Intellectual Property Office

BL O/732/21

05 October 2021

COUNCIL REGULATION (EC) No. 1610/96
CONCERNING THE CREATION OF A
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR PLANT PROTECTION PRODUCTS

APPLICANT	Erber Aktiengesellschaft
ISSUE	Whether application for supplementary protection certificate SPC/GB17/076 meets the requirements of Article 2 and Article 3(1)(b) of the Regulation
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to supplementary protection certificate (SPC) application SPC/BG17/076 ("the application") for a plant protection product filed in the name of Erber Aktiengesellschaft ("the applicant") on 30 November 2017[1]. The active substance that 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. This 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 inhibited growth of the animal. The patent describes how the microorganism converts trichothecenes by biochemical degradation in a controlled manner into substances which are physiologically harmless to the animal. The examples given in the patent all relate to feeds for pigs and chickens.

[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.

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 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. In turn, Commission Implementing Regulation (EU) No 1016/2013 of 23 October 2013 concerned the authorisation of a preparation of micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs.

5 Both of these Commission implementing regulations 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')[2]. 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.

6 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) [3].

7 The examiner objected to the registration of an SPC under Regulation (EC) 1610/96 (the "Plant Protection SPC Regulation")[4] on the grounds that the application did not comply with Article 2 or Article 3(1)(b) of that regulation. With regards to Article 2, the examiner objected on the grounds that the authorisation provided had not been subject to an administrative authorisation as laid down in Regulation 1170/2009 (hereafter the "Plant Protection Products to Market Regulation")[5]. Thus, as the application was not within the scope of Article 2, the requirement of Article 3(1)(b) of the Plant Protection SPC Regulation for a valid authorisation to place the product on the market as a plant

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[2] Regulation (EC) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; CELEX Document number: 32003R1831; published in Official Journal of the European Union L 268 on 18.10.2003.

[3] 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 01.06.2017.

[4] Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products; CELEX Document number: 31996R1610; published in Official Journal of the European Union L 198 on 08.08.1996.

[5] 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; CELEX Document number: 32009R1107; published in Official Journal of the European Union L 309 on 24.11.2009.

***Table 1**: A comparison of the documents filed in support of SPC application SPC/GB17/076 and the relevant date is shown in Table 1 for ease of reference.*

SPC Application		
Application No.	SPC/GB17/076	
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	

protection product in accordance with the Plant Protection Products to Market Regulation[5] had not been fulfilled. The examiner was of the view that the authorisation process under the Animal Nutrition Additives Regulation[2] was not the same as the authorisation process under Plant Protection Products to Market Regulation[5]. The examiner did not find any indication in either the Plant Protection Products to Market Regulation[5] or the Animal Nutrition Additives Regulation[2] that the legislator had intended products authorised under the latter to be amenable to SPC protection.

8 The examiner also raised objection under Article 7 of the Plant Protection SPC Regulation[4] on the grounds that the basic patent was granted in 2005 and the first authorisation (Commission Implementing Regulation (EU) 1016/2003) for the product was granted in 2013. The application was lodged in 2017, therefore a period of more than 6 months had expired since the authorisation for the product was granted.

9 The applicant disagreed with the examiner's assessment and submitted that an approval under Animal Nutrition Additives Regulation[2] was equivalent to a marketing authorisation under Plant Protection Products to Market Regulation[5]. The applicant set out in detail the similarities and differences between the authorisation processes under the Animal Nutrition Additives Regulation[2] and Plant Protection Products to Market Regulation[5]. In the view of the applicant, the requirement of Article 3(1)(b) of the Plant Protection SPC Regulation[4] had been met as the authorisation process under the Animal Nutrition Additives Regulation[2] was equivalent to one the Plant Protection Products to Market Regulation[5]. The examiner rejected this last point referring to the reasoning of the judgement of the CJEU in case C-527/17, *Boston Scientific Ltd* (hereafter *Boston Scientific*)[6].

10 Further correspondence between the applicant and examiner failed to resolve matters and the applicant requested a hearing. The case 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*)[7] 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*)[8]. 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/GB17/075 (from the same applicant and relating to the same active substance) 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

[6] CJEU judgement in case *C-527/17, Boston Scientific Ltd. v Deutsches Patent und Markenamt (25 October 2018).*

[7] CJEU judgement in case *C-130/11, Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents, Designs and Trade Marks (19 July 2012).*

[8] CJEU judgement in case *C-673/18, Santen SAS v Directeur-général de l'Institut National de la Propriété Industrielle (20 July 2020).*

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 (see letter dated 20 September 2020) indicating that "*Santen should not be relevant to the approach taken in the UK to Articles 3(d)/3(1)(d) (as applicable)*".

12 I apologise that it has taken me some time to complete and issue my decision.

Related decision

13 As noted above, this is the second of two SPC applications made by this applicant in relation to the active substance "*microorganism DSM 11798 of the Coriobacteriaceae family*". In the earlier application, the applicant was seeking an SPC for this active substance as part of a veterinary medicinal product. Please refer[9] to Intellectual Property Office (IPO) decision BL O/610/20, dated 4 December 2020, for further details on the application for an SPC under the medicinal products SPC regulation[10].

The Relevant Law

14 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.

15 In this case, we are concerned with (i) the plant protection SPC regulation[4]; (ii) the Plant Protection Products to Market Regulation[5]; and (iii) the Animal Nutrition Additives Regulation[2]. I have reproduced the relevant parts of this legislation below (with my emphasis added in **bold**).

The Plant Protection SPC Regulation – Regulation 1610/96

16 Recitals (3) to (6) are useful in setting out the purpose of the regulation concerning the creation of SPC protection for plant protection products. They are as follows:

> *….*
>
> *(3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;*
>
> *(4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is*

[9] For full decision, see BL O/610/20 (Erber Aktiengesellschaft), dated 4 December 2020, at https://www.ipo.gov.uk/p-challenge-decision-results/o61020.pdf.

[10] Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products; CELEX Document number: 32009R0469; published in Official Journal of the European Union L 152 on 16.06.2009

equivalent to that granted to medicinal products by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (4);

(5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

(6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector,

17 Recital (17) relates to the relationship between the plant protection SPC regulation[4] and the SPC regulation[11] . It states as follows:

(17) ***Whereas the detailed rules*** *in recitals 12, 13 and 14 and* ***in Articles 3 (2),*** *4, 8 (1) (c) and 17(2)* ***of this Regulation are also valid, mutatis mutandis****, for the interpretation in particular of recital 9 and* ***Articles 3,*** *4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92.*

Please note that Council Regulation (EEC) No 1768/92 has been codified and replaced by the SPC regulation[8].

18 Article 1 defines '*plant protection products*', '*active substances*', '*plant products*', '*harmful organisms*' and '*product'* as follows in so far as they relate to the present case:

1. 'plant protection products': active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms,

…

3. 'active substances': substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms; or

(b) on plants, parts of plants or plant products:

…

6. 'plant products': products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves, …

7. 'harmful organisms': pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;

8. 'product': the active substance as defined in point 3 or combination of active substances of a plant protection product;

9. …

19 Article 2 defines the scope of the regulation and reads as follows:

> ***Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC****, or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before Directive 91/414/ EEC was implemented by the Member State concerned,* ***may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.***

Please note that Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection on the market was repealed and superseded by the Plant Protection Products to Market Regulation (Regulation (EC) No 1107/2009 of 23 July 1996)[12]. Thus, all references to Directive 91/414/EEC in the plant protection SPC regulation, such as above, should be read as references to the corresponding article in the Plant Protection Products to Market Regulation.

20 Article 3 defines the conditions for obtaining a certificate as follows:

> *1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:*
>
> *(a) the product is protected by a basic patent in force;*
>
> ***(b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;***
>
> *(c) the product has not already been the subject of a certificate;*
>
> *(d) the authorization referred to in (b) is the first authorization to place the product on the market as a plant protection product.*
>
> *2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.*

21 Article 4 entitled 'Subject-matter of protection' states

[12] The Plant Protection Products to Market Regulation [Regulation (EC) No 1107/2009 of 23 July 1996] repealed Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. See Article 83 of Plant Protection Products to Market Regulation.

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

22 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 authorization referred to in Article 3 (1) (b) to place the product on the market as a plant protection product was granted.

2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

23 Article 8 concerns the contents of an application for an SPC and specifies:

1. The application for a certificate shall contain
(a) …

(b) a copy of the authorization to place the product on the market, as referred to in Article 3 (1) (b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I (points 1-7) or B.I (points 1-7) of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged;

(c) …

The Plant Protection Products to Market Regulation - Regulation 1107/2009[4]

24 As noted already, this regulation repealed and replaced Council Directive 91/414/EEC[13]. In my discussion and analysis below, I will refer to the relevant recitals and article of this regulation rather than to Directive 91/414/EEC.

25 Recitals (6) to (8) provide useful insight into the purpose of the regulation and state as follows:

(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.

(7) Plant protection products can however also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used.

[13] See Article 83 of Plant Protection Products to Market Regulation (see footnote 4)

> *(8)* ***The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture.*** *Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*

26 Recital (12) clarifies the roles of three different participants in the approval process, namely the Member States (highlighted in yellow), the European Food Safety Authority (EFSA) (highlighted in green), and the European Commission (highlighted in grey):

> *(12) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a rapporteur for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority established by 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 Authority). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active substance. Provisions should be included to ensure the transparency of the evaluation process.*

27 The subject matter and purpose of the regulation are set out in Article 1 as follows:

> *1. This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community.*
>
> *2. This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.*
>
> *3.* ***The purpose of this Regulation is to ensure*** *a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market* ***through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.***
>
> *4.* ***The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.*** *In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.*

28 Article 2 sets out the scope of the Regulation as follows:

1. This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances*, safeners or synergists,* ***and intended for one of the following uses:***

(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

(c) preserving plant products, *in so far as such substances or products are not subject to special Community provisions on preservatives;*

(d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

(e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants. ***These products are referred to as 'plant protection products'****.*

2. This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.

3. This Regulation shall apply to the following:

(a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as 'safeners';

(b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as 'synergists';

(c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants';

(d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'.

29 Article 3 defines '*plant products'*, '*harmful organisms'*, '*authorisation of a plant protection product'*, '*micro-organisms*', '*rapporteur Member State'*, and '*tests and studies*' as follows:

For the purposes of this Regulation, the following definitions shall apply:

1. …

6. 'plant products' means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying, or pressing, but excluding plants;

7. 'harmful organisms' means any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products;

8. …

10. 'authorisation of a plant protection product' means an administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory;

11. …

15. 'micro-organisms' means any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;

16. …

22. 'rapporteur Member State' means the Member State which undertakes the task of evaluating an active substance, safener or synergist;

23. 'tests and studies' means investigations or experiments whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products;

24. …

30 Article 4 sets out the approval criteria for active substances:

*1. **An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3**.*

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2. …

*3. **A plant protection product,** consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, **shall meet the following requirements:***

(a) it shall be sufficiently effective;

(b) it shall have no immediate or delayed harmful effect on human health, *including that of vulnerable groups,* ***or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;***

(c) *it shall not have any unacceptable effects on plants or plant products;*

(d) *it shall not cause unnecessary suffering and pain to vertebrates to be controlled;*

(e) shall have no unacceptable effects on the environment, *having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:*

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem

As referred to in this article, further detail of the approval procedure for active substances is provided in Annex II to this regulation. This is a lengthy and detailed Annex and I have referred below only to those sections which are relevant to the present application for an SPC.

31 Article 7 sets out the approval procedure for an active substance:

1. An application for the approval of an active substance *or for an amendment to the conditions of an approval* ***shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2)*** *or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.*

…

The application shall be examined by the Member State *proposed by the applicant, unless another Member State agrees to examine it.*

…

4. ***When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2)*** *and a list of any claims for data protection pursuant to Article 59.*

5. When assessing the application, the rapporteur Member State may at any time consult the Authority.

32 The content of the dossier to be submitted by the applicant are specified by Article 8(1) and 8(2):

1. The summary dossier shall include the following:

(a) ***information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met;*** *where the information submitted does not cover all zones or concern a crop which is not widely grown, justification for this approach;*

(b) for each point of the data requirements for the active substance, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

(c) for each point of the data requirements for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

(d) (d) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

(e) a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

(f) the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

(g) where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(h) an assessment of all information submitted.

2. ***The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1.*** *It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.*

33 Chapter III relates to the approval of plant protection products. Article 28 specifically sets out the requirements for placing a plant protection product on the market and states:

1. A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.

34 Article 29 sets out the requirements for authorisation:

1. Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principle referred to in paragraph 6 it complies with the following requirements:

(a) its active substances, safeners or synergists have been approved;

(b) …

(d) its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

(e) in light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

(f) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;

(g) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in all Member States, with appropriate limits of determination on relevant samples;

(h) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

(i) for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.

…"

Annex II of the Regulation

35 Section 3 of Annex II relates to the criteria used in the approval of an active substance. Subsection 3.1 sets out requirements for the dossier to be submitted with the application:

3. Criteria for the approval of an active substance

3.1. Dossier

The dossiers submitted pursuant to Article 7(1) shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).

In the case of an active substance, *safener or synergist* ***for which one or more representative uses includes use on feed*** *or food crops or leads indirectly to residues in food or feed,* ***the dossier submitted pursuant to Article 7(1) shall contain the information necessary to carry out a risk assessment and for enforcement purposes.***

The dossier shall in particular:

(a) permit any residue of concern to be defined;

(b) reliably predict the residues in food and feed, including succeeding crops;

(c) reliably predict, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;

(d) permit a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;

(e) permit, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

36 Subsection 3.2 of Annex II sets out the requirement to show the active substance is effective:

3.2. Efficacy

An active substance *alone or associated with a safener or synergist* ***shall only be approved where it has been established for one or more representative uses that the plant protection product****, consequent on application consistent with good plant protection practice and* ***having regard to realistic conditions of use is sufficiently effective****. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).*

The Animal Nutrition Additives Regulation – Regulation EC 1831/2003[2]

37 This regulation repealed and replaced Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs[14]. It has undergone a number of amendments since it first came into force. The references to Articles and other parts

[14] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs - see consolidated text on the EUR-Lex website at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01970L0524-20100901&qid=1606959126688 (accessed 31.08.2021).

of this regulation below are to the version that was in force when the present SPC application was filed in 2017.

38 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.*

39 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.

40 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.*

41 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 which set down the general principles of food law and food safety in the Community and established the European Food Safety Authority (EFSA)[15]. The definition of feed and feeding stuff from Regulation (EC) No 178/2002 are particularly identified[16], i.e.; "*feed" (or "feeding stuff") means any substance or product, including*

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[15] 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.

[16] Article 1 of this regulation 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.

additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;"

42 For the purposes of the present decision, the following definitions 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;

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

(l) ….

(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

43 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.

44 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:***

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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.

(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.

45 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 ……

46 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.*

47 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, as follows.

> *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. …*

48 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;***

49 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.

50 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.

51 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).

52 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[17]. 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****.*

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*

[17] 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.

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. ….

53 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. ….

54 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.

How this Regulation works

55 Insofar as it is relevant to the matters at issue in this case, I will summarise the system for approval of additives for use in animal nutrition set up under this Regulation works[18]:

(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.

[18] See description of Roel of the EFSA in dealing with Feed Additive applications at https://www.efsa.europa.eu/en/applications/feedadditives

(vi) Additives intended for use in animal nutrition must receive a favourable opinion from EFSA before being granted authorisation (by the Commission) 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.

Relevant Case Law

Court of Justice of the European Union (CJEU) judgment C-527/17, Boston Scientific[6]

56 This judgement 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.

57 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[19] rather than a marketing authorisation for a human medicinal product under Directive 2001/83/EC[20].

58 Boston Scientific Ltd 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™) coated in Paclitaxel.

59 The substance Paclitaxel had previously been known as the principal active ingredient in treating certain cancers and had been marketed 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 Directive 2001/83 concerning medicinal products.

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

[20] 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.

60 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.

61 The court considered, at paragraph 27, that it is 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*".

62 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.*

63 The court then considered the intention of the legislator, stating at paragraph 44, that:

> *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.*

64 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.

Issue to be decided

65 The first issue to be decided is whether the authorisation provided in support of this application (i.e., an approval under the Animal Nutrition Additives Regulation[2]) is a valid authorisation to place the product on the market as a plant protection product in accordance with the Plant Protection Products to Market Regulation as required by Article 2 and Article 3(1)(b) of the Plant Protection SPC Regulation. Both of these articles indicate that the authorisation provided in support of the SPC application must be one that meets the requirements of "*Article 4 of Directive 91/414/EEC"* or *"an equivalent provision of national law*". If the authorisation provided is considered not to meet the requirements of Article 2 of the Plant Protection SPC Regulation, then it is outside the scope of this regulation and there is no need to consider the application further. If the authorisation is considered to fall within the scope of Article 2, then it is necessary to consider if it is a valid authorisation under Article 3(1)(b) to place a plant protection product on the market in the UK

66 Should I decide that the authorisation under the Animal Nutrition Additives Regulation[2] is a valid authorisation under Article 2 and Article 3(1)(b), I will then need to consider the second issue as to whether the authorisation filed in support of the application was filed within the appropriate period for doing so under Article 7(1) of the Plant Protection SPC Regulation. The application refers to two authorisations in support of this SPC application – Commission Implementing Regulation EU 2017/930 dated 31/05/2017 and Commission Implementing Regulation EU 1016/2013 dated 23/10/2013. If it is necessary for me to consider this second issue, it will be necessary to confirm that Commission Implementing Regulation EU 2017/930 dated 31/05/2017 is the appropriate authorisation for the purpose of Article 7(1) and not Commission Implementing Regulation EU 1016/2013 dated 23/10/2013.

Role of the IPO in granting SPCs in the UK

67 It is relevant at this point to note that, as the body responsible for granting SPCs in the UK (see Article 9 of the plant protection SPC regulation), the role of the IPO is to determine if the applications received meet the requirements of the plant protection SPC regulation, in particular, Article 3. The IPO is not involved in the regulatory processes that lead to the grant of a marketing authorisation for a plant protection product. In the period relevant for this application, the latter was the responsibility of the Health and Safety Executive (HSE) at the national level in the UK[21] and of the European Food Safety Agency (EFSA) at the Community wide level[22]. The analysis below is based on my consideration and comparison of the Plant Protection Products to Market Regulation[5] with the Animal Nutrition Additives Regulation[2], in the versions

[21] See https://www.hse.gov.uk/brexit/regulating-pesticides.htm - **Health & Safety Executive** (HSE) (authorisation of plant protection products). The HSE is an executive agency of the Department of Environment, Food and Rural Affairs (Defra) in the UK (accessed 31.08.2021).

[22] See https://www.efsa.europa.eu/en - website of **European Food Safety Authority** (EFSA) (accessed 31.08.2021) describing its various roles and functions; see role of EFSA in dealing with authorisations for plant protection products at https://www.efsa.europa.eu/en/applications/pesticides

that were in force when the present SPC application was made, in so far as it is necessary to establish whether an approval under the latter can considered to fulfil the requirements of the former and so enable SPC protection under the plant protection SPC regulation.

The View of the Applicant

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

(a) The authorisation processes under the Plant Protection Products to Market Regulation[5] and the Animal Nutrition Additives Regulation[2] are equivalent

(b) The Plant Protection SPC Regulation[4] is not restricted to products for which a marketing authorisation has been obtained under the Plant Protection Products to Market Regulation[5] given that:

i) The Plant Protection SPC Regulation[4]; the Plant Protection Products to Market Regulation[5] and the Animal Nutrition Additives Regulation[2] all concern the same subject matter, namely microorganisms, as active substances;

ii) The microorganism subject of the present SPC application could qualify as a plant protection product as defined in the Plant Protection SPC Regulation[4] and the Plant Protection Products to Market Regulation[5];

(c) The decision in *Boston Scientific, C-527/17,* is not relevant. The applicant argued that[23]:

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 a marketing authorisation procedure conducted by a European Agency under European law and approved by the European Commission.

ii) the ruling in *Boston Scientific* relates to a medical device and not to a plant protection product which the applicant argues the present microorganism represents. The CJEU makes it clear in paragraphs 27 to 51 that a medical device can be distinguished from a medicinal product, because it is not a product that achieves its principal mode of action by pharmacological, immunological or metabolic means falls. The microorganism of strain DSM 11798 achieves its principal mode of action by metabolic means and so falls outside the definition of a 'medical device'. Consequently, the decision in C-527/17 is not relevant to the present application.

[23] These reasons are very similar to those that the applicant made in relation to why case *C-527/17, Boston Scientific* was not relevant to related application SPC/GB17/075 which sought the grant of an SPC for the same active substance being used as a veterinary medicinal product. See paragraph 64(c) in IPO decision BL O/610/20 (see Footnote 9 for details of decision).

The View of the Examiner

69 The examiner's view is clearly set out in the pre-hearing report of 12 March 2019. In their view, an authorisation under Animal Nutrition Additives Regulation[2] does not satisfy Article 3(1)(b) of the Plant Protection SPC Regulation[4] and that it cannot be considered an analogous process to that for the authorisation of a plant protection product. The examiner rebutted the arguments that the applicant had put forward in support for these authorisation processes being analogous and, in their view, the fact that the definitions used under the Plant Protection SPC Regulation[4]; the Plant Protection Products to Market Regulation[5] and the Animal Nutrition Additives Regulation[2] all concern the same subject matter, i.e. microorganisms as active substance, is not relevant. The fact that DSM 11789 strain could have been assessed as a plant protection product was not material as clearly it had not been considered under the code for plant protection products.

70 Although the microorganism, which is the subject of this SPC application, appears to fall under the definition of a plant protection product, as defined in the Plant Protection SPC Regulation[4] (ruling the granting procedure for an SPC) and the Plant Protection Products to Market Regulation[5] (rules authorisation procedure for plant protection products); this fact on its own, in the examiner's view, is not enough to confer compliance with Article 2 and is not sufficient for the grant of an SPC. In essence, just because the product in question may fall within the definition of a plant protection product does not mean that the requirement of Article 2 to have been subject to an authorisation procedure as laid down in the Plant Protection Products to Market Regulation[5] is satisfied.

71 The examiner considered the CJEU judgement in *Boston Scientific* to be relevant. This judgment concluded that Article 3(b) of the SPC Medicinal Regulation[10] is to be interpreted narrowly. The examiner relied on paragraph 27 of this judgement which states:

> *"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 their view, the CJEU's conclusion is generally applicable to deciding what products may be the subject of an SPC, i.e., it is not restricted to medical devices alone. The examiner also considered that this judgement is not specific to the SPC Medicinal regulation alone, that it applies to the plant protection SPC regulation as well.

Analysis

72 As mentioned above, I will consider first whether the approval under the Animal Nutrition Additives Regulation[2], i.e., Commission Implementing Regulation EU 2017/930 dated 31/05/2017 is a valid authorisation for the purpose of Article 2 and Article 3(1)(b) of the Plant Protection SPC Regulation[4]. If I find that this is indeed the case, I will then go on to consider the issue of whether or not this SPC application was filed within the deadline required under with Article 7(1) of the Plant Protection SPC Regulation.

***Compliance with** Article 2 and Article 3(1)(b) of the Plant Protection SPC Regulation*

73 According to the applicant this SPC application relates to a plant protection 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*". In effect, the active substance and the plant protection product including the active substance are identical. I am being asked to accept that the procedure used for approval to place this microorganism strain on the market in European Union under the Animal Nutrition Additives Regulation[2] as an additive for use in feed for avian species, such as poultry, and for use in feed for pigs, can be considered to meet the requirement of an authorisation procedure as laid down in Article 4 of the Plant Protection Products to Market Regulation (which, as noted above, has replaced Directive 91/414/EEC). This is the requirement set down in Article 2, entitled 'Scope', of the Plant Protection SPC Regulation. If an authorisation does not meet this requirement it falls outside the scope of this regulation.

74 In order to fulfil the conditions for grant under Article 3 of the Plant Protection SPC Regulation, specifically that of Article 3(1)(b), the application for an SPC must include "*a valid authorisation"* to place the product of interest on the market in Europe as part of a plant protection product granted "in accordance" with an authorisation procedure as laid down in Article 4 of the Plant Protection Products to Market Regulation.

75 On the face of it the answer to the question whether the approval under the Animal Nutrition Additives Regulation meets the requirement for a valid authorisation under Article 2 and 3(1)(b) of the Plant Protection Products to Market Regulation is straightforward. The approval for a feedstuff additive under the Animal Nutrition Additives Regulation is not one that has been granted using the procedure laid down in the Plant Protection Products to Market Regulation. It is granted under a different piece of EU legislation that relates to a different purpose than that required by the Plant Protection SPC Regulation. Therefore, an approval under the Animal Nutrition Additives Regulation is not relevant for the purpose of granting an SPC, i.e. the active substance identified in this SPC application is not the subject of an administrative authorisation procedure as laid down in the Plant Protection Products to Market Regulation[5]. As this is not an approval process that falls within the scope of Article 2 of the Plant Protection SPC Regulation, then this SPC application does not include a valid authorisation granted in accordance with Plant Protection Products to Market Regulation and so it does not meet the requirement of Article 3(1)(b) of the Plant Protection SPC Regulation.

76 Furthermore, the explanatory memorandum (EM) for the Plant Protection SPC Regulation, when discussing Article 4 of the regulation which deals with the subject-matter of protection, indicates that this regulation is only intended to apply to products that are authorised for use in plant protection – as stated in the article itself – and then it goes on to make clear that it does not apply to animal nutrition additives, i.e.:

> *"Furthermore, only uses in the plant protection field as defined in Directive 91/414/EEC come under the protection of the certificate (**authorized use of the product as an additive in animal feeding stuffs, for example, would not be protected under the certificate***."

77 Thus, it is clear that when the Plant Protection SPC Regulation was being drafted and undergoing its passage into EU law, the possibility that one might seek SPC protection for products approved for use as animal feeding stuffs was recognised and acknowledged[24]. It was thus considered appropriate to include a specific statement to indicate that this is not a use that should be subject to the protection offered by an SPC in the EM.

78 While such a statement in the EM may not have the same force as an explicit prohibition in the recitals or articles of the legislation itself (as occurred in relation to application SPC/GB/17/075 for an SPC for the same active substance but under the system for veterinary medicinal products[9]), it cannot be ignored. There is a clear statement in the EM to the Plant Protection SPC Regulation that it was not intended that this legislation should apply to products used in animal feeding stuffs, i.e. animal nutrition additives. This regulation and its associated explanatory memorandum (EM) are still in place and have not been repealed or amended to change this clear statement.

79 As noted already there have been a number of changes to the legislation concerning the approval of additives for use in animal nutrition since the Plant Protection SPC Regulation came into force but none of these have resulted in any indication that this situation has or should alter. For example, no changes were made when Directive 91/414 was repealed and replaced by the Plant Protection Products to Market Regulation. The latter clearly provided the opportunity to make a significant update to the way plant protection products are approved – see explanatory memorandum to the Plant Protection Products to Market Regulation[25] and the related report from the Commission explaining the reasons for moving from a Directive to a Regulation[26]; yet no change was made. Thus, the statement in the EM highlighted above, which is part of the materials that establish the purpose and objectives of this regulation, is still relevant and cannot be ignored, in my view.

80 Thus, I consider that there is a sufficient and clear indication in relation to the most relevant legislation, the Plant Protection SPC Regulation, that it was not envisaged by the legislators that an approval granted under the system for approving feed additives would be a suitable authorisation for the purposes of gaining SPC protection under this regulation.

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[24] (a) Council Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market entered into force and took effect in two-year period August 1991 to August 1993; (b) The Plant Protection SPC Regulation entered into force on 2 February 1997; (c) The Animal Nutrition Additives Regulation came into force on 28 October 2003 and took effect in 12 month period October 2003 – September 2004.

[25] See COM(2006) 388 final (dated 12.07.2006): Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market {SEC(2006) 930} {SEC(2006) 931} – including Explanatory Memorandum

[26] See COM(2001) 444 final (dated 25.07.2001), Report from the Commission to the European Parliament and the Council: Evaluation of the active substances of plant protection products (submitted in accordance with Article 8(2) of Council Directive 91/414/EEC on the placing of plant protection products on the market).

A Teleological Approach?

81 In the view of the applicant, the approach outlined above is too literal and is not in keeping with the way that EU legislation should be interpreted or in line with the purpose of the Plant Protection SPC regulation as set out, for example, in recitals (2)-(6) of this regulation.

82 Furthermore, the applicant considered that the statement in the EM (discussed above) does not carry the same weight as an explicit prohibition in the articles of the Plant Protection Products to Market Regulation or the Plant Protection SPC regulation itself.

83 The applicant asserted the need for a teleological interpretation of the Plant Protection SPC Regulation in reaching any decision on how Article 2 and Article 3(1)(b) of this regulation are to be understood and applied. At the hearing, the agent spent some time arguing that such an approach is necessary in this case; the examiner having taken too narrow a view when answering the question of what constitutes a marketing authorisation that can be considered equivalent to that under the Plant Protection Products to Market Regulation.

84 In support of their view, the applicant first started by putting matters in the context of the TRIPS Agreement[27]. As was indicated in the decision in relation to SPC/GB17/075, mentioned above, this Hearing Officer did not find this argument helpful in establishing the approach to take. I did not find it helpful in this case either for the same reasons[28]. It is not at issue that it is a well-established principle of EU law that when considering how the articles in EU legislation should be interpreted and applied, it is necessary not to take too literal an approach to the wording of the articles but rather to take account of the purpose and objectives behind the legislation in question[29]. Indeed, this is clear in the context of both SPC Regulations. The purpose of the SPC regulations (the Plant Protection SPC Regulation[2] and medicinal products SPC regulation[10]) has been discussed previously in the UK courts[30] and in the many references to the CJEU, such as *C-482/07 AHP*[31], that have been made concerning these regulations. In *AHP*, the CJEU observed (at paragraph 27) that when

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[27] 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.

[28] See paragraphs 82 & 83 of BL O/610/20 (Erber, concerning SPC application SPC/GB17/075)

[29] See discussion of teleological approach and references to relevant case law in paragraphs 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.

[30] See, for example, 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).

[31] See, for example, CJEU judgement *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; see especially paragraph 27.

considering Article 3(2) of the Plant Protection 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".*

85 In this case, adopting a teleological approach involves taking account of both the wording and the overall scheme and objectives of the respective legislation, i.e., the Plant Protection SPC Regulation, and of the Animal Nutrition Additives Regulation and the Plant Protection Products to Market Regulation in so far as they relate to the overall scheme and objectives of the Plant Protection SPC Regulation. While, I am required not to apply too literal an interpretation to the wording of the articles of interest, by the same token, I cannot ignore the meaning of the words in the relevant articles either.

86 I consider below whether applying this approach brings me to the same or a different view to the initial one that I have expressed in paragraph 80 above.

The Purpose and Scheme of the Plant Protection SPC Regulation

87 The starting point for this consideration is the Plant Protection SPC Regulation which sets down what is required to obtain an SPC for the active substance in a plant protection product. The recitals of the Plant Protection SPC Regulation make it clear that the intention of the EU legislator in creating SPC protection was to provide sufficient protection for plant protection products that are subject of lengthy and costly research and to compensate for the delay between receiving patent protection for the active substance in such a product and gaining an authorisation to place it on the market as a plant protection product[32]. Recital (4) indicates that the plant protection SPC system should offer the same level of protection for innovation as the medicinal SPC system. The fact that both systems should be considered in the same way is reinforced by recital (17) which specifically refers to the relationship between them and how they interact.

88 Article 1 of the Regulation provides a definition of what is a plant protection product and what is an active substance of a plant protection product. The latter definition is explicitly recognised to include micro-organisms which have "*general or specific action*" against harmful organisms or on plants. In this context plants also mean parts of plants and plant products. The plant protection product is the product that is made available to the user comprising the active substance in the form that it will be used, for example, on crops in a field. Further insight into the overall scheme and objectives of the Plant Protection SPC Regulation can be obtained from the Explanatory Memorandum (EM) to the proposal for the Plant Protection SPC Regulation[33]. In paragraph 66 of the EM which relates to Article 1, one is reminded (my emphasis added in bold) that:

> *"However, since the objectives of the patent system are different from those of the system of marketing authorization, it is important to stress that, for the purposes of the certificate,* ***the term "product" is not understood to mean***

[32] See Recitals (3) to (6) of Plant Protection SPC Regulation

[33] COM(94) 579 Final, 94/0285, 9 December 1994, Proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products

an agro-chemical product or a plant protection product in the wider sense, as presented for purchase by the final consumer, but in the narrower sense of active substance or combination of active substances contained in a plant protection product

Thus, there is a clear distinction between what is made available to the user and what is the subject of the SPC.

89 The scope of the Regulation (Article 2) further indicates that the regulation applies to products which have been placed on the market as a plant protection product and subject to an administrative authorisation procedure as laid down in Article 4 of the Plant Protection Products to Market Regulation. In paragraph 67 of the EM which relates to Article 2 of the regulation, it is pointed out that the proposal for a plant protection SPC regulation is to provide "*for a system identical to that in force since 2 January 1993 for medicinal products*",

90 Article 3 of the regulation then refers to the conditions for obtaining an SPC including the requirement for a valid authorisation to place the product on the market as a plant protection product. Paragraph 68 of the EM which relates to Article 3 discusses the two-stage authorisation process for plant protection products under Directive 91/414/EEC – which has continued in place under the Plant Protection Products to Market Regulation – and why this is important. Only plant protection products which comprise an active substance that has been approved under this two-stage approach qualify for SPC protection. I will discuss the relevance of this further below.

91 Article 4 is clear that the protection conferred by an SPC shall "*only*" extend to the product covered by the authorisation to place the corresponding plant protection product on the market. As discussed already, paragraph 69 of the EM which relates to Article 4, offers further detail on the 'subject matter of protection' as follows (my emphasis added in bold):

"69. ***The supplementary protection certificate is a sui generis protection*** *instrument inasmuch as it is linked to both an authorization to place the product on the market (the first granted in the State concerned) and to a previous patent (the basic patent). This is already evident from the conditions for obtaining the certificate, which require both that the basic patent is a current one and that the authorization is valid, failing which the certificate is void.*

The delimitation of the subject protected by the certificate also illustrates this duality since ***the protection afforded by the certificate is limited in two ways****.*

It is often the case in the plant protection field that a patent protects a series of products based on the same formula. However, only some of these products will subsequently be developed and only one might be placed on the market. ***In such a case, the certificate will protect only the product covered by the authorization and not all of the products protected by the patent.***

At the same time, the product authorized will itself be limited by the patent's subject-matter*. If the basic patent protects a compound x, where the authorized product consists of a combination of compound x and another active principle, only compound x will be protected by the certificate.*

Furthermore, the certificate will protect only the product covered by the authorisation, namely the product within the strict meaning of Article 2*."*

Lastly, the fact that the certificate is based on both the basic patent and the authorization can also be seen in the link between the protection afforded and the use of the product. *A new product patent normally gives the product absolute protection so that any use of the patented product, even for non-patented applications, constitutes an infringement, i.e. the patent protects all possible uses that the product may have.*

The certificate does not given [sic] ***such protection****. On the one hand, the link with the authorization system implies protection of the product covered by the first authorization, while limiting it to the uses of the product successively authorized prior to the expiry of the protection certificate.*

Plant health firms frequently develop new uses of the same product, which are the subject of new marketing authorizations. The marketing authorization is actually granted several years after the patent is filed, during which time the plant protection product undergoes multiple tests for one or more very specific uses. ***In view of this, it would seem to be logical to protect it, by means of the certificate, for the successive uses which have been the subject of authorizations.***

Furthermore, only uses in the plant protection field as defined in Directive 91/414/EEC come under the protection of the certificate (authorized use of the product as an additive in animal feedingstuffs, for example, would not be protected under the certificate.

On the other hand, the protection granted by the certificate is limited by that of the basic patent. In the case of a product patent, the limitation under the patent will not apply since this type of patent protects all possible uses of the product. However, in the case of an application patent, the certificate will protect only the use or uses claimed in the patent, provided that they were authorized prior to the expiry of the certificate. "

Thus, although it has not been included in an article of the Plant Protection SPC Regulation, it has been included in the material that sets out what the drafter considered to be essential information to explain how the regulation works. It is a clear indication that SPC protection does not apply to a product that is approved for use as an animal nutrition additive. This express exception is consistent with the overall purpose and objective of the Plant Protection SPC Regulation to provide SPC protection only for active substances in plant protection products which are clearly identified as such.

Approval under the Animal Nutrition Additives Regulation compared to Authorisation under the Plant Protection Products to Market Regulation

92 The applicant argued that, in all important aspects, a substance that meets the definition of an animal feed additive under the Animal Nutrition Additives Regulation would also meet the requirements for 'active substance' and for 'plant protection product' under the Plant Protection Products to Market Regulation. Thus, microorganism, DSM 11798, the subject of the present application for an SPC, which has already been approved as a feed additive, also meets the definition of 'plant protection product' as required by the Plant Protection Products to Market Regulation.

In addition, it also fulfils the definition of 'active substance' and 'plant protection product' under the Plant Protection SPC Regulation. As such it can be substituted for either or both in their view.

93 I consider that the applicant's argument that a specific feed additive also falls within the definition of a plant protection product, is taking too literal an approach – it is basically analysing the words to show that they can be interpreted to mean the same thing. This is not consistent with the teleological approach in my view. It does not take into account the fact that the overall purpose and scheme of the system for approving animal nutrition additives is both distinct from, and not the same as, that for a plant protection product. While both are part of the overall system that exists in the European Union for ensuring that plant and animal agriculture can be carried out in a safe and effective manner without detrimental effect on animals, plants and the environment, it cannot be denied that they relate to different parts of the system. I consider the scheme and purpose of the respective approval systems separately in more detail below

94 Before doing so however, I consider it relevant to observe that the applicant did not provide any information on whether any attempt was made to test this possible equivalence, i.e., they do not appear to have sought to protect this microorganism as a plant protection product, or at least enquired if it was feasible, so that they could consider possible SPC protection in the future. As I have noted already it is not the role of the IPO to decide what active substance from a plant protection product should be authorised – that is a matter for the party seeking the approval and the respective competent bodies at national and European level mentioned above. Whilst I am aware that EPSA carries out an assessment under the system for feed additives and that for plant protection products, there is nothing to suggest that they were asked to consider DSM 11798 as an active substance for a plant protection product. DSM 11798 was approved as an animal nutrition additive only. I cannot find any link, or the suggestion of a link, in the Animal Nutrition Additives Regulation and the Plant Protection Products to Market Regulation to suggest why a product approved under the first should also be considered to meet the requirements of the second. I can find nothing in either regulation that would suggest a reason to overcome the indication in the Plant Protection SPC Regulation discussed above. The basis for the applicant's argument in this regard is that a consideration of both approval processes as set down in the respective legislation suggests that they are the same.

95 Although it is argued by the applicant that the microorganism of interest in this case, DSM 11798, meets the definition of active substance and plant protection product, this does not, in my view, take appropriate account of the fact that animal nutrition additives and plant protection products each serve a different function and purpose. As such each should be distinguished accordingly as reflected in the legislation. The purpose of a plant protection product which includes an active substance (as defined under the SPC Plant Protection Regulation) is to prevent damage to plants that are of interest by removing harmful organisms from the plant of interest or by removing other plants which prevent the plants of interest from thriving. I characterise this as a direct purpose achieved by the active substance in its respective plant protection product. As the definitions in Article 1 of the Plant Protection SPC Regulation and Article 2 of the Plant Protection Products to Market Regulation make clear, the active substances in plant protection products exert their action – specific or general – on plants, parts of

plants or plant products directly – or on organisms which are harmful to plants by preventing the action of such organisms. Article 3 of the Plant Protection Products to Market Regulation makes clear that plant products referred to in this context "*means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plants*;". In this situation it is the plant being protected that is of interest because of its role in agriculture and food supply in Europe.

96 By contrast, I consider that an animal nutrition additive is not carrying out the same purpose or function as a plant protection product. Firstly, it is something that is added to feed which "*means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals*". It is for the purpose of providing a useful outcome in animals (not plants). This useful outcome is achieved – as referred to in Article 5(3) of the Animal Nutrition Additive Regulation – through a wider range of outcomes than for plant protection products, for example, improvement of colour in ornamental fish and birds. These outcomes are all about improving something in the animal. Although the animal feed we are dealing with in the present case is plant-based, in that it is derived from grasses and/or cereals, the effect of the micro-organism additive is to bring about an improvement in the animal consuming the feed. Specifically, the improvement provided by this feed additive is that the DSM 11789 micro-organism will break down trichothecene compounds produced by a mould contaminant (which may or may not be present). If left untreated, these mould derived contaminants in the feed have a detrimental effect on the animals that consume it. In my view, the animal nutrition additive has a different end focus (on the animal consuming the feed) then the plant protection product, which is clearly more directly focused on the plant.

97 The applicant also argued that, in addition to meeting the relevant definitions under the different regulations in question, the processes used to approve the products under the relevant regulations were equivalent in all important aspects.

98 The summary, supplied by the applicant, comparing the approval process under the Animal Nutrition Additives Regulation and the marketing authorisation process under the Plant Protection Products to Market Regulation, is helpful for comparing these processes at a high level. I have included it as Table 2 below. However, in order to reach a conclusion on whether these processes are equivalent for the purposes of the Plant Protection SPC Regulation, it is necessary to investigate them in more detail.

99 The authorisation process under the Plant Protection Products to Market Regulation is a two-stage process involving three bodies, namely the Member State which acts as rapporteur, the Commission, and the European Food Safety Authority (EFSA). The first stage is to seek authorisation of the active substance. This is done by submitting an application to the competent body of the rapporteur Member State which includes the results of safety and efficacy tests on the active substance. The rapporteur Member State prepares a draft assessment report on the admissibility of this application and the suitability of the active substance. The EFSA carries out an independent assessment on whether the active substance can meet the requirements of the regulation and confirms that the proposed analytical methods for these substances work. The Commission then prepares a draft regulation for approval of

Table 2. *A comparison of the approval process for animal nutrition additives and the authorisation process for plant protection products as set down in the respective regulations.*

	Regulation (EC) No. 1107/2009 (Plant Protection Products to Market Regulation[5])	**Regulation (EC) No. 1831/2003** (Animal Nutrition Additives Regulation[2])
European Agency drafts an opinion on the draft assessment report/application which is then examined by the Commission	Yes European Food Safety Authority (EFSA)	Yes European Food Safety Authority (EFSA)
Studies on quality, safety, and efficiency necessary	Yes	Yes
The European Commission adopts a decision and drafts Commission Implementation Regulation	Yes Implementation Regulation approves active substance	Yes Implementation Regulation approves marketing authorisation as such valid in all Member States
Market authorisation document	**Singly provided by each member state** (based on Implementation Regulation approving active substance	**Commission Implementing Regulation (EU) 2017/930** (rules market authorization as such already valid in all Member States

the active substance taking into account the reports of the rapporteur Member State and the EFSA. Once this draft commission regulation has been approved and published it is then possible to apply for a marketing authorisation for a plant protection product that uses the active substance. Such an application is made to the competent body of each Member State in which the plant protection product will be used. This approval application has to describe how the plant protection product will be used in the territory of the member state. This is the reason for the different zones identified in Annex 1 of the regulation which group the various member states in terms of

similarity of conditions[34]. The Member State grants an authorisation for the plant protection product which, under the principle of mutual recognition, also can be applied to the other member states in that zone. Although, it is the Commission that grants the authorisation for the active substance, it is the Member States which authorise the use of the plant protection product. Thus, the overall effectiveness and safety of the active substance is assessed and then, separately, the plant protection product containing this active substance is assessed for its effectiveness in the specific zone where it will be used.

100 In contrast, the grant of an approval for an animal nutrition additive only requires one level of authorisation. It does not have to take account different areas or zones within the Community in which it will be used. A feed additive is used differently to a plant protection product. For example, it is added to the feed and is not likely to be used in the open in the same way as a plant protection product and so environmental conditions and their impact may well have to be assessed very differently.

101 The feed additive is assessed by EFSA based on the dossier provided by the applicant, and a recommendation is passed on to the Commission for approval. The Commission draws up the implementing regulation on the basis of the recommendation from the EFSA.

102 Thus, I do not agree with the applicant's view that the approval process under the Animal Nutrition Additives Regulation and the marketing authorisation process under the Plant Protection Products to Market Regulation are highly similar and that they should be considered equivalent. I have set out a more detailed summary comparison of the requirements of the two authorisation processes in Table 3 (included as Annex 1 to this decision) which shows that the systems are not as similar as the applicant suggests.

103 Whilst both approval processes differ in substance, the context of the assessments carried out for the respective regulation is also pertinent. Although both approval processes involve submitting safety and efficacy test results, I do not consider that these are equivalent in purpose or the standards which have to be met. In the present application, safety and efficacy test results were submitted with a view to meeting the criteria under Article 5 of Animal Nutrition Additives Regulation. While these criteria include ensuring that the feed additive shall not have an adverse effect on animal health, I do not consider that this is the same standard that is required for the microorganism to be authorised as a plant protection product. Under the Animal Nutrition Additives Regulation, the efficacy of the microorganism in breaking down mycotoxins present in animal feed was assessed and what impact this will have on animals and the environment in which it is used. This is not the same, in my view, as testing an active substance for its effectiveness in protecting plants (or plant products) from organisms which affect their growth, maturity and development and, then testing a plant protection product comprising this active substance, for its effect and impacts on plants and the environment in which it will be used. Similarly, I consider that the manner in which such additives would be used and so the risks that flow for their prolonged use or exposure to the environment and/or to humans and to other animals

[34] Under the Plant Protection Products to Market Regulation, the whole EU is one zone only in some limited cases (e.g., Greenhouse uses, Post-harvest treatments, Treatment of empty storage rooms or containers, and Seed treatments) which are not relevant to the current SPC application.

are also different in scale and impact and this cannot be ignored. Indeed, it seems to me that is one of main reasons why there are different legal instruments for the approval of animal nutrition additives and the authorisation of plant protection products.

104 The applicant considers the fact that both systems use the same agency (EFSA) to carry out relevant assessments, means that *de facto* the same level of information and detail is required to determine the suitability of an additive for animal feed for poultry and pigs as will be required when assessing the suitability of an active substance that will be added to a plant protection product that will be used to promote the growth of grasses and cereals (the main component of the animal feed for pigs and poultry). However, this overstates and oversimplifies the situation in my view. EFSA as an agency is organised, in terms of scientific and technical expertise, to have the ability and the experience to determine the benefit and risks of using a particular substance for a number of different purposes in the Community Food and Agriculture field as set down in the relevant legislation and to understand how each assessment needs to be tailored specifically to the role that the respective substance is being used for (i.e., plant protection product, animal nutrition additive), based on how it exerts that role (its actual mechanism of action) and under what conditions. While I accept that feed additives and plant protection products are both substances that have important roles in the food and agricultural sector in the Community, and so are similar in that sense, they are independent of each other in terms of the steps and criteria to be followed to gain suitable approval for use in the member states of the European Community

105 Thus, while I accept that an initial assessment may suggest that the approval system under the Animal Nutrition Additives Regulation appears similar to the authorisation system under the Plant Protection Products to Market Regulation, upon further consideration, significance and pertinent differences are apparent.

106 The applicant and the agent referred, on a number of occasions to the recitals of the Animal Nutrition Additives Regulation and those of the Plant Protection Products to Market Regulation to illustrate that both are concerned with the same overall goal, i.e., to ensure that a high standard of protection for humans, animals and the environment is delivered and maintained and that human health, animal health and the environment are protected when plant protection products or animal nutrition additives are placed on the market, used or processed within the Community – see, for example, recitals 1, 2 and 4 of the Animal Nutrition Additives Regulation and recitals 6 and 8 of the Plant Protection Products to Market Regulation. No-one would, I think, disagree or doubt that both of these regulations are concerned with ensuring an effective legislative framework in the Food and Agriculture field but the comparison, in my view, does not stop there and the equivalence suggested is not as straightforward as the applicant implies. The impact of plant protection products, such as pesticides, on health and the environment can be very significant and adapting to the lessons learned is why the authorisation process for plant protection products (set up under Directive 91/414/EEC initially, and now continuing under the Plant Protection Products to Market Regulation) is based on a two-stage approval process.

107 So while I cannot deny that both types of approval are part of the landscape for dealing with food and agriculture within the European Union, this does not take full account of the purpose of the specific legislative instruments and the products that these legislative instruments relate to. I consider that the EU legislator is sufficiently aware

of the EU legislative instruments that govern the Community Food and Agriculture sector to recognise, for example, that when the feed additives legislation was being updated, or the Plant Protection Products to Market Regulation was being brought in to update and replace Directive 91/414/EEC, there was an opportunity, if it was justified, to make a change to either of these instruments and how they relate to each other or to the system for granting SPCs for plant protection products. However, nothing like this has been included in either of these pieces of legislation. Also, no amendments have been made since the Plant Protection SPC Regulation SPC regulation was enacted in 1996 to indicate that it should be applied to a wider or greater range of products and/or expanded to include a wider or greater variety of approval processes. While the applicant can assert that the wording used to describe the process for approval of animal nutrition additives and that used to describe the process of authorising plant protection products are similar, this is not enough in itself. Although, these two approval systems both operate in the Food and Agriculture sector of the European Community, this does not change the fact that these are two different EU legislative instruments which were put in place to achieve two different objectives (in terms of assessing and approving two different types of products that are used within the Community to help with the production of food).

108 Taking all of the above into account, I do not consider that the product for which a supplementary protection certificate has been applied for in this application, SPC/GB/17/076, has been subject to an administrative procedure as laid down in in the Plant Protection Products to Market Regulation [(EC) No 1107/2009], therefore the product is not eligible under Article 2 of the Plant Protection SPC Regulation to be the subject of an SPC certificate.

Relevance of C-579/17 (Boston Scientific)

109 As I have discussed above, I consider that the Plant Protection SPC Regulation is only intended to protect products authorised for use as plant protection products and that, as stated in the EM to that regulation, animal nutrition additives were excluded from the scope of this regulation.

110 Further, while it might appear possible for the microorganism of the present SPC application to meet the definition of an active substance and plant protection product under the relevant legislation, I cannot ignore the fact that it was not authorised as such and it has not been placed on the market as a plant protection product. In order to comply with Articles 2 and 3 of the plant protection SPC regulation, it is not enough to show that the active ingredient could fall within the definition of an active substance and plant protection product. It is necessary for the product to have a valid authorisation granted “in accordance with” the Plant Protection SPC Regulation. The recent decision from the CJEU in the *Boston Scientific* case is helpful to working out whether the approval under the Animal Nutrition Additives Regulation meets the requirement as a valid authorisation granted “in accordance with” the Plant Protection SPC Regulation.

111 The applicant argued that the CJEU ruling in *Boston Scientific (C-579/17)* is not relevant on the grounds that the present application does not relate to a medical device nor does the present application relate to an application for an SPC for a medicinal product under Medicinal Products SPC Regulation. While I agree that there are

differences between the facts of the present case and those relevant to *Boston Scientific,* in my view, the general reasoning set down in the judgement is relevant to the present case because it concerns the correct approach to deciding when something falls within the scope of both SPC regulations. Given that recital (4) of the Plant Protection SPC Regulation SPC Regulation indicates that the intention of the EU legislators in creating SPC protection for plant protection products was to provide a level of protection equivalent to that granted by SPCs for medicinal products; and Recital (17) makes it clear that certain recitals and articles of the Plant Protection SPC Regulation SPC Regulation are valid for the interpretation of the Medicinal Products SPC Regulation, the reasoning of the CJEU in the *Boston Scientific* case does indeed have relevance to the present case and can provide some helpful guidance.

112 Although it may seem a little unusual that the later Plant Protection SPC Regulation provides explicit means to interpret the earlier Medicinal Products SPC Regulation rather than to amend this regulation directly, it is nonetheless stated that providing this means of interpretation is part of the purpose and objective of the Plant Protection SPC Regulation.

113 As noted above, in its judgment in *Boston Scientific,* the CJEU considered the context in which a Paclitaxel-coated coronary stent was authorised to be placed on the market. It 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."*

Thus, even if a substance has undergone an analogous approval process (as the applicant claims occurred in the present case) to that specified under the Plant Protection SPC Regulation, it still would not fulfil the conditions of Article 2 of this regulation.

114 In reaching its conclusion the CJEU considered the objectives of the Medicinal Products 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"*

115 As recital 17 to the plant protection product SPC regulation indicates, Article 4 of that regulation is valid for interpreting Article 4 of the SPC regulation.

116 Thus, it is my view, that the general conclusions in the *Boston Scientific* case are also relevant to the present application. The Court has said that the clear intention of the EU legislature was to reserve SPC protection for the products for which the regulation was specifically developed by EU legislators. SPC protection has also been

specifically developed for plant protection products. It has not been developed for other types of products, such as animal nutrition additives.

117 The active substance of the present application has not been authorised to be placed on the market as a plant protection product. While there may well be some similarities between the approval process for animal nutrition additives and the authorisation process for plant protection products, the processes are not the same.

118 Thus, taking into account the judgment in *Boston Scientific,* I find further support for my view that the approval under the Animal Nutrition Additives Regulation does not meet the requirements of Article 2 of the Plant Protection SPC Regulation.

Compliance with Article 7 of the Plant Protection SPC Regulation

119 Given my conclusion above that the present application does not meet the requirements of Article 2, it is not necessary for me to go on to decide the second issue in relation to compliance with Article 7 of this regulation. However, it is necessary in my view to note the following in relation to this second issue, should this decision be the subject of an appeal.

120 The examiner stated[35] that in their 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 1016/2013 (the 2013 approval) and not the later one covered by Commission Implementing regulation 2017/930 (the 2017 approval).

121 I note that the applicant refers to the differences between the two implementing regulations: (i) the 2017 approval covers all trichothecenes as a class and not just one – deoxynivalenol – as in the 2013 approval; and (ii) the 2017 approval covers use in an additional & new species, i.e., in all avian species, as well as in pigs (covered by the 2013 approval).

122 Consequently, the applicant argued that the *Neurim* judgment[7] does not preclude the grant of an SPC for "*a different application of the same product for which a marketing authorisation has been granted*".

123 While preparing this decision (as noted above), the judgment of the CJEU in the *Santen* case[8] was issued and the CJEU found that the approach adopted in *Neurim* is no longer to be followed. In answer to this, the applicant stated that the latter *Santen* judgment should not affect how the *Neurim* judgement is applied in the UK to questions relating to Article 3(1)(b) of the Plant Protection SPC Regulation. The applicant did not provide further details or explanation in support of this statement in their response.

124 I interpret this statement from the applicant to mean that they consider that given the approaching withdrawal of the UK from the EU at end of 2020, going forward it is not necessary to take CJEU case-law into account in relation to SPCs in the UK. 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 would

[35] See Official Examination report (paragraph 4) dated 9 January 2018

have to take account of this latest CJEU decision in deciding the question of compliance with Article 7.

125 However, given my conclusion above that the approval process under the Animal Nutrition Additives Regulation is not a valid authorisation for the purposes of Article 2 and Article 3(1)(b) of the Plant Protection SPC Regulation, it will not be necessary to decide the question of compliance with Article 7.

Conclusion

126 Taking all of the above into account, I do not consider that the product for which supplementary protection certificate SPC/GB/17/076 has been applied for in the present application, has been subject to an administrative procedure as laid down in in the Plant Protection Products to Market Regulation (which repealed and replaced Directive 91/414/EEC).

127 Therefore, this product is not eligible under Article 2 of the Plant Protection SPC Regulation to be the subject of a supplementary protection certificate and falls outside the scope of this regulation.

128 Furthermore, and as a consequence, neither (i) 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 (ii) 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, approved under the Animal Nutrition Additives Regulation, meets the requirement under Article 3(1)(b) of the Plant Protection SPC Regulation for a valid authorisation to place the product on the market as a plant protection product

129 As a consequence, application SPC/GB/17/076 does not meet the requirements laid down in the Plant Protection SPC Regulation and is rejected under Article 10(2) of the regulation.

130 Given my conclusion in relation to Article 2 of the Plant Protection SPC Regulation, I did not go on to decide the question of compliance with Article 7(1) of this regulation.

Other Matters

Relationship between this SPC Application and SPC Application SPC/GB17/075

131 The applicant considered that there is no reason why this SPC application and that for SPC/GB17/075 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.

132 The present SPC application concerns the use of this microorganism active substance in a plant protection product whereas the that under application SPC/GB17/075 related to the same active substance for use in a veterinary medicinal product.

133 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 in the present case equivalence between the approval under the Animal Nutrition Additives Regulation and an authorisation under the Plant Protection Products to Market Regulation[4]; while in the previous case (SPC/GB17/075) claiming equivalence between the same approval under the Animal Nutrition Additives Regulation and an authorisation for a veterinary medicinal product under Directive 2001/82/EC (hereafter the Veterinary Medicinal Products Directive). Thus, in affect the applicant is arguing that the approval under the Animal Nutrition Additives Regulation can simultaneously meet the requirements as an authorisation for a veterinary product and as an authorisation for a plant protection product.

134 In support of their argument that the authorisation under the Veterinary Medicinal Products Directive and that under the Plant Protection Products to Market Regulation should be considered 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. This court 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.

135 In my analysis above I have concluded that the equivalence that the applicant claims between the Animal Nutrition Additives Regulation and the Plant Protection Products to Market Regulation decision is not justified and hence this application for an SPC for an active substance in a plant protection product fails.

136 In my decision in relation to SPC/GB17/075, this hearing officer concluded that the equivalence that the applicant claims between the approval process under the Animal Nutrition Additives Regulation and the authorisation under the Veterinary Medicinal Products Directive is not justified and hence that the application for SPC/GB17/075 failed[10]. Consequently, it will not 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 the Plant Protection SPC Regulation. This situation would only have arisen if it was considered that both SPC applications could be granted.

Appeal

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

Dr L Cullen

Deputy Director, acting for the Comptroller

***Table 3**: A detailed comparison of the authorisation process under the* **Plant Protection Products to Market Regulation** and the approval system under the **Animal Nutrition Additives Regulation** *(see also Table 2.)*

Plant Protection Products to Market Regulation [Regulation (EC) 1107/2009]	**Animal Nutrition Additives Regulation** [Regulation (EC) 1831/2003]
1. Submit application for approval of active substance to the rapporteur Member State (Art. 7(1))	1. Submit application to the Commission (Art. 7)
Contents of the application: (Art. 8) (a) information about the representative uses of plant protection product containing the active substance demonstrating approval criteria of Article 4 are met (b) results tests demonstrating compliance with Art 4(2) and 4(3), i.e. that there are no harmful effects on human health or animal health or unacceptable effects on the environment and the active substance is effective and has no immediate or delayed harmful effects on human health (c) summaries and results of tests and studies relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a) (d) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;	Contents of the application: (Art. 7(3)) (a) applicant name and address; (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; (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). [*i.e. feed additive does 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,*

(e) a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for; (f) the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval; (g) where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information; (h) an assessment of all information submitted.	*(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.* *And, 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 feedingstuffs, or* *(g) have a coccidiostatic or histomonostatic effect.]* (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.
2. Rapporteur Member State notifies the applicant, other Member States, the Commission and the European Food Safety Authority of the admissibility of the application and assesses the active substance (Art 9(3) Regulation 1107/2009)	2. Commission sends application to the European Food Safety Authority (EFSA) (Art 7(1) Regulation 1831/2003) EFSA gives an opinion on the application (Art. 8(1) Regulation 1831/203)
3. Rapporteur Member State prepares a draft assessment report on the active substance and submits it to the Commission with a copy to the EFSA. (Art 11(1) Regulation 1107/2009). The EFSA circulates the draft assessment to the applicant and other Member States (Art 12(1) Regulation 1107/2009). EFSA adopts a conclusion on whether the active substance can be expected to meet the approval criteria and communicates this to the applicant, the Member States and the Commission (Art 12(2) Regulation 1107/2009).	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 Regulation (Art 13(1) and Art 79(1) Regulation 1107/2009) Draft Regulation is adopted in accordance with procedure referred to in Article 78(3) and 79(2) of Regulation 1102/2009) 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.	4. Commission prepares a draft Implementing Regulation 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. 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. Approved Regulation on active substances made available to the public by the Commission (Art 13(4) Regulation 1102/2009)	5. Commission adopts the Implementing Regulation
6. Application for marketing authorisation of a plant protection product submitted to each Member State in which its use is intended (Art 28(1), 29(1), and 33(1) Regulation 1107/2009)	6. Commission Implementing Regulation published in Community register of feed additives (Art 17 Regulation 1831/2003)
7. Member States grant authorisation for the plant protection product. Member State informs the applicant and the Commission of the decision to grant the authorisation (Art 35(1), 36(1), 41(1) and Art 36(3) Regulation 1107/2009)	
8. Member State makes public notification of granted marketing authorisation (Art 57(1) Regulation 1107/2009)	