approve the application and register the designation of origin, geographical indication or traditional speciality guaranteed;
	(b) a person marketing a product that is, or may be, affected by the decision not to register the designation of origin, geographical indication or traditional speciality guaranteed.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
<del>-</del>	The persons are:	Power to:
application made under Article 53 to make an amendment o a product specification relating to a protected designation of origin, protected		(a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register;
protected traditional speciality guaranteed	in relation to the approacher,	(b) remit the matter to the Secretary of State with a

Decision	Persons who may appeal against the decision	FTT powers
	(b) a person marketing a product that is, or may be, affected by the amendment of the product specification.	direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an	The persons are:	Power to:
application made under Article 53 to make an amendment to a product specification relating to a protected designation of origin, protected geographical indication or	the application to amend the product specification;  (b) a person marketing a product that is, or may be,	(a) quash the decision and direct the Secretary of State to approve the application and attach a copy of the amended product specification to the register;
protected traditional speciality guaranteed	affected by the decision not to approve the application to amend the product specification.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
Decision of the Secretary of	The persons are:	Power to:
protected traditional speciality	a reasoned statement of opposition under Article 51(2)	(a) quash the decision and direct the Secretary of State (if appropriate) to restore the register;
State's initiative	(b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected designation of origin, protected geographical indication or protected traditional speciality guaranteed.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny relating to the cancellation and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of	The persons are:	Power to:
State to approve an application made under Article 54 to cancel the registration of a protected designation of origin, protected geographical indication or protected traditional speciality	a reasoned statement of opposition under Article 51(2) as read with Article 7(1) and	(a) quash the decision and direct the Secretary of State to (if appropriate) restore the register, or
guaranteed	(b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected designation of origin, protected geographical indication or protected traditional speciality guaranteed	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to rectify the register in the meantime.

guaranteed.

Decision	Persons who may appeal	FTT powers
	against the decision	
Decision of the Secretary of	The persons are:	Power to:
State to reject an application		
made under Article 54 to cancel	· , 1	(a) quash the decision and
the registration of a protected designation of origin, protected		direct the Secretary of State to cancel the registration;
0 0 1	designation of origin, protected	,
protected traditional speciality	geographical indication or	(b) remit the matter to the
guaranteed	protected traditional speciality	Secretary of State with a
	guaranteed;	direction to repeat the scrutiny of the application."
	(b) a person marketing a	• •
	product that is, or may be,	
	affected by the decision not	
	to cancel the registration	
	the protected designation of	
	origin, protected geographical	
	indication or protected	
	traditional speciality	
	guaranteed.	

#### SCHEDULE 2

Regulation 8(14)

Commission Implementing Regulation (EU) No 716/2013: new Annexes 1 to 5

# "ANNEX 1

# APPLICATION TO REGISTER A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

## Geographical indication to be registered ...

# Category of the spirit drink

# **Applicant**

Name of legal or natural person ...

Full address (street number and name, town/city and postal code, country) ...

Legal status, size and composition (in the case of legal persons) ...

Nationality ...

Tel., e-mail

#### **Intermediary (if applicable)**

Third-country authority

Name(s) of intermediary(ies) ...

Full address(es) (street number and name, town/city and postal code, country) ...

Tel., e-mail ...

#### Proof of protection in third country ...

#### **Technical file**

Number of pages ...
Name(s) of signatory(ies) ...
Signature(s) ...

# ANNEX 2

#### TECHNICAL FILE

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

#### Geographical indication to be registered ...

# Category of the spirit drink

# Description of the spirit drink

- Physical, chemical and/or organoleptic characteristics
- Specific characteristics (compared to spirit drinks of the same category)

#### Geographical area concerned

# Method for obtaining the spirit drink

#### Link with the geographical environment or origin

- Details of the geographical area or origin relevant to the link
- Specific characteristics of the spirit drink attributable to the geographical area

#### National/regional provisions

# **Applicant**

- Third Country or legal/natural person ...
- Full address (street number and name, town/city and postal code, country) ...
- Legal status (in the case of legal persons) ...

#### Supplement to the geographical indication

# Specific labelling rules

[(\*) delete as appropriate]

# ANNEX 3

#### OBJECTION TO A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ... [for official use] Number of pages (including this page) ... File number ... [for official use] **Objector** Name of legal or natural person ... Full address (street number and name, town/city and postal code, country) ... Nationality ... Tel., e-mail ... Intermediary (if applicable) Third-country authority (optional) Name(s) of intermediary(ies) ... Full address(es) (street number and name, town/city and postal code, country) ... Objected geographical indication ... **Prior rights** Registered geographical indication (\*) National geographical indication (\*) [(\*) delete as appropriate] Name ... Registration number ... Date of registration (DD/MM/YYYY) ... Trademark Sign ... List of products and services ... Registration number ... Date of registration ... Country of origin ... Reputation/renown (\*) ...

#### Grounds for objection

Name of signatory ... Signature ...

# ANNEX 4

#### APPLICATION TO CANCEL A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

Author of request of cancellation ...

File number ...

[for official use]

Name of legal or natural person ...

Full address (street number and name, town/city and postal code, country) ...

Nationality ...

Tel., e-mail ...

Contested geographical indication ...

Legitimate interest of the author of the request ...

Statement by the third country (where relevant)...

#### Grounds for cancellation

Name of signatory ...

Signature ...

# ANNEX 5

APPLICATION TO AMEND THE TECHNICAL FILE OF A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

# **Intermediary (if applicable)**

Third-country authority (optional)

Name(s) of intermediary(ies) ...

Full address(es) (street number and name, town/city and postal code, country) ...

Tel., e-mail ...

#### Name of the geographical indication

# Specification heading affected by the amendment

Protected name (\*)

Description of product (\*)

Geographical area (\*)

Link (\*)

Names and addresses of control authorities (\*)

Other (\*)

[(\*) delete as appropriate]

#### Amendment

Amendment to the product specification not entailing an amendment of the main specifications (\*)

Amendment to the product specification entailing an amendment to the main specifications (\*)

[(\*) delete as appropriate]

### Explanation of the amendment ...

#### **Amended main specifications**

[on separate sheet]
Name of signatory ...
Signature ..."

SCHEDULE 3

Regulation 9(3)(b), (20)(c), (22), (29), (34)(b) and (36)

Regulation (EU) No 251/2014 of the European Parliament and of the Council: new provisions

# PART 1

# Article 2(1): new definitions

- "(4) 'constituent nation' means England, Northern Ireland, Scotland or Wales;
- (5) 'country', in relation to the United Kingdom, means the United Kingdom as a whole and does not mean any of the individual constituent nations forming part of the United Kingdom;
- (6) 'enactment' includes enactments of the type specified in paragraphs (a) to (f) of the definition of 'enactment' in section 20(1) of the European Union (Withdrawal) Act 2018 but does not include enactments of the type specified in paragraphs (g) and (h) of that definition;
  - (7) 'FTT' means the First-tier Tribunal;
- (8) 'register' means the register established and maintained by the Secretary of State pursuant to Article 21;
  - (9) 'third country' means any country, other than the United Kingdom, and includes:

- (a) the Bailiwick of Guernsey;
- (b) the Bailiwick of Jersey;
- (c) the Isle of Man."

## Article 24: new paragraph 3

- "3. In a case where the proposed amendment is only minor and the Secretary of State decides not to follow the procedure laid down in Articles 14(2) and 15, the Secretary of State, after making a decision in relation to the application, must publish in such manner as appears appropriate to the Secretary of State from time to time:
  - (a) a notice informing the applicant and the public of the decision made in relation to the application, and
  - (b) where the application is approved, a copy of the single document and product specification for the geographical indication incorporating the approved amendment."

# PART 3

#### New Articles 25a to 25d

# "Article 25a

#### Appeals: general

- 1. An appeal may be made to the FTT against a decision of the Secretary of State specified in the first column of the table in Annex 4.
  - 2. Such an appeal may be made:
    - (a) in all cases, by a person specified in the corresponding entry in the second column of the table in Annex 4;
    - (b) in the case of a decision affecting an application submitted by the authorities of a third country, the authorities of that third country.
  - **3.** In determining such an appeal, the FTT:
    - (a) must consider the decision appealed against afresh, and
    - (b) may take into account evidence that was not available to the Secretary of State.
  - **4.** The FTT may:
    - (a) dismiss the appeal, or
    - (b) if it allows the appeal, exercise any power specified in the corresponding entry in the third column of the table in Annex 4.
- **5.** The Secretary of State may consider a decision specified in the first column of the table in Annex 4 afresh if evidence becomes available to the Secretary of State after making the original decision that was not available to the Secretary of State at the time of the original decision.
- **6.** Paragraph 5 applies even though an appeal has been made to the FTT in respect of the original decision.

- 7. Where the Secretary of State decides to consider an original decision afresh in a case where an appeal has been made to the FTT in respect of that decision, the appeal to the FTT is suspended until such time as the Secretary of State has made a fresh decision in relation to the matter.
- **8.** If the Secretary of State makes the same decision again, the appeal to the FTT restarts. If the Secretary of State makes a different decision, the appeal to the FTT ceases unless the FTT directs otherwise.

#### Article 25b

Appeals: applications to register geographical indications

- 1. Where an appeal is made to the FTT relating to a decision to approve an application to register a geographical indication and the Secretary of State has made an entry in the register relating to that geographical indication, the entry in the register is to be maintained but is in suspense and must be marked to indicate that it is in suspense until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.
- **2.** Where an appeal is made to the FTT relating to a decision to approve an application to register a geographical indication and the Secretary of State has not made an entry in the register relating to that geographical indication, the Secretary of State must not make an entry in the register until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.

#### Article 25c

Appeals: applications to amend product specifications

- 1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application made under Article 24 to amend a product specification for a geographical indication and the Secretary of State has not updated the entry in the register relating to the indication to incorporate the approved amendment.
- 2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing entry in the register relating to the geographical indication is to be maintained but must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
- **3.** Paragraph 4 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application made under Article 24 in relation to the amendment of a product specification for a geographical indication and the Secretary of State has updated the entry in the register relating to the geographical indication to incorporate the approved amendment.
- **4.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the previous entry in the register for the protected geographical indication is to be restored but the entry in the register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
- **5.** Paragraph 6 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application made under Article 24 to amend a product specification for a protected geographical indication.
- **6.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing entry in the register is to be maintained

but the entry in the register must be marked to indicate that an appeal relating to an application to amend the specification is pending.

#### Article 25d

Appeals: applications to cancel geographical indications

- 1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected geographical indication under Article 25 and the Secretary of State has not removed the entry in the register relating to the geographical indication.
- **2.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register for the geographical indication is to be maintained but must be marked to indicate that an appeal relating to its cancellation is pending.
- **3.** Paragraph 4 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected geographical indication and the Secretary of State has removed the entry in the register for the geographical indication.
- **4.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register must be restored but must be marked to indicate that an appeal relating to its cancellation is pending.
- **5.** Paragraph 6 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State not to cancel the registration of a protected geographical indication.
- **6.** Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register relating to the protected geographical indication must be marked to indicate that an appeal relating to the cancellation of the entry is pending."

# PART 4

#### New Article 33

#### "Article 33

#### Provisions relating to regulations

- **1.** Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.
  - **2.** Such regulations may:
    - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct EU legislation);
    - (b) make different provision for different purposes.
- **3.** Except as specified in paragraph 4, a statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

4. A statutory instrument containing regulations under Article 28 may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament."

#### PART 5

Annex 1, point (5): new subparagraph

"In this point, 'relevant water quality legislation' means:

- (a) in relation to aromatised wine products marketed in England:
  - (i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007(1);
  - (ii) the Water Supply (Water Quality) Regulations 2016(2);
  - (iii) the Private Water Supplies (England) Regulations 2016(3);
- (b) in relation to aromatised wine products marketed in Northern Ireland:
  - (i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Northern Ireland) Regulations 2015(4);
  - (ii) the Private Water Supplies Regulations (Northern Ireland) 2017(5);
  - (iii) the Water Supply (Water Quality) Regulations (Northern Ireland) 2017(6);
- (c) in relation to aromatised wine products marketed in Scotland:
  - (i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007(7);
  - (ii) the Public Water Supplies (Scotland) Regulations 2014(8);
  - (iii) the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017(9);
- (d) in relation to aromatised wine products marketed in Wales:
  - (i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015(10);
  - (ii) the Private Water Supplies (Wales) Regulations 2017(11);
  - (iii) the Water Supply (Water Quality) Regulations 2018(12)."

<sup>(1)</sup> S.I. 2007/2785, amended by S.I. 2009/1598, 2010/433, 2011/451, 1043, 2014/1855, 2018/352.

<sup>(2)</sup> S.I. 2016/614, amended by S.I. 2017/506, 2018/706.

<sup>(3)</sup> S.I. 2016/618, amended by S.I. 2017/506, 2018/707.

<sup>(4)</sup> S.R. 2015 No.365, amended by S.R. 2017 No.201.(5) S.R. 2017 No. 211.

<sup>(6)</sup> S.R. 2017 No. 212.

<sup>(7)</sup> S.S.I. 2007/483, amended by S.S.I. 2009/273, 2010/89, 127, 2011/94, 2014/312, 2015/100, 363, 2017/287.

<sup>(8)</sup> S.S.I. 2014/364; relevant amending instruments are S.S.I. 2015/346, 2017/281.

<sup>(9)</sup> S.S.I. 2017/282, amended by S.S.I. 2017/321.

<sup>(10)</sup> S.I. 2015/1867 (W. 274), amended by S.I. 2017/935.

<sup>(11)</sup> S.I. 2017/1041 (W. 270).

<sup>(12)</sup> S.I. 2018/647 (W. 121).

# New Annex 4

# "ANNEX 4

# **APPEALS**

Decision	Persons who may appeal against the decision	FTT powers
Decision of the Secretary of State to approve an application	The persons are:	Power to:
made under Article 11 or 13a to register a geographical indication	<ul><li>(a) a person who lodged a duly substantiated statement of opposition under Article 15;</li><li>(b) a person marketing a product that is, or may be,</li></ul>	(a) quash the decision and (if appropriate) direct the Secretary of State to reject the application and (if appropriate restore the register;
	affected by the registration of the geographical indication.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an application	The persons are:	Power to:
made under Article 11 or 13a to register a geographical indication	the application to register the geographical indication;	(a) quash the decision and direct the Secretary of State to register the geographical indication;
	(b) a person marketing a product that is, or may be, affected by the decision not to register the geographical indication.	(b) remit the matter to the Secretary of State with a direction to repeat the scruting of the application.
Decision of the Secretary of	The persons are:	Power to:
State to approve an application made under Article 24 to amend a product specification for a protected geographical indication	of an application to which the	(a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register;
	read with Article 24(2);	(b) remit the matter to the Secretary of State with a
	(b) in relation to the approval of any application under Article 24(2), a person marketing a product that is, or may be, affected by the	direction to repeat the scruting of the application and (if appropriate) to restore the register in the meantime.

Decision	Persons who may appeal	FTT powers
	against the decision amendment of the product specification.	
Decision of the Secretary of State to reject an application	The persons are:	Power to:
made under Article 24 to amend a product specification for a protected geographical indication	the application to amend the	(a) quash the decision and direct the Secretary of State to approve the application and update the register;
	(b) a person marketing a product that is, or may be, affected by the decision to reject the application to amend the product specification.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
Decision of the Secretary of	The persons are:	Power to:
State under Article 25 to cancel the registration of a protected geographical indication on the Secretary of State's initiative	(a) a person who lodged a duly substantiated statement of opposition under Article 15 as read with the second paragraph of Article 25;	(a) quash the decision and (if appropriate) direct the Secretary of State to restore the register;
	(b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected geographical indication.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny relating to the cancellation of the registration and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of	The persons are:	Power to:
State to approve an application made under Article 25 to cancel the registration of a protected geographical indication	(a) a person who lodged a duly substantiated statement of opposition under Article 15 as read with the second paragraph of Article 25;	(a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register;
	(b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected geographical indication.	(b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of	The persons are:	Power to:
State to reject an application made under Article 25 to cancel the registration of a protected geographical indication		(a) quash the decision and direct the Secretary of State to cancel the registration;
	Des Brahmon malounon,	(b) remit the matter to the

Secretary of State with a

Decision	Persons who may appeal FTT powers against the decision
	(b) a person marketing a product that is, or may be, affected by the decision not to cancel the registration of the protected geographical indication.

#### **SCHEDULE 4**

Regulation 10(9)

Commission Delegated Regulation (EU) No 664/2014, Article 6: new paragraphs 3a to 3d and 4 to 4l

- "3a. Temporary amendments concerning products originating in third countries must be communicated to the Secretary of State before the end of the period of two weeks beginning with the day after the first day on which the amendments apply in the relevant third country.
- **3b.** The temporary amendments must be communicated to the Secretary of State by a group having a legitimate interest or by the authorities of the relevant third country.
  - **3c.** The communication must be accompanied by:
    - (a) the reasons for the amendments, and
    - (b) as appropriate, evidence of the relevant sanitary and phytosanitary measures or a copy of a document issued by the authorities of the relevant third country recognising the natural disaster or adverse weather conditions.
- **3d.** The Secretary of State must make the temporary amendments public in such manner as appears appropriate to the Secretary of State from time to time.
- **4.** Paragraphs 4a to 4l apply to an application for a temporary amendment to a product specification for a protected designation of origin, protected geographical indication or traditional speciality guaranteed ('the temporary amendments application') concerning the production of products originating in the United Kingdom where it is impossible or difficult to comply with a requirement in a product specification in relation to the production of a product in the United Kingdom:
  - (a) because of the imposition of an obligatory sanitary or phytosanitary measure in the United Kingdom by a public authority, including the Secretary of State, or
  - (b) for reasons linked to a natural disaster or adverse weather conditions recognised by a public authority, including the Secretary of State.
  - **4a.** The temporary amendments application may be made to the Secretary of State.
- **4b.** The procedure laid down in Articles 49 to 52 of Regulation (EU) No 1151/2012 does not apply to the temporary amendments application.
- **4c.** The temporary amendments application may be made by a group having a legitimate interest in the relevant protected designation of origin, protected geographical indication or traditional speciality guaranteed. If the application is not made by the group that submitted the application to register the relevant protected designation of origin, protected geographical indication or traditional speciality guaranteed ('the original applicant group'), the Secretary of State must give the original applicant group the opportunity to make comments on the application if that group still exists.

- **4d.** The temporary amendments application must:
  - (a) describe the amendment applied for,
  - (b) be accompanied by a copy of the product specification annotated in a way to show the proposed temporary amendment,
  - (c) compare, for each amendment—
    - (i) the original product specification against the proposed amended product specification, and
    - (ii) where relevant, the original single document against the proposed amended single document,
  - (d) provide a summary of the reasons why an amendment is required, explaining how the circumstances specified in point (a) or (b) of paragraph 4 affect the production of products to which the protected designation of origin, protected geographical indication or traditional speciality guaranteed applies,
  - (e) be accompanied, as the case may be, by:
    - (i) evidence of the sanitary or phytosanitary measure or a reference to that measure that will enable the Secretary of State to identify the measure, and obtain a copy of it, easily, or
    - (ii) a copy of a document issued by the relevant public authority recognising the natural disaster or adverse weather conditions or a reference to that document that will enable the Secretary of State to identify the document, and obtain a copy of it, easily,
  - (f) provide an estimate, where this is possible, of the period during which it is anticipated that the temporary amendment will need to apply, and
  - (g) be self-sufficient and contain all amendments to the product specification, and, where relevant, to the single document, for which approval is sought.
- **4e.** A temporary amendments application that does not comply with paragraph 4d is not admissible. The Secretary of State must inform the applicant if the application is inadmissible as soon as reasonably practicable after receiving the application.
- **4f.** The Secretary of State may approve a temporary amendments application if the Secretary of State considers that a temporary amendment to the product specification is appropriate.
- **4g.** Where a temporary amendments application is approved, the Secretary of State must specify the period for which the temporary amendment is approved.
- **4h.** That period may be specified by reference to a set period of time or may be specified by reference to the a period expiring on the happening of an event specified in the decision. The Secretary of State, in deciding the period, must take into account the conditions prevailing at the time the decision to approve the application is taken and the period for which the Secretary of State anticipates that those conditions will continue.
- **4i.** The Secretary of State may extend the temporary amendment on one or more occasions if the Secretary of State considers it is appropriate to do so having regard to the conditions prevailing at the time that decision is made.
- **4j.** After making a decision in relation to a temporary amendments application, the Secretary of State must publish in such manner as appears appropriate to the Secretary of State:
  - (a) a notice informing the applicant and the public of the decision made in relation to the application, and

- (b) where the application is approved, details of the temporary amendments made to the product specification and the period during which those temporary amendments apply.
- **4k.** Where a temporary amendments application is approved and the period during which such temporary amendments are to apply is extended, the Secretary of State must, on each occasion the period is extended, publish in such manner as appears appropriate to the Secretary of State a notice informing the applicant and the public of the extension of the period.
- **41.** In this paragraph 'public authority' has the meaning given in section 20(1) of the European Union (Withdrawal) Act 2018."

#### SCHEDULE 5

Regulation 12(11)(e)

Commission Implementing Regulation (EU) No 668/2014, Article 14: new paragraphs 3, 3a, 3b and 4

"3. Where the Secretary of State approves an amendment to a product specification and the change in the product specification affects other information recorded in the relevant register, the Secretary of State must delete the original data, record the new data in the register and attach a copy of the approved amended product specification to the register. The new data, and the provisions in the approved amended product specification, take effect immediately after the expiry of 20 days beginning with the day on which the new data is recorded in the register and the copy of the amended product specification is attached to the register or, if a copy of the amended product specification is attached to the register at a later date, immediately after the expiry of 20 days beginning with the day on which the copy of the amended product specification is attached to the register.

Where the Secretary of State approves an amendment to a product specification and the change in the product specification does not affect other information recorded in the relevant register, the Secretary of State must replace the copy of the product specification attached to the entry in the register with a copy of the approved amended product specification. The provisions in the approved amended product specification take effect immediately after the expiry of 20 days beginning with the day on which the copy of the approved amended product specification is attached to the register.

- **3a** Where the Secretary of State receives a communication of the type referred to in Article 6(3a) of Delegated Regulation (EU) No 664/2014 relating to a temporary amendment of a product specification concerning the production of a product originating in a third country, the Secretary of State must include an entry in the relevant register relating to the temporary amendment of the product specification. The temporary amendment takes effect from the time that entry is made. From that time the provisions of the product specification attached to the register apply as read with those temporary amendments until the entry relating to the temporary amendment is removed from the register.
- **3b** Where the Secretary of State approves an application to amend a product specification to which Article 6(4) of Delegated Regulation (EU) No 664/2014 applies (an application for a temporary amendment to a product specification concerning the production of products originating in the United Kingdom), the Secretary of State must include an entry in the relevant register relating to the temporary amendment of the product specification. The temporary amendment takes effect from the time that entry is made. From that time the provisions of the product specification attached to the register apply as read with those temporary amendments until the entry relating to the temporary amendment is removed from the register.

**4.** Where the Secretary of State makes a decision to cancel a protected designation of origin, protected geographical indication or traditional speciality guaranteed pursuant to Article 54 of Regulation (EU) No 1151/2012, the Secretary of State must delete the name from the register concerned. The cancellation takes effect from the day after the day on which the entry is deleted from the register."

#### SCHEDULE 6

Regulation 13(32)(a)

Commission Delegated Regulation (EU) 2018/273, Annex 7, Parts 1 and 2: new Parts

# "PART 1 Specimen of the VI-1 document referred to in Article 22

Exporter (name and address)	THIRD COUNTRY OF ISSUE:	
	VI 1 Serial No	
	DOCUMENT FOR THE IMPORT OF WINE, GRAPE JUICE OR GRAPE MUST INTO THE UNITED KINGDOM	
2. Consignee (name and address)	3. Customs stamps (for official use only)	

Document Generated: 2023-05-10

Praft Legislation: This is a draft item of legislation and has not yet been made as a UK Statutory Instrument. This draft has been replaced by a new draft, No. 788

4. Means of transport and transport details	5. Place of unloading (if different from 2)
6. Description of the imported product	7. Quantity in I/hl/kg (1)
	8. Number of containers
9. CERTIFICATE	
The product described above <sup>(2)</sup> □ is/ □ is not int with the United Kingdom definitions or categorie using oenological practices <sup>(2)</sup> □ recommended at United Kingdom.	s of grapevine products and has been product
Full name and address of the competent body:	Place and date:
Stamp:	Signature, name and title of the official:
10. ANALYSIS REPORT (describing the analyticabove)	cal characteristics of the product described
FOR GRAPE MUST AND GRAPE JUICE  — Density:	
FOR WINE AND GRAPE MUST STILL IN FER	RMENTATION
— Total alcoholic strength:	— Actual alcoholic strength:
FOR ALL PRODUCTS	
— Total dry extract:	— Total sulphur dioxide
— Total acidity: — Volatile acidity:	— Citric acidity:
Full name and address of the designated body or	department (laboratory)

Document Generated: 2023-05-10 **Draft Legislation:** This is a draft item of legislation and has not yet been made as a UK Statutory Instrument. This draft has been replaced by a new draft, No. 788

Stamp:	Place and date:
	Signature, name and title of official:

<sup>(1)</sup> Delete as appropriate.
(2) Put an 'X' in the appropriate box.

# Attribution (entry into free circulation and issue of extracts)

Quantity	11.	No and date of the customs document of release into free circulation and of the extract	12.	Full name and address of consignee (extract)	13.	Stamp of the competent authority
Available						
Attributed						
Available						
Attributed						
Available						
Attributed						
Available						
Attributed						
14. Other rema	arks					

# PART 2 Specimen of the VI-2 document referred to in Article 22

INITED VINCDOM			
UNITED KINGDOM			
1. Consignor (name and address)	VI 2 Serial No		
	EXTRACT OF A DOCUMENT FOR THE IMPORT OF WINE, GRAPE JUICE OR GRAPE MUST INTO THE UNITED KINGDOM		
2. Consignee (name and address)			
3. Extract VI 1 document	4. Extract of VI 2 extract		
No	No		
Issued by (name of third country):	Stamped by (full name and address of the customs office within the United Kingdom):		
On:	On:		
5. Description of the imported product	6. Quantity in l/hl/kg (1)		
	7. Number of containers		
8. CONSIGNOR'S DECLARATION <sup>(2)</sup> The VI 1 document referred to in box 3 □ /The extract referred to in box 4 □ was completed in respect of the product described above and comprises: □ a CERTIFICATE to the effect that the product described above □ is/□ is not intended for direct human consumption, complies with the United Kingdom definitions or categories of grapevine products and has been product using oenological practices <sup>(2)</sup> □ recommended and published by the OIV/□ authorised by the United Kingdom. □ an ANALYSIS REPORT showing that the product has the following analytical characteristics: FOR GRAPE MUST AND GRAPE JUICE			
— Density:			

FOR WINE AND GRAPE MUST STI	LL IN FERMENTATION	1		
— Total alcoholic strength:	— Actual alco	pholic strength:		
FOR ALL PRODUCTS  — Total dry extract:	— Total sulph	nur dioxide:		
·	— Volatile acidity: -			
<ul> <li>□ an ENDORSEMENT (2) from the competent authority certifying that:</li> <li>— the wine covered by this document is certified as having been produced in the wine-growing region and was given the geographical indication shown in box 5 in accordance with the provisions of the country of origin.</li> <li>— the alcohol added to this wine is certified as being wine alcohol.</li> </ul>				
9. CUSTOMS				
Declaration certified as true Place and date:	tamp:	Full name and address of the customs office concerned:		
Signature:				

<sup>(1)</sup> Delete as appropriate.
(2) Put an 'X' in the appropriate box.

# Attribution (entry into free circulation and issue of extracts)

Quantity	10.	No and date of the customs document of release into free circulation and of the extract	11.	Full name and address of consignee (extract)	12.	Stamp of the competent authority	
Available							
Attributed							
Available							
Attributed							
Available							
Attributed							
Available							
Attributed							
13. Other remarks							

# SCHEDULE 7

Regulation 16

#### Revocations

- **1.** Council Decision 94/184/EC concerning the conclusion of an Agreement between the European Community and Australia on trade in wine.
- **2.** Council Decision 97/361/EC concerning the conclusion of an Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks.

- **3.** Commission Decision 2000/192/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.
- **4.** Commission Decision 2001/339/EC concerning an Exchange of Letters amending point B of the Annex to the Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names.
- **5.** Commission Decision 2001/581/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.
- **6.** Council Decision 2001/916/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.
- 7. Council Decision 2001/917/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Interim Agreement between the European Community, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.
- **8.** Council Decision 2001/918/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Croatia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.
- **9.** Council Decision 2001/919/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Interim Agreement between the European Community, of the one part, and the Republic of Croatia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.
- 10. Council Decision 2001/920/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Europe Agreement establishing an association between the European Communities and their Member States, acting within the framework of the European Union, of the one part, and the Republic of Slovenia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.
- 11. Council Decision 2002/51/EC on the conclusion of an Agreement between the European Community and the Republic of South Africa on trade in wine.
- **12.** Council Decision 2002/53/EC concerning the provisional application of the Agreement between the European Community and the Republic of South Africa on trade in wine.
- **13.** Council Decision 2002/55/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of South Africa on trade in wine.
- **14.** Commission Decision 2002/650/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.

- **15.** Commission Decision 2003/898/EC concerning the conclusion of an agreement amending the Agreement between the European Community and Australia on trade in wine.
- **16.** Council Decision 2004/91/EC on the conclusion of the agreement between the European Community and Canada on trade in wines and spirit drinks.
- 17. Commission Decision 2004/387/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the United Mexican States concerning amendments to Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, taking into account the enlargement.
- **18.** Commission Decision 2004/483/EC on the conclusion of an Agreement in the form of an exchange of letters between the European Community and the United Mexican States concerning amendments to Annex I of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, taking into account the enlargement.
- 19. Commission Decision 2004/785/EC on the conclusion of an Agreement in the form of an exchange of letters between the European Community and the United Mexican States concerning amendments to Annex II of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks.
- **20.** Council Decision 2005/798/EC concerning the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the United States of America on matters related to trade in wine.
- 21. Council Decision 2006/136/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to the Agreement on Trade in Wines annexed to the Agreement establishing an Association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.
- **22.** Council Decision 2006/232/EC on the conclusion of the Agreement between the European Community and the United States of America on trade in wine.
- **23.** Commission Decision 2006/567/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendices I, II, III and IV of the Agreement on Trade in Wines annexed to the Association Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.
- **24.** Commission Decision 2006/569/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendix VI of the Agreement on Trade in Wines annexed to the Association Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.
- **25.** Commission Regulation (EC) No 555/2008 laying down detailed rules for implementing Council Regulation (EC) No 479/2008 on the common organisation of the market in wine as regards support programmes, trade with third countries, production potential and on controls in the wine sector.
- **26.** Council Decision 2009/49/EC on the conclusion of the Agreement between the European Community and Australia on trade in wine.
- **27.** Commission Decision 2009/104/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendix V of the Agreement on Trade in Wines annexed to the Association

Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.

- **28.** Council Decision 2011/51/EU on the signing of the Agreement between the European Union and the Swiss Confederation on the protection of designations of origin and geographical indications for agricultural products and foodstuffs, amending the Agreement between the European Community and the Swiss Confederation on trade in agricultural products.
- **29.** Council Decision 2011/620/EU on the signing, on behalf of the Union, of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs.
- **30.** Council Decision 2011/738/EU on the conclusion of the Agreement between the European Union and the Swiss Confederation on the protection of designations of origin and geographical indications for agricultural products and foodstuffs, amending the Agreement between the European Community and the Swiss Confederation on trade in agricultural products.
- **31.** Commission Implementing Decision 2011/751/EU on the notification of a proposal for amendment to the Annexes to the EC-US Agreement on trade in wine.
- **32.** Council Decision 2012/164/EU on the conclusion of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs.
- **33.** Commission Implementing Decision 2012/275/EU on the inclusion of vine varieties in Appendix IV of the Protocol on wine labelling as referred to in Article 8(2) of the EC-US Agreement on trade in wine.
- **34.** Council Decision 2012/292/EU on the signing, on behalf of the Union, of the Agreement between the European Union and the Republic of Moldova on the protection of geographical indications of agricultural products and foodstuffs.
- **35.** Council Decision 2012/533/EU on the position to be taken by the European Union within the Joint Committee set up by Article 11 of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs, as regards the adoption of the rules of procedure of the Joint Committee.
- **36.** Council Decision 2013/7/EU on the conclusion of the Agreement between the European Union and the Republic of Moldova on the protection of geographical indications of agricultural products and foodstuffs.
- **37.** Council Decision 2013/482/EU on the position to be taken by the European Union within the Joint Committee set up by Article 11 of the Agreement between the European Union and the Republic of Moldova on protection of geographical indications of agricultural products and foodstuffs, as regards the adoption of the rules of procedure of the Joint Committee.
- **38.** Council Decision 2014/429/EU on the position to be adopted on behalf of the European Union within the Association Council set up by the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America, on the other, as regards the adoption of a decision by the Association Council on the inclusion in Annex XVIII of the respective geographical indications protected in the territory of the parties.
- **39.** Commission Delegated Regulation (EU) 2016/1149 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector.
- **40.** Commission Implementing Regulation (EU) 2016/1150 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector.

- **41.** Council Decision (EU) 2016/2136 on the signing, on behalf of the European Union, of the Agreement between the European Union and Iceland on the protection of geographical indications for agricultural products and foodstuffs.
- **42.** Council Decision (EU) 2017/1912 on the conclusion of the Agreement between the European Union and Iceland on the protection of geographical indications for agricultural products and foodstuffs.

#### SCHEDULE 8

Regulation 17(3) and (4)(g)

The Veterinary Medicines Regulations 2013: new provisions

#### PART 1

## New Schedule 1A

#### "SCHEDULE 1A

Regulation 4(4)

#### Converted EU marketing authorisations

- 1. In this Schedule—
  - "converted EU marketing authorisation" means an EU marketing authorisation to which paragraph 2 applies;
  - "EU marketing authorisation" means a marketing authorisation for a veterinary medicinal product granted by the European Commission in accordance with Title 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(13).
- 2. This paragraph applies to an EU marketing authorisation which—
  - (a) was granted before exit day, and
  - (b) remains in force immediately before exit day.
- **3.** A converted EU marketing authorisation has effect on and after exit day for the purposes of these regulations as if it were a marketing authorisation granted by the Secretary of State under these Regulations on the date it was originally granted—
  - (a) on the terms which were in force immediately before exit day,
  - (b) with the benefit of any periods of data marketing exclusivity from which the holder benefited immediately before exit day, and
  - (c) subject to any suspension or post-authorisation obligations which were in force immediately before exit day.
  - 4. Without prejudice to the generality of paragraph 3—
    - (a) the holder of a converted EU marketing authorisation is subject to the annual fee as set out in paragraph 26 of Schedule 7;

<sup>(13)</sup> OJ No L 136, 30.4.2004, p 1, as last amended by Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p 38).

(b) a converted EU marketing authorisation is to be treated as having been granted in accordance with regulation 4(3) and Schedule 1 for the purposes of Regulation (EC) No 469/2009."

#### PART 2

# Schedule 7, paragraph 15: new table

#### "Parallel imports

Application	Fee (£)
Application where the imported product is identical to the UK authorised product	2,130
Application where the imported product is therapeutically similar to the UK authorised product (can only be applied to imported products for non-food producing species)	

#### SCHEDULE 9

Regulation 18(2), (3),(4)(a) and (6)

Regulation (EC) No 470/2009 of the European Parliament and of the Council: new provisions

# PART 1

# New Article 8

#### "Article 8

Application for a maximum residue limit

- 1. An application under these Regulations for a new or amended maximum residue limit for a substance intended for use in a veterinary medicinal product must be made to the appropriate authority.
- **2.** An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety of the substance.
  - 3. The applicant must pay to the appropriate authority the application fee, which is—
    - (a) for a new maximum residue limit in respect of a substance, £62,300;
    - (b) for an amended maximum residue limit in respect of a substance, £18,850.
- **4.** The appropriate authority must ensure that where a valid application is received, the substance is classified under Article 14 within 210 days.
- **5.** For the purposes of paragraph 4 an application is valid when both the requirements in paragraphs 2 and 3 have been complied with.
- **6.** As soon as practicable after the substance is classified under Article 14, the appropriate authority must publish—

- (a) a notice setting out the classification;
- (b) the assessment report that has been prepared, with any commercially confidential or personal information deleted.
- 7. If the appropriate authority classifies a substance under Article 14(2)(b) or (d), it must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee under regulation 29 of the Veterinary Medicines Regulations 2013.
- **8.** For the purposes of paragraph 7, regulations 29 and 30 of the Veterinary Medicines Regulations 2013 are to be read as if references to the Secretary of State were references to the appropriate authority."

#### New Article 9

#### "Article 9

Further power for appropriate authority to classify substances

- 1. The appropriate authority may classify a substance intended for use in a veterinary medicinal product which is to be administered to food-producing animals under Article 14 without an application having been made under these Regulations.
- **2.** The power in paragraph 1 includes power to classify a substance which has previously been classified under Article 14."

# PART 3

# Article 10(1): new paragraphs

- "1. An application for the classification of a pharmacologically active substance intended to be used in a biocidal product used in animal husbandry pursuant to Article 19(7) of Regulation (EU) 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products must be made under Article 8, notwithstanding that it is not a substance intended for use in a veterinary medicinal product to be administered to food-producing animals.
- **1A.** The power to classify a substance under Article 9 may be exercised in respect of a pharmacologically active substance intended to be used in a biocidal product used in animal husbandry, notwithstanding that it is not a substance intended for use in a veterinary medicinal product to be administered to food-producing animals, where the Secretary of State considers it appropriate to do so for the purposes of Article 19(1)(e) of Regulation (EU) 528/2012.
- **1B.** Where proposals are made for the classification of a substance under Article 9 in the circumstances described in paragraph 1A by a devolved authority, the Secretary of State must have regard to such proposals when exercising functions under that paragraph.
- **1C.** In this Article, "devolved authority" has the meaning given in section 20(1) of the European Union (Withdrawal) Act 2018."

# New Article 14A

# "Article 14A

# MRL register

- **1.** The appropriate authority must maintain a register ("the MRL register") in accordance with this Article.
  - 2. The MRL register must contain—
    - (a) a list of substances which have been classified under Article 14;
    - (b) in respect of each such substance—
      - (i) any maximum residue limit or other matter established under paragraph 2 of Article 14;
      - (ii) any conditions or restrictions included in the classification pursuant to paragraph 7 of Article 14.
  - **3.** The MRL register must be kept up to date.
  - 4. The MRL register must contain a search facility.
- **5.** The appropriate authority must make the MRL register available for inspection by the public on a website maintained by the appropriate authority."