BL O/610/20

04 December 2020

**COUNCIL REGULATION (EC) No. 469/2009**
**CONCERNING THE SUPPLEMENTARY**
**PROTECTION CERTIFICATE**
**FOR MEDICINAL PRODUCTS**

| | |
|---|---|
| APPLICANT | Erber Aktiengesellschaft |
| ISSUE | Whether application for supplementary protection certificate SPC/GB17/075 meets the requirements of Article 2 and Article 3(b) of the Regulation |
| HEARING OFFICER | Dr L Cullen |

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# DECISION

## Introduction

1 This decision relates to supplementary protection certificate (SPC) application SPC/BG17/075 ("the application") for a veterinary medicinal product filed in the name of Erber Aktiengesellschaft ("the applicant") on 30 November 2017[1]. The product the applicant is seeking to protect is "*microorganism DSM 11798 of the Coriobacteriaceae family*".

2 The basic patent on which the application relies is EP(UK) 1042449 ("the patent") entitled "*Microorganism, method for obtaining same and feed additive*". The patent was filed on 21 December 1998 with an earlier priority date of 30 December 1997 and was granted by the European Patent Office (EPO) on 4 May 2005. The patent expired on 20 December 2018.

3 The patent relates to a microorganism of the genus *Eubacterium* and its use as an animal feedstuff additive. The microorganism is effective in destroying trichothecenes (which belong to the mycotoxins class of compounds). Trichothecenes are naturally produced by mould fungi which grow on animal feedstuffs such as cereals and grasses. Exposure to trichothecenes can result in inhibited productivity and growth of the animal. The patent describes how the microorganism converts trichothecenes by biochemical degradation in a controlled manner into substances which are

[1] This decision relates to an SPC application that was applied for in 2017 and as such it is necessary to apply the relevant law that was in force at that time in the UK. This is set out in the decision below.

physiologically harmless to the animal. The examples given in the patent all relate to feeds for pigs and chickens.

4 The authorisation provided in support of the application is Commission Implementing Regulation EU2017/930 of 31 May 2017 concerning the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for all avian species and amending earlier Commission Implementing Regulation (EU) No 1016/2013 of 23 October 2013.

5 Commission Implementing Regulation (EU) No 1016/2013 concerns the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs.

6 Both Commission Implementing Regulation EU2017/930 of 31 May 2017 and Commission Implementing Regulation (EU) No 1016/2013 of 23 October 2013 were granted in accordance with Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (hereafter the 'Animal Nutrition Additives Regulation'). A summary of the marketing authorisation documents filed in support of this SPC application, their relevant dates and the animal species they relate to is provided in Table 1 below.

7 As noted above, the SPC application in question was filed on 30 November 2017. I note that Commission Implementing Regulation EU2017/930 was adopted by the European Commission on 31 May 2017 and came into force on 20 June 2017 (i.e., on the 20th day following its publication in the Official journal of the European Union on 1 June 2017[2]).

8 The examiner objected to the registration of an SPC under Regulation (EC) 469/2009[3] ('the SPC regulation') on the grounds that the application did not comply with Articles 2 or 3(b) of that regulation. With regards to Article 2, the examiner objected on the grounds that the authorisation provided had not been subject to administrative authorisation as laid down in Directive 2001/82/EC (the 'veterinary medicinal products' directive)[4]. Therefore, as the application was not within the scope of Article 2, the requirement of Article 3(b) of the SPC regulation that a valid authorisation to place the product on the market as a medicinal product in accordance with Directive 2001/82/EC also was not fulfilled. The examiner was of the view that the authorisation process under the Animal Nutrition Additives Regulation (Regulation EC 1831/2003) was not the same as the authorisation process under Directive 2001/82/EC for a veterinary medicinal product. The examiner did not find any indication in either the Veterinary Medicinal Products Directive or the Animal Nutrition Additives Regulation that the

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[2] Commission Implementing Regulation (EU) 2017/930 of 31 May 2017 concerning the authorisation of a preparation of a microorganism strain DSM 11798 of the Coriobacteriaceae family as a feed additive for all avian species and amending Implementing Regulation (EU) No 1016/2013 (Text with EEA relevance. ) C/2017/3485. CELEX Document number: 32017R0930; published in Official Journal of the European Union L 141/6 on 1.6.2017.

[3] Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products.

[4] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

**Table 1**: A comparison of the documents filed in support of SPC application SPC/GB17/075 and the relevant date is shown in Table 1 for ease of reference.

| **SPC Application** | | |
|---|---|---|
| **Application No.** | SPC/GB17/075 | |
| **Proposed product definition** | Microorganism DSM 11798 of the Coriobacteriaceae family | |
| **Filing date** | 30 November 2017 | |
| **Legal basis** | Regulation (EU) No. 469/2009 | |
| **Marketing Authorisations** | | |
| *MA* | Implementing Regulation (EU) 2017/930 | Implementing Regulation (EU) No 1016/2013 |
| *Title* | Preparation of a microorganism strain DSM 11798 of the Coriobacteriaceae family as a feed additive for all avian species and amending Implementing Regulation (EU) No 1016/2013 | Preparation of a microorganism strain DSM 11798 of the Coriobacteriaceae family as a feed additive for pigs |
| *Additive* | Preparation of a microorganism strain DSM 11798 of the Coriobacteriaceae family | Preparation of a microorganism strain DSM 11798 of the Coriobacteriaceae family |
| *Contaminant treated* | For the reduction of contamination of feed **by trichothecenes** | For the reduction of contamination of feed by deoxynivalenol (DON) |
| *Animal(s) affected* | **All avian species**; Pigs | Pigs |
| *Date of MA* | 31 May 2017 | 23 October 2013 |
| *Legal Basis* | Regulation (EC) No. 1831/2003 on additives for use in animal nutrition as amended by Regulation (EC) No. 386/2009 regarding the establishment of a new functional group of feed additives | |
| ***Basic Patent*** | | |
| *Patent No.* | EP(UK) 1042449 | |
| *Title* | Microorganism, method for obtaining same and feed additive | |
| *Filing date* | 21 December 1998 | |
| *Priority date* | 30 December 1997 | |
| *Date of grant* | 04 May 2005 | |
| *Date of expiry* | December 2018 | |

legislator had intended products authorised under Regulation EC 1831/2003 to be amenable to SPC protection.

9 The examiner also raised objection under Article 7 of the SPC regulation on the grounds that the basic patent was granted in 2005 and the earliest authorisation (i.e. Commission Implementing Regulation (EU) No. 1016/2003) for the product was granted in 2013. The SPC application was lodged in 2017, therefore a period of more than 6 months had expired since the authorisation for the product was granted. The applicant disagreed with the examiner's assessment and submitted that a marketing authorisation under Regulation 1831/2003 was equivalent to one under Directive 2001/82/EC. The applicant set out in detail the similarities and differences between the authorisation processes under the Animal Nutrition Additives Regulation and the Veterinary Medicinal Products Directive. Therefore, the requirement of Article 3(b) of the SPC Regulation had been met as the authorisation process under regulation 1831/2003 was equivalent, in the view of the applicant, to one under Directive 2001/82/EC. The examiner rejected this reasoning, making reference to the judgement of the CJEU in *Boston Scientific Ltd* (C-527/17).

10 The matter came before me at an oral hearing on 6 June 2019 in London. The applicant was represented at the hearing by Mr. Richard Leoni of Patent Boutique LLP. Dr Laura Starrs was in attendance as assistant to the hearing officer.

11 Following the hearing, the relevance of the judgment of the CJEU in case C-130/11 *Neurim* (hereafter *Neurim*)[5] for determining whether a new use of a known product may be the basis for a further SPC was considered by the CJEU in its judgment in case C-673/18 *Santen* (hereafter *Santen*)[6]. At the hearing and in their written submissions, the applicant made reference to the *Neurim* judgement as basis for being able to grant this SPC application and related application SPC/GB17/076 in so far as this application relates to a "*new use of an active substance which has already been the subject of a marketing authorisation*". In each instance, there is an earlier Commission Implementing Regulation and the applicant argues that the later Implementing regulation cited in support of each SPC application can be used as the relevant marketing authorisation given that it relates to a new class of compounds and to use in a new species (see bold highlights in Table 1). Upon issue of the *Santen* judgment in July 2020, the views of the applicant were requested in writing as to the relevance of this decision to the issues to be decided in this case. The applicant responded in writing indicating that in their view "*Santen should not be relevant to the approach taken in the UK to Articles 3(d)/3(1)(d) (as applicable)*".

[5] *C-130/11, Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents, Designs and Trade Marks,*

[6] *C-673/18, Santen SAS v Directeur-général de l'Institut National de la Propriété Industrielle.*

## The Relevant Law

12 It is a common tenet of EU law that it is defined having regard to both the purpose of the relevant EU legislation - as set out in the recitals - and the substance of this legislation - as set out in the articles.

13 In this case, we are concerned with (i) the SPC regulation[7] and the plant protection SPC regulation in so far as the latter relates to the SPC regulation; (ii) the Veterinary Medicinal Products Directive[8]; and (iii) the Animal Nutrition Additives Regulation[10]. I have reproduced the relevant parts of this legislation below (with my emphasis added in **bold**).

### *The SPC Regulation – Regulation 469/2009[7]*

14 Recitals (3), (4), (8) and (10) of Regulation (EC) 469/2009 state as follows:

*(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*

*(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.*

*(8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.*

*(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years.* ***The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.***

15 Article 1 defines 'medicinal product' and 'product', as follows:

> *For the purposes of this Regulation, the following definitions shall apply:*
>
> ***(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;***
>
> *(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;*

[7] Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

…

16 Article 2 of the SPC Regulation defines the scope of the regulation (emphasis added) and reads:

> ***Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in*** *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or* ***Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.***

17 Article 3 of the SPC Regulation defines the conditions for obtaining a certificate (emphasis added) as follows:

> *1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:*
>
> *(a) the product is protected by a basic patent in force**;***
>
> *(b)* ***a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate****;*
>
> *(c) the product has not already been the subject of a certificate;*
>
> *(d) the authorisation referred to in point (b) is the first authorisation to place the product on the marker as a medicinal product.*

18 Article 7 sets out time limits for lodging the application as follows:

> *1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.*
>
> *2. Notwithstanding paragraph 1, where the authorisation to place the product on the marker is granted before the basic patent is granted, the application for a certificate shall be lodged six months of the date on which the patent is granted.*

19 Article 8(1)(b) concerns the content of an application for an SPC and specifies:

> *The application for a certificate shall contain:*
>
> *(a) …*
>
> *(b)* ***a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in*** *Article 11 of Directive 2001/83/EC or* ***Article 14 of Directive 2001/82/EC****.*

## *The Veterinary Medicinal Products Directive – Directive 2001/82/EC*[8]

20 Article 1 of Title I of the directive provides the following definitions:

> ***2. Veterinary medicinal product:***
>
> ***(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or***
>
> ***(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action****, or to making a medical diagnosis.*
>
> *3. Substance:*
>
> *Any matter irrespective of origin which may be:*
>
> - *human, e.g.*
>
>  *human blood and human blood products;*
>
> - *animal, e.g.*
>
>  *micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;*
>
> - *vegetable, e.g.*
>
>  *micro-organisms, plants, parts of plants, vegetable secretions, extracts;*
>
> - *chemical, e.g.*
>
>  *elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.*
>
> *…*
>
> *6. Medicated feedingstuffs:*
>
> *Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventative properties or other properties as a medicinal product covered by point 2.*

21 Article 2 of Title II sets out the scope of the directive as follows:

> *1.* ***This Directive shall apply to veterinary medicinal products, including pre-mixes for medicated feeding stuffs, intended to be placed on the market in***

[8] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

***Member States and prepared industrially or by a method involving an industrial process.***

*2. In cases of doubt, where, taking into account all its characteristics. A product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of this Directive shall apply.*

22 Article 3 of Title II further says:

***1. This Directive shall not apply to:***

***…***

***(d) any additives covered by Council Directive 70/524/EEC[9] of 23 November 1970 concerning additives in feeding stuffs where they are incorporated in animal feeding stuffs and supplementary animal feeding stuffs in accordance with that Directive;***

*…*

23 Title III of this directive concerns placing veterinary medicinal products on the market. Chapter 1, Article 12 sets out the requirements of an application for a marketing authorisation as follows:

***1. For the purposes of obtaining a marketing authorisation in respect of a veterinary medicinal product,*** *otherwise than under the procedure established by Regulation (EC) No 726/2004,* ***an application shall be lodged with the competent authority of the Member State concerned.***

*…*

*2. A marketing authorisation may only be granted to an applicant established in the Community.*

***3. The application for marketing authorisation shall include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The file shall be submitted in accordance with Annex I*** *and shall contain, in particular, the following information:*

(a) *name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;*

(b) *name of veterinary medicinal product;*

(c) *qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international nonproprietary name (INN) recommended by the WHO, where an INN exists, or its chemical name;*

(d) *description of the method of manufacture;*

(e) *therapeutic indications, contra-indications and adverse reactions;*

[9] Council Directive of 23 November 1970 concerning additives in feeding-stuffs

(f) *dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;*

(g) *reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants;*

(h) *indication of the withdrawal period in the case of medicinal products intended for food-producing species;*

(i) *description of the testing methods employed by the manufacturer;*

(j) *results of:*

- *pharmaceutical (physico-chemical, biological or microbiological) tests,*
- *safety tests and residue tests,*
- *pre-clinical and clinical trials,*
- *tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions to limit it.*

*(k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;*

*(l) a summary in accordance with Article 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the package leaflet, in accordance with Articles 58 to 61;*

*(m) a document showing that the manufacturer is authorised in his own country to produce veterinary medicinal products;*

*(n) copies of any marketing authorisation obtained in another Member State or in a third country for the relevant veterinary medicinal product, together with a list of those Member States in which an application for authorisation submitted in accordance with this Directive is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with Article 14 or approved by the competent authority of the Member State in accordance with Article 25 and copies of the package insert proposed, details of any decision to refuse authorisation, whether in the Community or a third country and the reasons for that decision. All this information shall be updated on a regular basis;*

*(o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country;*

*(p) in the case of veterinary medicinal products intended for one or more food-producing species and containing one or more pharmacologically active substances not yet included, for the species in question, in Annexes 1, 11 or 111 to Regulation (EEC) No 2377/90, a document certifying that a valid application for the establishment of maximum residue Ill-nits has been submitted to the Agency in accordance with the aforementioned Regulation.*

*The documents and particulars relating to the results of the tests referred to in point (j) of the first subparagraph shall be accompanied by detailed and critical summaries, drawn up as specified in Article 15.*

## *The Animal Nutrition Additives Regulation – Regulation 1831/2003*[10]

24 Regulation (EC) No. 1831/2003 of 22 September 2003 on additives for use in animal nutrition repealed and replaced Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs[11].

25 The Animal Nutrition Additives Regulation has undergone a number of amendments since it first came into force. The references to Articles and other parts of this regulation below are to the form that was in force when the SPC application was filed in 2017.

26 Recital (4) of this regulation gives some insight into the purpose of the regulation and says:

> ***In order to protect human health, animal health and the environment, feed additives should undergo a safety assessment through a Community procedure before being placed on the market, used or processed within the Community.*** *Since pet food is not part of the human food chain and has no environmental impact on arable land, specific provision for additives in pet food are appropriate.*

27 Recital (33) indicates that one of the purposes of the Animal Nutrition Additives Regulation is to repeal Directive 70/524/EEC:

> *Directive 70/524/EEC should be repealed. However, labelling provisions applicable to compound feedingstuffs incorporating additives should be maintained until a revision of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs is completed.*

This is given effect in Article 23 of Animal Nutrition Additives Regulation - see below.

28 Article 1 sets out the scope of the Regulation as follows:

> ***1. The purpose of this Regulation is to establish a Community procedure for authorising the placing on the market and the use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives,*** *whilst ensuring the effective functioning of the internal market.*
>
> ***2. This Regulation shall not apply to:***

[10] Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

[11] For details of this directive see consolidated test on the EUR-Lex website at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01970L0524-20100901&qid=1606959126688

…

*(**b) veterinary medicinal products as defined in Directive 2001/82/EC,** with the exception of coccidiostats and histomonostats used as feed additives.*

29 Article 2 sets out the definitions used in this regulation including those terms which have been defined in earlier relevant EU legislation, in particular, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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. The definition of feed and feedingstuff from Regulation (EC) No 178/2002 are particularly identified[12]. The term is defined as follows in Regulation (EC) No 178/2002; "*feed" (or "feedingstuff") means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals*;"

30 For the purposes of the present decision the following definition from Article 2 are relevant:

(a) 'feed additives' means substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3);

….

(i) antimicrobials' means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa;

(j) antibiotic' means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;

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[12] Article 1 of Regulation (EC) No 178/2002 defines its aim and scope as follow:

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, ***this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.***

***It establishes the European Food Safety Authority***. (my emphasis)

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

(k) coccidiostats' and 'histomonostats' means substances intended to kill or inhibit protozoa

….

(m) 'micro-organism' means: colony-forming micro-organisms.

(n) 'first placing on the market' means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed

31 Chapter II of this regulation covers the provisions related to the authorisation, use, monitoring and transitional measures applicable for feed additives. It comprises Articles 3-15 and includes Annex I as referred to in Article 6.

32 Article 3 sets out the conditions for placing feed additives on the market as follows:

> ***1. No person shall place on the market, process or use a feed additive unless:***
>
> ***(a) it is covered by an authorisation granted in accordance with this Regulation;***
>
> *(b) the conditions for use set out in this regulation, including the general conditions set out in Annex IV, unless otherwise provided for in the authorisation, and in the authorisation of the substance are met; and*
>
> *(c) the conditions on labelling set out in this Regulation are met.*

33 Article 4 provides further that the application seeking authorisation for a feed additive or alternatively for a new use of a feed additive is subject to the procedures set down in this regulation or, in emergency situations, to the procedure set down in the relevant Articles' of Regulation (EC) No 178/2002:

> *1. Any person seeking an authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.*
>
> *2.* ***An authorisation shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation****, or in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002*
>
> *3 ……*

34 Article 5 sets out the conditions for authorisation as follows:

> *1.* ***No feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated*** *in accordance with the implementing measures referred to in Article 7* ***that****, when used in accordance with conditions to be set out in the Regulation authorising the use of the additive,* ***it satisfies the requirements of paragraph 2, and has at least one of the characteristics set out in paragraph 3****.*

*2. The feed additive shall not:*

*(a) have an adverse effect on animal health, human health or the environment,*

*(b) be presented in a manner which may mislead the user,*

*(c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.*

***3. The feed additive shall:***

*(a)* ***favourably affect the characteristics of feed,***

*(b) favourably affect the characteristics of animal products,*

*(c) favourably affect the colour of ornamental fish and birds,*

*(d) satisfy the nutritional needs of animals,*

*(e) favourably affect the environmental consequences of animal production,*

*(f)* ***favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs****, or*

*(g) have a coccidiostatic or histomonostatic effect.*

35 Article 6 lists the categories of feed additives into which such additives are classified and indicates that Annex 1 of the regulation is used to further classify the feed additive of interest according to its principal function.

*1. A feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, in accordance with the procedure set out at Articles 7, 8 and 9:*

***(a) technological additives: any substance added to feed for a technological purpose;***

*(b) sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;*

*(c) nutritional additives;*

*(d) zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment;*

*(e) coccidiostats and histomonostats.*

*2. Within the categories referred to in paragraph 1, feed additives shall further be allocated within one or more of the functional groups mentioned in Annex I, according to their principal function or functions, in accordance with the procedure specified in Articles 7, 8 and 9.*

*3. …*

36 Annex I of this regulation is entitled ‘Additive groups’ and is relevant to Article 6. It provides the list of the functional groups which are used to further define the category

of feed additive. Of interest in this case are the functional groups that fall within the definition of "technological additives":

> *1. In the category "technological additives", the following functional groups are included:*
>
> *…*
>
> *(m)* ***substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion or mycotoxins or modify their mode of action;***

37 Articles 7-9 together set out the procedure for considering and authorising an application for a feed additive or a new use of a feed additive. Firstly, Article 7 sets out the requirements of an application for an authorisation, secondly Article 8 describes the process by which the ***European Food Safety Authority*** (hereafter the EFSA) establishes its opinion on the application and the elements that make up that opinion, then based on this opinion. Article 9 indicates the procedure by which the Commission approves or denies the authorisation.

38 Article 7 reads as follows:

> *1.* ***An application for an authorisation as provided for in Article 4 shall be sent to the Commission. The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority*** *(hereinafter referred to as the Authority).*
>
> *2. The Authority shall.*
>
> *(a) acknowledge receipt of the application, including the particulars and documents referred to in paragraph 3, in writing, to the applicant within 15 days of its receipt, stating the date of receipt;*
>
> *(b) make any information supplied by the applicant available to the Member States and the Commission;*
>
> *(c) make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).*
>
> *3. At the time of application, the applicant shall send the following particulars and documents directly to the Authority:*
>
> *(a) his name and address;*
>
> *(b) the identification of the feed additive, a proposal for its classification by category and functional group under Article 6, and its specifications, including, where applicable, purity criteria;*
>
> *(c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;*

*(d) a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria laid down in Article 5(2) and (3);*

*(e) proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended;*

*(f) a written statement that three samples of the feed additive have been sent by the applicant directly to the Community reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex II,*

*(g) for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;*

*(h) a summary containing the information provided under points (a) to (g);*

*(i) for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation.*

39 Article 8 refers to the role of the EFSA and sets out the elements that the Authority will provide when issuing an opinion in favour of authorising the feed additive

*1. The Authority shall give an opinion within six months of receipt of a valid application. This time limit shall be extended whenever the Authority seeks supplementary information from the applicant under paragraph 2.*

*2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority after consultation with the applicant.*

*3. In order to prepare its opinion, the Authority:*

*(a) shall verify that the particulars and documents submitted by the applicant are in accordance with Article 7 and undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5;*

*(b) shall verify the report of the Community Reference Laboratory.*

*4. In the event of an opinion in favour of authorising the feed additive, the opinion shall also include the following elements:*

*(a)….*
*(b)….*
*(c) depending on the outcome of the assessment, specific conditions or restrictions in relation to handling, post-market monitoring requirements and*

*use, including animal species and categories of animal species for which the additive is to be used;*
*(d)….*
*(e)….*

*5. The Authority shall without delay forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the feed additive and stating the reasons for its conclusion.*

*6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 18(2).*

40 Article 9 sets out how this opinion from the EFSA forms the basis of an implementing regulation from the Commission that will approve or deny authorisation. According to part 3 of this Article, the decision of the Commission to approve or deny authorisation of the feed additive is made with the assistance of the Standing Committee on the Food Chain and Animal Health which is set up according to Article 58 of Regulation EC 178/2002[13]. This committee is made up of representative from the Members States and is chaired by a representative of the European Commission. Article 9 reads as follows:

*1. Within three months of receipt of the opinion of the Authority,* ***the Commission shall prepare a draft Regulation to grant authorisation or to deny authorisation. This draft shall take into account the requirements of Article 5(2) and (3),*** *Community law and other legitimate factors relevant to the matter under consideration* ***and in particular benefits for animal health and welfare and for the consumer of animal products.***

***Where the draft is not in accordance with the opinion of the Authority, it shall provide an explanation of the reasons for the differences.***

*…….*

*2. ….*

*3. ….*

*4.* ***The Commission shall without delay inform the applicant of the Regulation adopted in accordance with paragraph 2****.*

[13] Article 58 of Regulation (EC) No 178/2002 entitled 'Committee' reads as follows:

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the "Committee", composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*5. A Regulation granting the authorisation shall include the elements mentioned in Article 8(4)(b), (c), (d) and (e) and an identification number.*

*6. ….*

*7. ….*

*8. **The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 14.** The authorised feed additive shall be entered in the Register referred to in Article 17 (hereinafter referred to as the Register). Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7.*

*9. ….*

41 Article 22, entitled 'Committee procedure' states:

*1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation EC No 178/2002 (hereinafter referred to as the Committee).*

*2. ….*

*3. ….*

42 Article 23, entitled "Repeals", refers to Directive 70/524/EEC as follows:

***1. Directive 70/524/EEC shall be repealed with effect from the date of application of this Regulation.** However, Article 16 of Directive 70/524/EEC shall remain in force until Directive 79/373/EEC has been revised to include rules concerning the labelling of feedingstuffs incorporating additives.*

*…..*

***4. References to Directive 70/524/EEC shall be construed as references to this Regulation.***

## Relevant Case Law

*Court of Justice of the European Union (CJEU) - C-527/17, Boston Scientific*

43 This decision relates to a combined medical device and medicinal product and whether such a device is capable of being protected by a Supplementary Protection Certificate as a medicinal product under Regulation (EC) No. 469/2009.

44 The relevance to the present case stems from the fact that the relevant marketing authorisation on which the SPC application was based was for a medical device under

Directive 93/42/EEC rather than a marketing authorisation for a human medicinal product under Directive 2001/83/EC.

45 Boston Scientific had applied for an SPC for a stent coated with Paclitaxel on the basis of a European patent related to the use of the substance to reduce restenosis following angioplasty and had gained a CE certificate in relation to a stent (TAXUS$^{TM}$) coated in Paclitaxel.

46 The substance Paclitaxel had previously been known as the principal active ingredient in treating certain cancers and had been marked under the name of Taxol. During the process of obtaining marketing authorisation under Directive 93/42/EEC concerning medical devices, the quality, safety and usefulness of the substance were verified by analogy with the methods specified in Annex I to the medicinal products Directive (2001/83).

47 The question referred to the CJEU in this case was:

> *Must Article 2 of Regulation [No 469/2009] be interpreted as meaning that, for the purposes of that regulation, an authorisation under Directive [93/42] for a combined medical device and medicinal product within the meaning of Article 1(4) of [that directive] is to be treated as a valid [MA] under Directive [2001/83], where, as part of the authorisation procedure laid down in Annex I, Section 7.4, first paragraph, to Directive [93/42], the quality, safety and usefulness of the medicinal product component has been verified by the medicinal products authority of a Member State in accordance with Directive [2001/83]?*

Essentially, this question concerned whether an authorisation under Directive 93/42 for a medical device incorporating as an integral part a substance, which if used separately may be considered as a medicinal product within the meaning of Article 1 of Directive 2001/83, should be treated in the same way, for the purposes of applying the SPC regulation, as an marketing authorisation procedure for that substance under Directive 2001/83.

48 The court considered at paragraph 27 that is was clear from the wording of Article 2 of the SPC Regulation that "*a product may be the subject of an SPC **only** if it has been subject, as a medicinal product, to an MA procedure as laid down in Directive 2001/84*".

49 The court, referring to the substance "*such as that at issue .. which forms an integral part of a medical device*", concluded in paragraphs 40-42 that:

> *40 It follows from the foregoing that such a substance does not fulfil any of the conditions laid down in Article 2 of Regulation No 469/2009 in order to be eligible for an SPC, even if the quality, safety and usefulness of that substance are verified by analogy with the methods specified in Annex I to Directive 2001/83.*
>
> *41 Such an interpretation of Article 2 of that regulation is borne out by both the context of that article and the objective pursued by that regulation.*
>
> *42 As regards the context of which that article forms part, it should be noted that Article 3(b) of Regulation No 469/2009 provides that an SPC may be granted*

*only on condition, inter alia, that the relevant product has been granted, as a medicinal product, a valid MA in accordance with Directive 2001/83. An SPC cannot therefore be granted for a product which has been the subject of prior authorisation not as a medicinal product, but as a substance forming an integral part of a medical device.*

50 The court then considered the intention of the legislator stating at paragraph 44:

> *As regards the objectives pursued by Regulation No 469/2009, it is apparent from the title of that regulation and from recitals 3, 4 and 8 to 10 thereof that the EU legislature intended to reserve the grant of SPCs to medicinal products alone, to the exclusion of both medical devices and substances used as adjuvant products of a medical device.*

51 It was clear that the substance at issue (Paclitaxel) was not assessed as a medicinal product but for its intended uses as an accessory of the TAXUS medical device. In such a case the court concluded that there was no specific provision of EU law that provided for the possibility of obtaining an SPC.

## The Animal Nutrition Additives Regulation EC 1831/2003 – how it works

52 Insofar as it is relevant to the discussion and analysis below regarding the issues to be decided, it is necessary to be aware of the following features regarding how the system for approval of additives for use in animal nutrition set up under Regulation EC 1831/2003 works:

(i) Applications for authorisation of a feed additive are submitted to the European Commission. The Commission then ensures that Member States are informed and forwards the applications to the European Food Safety Authority (EFSA).
(ii) The applicant must send to EFSA a copy of the application and the complete dossier (which includes applicant's name and address, a description of the method of production, manufacturing and intended uses of the additive, proposed conditions for placing the additive on the market, the safety and efficacy studies).
(iii) EFSA is responsible for conducting the risk assessment based on the dossier submitted by the applicant.
(iv) The applicant must also send samples of the feed additive to the European Union Reference Laboratory (EURL)for analysis.
(v) EFSA may, if necessary, ask the applicant for further information during the assessment procedure.
(vi) Additives intended for use in animal nutrition must receive a favourable opinion from EFSA before being granted authorisation for their use and placed on the market. Within 6 months of receipt of an application, the EFSA gives an opinion based on the information provided by the applicant. The evaluation report prepared by the EURL on the method of analysis of the additive is included in the opinion. If the opinion is favourable, it will include information on the specific conditions or restrictions relating to handling, monitoring requirements following placing on the market and use of the additive, including the animal species and categories of animals for which the additive is to be used: information on specific

additional requirements for labelling of the additive, and, where appropriate, a proposal for the establishment of *maximum residue limits* in the relevant foodstuffs of animal origin.

(vii) Based on the EFSA opinion, the Commission decides whether to authorise or deny the authorisation of the additive. The Commission prepares a draft implementing Regulation to grant or deny the authorisation.

(viii) The Commission is assisted in the procedure by the Member States within the Standing Committee on Plants, Animals, Food and Feed, in this instance the section dealing with Animal Nutrition.

## Issues to be decided

53 The first issue to be decided is whether the authorisation provided in support of this application (i.e., an authorisation under EC Regulation 1831/2003 for an additive for use in animal nutrition) is a valid authorisation to place the product on the market as a veterinary medicinal product in accordance with Directive 2001/82/EC as required by Article 2 and Article 3(b) of the SPC regulation.

54 Should I decide that the authorisation under Regulation 1831/2003 is a valid authorisation under Article 2 and Article 3(b), the second issue I will need to consider is if the authorisation filed in support of the application is the first such authorisation to place the product on the market. The application refers to two authorisations in support of their SPC application – Commission Implementing regulation EU 2017/930 dated 31/05/2017 and EU 1016/2013, dated 23/10/2013.

55 Having established which is the first such authorisation, I will then need to consider whether the application complies with Article 7(1) of the SPC Regulation which requires that that the application for the SPC is made within 6 months of the grant of the marketing authorisation.

### *Role of the IPO*

56 It is appropriate at this point to observe that the role of the IPO as the body responsible for granting SPCs in the UK (see Article 9 of the SPC Regulation) is to determine if the applications for SPCs received meet the requirements of the SPC regulation, in particular, Article 3. If so, an SPC shall be granted (see Article 10 of the SPC Regulation). The SPC is granted for a period, calculated using the algorithm outlined in Article 13, for a product that is covered by a patent and is the active ingredient (or combination of active ingredients) in a medicinal product which has been authorised for veterinary use under Directive 2001/82/EEC (or human use under Directive 2001/83/EEC). The SPC is designed to compensate the applicant for the loss of the term of their patent while gaining the necessary regulatory approval to place the medicinal product comprising this product on the market.

57 The IPO is not involved in the regulatory processes that lead to the grant of a marketing authorisation for a veterinary product. In the period relevant for this application, the latter was the responsibility of the Veterinary Medicines Directorate (VMD) at the

national level in the UK[14] and of the European Medicines Agency (EMA) at the Community wide level[15].

58 The analysis below is based on my consideration and comparison of the SPC Regulation with Directive 2001/82/EC (the Veterinary Medicinal Products Directive) and Regulation 1831/2003 (the Animal Nutrition Additives Regulation), in the versions that were in force when the SPC application was made, and my consideration of all the materials on file and the submissions made at the oral hearing.

## Views of the Examiner and the Applicant

### *The View of the Examiner*

59 The examiner's view is clearly set out in the pre-hearing report of 12 March 2019. In the examiner's view, an authorisation under Regulation 1831/2003 does not satisfy Article 3(b) and that it could not be considered an analogous process to that for the authorisation of a veterinary medicine. The examiner refuted three reasons that the applicant had previously put forward as support for the two authorisation processes being analogous, these are:

*"1. Directive 2001/82/EC as well as Regulation (EC) 1831/2003 concern microorganisms for preventing disease in animals. Thus, both Regulations concern the same subject matter as such*

*2. Directive 2001/82/EC and Regulation (EC) 1831/2003 specifically exclude one another. This fact proves that these Regulations are closely related.*

*3. The microorganism subject to this SPC qualifies as a medicinal product and product as defined in Regulation (EC) 469/2009 (ruling the granting procedure for an SPC) disease both 2001/82 and 1831/2003 concern microorganisms as active substances, because the regulations exclude one another and because microorganisms qualify as a product under 469/2009."*

60 In relation to the first reason, the examiner did not consider it relevant that both regulations can concern the same subject matter. The fact that DSM 11789 strain could have been assessed as a veterinary medicine was not material as it clearly had not been considered under the veterinary medicine code.

61 As regards the second reason, the fact that Directive 2001/82 and Regulation 1831/2003 exclude one another meant that the rewards that flow from Directive 2001/82 (i.e. possibility of obtaining an SPC) are not also available to authorisations under Regulation 1831/2003. In the examiner's view, if the legislator had intended for

[14] See VMD website at https://www.gov.uk/government/organisations/veterinary-medicines-directorate/about. The VMD is an executive agency of the Department of Environment, Food and Rural Affairs (Defra) in the UK.

[15] See EMA website at http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=

feed additives to be amenable to SPC protection, they could have done so by amending Regulation 469/2009.

62 In response to the third reason, the examiner's view was that finding that the definition under Article 1 is satisfied is not sufficient for the grant of an SPC and it does not on its own confer compliance with Article 2. In essence, just because the product in question may fall within the definition of a medicinal product does not mean that the requirement to have been subject to an authorisation procedure as laid down in Directive 2001/82/EC is satisfied.

63 The examiner considered the CJEU judgement in *Boston Scientific* to be relevant as it showed that Article 3(b) or the SPC Regulation is to be interpreted narrowly. The examiner relied on paragraph 27 of the judgement where it says:

*"It is thus clear from the actual wording of that Article 2 that a product may be the subject of an SPC only if it has been subject, as a medicinal product, to an MA procedure as laid down in Directive 2001/83."*

In the view of the examiner, the CJEU's conclusion is generally applicable and not restricted to medical devices. Specifically, the examiner was of the view that the present application was not amenable to SPC protection as the product was not assessed as a veterinary medicinal product.

## *The View of the Applicant*

64 The applicant has raised several arguments in favour of granting the present SPC application. In summary, these are:

a. The authorisation procedure under Regulation 1831/2003 which the microorganism was subject to in the present application is highly similar to the procedure under Directive 2001/82/EC;

b. Regulation (EC) No 469/2009 is not restricted to products for which a marketing authorisation have been obtained under Directive 2001/82/EC;

   i. Directive 2001/82/EC and Regulation (EC) No 1831/2003 both concern microorganisms for preventing disease in animals;

   ii. Directive 2001/82/EC and Regulation (EC) No 1831/2003 are closely linked and specifically exclude one and other;

   iii. The microorganism qualifies as a medicinal product in accordance with Regulation (EC) No 469/2009;

   iv. Accepting SPC applications for medicinal products authorised under Directive 2001/82/EC while rejecting medicinal products authorised under Regulation (EC) No 1831/2009 as feed additives represents an unequal application of law and contravenes the prohibition of discrimination set out in the TRIPs agreement.

c. The decision in *Boston Scientific (C-527/17)* is not relevant as it relates to medical devices and so does not have wider applicability than that. The

applicant disagreed with the examiners view that the CJEU's ruling can be applied to the present case because.

i. the authorisation in the case of *Boston Scientific* was obtained by a certification process carried out by national institutions using the relevant national standards. In contrast, the present SPC application concerns marketing authorisation procedures conducted by European Agencies under European law and approved by the European Commission.

ii. Secondly, the ruling in *Boston Scientific* relates to a medical device and not a medicinal product which the applicant argues the present microorganism represents. The CJEU makes it clear in paragraphs 27 to 51 that a medical device has to be distinguished from a medicinal product. In particular, a product which does not achieve its principal mode of action by pharmacological, immunological or metabolic means falls under the definition of a 'medical device'. Conversely, a product which achieves its principal intended action in the human body by such means may be classified as a 'medicinal product' within the meaning of Directive 2001/83[16]. The Court emphasized that if an active ingredient contained in a medical device only mediates its effect ancillary to that of the device, it cannot be categorized independently from the device.

iii. Notably the present SPC application concerns the microorganism of strain DSM 11798. This microorganism itself achieves its principal mode of action by pharmacological, immunological or metabolic means and thus falls under the definition of a 'medicinal product' in accordance with Regulation No 469/2009. Consequently, the decision in C-527/17 is not relevant to the present application which found that the product at issue did not fall within the definition of a 'medicinal product' in accordance with Regulation No 469/2009.

## Analysis

65 I will look first at the question of compliance with Article 7 before turning to consider the question of compliance with Article 2 and Article 3(b) of the SPC Regulation.

## Compliance with Article 7 of the SPC Regulation

66 The examiner has stated[17] that that in his view the authorisation to be taken into account for the purposes of working out whether the SPC application had been made in time under Article 7 was that covered by Commission Implementing regulation

[16] See Paragraph 33, C-527/17 Boston Scientific

[17] See Official Examination report dated 9 January 2018

1016/2013 and not the later one covered by Commission Implementing regulation 2017/930.

67 In order to determine this, it is first necessary to establish if an authorisation under the Animal Nutrition Additives Regulation is a valid one under Article 2 and Article 3(b) of the SPC regulation. If the answer to that question is yes, then it is necessary to determine if, as the applicant claims, the later of the two implementing regulations is the correct authorisation for the purposes of Article 7. As the applicant noted in their response dated 10 July 2018, this is a question under Article 3(d), in so far as it is necessary to establish if the authorisation cited in support of the SPC application is the first such valid authorisation for that active substance.

68 I note that the applicant refers to the differences between the two implementing regulations in terms of (a) the 2017 regulation covers all trichothecenes as a class and not just one – deoxynivalenol; (b) the 2017 regulation covers use in a new species, i.e., in all avian species, as well as in pigs.

69 The applicant argued that the *Neurim* judgment does not preclude the grant of an SPC for "*a different application of the same product for which a marketing authorisation has been granted*".

70 However, as noted already, while preparing this decision, the judgment of the CJEU in the *Santen* case was issued. The CJEU found that the above so-called *Neurim* approach is no longer to be followed. The applicant offered the view that the latter *Santen* judgment should not affect how the *Neurim* judgement is applied in the UK to questions relating to Article 3(b) of the SPC regulation or Article 3(1)(b) of the plant protection products SPC regulation.

71 However, the case law of the CJEU is still binding on me in relation to SPC applications in progress before the end of the transition period on 31 December 2020. Thus, I will have to take account of this latest CJEU decision in deciding the question of compliance with Article 7. However, if I find that the approval process under the Animal Nutrition Additives Regulation is not a valid authorisation under Article 2 and Article 3(b) of the SPC regulation, it will not be necessary to decide this question.

## Compliance with Article 2 and Article 3(b) of the SPC Regulation

72 According to the applicant this SPC application relates to a veterinary medicinal product. They consider that the active substance for which the SPC is being sought is the specific strain "*microorganism DSM 11798 of the Coriobacteriaceae family*". I am being asked to accept that the procedure used for approval to place this microorganism strain on the market in European Union under Regulation (EC) No 1831/2003 as an additive for use in animal feed, in particular for use in feed for avian species, for example poultry, and in feed for pigs, can be considered to meet the requirement for "*an administrative authorisation procedure as laid down in Directive 2001/82/EC relating to veterinary medicinal products*". This is the requirement of Article 2 of the SPC regulation. If an authorisation does not meet this requirement it falls outside the scope of the SPC regulation.

73 A valid authorisation to place the product of interest as part of a medicinal product on the market in Europe for veterinary use granted "*in accordance with Directive 2001/82/EC*" is necessary to fulfil the requirement under Article 3(b) of the SPC Regulation for the grant of an SPC.

74 On the face of it the answer to this question is straightforward. The approval for a feedstuff additive under Regulation (EC) No 1831/2003 (hereafter the animal nutrition additives regulation) is not one granted using the procedure laid down in the Veterinary Medicinal Products Directive (Directive 2001/82/EC). It is granted under a different piece of EU legislation rather than that required by the SPC Regulation. Therefore, such an approval is not relevant for the purpose of granting an SPC, i.e. it is not the subject of "*an administrative authorisation procedure as laid down in Directive 2001/82/EC relating to veterinary medicinal products"* and as such it is not a valid authorisation granted "*in accordance with Directive 2001/82/EC* ".

75 The SPC regulation refers to marketing authorisations granted under Directive 2001/82/EC for veterinary products and Article 3(2) of this directive specifically excludes additives covered by Council Directive 70/524/EEC of 23rd of November 1970 concerning additives in feeding stuffs[18]. This council directive has been repealed and replaced by Regulation EC 1831/2003 (the Animal Nutrition Additives Regulation), which is the legal basis for the approval provided in support of the present SPC application. It is clear from recital (33) and Article 23(1) of the Animal Nutrition Additives Regulation that this regulation repeals the earlier directive. The scope of the Animal Nutrition Additives Regulation is set out in Article 1 which indicates the matters to which the regulation applies as well as those to which it does not apply: Article 1(2)(b) states that veterinary medical products as defined in Directive 2001/82/EC are not in scope of the Animal Nutrition Additives Regulation

76 Furthermore, if one considers Directive 2001/82/EC itself, the demarcation between veterinary products which are referred to in the directive as "veterinary medicinal products" and animal nutrition additives is maintained. Article 3(1)(d) of this directive states that it does not apply to any additives covered by Council directive 70/524/EEC which, as I have already noted, has been replaced by the Animal Nutrition Additives Regulation.

77 The principal driver for the replacement of Directive 70/524/EEC (the Additives in Feeding Stuffs Directive) by the Animal Nutrition Additives Regulation was the creation and development of a community wide procedure for carrying out a scientific risk assessment on the safety of animal nutrition additives. This is acknowledged in recitals (4), (5) and (14) and Article 8 of the Animal Nutrition Additives Regulation (see above). The European Foods Safety Agency (EFSA) was created and established under Regulation EC 178/2002[19] to perform this role shortly before the Animal Nutrition Additives Regulation came into effect in 2003. EFSA is a European body established under a different legal instrument[19] and to perform a different function to

[18] Directive 70/524/EEC of 23rd of November 1970 concerning additives in feeding stuffs

[19] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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. See entry for this regulation on EUR-Lex database of EU Legislation at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178&qid=1606488341099

that carried out by the European Medicines Agency (EMA). The EMA is the body responsible for carrying out the authorisation process for veterinary medicinal products in the European Union which was established under Regulation EC 726/2004[20].

78 When, as referred to in recital 8 of the Animal Nutrition Additives Regulation, the additives in feeding stuffs directive was updated in 2003 in order to take account of the experience gained applying the directive within the EU and the technological progress and scientific developments that had occurred since 1970 when the directive was first implemented, the exclusion of veterinary medicinal products discussed above was also maintained.

79 Turning to the SPC regulation itself, Article 2 states that the product for which an SPC is being sought must be "*subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/82/EC".*

80 Thus, it is clear from the above comparison, that the system for granting approvals for use of additives in animal feed is not comparable to the system for granting authorisation for the use of veterinary medicinal products in animals. As such, it appears – from a first examination of the three different pieces of EU legislation involved – the SPC regulation, the Animal Nutrition Additives Regulation and the Veterinary Medicinal Products Directive - that it is not possible to accept an approval granted under the system for approving feed additives as a suitable authorisation under the SPC regulation.

*A Teleological Approach?*

81 The approach outlined above is too literal in the view of the applicant and is not in keeping with the way that EU legislation should be interpreted. The applicant has raised the general issue of the need for a teleological interpretation of the SPC Regulation in reaching any decision on how Article 2 and Article 3(b) of this regulation are to be understood and applied. At the hearing, the agent spent some time arguing that a teleological approach is necessary when considering this application (and related SPC application SPC/GB17/076 which is the subject of a separate decision) given that they considered the examiner had taken too literal an approach, for example, by focusing on the explicit exclusions discussed above and taking too narrow an approach to how to answer the question of what constitutes a marketing authorisation that can be considered to be equivalent to that under Directive 2001/82/EC.

82 The applicant started by putting matters in the context of the TRIPS agreement[21] which states that patent protection should be available in all fields of technology and suggesting that SPCs should be considered in the same way as patents, for example, because the UK Patents Act 1977 does not, in their view, make any distinction between SPCs and Patents (see section 128B and Schedule 4A). The agent went on

[20] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[21] The Agreement on Trade-Related Aspects of Intellectual Property Rights (of 1 January 1995) – see https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

to add that, for enforcement purposes, patents and SPCs are considered to be the same and observed that, as the European enforcement directive[22], which refers to SPCs and patents directly and has been implemented into UK law by statutory instrument 2006/1028 (Schedule 2), requires all EU member states to observe their obligations under TRIPS. The agent then considers that in the UK SPCs are the subject of the provisions of TRIPs and so are also subject to the prohibition in TRIPS against any discrimination of patent rights based on field of technology. The agent argued at the hearing that this means that a teleological approach should be taken to the SPC regulation because, if the TRIPS Agreement tells you that you can't discriminate on the basis of fields of technology, the SPC regulation, and in particular the sections that I am concerned with in this decision, in particular, Article 2 and, either Article 3(b) or Article 3(1)(b), depending on which SPC regulation, the medicinal products one or the plant protection products one, is being considered — has to be interpreted in this same light. So, in a nutshell, TRIPS via the EU enforcement directive and how it has been implemented in the UK would predicate a non-literal approach to the interpretation of those articles in the SPC regulations.

83 However, I am not sure how relevant arguments based on the TRIPS Agreement are in this context. I note that the TRIPS agreement obliges its contracting states to provide patent protection for all inventions which fulfil the conditions specified therein and for a period of 20 years (see Articles 27 and 33 respectively). It does not make any reference to instruments which extend the patent term beyond 20 years, such as patent term extensions or, standalone instruments, such as supplementary protection certificates. These term extensions are not available in all areas of technology and so I do not consider that this TRIPS based argument is helpful to me in establishing the approach I should take.

84 As I have set out in some previous decisions[23], it is a well-established principle of EU law that it is necessary to take account of the purpose and objectives behind the EU legislation in question – the so-called teleological approach[24]. The purpose of the SPC regulation has been discussed previously in the UK courts[25] and in the many references to the CJEU that have been made concerning the interpretation of this regulation, such as *C-482/07 AHP* [26]. In this decision, the CJEU observed (at paragraph 27) that when considering a particular article of the plant protection

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[22] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights

[23] (i) *Cerus Corporation* (BL O/141/14) https://www.ipo.gov.uk/p-challenge-decision-results/o14114.pdf; (ii) *Leibniz-Institut fur Neue Materialien Gemeinnutzige GmbH* (BL O/328/14) https://www.ipo.gov.uk/p-challenge-decision-results/o32814.pdf, and (iii) *Angiotech Pharmaceuticals* (BL O/466/15) https://www.ipo.gov.uk/p-challenge-decision-results/o46615.pdf

[24] See discussion of teleological approach and references to relevant case law in paras 14 & 15 of IPO decision BL O/389/09 (Neurim) at http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/o38409.pdf

[25] See Draco A.B.'s SPC application [1996] RPC 417 which also refers to House of Lords decision in R. v. Henn, R. v. Darby [1981] A.C. 850 and to paragraphs 2.266 and 2.268 of Volume 51 of Halsbury's Laws of England (4th edition).

[26] See, for example *C-482/07 AHP Manufacturing BV* v *Bureau voor de Industriële Eigendom at* http://curia.europa.eu/juris/document/document.jsf?text=&docid=73083&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=194830; especially para 27.

products SPC Regulation, it *"must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part".* Thus, in adopting a teleological approach for my consideration of the SPC Regulation, I am required not to apply too literal an interpretation to the wording of the articles. However, this approach does not require me to ignore the meaning of the words in the articles, it requires me to also take into account the overall scheme and objectives of the legislation of which these articles are part. In following a teleological approach, I must take into account both the wording and the overall scheme and objectives of the SPC Regulation, the Animal Nutrition Additives Regulation and Veterinary Medicinal Products Directive, to arrive at a view about whether an approval under the Animal Nutrition Additives Regulation can be considered to meet the requirements for a valid authorisation under Articles 2 and 3(b) of the SPC regulation.

85 In the series of Patent Office decisions[23] BL O/141/14 (Cerus); BL O/328/14 (Liebniz) and BL O/466/15 (Angiotech), discussion of the teleological approach arose in relation to whether an approval under the medical devices legislation (Council Directive 93/42/EC)[27] "*incorporates, as an integral part,* ***a substance which, if used separately, may be considered to be a medicinal product*** *within the meaning of Article 1 of Directive 65/65/EEC* [i.e., Directive 2001/83/EC] *and which is liable to act upon the body with action ancillary to that of the device, that device must be assessed and authorized in accordance with this Directive*" (my emphasis added). In that situation, a possible link between the purpose and objective of the Medical Devices Directive and the Human Medicinal Products Directive[28] was acknowledged even though there was an explicit exclusion in the Medical Devices Directive indicating that it did not apply to medicinal products covered by Directive 2001/83/EC. This needed to be taken into account when considering the scheme and purpose of the two directives and the approval systems they related to. The Medical Devices Directive gave some guidance about the relationship between the two directives and how to work out which one applied when, i.e. "***In deciding whether a product falls under that Directive ( i.e. the medicinal products directive Dir 2001/83/EC) or this Directive (i.e. the medical devices directive, Dir 93/42/EC), particular account shall be taken of the principal mode of action of the product".*** I note that there is no such pointer in the Animal Nutrition Additives Regulation or the Veterinary Medicinal Products Directive that suggest a reason why a product approved under the first might meet the requirements of the second.

*Regulation (EC) No 469/2009 is not restricted to marketing authorisations under Directive 2001/82/EC*

86 The applicant has proposed a number of arguments to support their interpretation of how Article 2 of the SPC regulation is met and, subsequently, how the requirement of Article 3(b) and Article 7 (which refers specifically to Art 3(b)) are met.

87 The applicant contends that Regulation (EC) No 469/2009 is not restricted to marketing authorisations issued under Directive 2001/82/EC and that the examiner has taken too stringent a reading of the SPC Regulation. In this case, they contend

[27] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[28] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

that it is appropriate to apply the legislation in an analogous way since the specific situation of an authorisation for an animal feed is not encompassed in the literal text of Article 3(b). There are two main reasons for doing this in the view of the applicant:

*(i) Directive 2001/82/EC and Regulation (EC) No 1831/2003 both concern microorganisms for preventing disease in animals*

88 In support of this view, the applicant firstly points out that both Directive 2001/82/EC and Regulation 1831/2003 concern microorganisms for preventing disease in animals. Article 1(2) of Directive 2001/82/EC defines a veterinary medicinal product as any substance or combination of substances presented for treating or preventing disease in animals. They also go on to say that any substance or combination of substances which may be administered to animals with a view to restoring, correcting or modifying physiological functions in animals is also considered a veterinary medicinal product. Article 1(4) of the same Directive makes it clear that microorganisms fall within the definition of '*substance'*. Articles 2 and 5 of Regulation (EC) No 1831/2003 define a microorganism as a feed additive that favourably affects animal performance or welfare, i.e. treating or preventing disease in animals. As indicated above the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family is classified as a technological additive i.e. a "*substance for reduction of the contamination of feed by mycotoxins: substance that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action"* under the Animal Nutrition Additives Regulation. From this, the applicant argues that both Directive 2001/82/EC and Regulation (EC) No 1831/2003 concern microorganisms as active substances for treating or preventing disease in animals. Consequently, the microorganism strain that is the subject of the present SPC application would in principle fall under both legislative instruments.

89 Given that both of these instruments appear to apply to microorganisms for treating or preventing disease in animals, the applicant goes on to argue that the microorganism strain DSM 11798 of the *Coriobacteriaceae* family that is the subject of this SPC application can be considered a '*product'* and a *'medicinal product*' in accordance with the definitions of Articles 1(a) and 1(b) of Regulation (EC) 469/2009. The applicant draws support for this from the basic patent. Specifically, as described in paragraph [0002] of the basic patent (EP 1042449 B1) mycotoxins, especially trichothecenes, in animal feed harm the animal's health. As further described in the literature[29], mycotoxins cause emesis, weight loss, nervous disorders, cardiovascular alterations, immunodepression, haemostatic derangements, skin toxicity, decreased reproductive capacity and bone marrow damage when consumed e.g. orally. The basic patent also discloses that the microorganism strain DSM 11798 of the *Coriobacteriaceae* family detoxifies trichothecenes (paragraph [0007) and, as shown in paragraphs [0066]-[0072], if a feed comprising this microorganism strain is applied to animals, the negative effects of mycotoxins are reduced, and animals are in general healthier and fitter. Thus, the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family can be classified as a substance for treating or preventing disease provoked by mycotoxins in animals. This means, in the opinion of the applicant, that the microorganism strain DSM 11798 of the *Coriobacteriaceae* family qualifies as a 'product' and 'medicinal product' in accordance with Regulation (EC)

[29] See Chapter 34 entitled *'Trichothecene Mycotoxins*' in Medical Aspects of Chemical and Biological Welfare, by Wannemacher and Wiener (1997, pages 655-676)

469/2009. Therefore, Regulation (EC) 469/2009 should apply to the microorganism strain that is the subject to this SPC application.

*(ii) Directive 2001/82/EC and Regulation (EC) No 1831/2003 are closely linked and specifically exclude one another*

90 In the view of the applicant the mutual exclusion referred to in both these legal instruments and outlined above merely emphasises the similarity of the authorising procedures under each because "*if these products were indeed fundamentally different, there would be no need to exclude the one or the other*"[30]. I do not find this a convincing argument. The European legislator was clearly aware of both the system for approving feed additives and the system for approving veterinary medicinal products and the exclusion of each from the respective legal instruments has been maintained through a number of revisions of the Veterinary Medicinal Products Directive and through the changes from a directive to a regulation for animal nutrition additives.

91 In my view there is merit in such an approach as there is a different overall objective being achieved by the two instruments. Looking at the overall scheme and objective of the Animal Nutrition Additives Regulation, it is about ensuring that the additives in animal feed have a beneficial effect on the food used to feed animals and does not have an adverse impact downstream on the animals that eat the feed or the animals (such as humans) that eat the animals (e.g., cows, chickens, pigs) that eat the feed! The Veterinary Medicinal Products Directive is about ensuring the effective cure and prevention of disease in animals and this covers diagnosis of disease at well. The purpose of both systems may be considered to be related but is clearly not the same – one is about food, the other medicine – for animals. For the purposes of the present case, I do not consider that the approval process under each instrument can be considered sufficiently similar for them to be considered equivalent in the manner suggested by the applicant.

92 This teleological approach suggested by the applicant does not in my view take sufficient account of the overall scheme and purpose of the SPC Regulation, the Animal Nutrition Additives Regulation and the Veterinary Medicinal Products Directive. It does in effect require me to ignore the specific exclusions in the Animal Nutrition Additives Regulation and the Veterinary Medicinal Products Directive and to take instead a very broad interpretation in order to arrive at the situation where the approval under the Animal Nutrition Additives Regulation is considered to be the same as an authorisation as laid down in the Veterinary Medicinal Products Directive.

## *The purpose of the SPC Regulation*

93 The recitals of the SPC Regulation make it clear that the intention of the EU legislator in creating SPC protection was to provide sufficient protection for medicinal products that are the subject of lengthy and costly research[31] and to compensate for the delay between receiving patent protection for such a product and gaining authorisation to

[30] Applicant's letter of 22 February 2019

[31] See Recital (3), Regulation 469/2009, the SPC regulation

place it on the market as a medicinal product[32]. Recitals (3) and (4) both refer to "*medicinal products*" and "*authorisation to place the medicinal product on the market*". Furthermore, Recital (1) is clear that the protection granted by the SPC Regulation should be "*strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product*". The scope of the Regulation (Article 2) further indicates that it applies only to medicinal products which have been subject of an approval as a medicinal product either for humans or animals.

*The Purpose of the Animal Nutrition Additives Regulation*

94 This regulation is part of the system in the European Community for providing safe food. This system provides for the free movement of safe and wholesome food within the internal market of the EU and so contributes to the health and well-being of its citizens. This is clear from the recitals to this regulation which refer to the importance of safe and good quality feeding stuffs for livestock production and the need for a system to ensure that anything added to the feed of animals is safe and has been subject to a suitable safety assessment at community level. The role of the European Food Safety Agency in helping to achieve this is emphasised, for example in Recitals (5) and (14).

95 The role of the European Commission in granting the authorisation of a feed additive is explicit from recital 17 and Article 9 because it is relevant that other factors may have to be taken into account when approving such additives. As recital 17 states:

> "*It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and* ***that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products"*** (my emphasis added)

96 Thus, while it is acknowledged that it is part of the overall policy within the EU to ensure a "*high level of protection of human life and health*" (Recital 3), it is not the specific scheme or purpose of the Animal Nutrition Additives Regulation. The scope of the regulation as laid out in Article 1 makes it clear that its purpose is to "*establish a Community procedure for authorising the placing on the market and use of feed additives…in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers'* ***interests in relation to feed additives***". This is by contrast to Directive 2001/83/EC and the SPC regulation, which are specifically about the treatment of disease in animals using veterinary medicinal products and determining the risks and benefit from treating these diseases – see for example Recitals 2 and 6 and Articles 11 & 12 of Directive 2001/83/EC. There is, in my view, an important issue of degree here. The amount and level of testing that has to be carried out to establish clinical benefit for a veterinary medicinal product – as set out in Annex 1 to the Veterinary Medicinal; Products Directive, is going to be of a greater and more significant degree, then the testing needed to establish safe use of a feed additive. Clearly both are within the general context of ensuring a "*high level of protection of human life and health*" but the

[32] See Recital (4), Regulation 469/2009, the SPC regulation

areas they address within that envelope are different and require a different approach. For example, feed additives are usually given to healthy animals and should not cause much harm, whereas veterinary products are usually given to animals that are sick and need to be cured. Thus, what is an acceptable result or outcome in both of those situations is not likely to be the same (or analogous or equivalent).

97 The issue of how to consider whether different approval systems are sufficiently close in operation to be considered analogous or 'in accordance with' for the purpose of the grant of an SPC under the SPC regulation came up previously in relation to the system for approving medical devices that include a substance which on its own may be considered as a medicinal product and the system for approving human medicinal products. In the *Cerus, Leibniz and Angiotech* decisions[23] discussed previously, I examined in some detail both the wording of the relevant articles (and associated annexes) and the overall scheme and objective of the Medical Devices Directive and the Human Medicinal Products Directive. I concluded that the difference between the two was one of degree and that this was why the two systems could not be considered analogous or 'in accordance with'. The assessment for medical devices is not the same as the assessment for human medicinal products[33]. This approach has been upheld by the CJEU in the *Boston Scientific* judgment.

98 I consider that the same situation has arisen in this case - what at first look appears to be two legal instruments putting in place systems that have some similarity and so might be thought to be equivalent or analogous, turn out, when considered in more detail and, particularly, when the overall scheme and purpose of each is taken into account alongside the relevant articles and provisions of each legal instrument, that they are not after all sufficiently alike to be deemed equivalent or analogous.

99 The applicant argues that that this distinction between medicinal products and animal nutrition additives is only based on historical reasons and should not be considered relevant in present times. This is supported in their view by the fact that antibiotics, other than coccidiostats or histomonostats, shall not be authorised as feed additives[34]. The applicant argues that this means that a substance which is a medicinal product such as an antibiotic cannot be authorised as a medicinal product under Directive 2001/82/EC. Rather it must be authorised as a feed additive under Regulation 1831/2003. In the applicant's view this shows that the reasons why certain authorisation processes have to be followed do not reflect whether a certain product is indeed used as a medicinal product or not.

100 However, the Explanatory Memorandum (EM)[35] to the Animal Nutrition Additives Regulation provides more insight into the EU legislator's motivations in excluding medicinal products from authorisation as feedstuff additives. In Section 3, entitled "Scope", the EM states:

[33] See, for example paras 80-84 and 92-93 in Cerus (BL O/141/14), paras 80-84 in Leibniz (BL O/328/14) and paras 88-96 in Angiotech (BL O/466/15)

[34] Article 5(4), Regulation (EC) No 1831/2003, the Animal Nutrition Additives Regulation

[35] COM(2002) 153 final

*"Except for coccidiostats fed to healthy animals during their entire productive life, compounds used in disease prevention, namely antibiotics, are not authorised as feed additives.*

*The use of coccidiostats as feed additives will thus continue to be permitted but Maximum Residue Limits (MRLs) will be fixed in order to avoid risks to human or animal health. Under the current European system of intensive husbandry, the treatment of farmed animals, in particular poultry, by coccidiostats is, according to operators, indispensable. Therefore, if such substances could not be administered as additives, they would in any case be administered as medicate feed, with a possible increase of costs and an increase of doses…the maintaining of the status of coccidiostats as feed additives requires that a new evaluation of these substances takes place…."*

101 In my view what this is saying is that particular antibiotics used in certain low levels can be authorised as feed additives but that generally veterinary medical products are not to be authorised as feed additives. A Maximum Residue Limit is set to avoid the risks to human and animal health that higher doses may bring, for example in building resistance to antibiotics. In this particular situation, these antibiotics are not considered veterinary medicinal products. All other substances defined in Directive 2001/82/EC as veterinary medicinal products are excluded from being authorised as animal feedstuff additives under Regulation 1831/2003.

102 I also find support for this view in the fact that it is clear that the pre-mixes used to prepare medicated feedingstuffs require an approval under Directive 2001/82/EC (even though the medicated feedingstuffs prepared from these pre-mixes do not), i.e., any material that has a veterinary medicinal effect and is to be used to prepare animal feedstuffs with curative or presentative properties[36].

103 An approval under the Animal Nutrition Additives Regulation for use of low levels of coccidiostats and histomonostats[37] as feed additives is possible if the maximum level allowed are controlled so that they will not have an adverse impact downstream on health of humans or animals who consume the feed using these additives or consume animals fed on feed using these additives. This is not the same as obtaining an approval for use of an antibiotic to treat a bacterial infection in animals. The prohibition on approving antibiotics as feed additives in Article 5(4) has developed with experience because of the adverse downstream impact using these types of compounds as feed additives has had in causing a build-up of resistance to such compounds when subsequently used to treat veterinary disease. Thus, I consider that such specific provisions which refer to what can and cannot be approved under the respective legislation are not just historical artefacts, they reflect experience and are present for a reason and so need to be taken into account when making any comparison and/or assessment of what is (and is not) equivalent or analogous.

104 The applicant has previously argued that this mutual exclusion emphasises the similarity of the authorising procedures under each legal instrument because if these products were indeed fundamentally different, there would be no need to exclude the

[36] See recital (10), Article 1(5), 1(6) and 2(1) of Directive 2001/82/EC, the veterinary medicinal products directive.

[37] See article 2(j) and 2(k) of Regulation 2003/1831. These agents are used to kill or inhibit protozoa which are often found as parasites on the feed crops and/or in animal gut.

one or the other. As I have said above, I do not accept this argument. In my view, the EU legislator had deliberately chosen to make a distinction between the purpose of the products being authorised.

*Definition of Medicinal Product*

105 The active substance that is the subject of this SPC application is defined under the Animal Nutrition Additives Regulation as a technological additive, in particular: "*substances for reduction of the contamination of feed by mycotoxins: substances that can suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action*" – see Article 6(1) and Part 1(m) of Annex 1 of Regulation EC 2003/1831.

106 The applicant has argued that this microorganism which has been approved as an animal nutrition additive under Regulation EC 1831/2003 also meets the definition of a medicinal product as set out in Article 1 of Directive 2001/82/EC. At the hearing the applicant's agent explained that the microorganism acts in two ways to improve the wellbeing of the animal. Firstly, the microorganism acts on the feedstuff itself to detoxify (i.e. break down) mycotoxins that may be present on the feed before it is given to the animal. Secondly, the animal may already have ingested the mycotoxin or already have it present in their gut. In this situation, the microorganism added to the feed can also act to break down the mycotoxin in the animal's gut once it has been ingested. In effect, the applicant argues that the microorganism is acting directly on the animal in order to improve its wellbeing, i.e. by preventing the detrimental effects on the animal's health from exposure to mycotoxins . This, in the view of the applicant means that the microorganism is a substance presented for treating animals with a view to correcting or modifying physiological functions as in the definition of a medicinal product in Article 1 of the SPC Regulation.

107 However, I do not consider that this argument takes due account of the requirement that the SPC Regulation and Directive 2001/83/EC apply to medicinal products, those products that are for the treatment or prevention of disease in animals. These products are directed to the treatment of a specific disease and are tested clinically to establish that the benefit to the treatment for the specific disease provides sufficient benefit to overcome any risk identified. This is not about the general improvement of the well-being of the healthy animal provided by good quality feed additives. The active substance referred to in this application is not used for the treatment of a particular animal disease. It does not exert its effect directly on a particular disease or prevent a disease from being contracted. By delivering good quality animal feed, the general health of the animal is maintained. As indicated in the patent, if the animal feed that is treated with microorganism DSM 1178 has trichotocene mycotoxins present, it will remove a possible toxin that can inhibit animal growth, cause irritation of the gut and result in the animal needing to consume more foodstuff in order to achieve progress. I cannot ignore the fact that the scheme under which the feed additive is approved is part of the overall system for promoting agriculture and safe and effective use and movement of food within the European Union (EU). The scheme under which an active substance eligible for SPC protection is approved is not the scheme for promoting agriculture and safe and effective movement of food. I can accept that both these schemes may sit alongside each other and that it is necessary to take account of the levels at which some animal nutrition additives are being used in

animals because they can have an impact on the subsequent use of the same substance in a veterinary medicinal product. However, each will have been approved under different systems with different purposes . I am satisfied that it is just not enough to consider if the words used to define the veterinary medicinal product in Directive 2001/82/EC are the same or very similar to those used in the Animal Nutrition Additives Regulation. I would suggest that this last point may even be considered a failure on the part of the applicant to take proper account of the teleological approach in that it is not, in my view, taking proper account of the overall scheme of the legislation concerned.

*Authorisation Procedures under Directive 2001/82/EC and Regulation (EC) No 1831/2003*

108 In their correspondence with the examiner and again at the hearing, the agent for the applicant raised the similarities in the approaches used for approving a feed additive under the Animal Nutrition Additives Regulation and a veterinary medicinal product under Directive 2001/82/EC. They directed this comparison to the fact that both instruments refer to a centralised authorisation process.

109 These similarities were summarised by the applicant in a Table enclosed with their letter of 22 February 2019 which I have reproduced (see Table 2). The summary supplied by the applicant is helpful in comparing the two authorisation processes at a high level. As such, I consider that all this shows is that the Commission has adopted its standard model or approach for delivery of a community service that is related to the movement of goods and animals through the internal market, i.e. use a regulation binding on all member states as a means to achieve a similar standard or outcome across the EU, create a centralised agency to carry out a technical assessment , provide the technical assessment as an opinion to the European Commission who will decide to approve or not approve. I do not consider that this is thus very helpful in exploring just how similar or equivalent each of the respective approval processes is.

110 Thus, in order to reach a conclusion on whether the procedures are equivalent for the purposes of the SPC Regulation it is necessary to look at these in more detail. The point I must address is the fact the different European agencies set up under different EU legislation and carrying out a different set of assessments ruled by a different set of criteria are involved.

111 In the case of a veterinary medicinal product, it is the EMA, established under Regulation (EC) No 726/2004[38], which makes a technical assessment of the application. The contents of the application are governed by Article 31 (1) of Regulation (EC) No. 726/2004 in conjunction with Article 12(3)(a) - (p) of Directive 2001/82/EC. Of particular relevance to this case are the requirements for the application to include the results of tests done on the veterinary medicinal product (see Art. 12(3)(j) of Directive 2001/82/EC), such as pharmaceutical tests, safety tests, residue tests, pre-clinical and clinical trials and tests assessing the potential risks posed by the medicinal product for the environment. The detailed approach to be

[38] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

***Table 2.*** *A comparison of the centralised procedure used to approve additives for use in animal nutrition and veterinary medicinal products as set down in the respective regulations*

| | **Regulation (EC) No. 726/2004 and Directive 2001/82/EC veterinary medicinal products** | **Regulation 1831/2003 (additives for use in animal nutrition** |
|---|---|---|
| **Application must be submitted to European Agency** | Applicant applies directly to the European Medicines Agency | Commission forwards application to European Food Safety Authority |
| **Studies on animal health and environment are necessary** | Yes | Yes |
| **European Agency drafts an opinion which is examined by the Commission** | Yes<br><br>Opinion prepared by European Medicines Agency | Yes<br><br>Opinion prepared by European Food Safety Authority |
| **The Commission adopts a decision on the market authorisation** | Yes | Yes |
| **Market authorisation document** | Decision to grant an authorisation (sent to applicant) | Commission Implementing Regulation published online – available for all |

followed is set out down in Annex 1 to the directive. The purpose is to provide a risk-benefit profile for the use of the veterinary medicinal product directly in animals to achieve a clinical outcome – cure or prevention of disease.

112 For animal nutrition additives, it is the European Food Safety Authority (EFSA) established under Regulation 178/2002[39] that makes a technical assessment of the application. The contents of the application are governed by Article 7(3) of the same regulation. In particular, the application must include the results of studies conducted to ensure the feed additive does not have an adverse effect on animal or human health or the environment[40], and the additive favourably affects animal production, performance or welfare[41]. However, these effects are not direct medicinal effects, they are downstream, the feed additive is added to the feed and is targeted to contaminants in the feed. The feed additive is not a product which exerts its effect in

[39] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

[40] Article 5(2)(a) of Regulation (EC) No 1831/2003, the Animal Nutrition Additives Regulation

[41] Article 5(3)(f) of Regulation (EC) No 1831/2003, the Animal Nutrition Additives Regulation

the animal directly to cure or prevent a disease or condition where it is necessary to restore, correct or modify a physiological function to bring about this outcome.

113 For the microorganism that is the subject of the present SPC application, the safety and efficacy tests are summarised in two scientific opinions of the EFSA[42]. Both of these opinions relate to the safety and efficacy of microorganism DSM 11798 when used as a feed additive for pigs or chickens. It is clear that both opinions have been given in the context of approving a feed additive and that the standards for compliance are those set out in Regulation (EC) 1831/2003 (in particular the requirements of Article 5). For example, the first paragraph of the summary of the 2013 report reads as follows:

> *"Following a request from the European Commission, the Panel on Additives and Products or Substance used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety for the target animals, consumers, users and the environment and the efficacy of a bacterial product when used as a technological additive to reduce the concentration of contaminating trichothecene mycotoxins in feed."*

The Background and Terms of Reference sections of the report further make it clear that the task of the EFSA is to deliver an opinion of safety and efficacy of the microorganism **in the context of its use as a feed additive**.

114 It is my view that I cannot ignore the context in which the marketing authorisation for the microorganism subject of this SPC application has been made. Safety and efficacy test results were submitted with a view to meeting the criteria for feed additives as required under Article 5 of Regulation (EC) No 1831/2003. While these criteria include ensuring that the feed additive shall not have an adverse effect on animal health and shall favourably affect animal welfare, I do not consider that this is the same standard that is required for the microorganism to be authorised as a veterinary medicinal product under Directive 2001/82/EC. The efficacy of the microorganism has been assessed to determine if it is effective in detoxifying mycotoxins present in animal feed. It has not, in my view, been tested for its effectiveness in treating or preventing disease in the animal or in restoring, correcting or modifying physiological functions in sick animals experiencing. Similarly, tests on safety of the microorganism are focussed on whether it has an adverse effect on animals when it is administered as an additive to feed to detoxify mycotoxins that may be present on the feed.

115 The centralised agencies involved in each of these assessment procedures will still only be required to carry out the assessment necessary to meet the requirements of the legislation under which the assessment has been put in place. As discussed in the Cerus, Leibniz and Angiotech decisions[23] already mentioned, the competent body carrying out the assessment to determine approval can be doing so under a number of different pieces of legislation and just because it is doing so does not mean that all these assessments will be deemed to be analogous or equivalent. .

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[42] Scientific Opinion on the safety and efficacy of micro-organism DSM 11798 when used as a technological feed additive for pigs, EFSA Journal 2013; 11(5): 3203 and Safety and efficacy of microorganism DSM 11798 as a technological additive for all avian species. EFSA Journal 2017; 15(1):4676.

***Table 3**: A detailed comparison of the two authorisation processes (see also Table 2):*

| Veterinary Medicines | Animal Feed Additives |
|---|---|
| 1. Submit application to the European Medicines Agency (EMA) (Art. 4(1) Regulation (EU) No. 726/2004). | 1. Submit application to the Commission (Art. 7 Regulation 1831/2003) |
| Contents of the application:<br>(Art. 31 (1) of Regulation (EU) No. 726/2004 in conjunction with Art. 12(3)(a) - (p) of Directive 2001/82/EC).<br><br>(a) applicant name;<br><br>(b) product name;<br><br>(c) qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non-proprietary name or its chemical name;<br><br>(d) description of the method of manufacture;<br><br>(e) therapeutic indications, contra-indications and adverse reactions; | Contents of the application:<br>(Art. 7(3) Regulation 1831/2003)<br><br>(a) applicant name and address;<br><br>(b) the identification of the feed additive, a proposal for its classification by category and functional group, and its specifications, including, where applicable, purity criteria;<br><br>(c) a description of the method of production, manufacturing and intended uses of the feed additive, of the method of analysis of the additive in feed according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites, in food;<br><br>(d) **a copy of the studies which have been carried out and any other material which is available to demonstrate** |

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| (f) dosage, pharmaceutical form, method and route of administration and proposed shelf life;<br><br>(g) reasons for any precautionary and safety measures when storing, administering product and disposing of waste, **indication of potential risks to the environment, to human and animal health and to plants**;<br><br>(h) indication of the withdrawal period in the case of medicinal products intended for food-producing species;<br><br>(i) description of the testing methods;<br><br>(j) **test results (pharmaceutical, safety tests, residue tests, pre-clinical and clinical trials, tests assessing the potential risks posed by the medicinal product for the environment)**<br><br>(k) a detailed description of the pharmacovigilance and risk management systems;<br><br>(l) a summary of the product characteristics, a mock-up of the immediate packaging and the outer packaging and the package leaflet;<br><br>(m) a document showing that the manufacturer is authorised in his own country to produce veterinary medicinal products;<br>(n) copies of any marketing authorisation obtained in another Member State or in a third country; | **that the feed additive satisfies the criteria laid down in Article 5(2) and (3).**<br><br>*i.e. feed additive does not:*<br>*(a)* ***have an adverse effect on animal health, human health or the environment,***<br>*(b) be presented in a manner which may mislead the user,*<br>*(c) harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.*<br><br>*And, feed additive shall:*<br>*(a) favourably affect the characteristics of feed,*<br>*(b) favourably affect the characteristics of animal products,*<br>*(c) favourably affect the colour of ornamental fish and birds,*<br>*(d) satisfy the nutritional needs of animals,*<br>*(e) favourably affect the environmental consequences of animal production,*<br>*(f)* ***favourably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs****, or*<br>*(g) have a coccidiostatic or histomonostatic effect.*<br><br>(e) proposed conditions for placing the feed additive on the market, including labelling requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), use levels in complementary feedingstuffs and animal species and categories for which the feed additive is intended;<br><br>(f) a written statement that three samples of the feed additive have been sent by the applicant directly to the |

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| (o) proof applicant has the services of a qualified person responsible for pharmacovigilance and necessary means for the notification of any adverse reaction;<br><br>(p) in the case of veterinary medicinal products intended for one or more food-producing species and containing one or more pharmacologically active substances not yet included, for the species in question, in Annexes 1, 11 or 111 to Regulation (EEC) No 2377/90, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with the aforementioned Regulation. | Community reference laboratory referred to in Article 21, in accordance with the requirements set out in Annex II,<br><br>(g) for additives which, according to the proposal under point (b), do not belong to either category (a) or category (b) referred to in Article 6(1), and for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, a proposal for post-market monitoring;<br><br>(h) a summary containing the information provided under points (a) to (g);<br><br>(i) for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs, details of any authorisation granted in accordance with the applicable legislation. |
| 2. **Committee for medicinal products for veterinary use of the EMA** gives an opinion on the application (Art. 55, Art. 56(1)(b) and Art. 32(1) of Regulation (EU) No. 726/2004) | 2. Commission sends application to the European Food Safety Authority (EFSA) (Art 7(1) Regulation 1831/2003)<br><br>**EFSA gives an opinion on the application** (Art. 8(1) Regulation 1831/203) |
| 3. Opinion forwarded to the Applicant, the Commission and the Member States (Art. 34(1) of Regulation (EU) No. 726/2004). | 3. Opinion forwarded to the applicant, Commission and Member States (Art 8(5) Regulation 1831/2003) and made publicly available (Art 8(6) Regulation 1831/2003) |
| 4. Commission prepares a draft decision and forwards it to Applicant and Member States (Art 35(1) Regulation (EU) No. 726/2004) | 4. Commission prepares a draft Implementing Regulation |

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| Draft decision adopted in accordance with procedure of Article 87(3) of Regulation (EU) No. 726/2004 with reference to Art. 4 and 7 of Decision 1999/468/EC.<br><br>Commission submits the draft decision to a Committee composed of the representatives of the Member States. If the Committee has no concerns on the draft, the decision shall be adopted by the Commission. | Draft authorization adopted in accordance with the procedure referred to in Article 22(2) of Regulation (EC) 1831/2003 with reference to Art. 5 and 7 of Decision 1999/468/EC.<br><br>Commission submits the draft decision to a Committee composed of the representatives of the Member States. If the Committee has no concerns on the draft, the decision shall be adopted by the Commission. |
| 5. Commission takes final decision (Art 38(1) Regulation (EU) No. 726/2004) and notifies applicant (Art. 81 (1) of Regulation (EU) No. 726/2004). | 5. Commission adopts the Implementing Regulation |
| 6. Authorisation and EPAR published in OJEU (Art. 38(2) and (3) of Regulation (EU) No. 726/2004) | 6. Commission Implementing Regulation published in Community register of feed additives (Art 17 Regulation 1831/2003) |

For example, in the UK, the MHRA carries out assessments on medical devices and medicinal products but does not consider that these assessments are equivalent (see paras 80-84 & 92-93 in Cerus decision)[23]. I do not agree with the applicant's view that the authorisation processes are highly similar and that they should be considered analogous. I do not consider that the assessment made by the EFSA in relation to the microorganism's use as an animal feedstuff additive under Regulation (EC) No. 1831/2003 is equivalent to an assessment of the EMA in relation to a substance to be authorised as a veterinary medicine. Therefore, the marketing authorisation presented in support of the present SPC application has not been subject to a procedure that can be considered the same as the that under Directive 2001/82?EC, and as such is not considered to within the scope of Article 2 or to be "*in accordance with*" Directive 2001/82/EC as required by Article 3(b) of the SPC Regulation.

*Relevance of CJEU Judgment C-527/17 Boston Scientific*

116 I find support for my view in the CJEU decision in the *Boston Scientific* case. The examiner argued that paragraph 27 of this judgement makes clear that Article 3(b) of the SPC regulation is interpreted narrowly and that the application for an SPC must fall within the scope of Article 2. He considered that this is a general point and not limited to either SPC regulation or the fact that the question referred in this case related to an approval under the medical devices directive.

117 Although the case concerned the question of whether an approval granted under the Medical Devices Directive could be considered in the same way as an approval granted under the human medicinal products directive, Directive 2001/83/EC, this decision made some general points about how to apply the SPC regulation. The CJEU stated that the SPC regulation applies only to products used as medicinal products. In reaching their judgement the CJEU considered the objectives of the SPC regulation. At paragraph 43 the court pointed out that:

> *"it is apparent from Article 4 of Regulation No 469/2009 that an SPC can only protect a product which is used as a medicinal product".*

The court then went on to say, at paragraph 44, that

> *"it is apparent from the title of that regulation and from recitals 3, 4, and 8 to 10 thereof that the EU legislature intended to reserve the grant of SPCs to medicinal products alone"*

118 The applicant has argued that the CJEU ruling in *Boston Scientific* is not relevant on the grounds that the present application does not relate to a medical device. While it is the case that *Boston Scientific* relates to a medical device, the question that was asked concerns how to decide if an approval granted under another EU legal instrument can be considered to be equivalent to that granted under the Human Medicinal Products Directive. If they are equivalent, then this would suggest that, in the present case, an approval under the Animal Nutrition Additives Regulation would serve as an authorisation for the purposes of Article 2 and for the grant of an SPC under Article 3(b) of the SPC regulation. In this situation the approval provided under the Animal Nutrition Additives Regulation would be for an active substance that falls under the definition of a medicinal product under both the Veterinary Medicinal Products Directive and under the SPC regulation. As the judgement concluded that

SPCs can only be granted for medicinal products, then the current application can be considered to fall within this requirement. The microorganism strain, in the view of the applicant, meets the definition of a medicinal product and it achieves "*its principal mode of action by pharmacological, immunological or metabolic means*" which was found not to be the case for the product at issue in the *Boston Scientific* case. However, as I have indicated above, I do not agree that the microorganism that is the subject of this SPC application does meet the definition of a medicinal product under the Veterinary Medicinal Products Directive and the SPC Regulation

119 It is my view that these general conclusions in the *Boston Scientific* case are also applicable to the present application. The Court has said that the clear intention of the EU legislature was to reserve SPC protection for medicinal products. The active substance of the present application for which SPC protection is sought has not been authorised to be placed on the market as a medicinal product. Although, the definition of medicinal product under the SPC regulation appears to apply to the microorganism in question, the definition cannot be considered separately from the overall purpose and scheme of the EU legislataion it applies to. Just because the microorganism might also appear to meet the definition under the SPC regulation and Directive 2001/82/EC is not enough. The actual assessment carried out in terms of the relevant testing and other requirements as set down in the Veterinary Medicinal Products Directive including the identification and characterisation of the veterinary disease to be treated must also be part of this consideration. I am not convinced that an assessment under the Animal Nutrition Additives Regulation to determine if the proposed additive meets the requirements of Article 5(2) and 5(3) of this regulation is sufficient.

120 The applicant suggests the fact that the authorisation process under both instruments is carried out by a centralised body at European level is also a factor which distinguishes the present application from the conclusion in *Boston Scientific*. I do not agree. Firstly, an authorisation for a veterinary medicinal product can be carried out by a national competent body under the mutual recognition and decentralised procedures (see Chapter 4, Article 31 et seq. of Directive 2001/82/EC) and not just under the centralised procedure provided by the EMA.

121 Furthermore, as I have discussed above, I consider that there was, what I shall refer to as, a pointer between the Medical Devices Directive and the Human Medicinal Products Directive in the situation in *Boston Scientific* because of the fact that the Medical Device Directive did refer to the approval process carried out on a device involving a substance as being verified by analogy with the process described in the Human Medicinal Products Directive. The CJEU concluded at paragraph 40 that:

> *"a substance does not fulfil any of the conditions laid down in Article 2 of Regulation No 469/2009 in order to be eligible for an SPC, even if the quality, safety and usefulness of that substance are verified by analogy with the methods specified in Annex I to Directive 2001/83."*

Therefore, even if a substance has undergone a highly similar authorisation process – which is even more closely matched that the two we are looking at in the present case - it still would not fulfil the conditions of Article 2 of the SPC Regulation.

## Relationship between this SPC Application and SPC Application SPC/GB17/076

122 The applicant considers that there is no reason why both of these SPC applications cannot be granted even though they both relate to the same active substance, i.e. "*Microorganism DSM 11798 of the Coriobacteriaceae family*", as set down in the respective Patents Form SP1 for each application.

123 The SPC under this application (SPC/GB17/075) concern the use of the microorganism active substance in a veterinary medicinal product whereas the SPC under application SPC/GB 17/076 relate to the same active substance for use in a plant protection product.

124 Although the applicant is using the same authorisation under the Animal Nutrition Additives Regulation in support of both of these SPC applications, they have been differentiated by claiming equivalence between the approval under the Animal Nutrition Additives Regulation and Directive 2001/82/EC in this application while at the same time also claiming equivalence between the same approval under the Animal Nutrition Additives Regulation and that under Regulation (EC) 1107/2009, the plant protection products to market regulation[43] .

125 In support of their argument that the SPC regulation and plant protection products regulation should be consider separately, the applicant provided a translation of a decision from the national court in Hungary which is the first instance appeal court for decisions from the Hungarian Patent Office which concluded that an SPC could be granted for the active substance in a plant protection product even though there was an earlier SPC for the same active substance in a veterinary medicinal product.

126 In my analysis above I have concluded that the equivalence that the applicant claims between the Animal Nutrition Additives Regulation and the Directive 2001/82/EC decision is not justified and hence this application for an SPC for an active substance in a veterinary medicinal product fails.

127 However, if this case is subject to appeal and my decision was found to be in error and that this SPC application does in fact meet the requirements of Article 2 and Article 3(b) of the SPC regulation, it will be necessary to consider if the present applicant is entitled to hold a second SPC for the same active substance in accordance with Article 3(2) of Regulation EC 1610/96, the plant protection products SPC regulation.

## Conclusions

128 Taking all of the above into account, I do not consider that an approval issued under Regulation (EC) 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition meets the requirement under

[43] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC – see EUR-Lex database of EU legislation at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1107&qid=1607018248784

Article 2 of the SPC regulation that the product for which an SPC is being sought has been subject to an administrative authorisation procedure as laid down in Directive 2001/82/EC. Thus, this application for an SPC is considered to fall outside the scope of the SPC Regulation.

129 As a consequence, I consider that neither Commission Implementing Regulation EU2017/930 of 31 May 2017 concerning the authorisation of a preparation of a micro-organism strain DSM 11798 of the Coriobacteriaceae family as a feed additive for all avian species and amending Implementing Regulation (EU) No 1016/2013 of 23 October 2013 or Commission Implementing Regulation (EU) No 1016/2013 concerning the authorisation of a preparation of a micro-organism strain DSM 11798 of the Coriobacteriaceae family as a feed additive for pigs can be deemed to meet the requirement under Article 3(b) of the SPC Regulation for a valid authorisation to place the product that is the subject of the SPC application (i.e. *microorganism DSM 11798 of the Coriobacteriaceae family)* on the market as a medicinal product in accordance with Directive 2001/82/EC.

130 As a consequence of my finding in relation to Article 2 and Article 3(b), I do not need to consider the situation in relation to Article 7 of the SPC regulation

131 As I have concluded that application SPC/GB17/075 does not meet the requirements laid down in the SPC Regulation, this application is rejected under Article 10(2).

## Appeal

132 Any appeal must be lodged within 28 days after the date of this decision.

Dr L Cullen

Deputy Director, acting for the Comptroller