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."

PART 2

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."

PART 4

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."