SCHEDULE 9

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."