European Parliament
2014-2019

Committee on Legal Affairs
The Chair

03.09.2015

Mr Czesław Adam Siekierski
Chair
Committee on Agriculture and Rural Development
BRUSSELS

Subject: Opinion on the legal basis of the proposal for a Regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (COM(2014/0556 – C8-0143/2014 – 2014/0255(COD))

Dear Mr Chair,

By letter of 11 June 2015 the Committee on Agriculture and Rural Development asked the Committee on Legal Affairs, pursuant to Rule 39(2) of the Rules of Procedure, for an opinion on the appropriateness of the legal basis for the above-mentioned proposal.

The Commission's proposal aims at regulating the manufacture, placing on the market and use of medicated feed and at repealing Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[1].

The Commission proposes as the legal basis for its proposal Article 43 TFEU, which relates to the implementation of the common agricultural policy, and Article 168(4)(b) TFEU, which relates to the adoption of measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

The rapporteur for the file in the Committee on Agriculture and Rural Development, Mrs Aguilera, is intending to table an amendment specifying that the legal basis for the Regulation is paragraph 2 of Article 43 TFEU rather than Article 43 TFEU in its entirety. Her amendment would leave the other legal basis of the Regulation, namely Article 168(4)(b)

[1] OJ L 92, 7.4.1990, p. 42–48.

TFEU, untouched. In this context, the Committee on Agriculture and Rural Development seeks the Committee on Legal Affairs' opinion as to whether this correction to the legal basis of the proposal would be appropriate.

I. Background

To date, medicated feed to treat farmed animal diseases has been regulated by Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community. This Directive was adopted before the internal market was created and it has never been adapted in substance. The national transposition of this legal instrument has given freedom to the Member States regarding the interpretation and the implementation of its provisions. According to the Commission this flexibility has contributed to some problems: the Directive gives no indication as to what standards to apply in approving plants or the acceptable techniques to produce medicated feed; whether those standards should be technology-based or results-based; it does not provide for homogeneity criteria; it is silent about the concept of carry-over of medicated feed between batches, about the specific labelling of medicated feed and about medicated feed for pets, and it is vague as to whether feed may be prepared in advance of prescription in the feed mill, allowing Member States to arrive with different interpretations. Furthermore, from the Commission's perspective the legislation now in force is likely to perpetuate existing discrepancies in its implementation between the Member States, thus creating an uneven playing field for professional operators on the single market.

The purpose of the proposal is therefore to update the current legislation on medicated feed by repealing Directive 90/167/EEC, while simultaneously harmonising at a high safety level the manufacture, marketing and use of medicated feed and intermediate products in the European Union. The resulting Regulation will allow the anticipated medicated feed production, mobile and on-farms mixing, and will set up parameters for these schemes. The provisions of the draft proposal include measures for disposal of not used medicated feed on farm. EU wide limits will be set for the carry-over of veterinary medicines in feed that should be adapted based on an assessment of the risk for the animals and the humans with regards to the different types of active substances.

II. The relevant Treaty Articles

The proposed legal bases for this proposal are Articles 43 and 168(4)(b) TFEU.

Article 43 TFEU reads as follows (emphasis added in paragraph 2):

Article 43
(ex Article 37 TEC)

1. The Commission shall submit proposals for working out and implementing the common agricultural policy, including the replacement of the national organisations by one of the forms of common organisation provided for in Article 40(1), and for implementing the measures specified in this Title.

These proposals shall take account of the interdependence of the agricultural matters mentioned in this Title.

2. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall establish the common organisation of agricultural markets provided for in Article 40(1) and the other provisions necessary for the pursuit of the objectives of the common agricultural policy and the common fisheries policy.

3. The Council, on a proposal from the Commission, shall adopt measures on fixing prices, levies, aid and quantitative limitations and on the fixing and allocation of fishing opportunities.

4. In accordance with paragraph 2, the national market organisations may be replaced by the common organisation provided for in Article 40(1) if:

(a) the common organisation offers Member States which are opposed to this measure and which have an organisation of their own for the production in question equivalent safeguards for the employment and standard of living of the producers concerned, account being taken of the adjustments that will be possible and the specialisation that will be needed with the passage of time;

(b) such an organisation ensures conditions for trade within the Union similar to those existing in a national market.

5. If a common organisation for certain raw materials is established before a common organisation exists for the corresponding processed products, such raw materials as are used for processed products intended for export to third countries may be imported from outside the Union.

According to **Article 40(1) TFEU** a common organisation of agricultural markets shall be established "*[i]n order to attain the objectives set in Article 39*".

Article 39 TFEU reads as follows:

Article 39
(ex Article 33 TEC)

1. The objectives of the common agricultural policy shall be:

(a) to increase agricultural productivity by promoting technical progress and by ensuring the rational development of agricultural production and the optimum utilisation of the factors of production, in particular labour;

(b) thus to ensure a fair standard of living for the agricultural community, in particular by increasing the individual earnings of persons engaged in agriculture;

(c) to stabilise markets;

(d) to assure the availability of supplies;

(e) to ensure that supplies reach consumers at reasonable prices.

2. In working out the common agricultural policy and the special methods for its application, account shall be taken of:

(a) the particular nature of agricultural activity, which results from the social structure of agriculture and from structural and natural disparities between the various agricultural regions;

(b) the need to effect the appropriate adjustments by degrees;

(c) the fact that in the Member States agriculture constitutes a sector closely linked with the economy as a whole.

Article 168(4)(b) reads as follows:

Article 168(4)(b)
(ex Article 152 TEC)

(...)

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(...)

> *(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;*

(...)

III. The case law on legal basis

The choice of legal basis is important because the Union is constitutionally founded upon the principle of conferral of competences and its institutions can only act in a manner consistent with the mandate provided to them by the Treaty[1].

Certain principles emerge from the case law of the Court as regards the choice of legal bases. First, in view of the consequences of the legal basis in terms of substantive competence and the procedure, the choice of the correct legal basis is of constitutional importance[2]. Secondly, the choice of legal basis for an EU measure must rest on objective factors that are amenable to

[1] Opinion 2/00 on the *Cartagena Protocol* [2001] E.C.R. I-9713, para. 3; Opinion 1/08 on the *General Agreement on Trade in Services* [2009] E.C.R. I-01255, para. 110.
[2] Opinion 2/00 on the *Cartagena Protocol* [2001] E.C.R. I-9713, para. 5; Case C-370/07 *Commission v Council* [2009] E.C.R. I-08917, paras 46-49; Opinion 1/08 on the *General Agreement on Trade in Services*, [2009] E.C.R. I-01255, para. 110.

judicial review; these include, in particular, the aim and content of that measure[1]. The fact that an institution wishes to participate more fully in the adoption of a given measure, the work carried out in other respects in the sphere of action covered by the measure and the context in which the measure was adopted are all irrelevant.[2]

The choice of an incorrect legal basis may therefore justify the annulment of the act in question[3].

As regards multiple legal bases, if examination of the proposed measure reveals that it pursues a twofold purpose or that it has a twofold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, that measure must be based on a single legal basis, namely that required by the main or predominant purpose or component[4]. On the other hand, where a measure has several contemporaneous objectives or components which are indissolubly linked with each other without one being secondary and indirect in respect of the others, the measure must be based on the various relevant Treaty provisions[5].

Recourse to a dual legal basis is nevertheless not possible where the procedures laid down for each legal basis are incompatible with each other or where the use of two legal bases is liable to undermine the rights of the Parliament[6].

IV. The aim and content of the proposed regulation

The scope of the proposed Regulation covers the manufacture, placing on the market and use of medicated feed in food-producing animals and in pets within the European Union[7]. Recital 2 to the proposal states that "[l]ivestock production occupies a very important place in the agriculture of the Union. The rules concerning medicated feed have significant influence on the keeping and on the rearing of animals, including non-food producing animals, and on the production of products of animal origin."

If adopted, the Regulation will repeal Council Directive 90/167/EEC. Recital 4 to the proposal specifies that "[e]xperience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the Internal Market and to explicitly give and improve the possibility to treat non-food producing animals by medicated feed."

---

[1] Case C-411/06 *Commission* v *Parliament and Council* [2009] E.C.R. I-7585, para. 45, and the case-law cited therein, and Case C-130/10 *Parliament* v *Council* [2012] E.C.R., para. 42 and the case-law cited therein.
[2] Case C-269/97 *Commission* v. *Council* [2000], E.C.R. I-2257, para. 44.
[3] Opinion 2/00 on the *Cartagena Protocol* [2001] E.C.R. I-9713, para. 5.
[4] Case C-42/97 *Parliament v Council* [1999] E.C.R. I-868, paras. 39-40; Case C-36/98 *Spain v Council* [2001] E.C.R. I-779, para. 59; Case C-211/01 *Commission v Council* [2003] E.C.R. I-8913, para. 39.
[5] Case C-165/87 *Commission v Council* [1988] E.C.R. 5545, para. 11; Case C-178/03 *Commission v European Parliament and Council* [2006] E.C.R. I-107, paras. 43-56.
[6] Case C-178/03 *Commission* v *European Parliament and Council* [2006] E.C.R. I-107, para. 57; Joined Cases C-164/97 and C-165/97 *Parliament* v *Council* [1999] E.C.R. I-1139, para. 14; Case C-300/89 *Commission* v *Council* ("Titanium dioxide") [1991] E.C.R. I-2867, paras. 17-25; Case C-338/01 *Commission v Council* [2004] E.C.R. I-4829 (Recovery of Indirect Taxes), para. 57.
[7] The Regulation would not apply to veterinary medicinal products used as the medicinal component of medicated feed as they are covered by specific legislation on veterinary medicinal products.

In this connection, the explanatory memorandum to the proposal states that "(t)he aim of the review of the medicated feed rules is to harmonise at a high safety level the manufacture, marketing and use of medicated feed and intermediate products in the EU and to reflect technical progress in this field", and furthermore stresses that "the existing legislation is likely to perpetuate existing discrepancies in its implementation between the Member States. This creates an uneven playing field for professional operators on the single market. There is a need to harmonise implementation of the legislation, reduce financial and administrative burdens and support innovation."

Recital 24 to the proposal, for its part, while primarily dealing with the issues of subsidiarity and proportionality, concisely enumerates the objectives of the Regulation, namely "ensuring a high level of protection of human and animal health, providing adequate information for users and strengthening the effective functioning of the internal market [...]."

The proposed Regulation lays down rules for the manufacture, composition, placing on the market and use of medicated feed. The general manufacture requirements laid down in Regulation (EC) No 183/2005[1] apply. Article 4 of the proposed Regulation imposes on business operators in the field of medicated feed the obligation to put in place, implement and maintain permanent written procedures based on the hazard analysis and critical control points system. Furthermore, according to Article 5, medicated feed may only be manufactured from veterinary medicinal products authorised under the veterinary medicinal products legislation[2].

The proposal also establishes rules for the homogeneous incorporation of the veterinary medicinal product into the feed and requirements in order to avoid carry-over of active substances from veterinary medicinal products into non target feed. It also incorporates rules on anticipated production, labelling and packaging of medicated feed. Articles 12 to 14 of the proposal regulate the approval of feed business operators and establish the rules with which those operators need to comply in order to manufacture medicated feed.

The proposed Regulation lays down in Articles 15 to 17 specific rules for the prescription, the validity of the prescription, the use of medicated feed containing antimicrobials in food-producing animals and the quantities required for the treatment of animals with medicated feed. Manufacturers, distributors and users of medicated feed must keep daily records for the effective tracing of medicated feed. For veterinary medicinal products authorised at national level, the proposed Regulation sets intra-Union rules for trade of medicated feed in order to prevent distortions in competition.

The proposal furthermore imposes on the States the obligation to lay down rules on penalties to infringements of the provisions of the Regulation and to take all measures necessary to ensure that they are implemented.

[1] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1–22).
[2] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1–66).

V. Determination of the appropriate legal basis

Having regard to the fact that the aim and content of the proposal is to harmonise by means of a Regulation the manufacture, marketing and use of medicated feed, which is generally used to treat animal diseases in large groups of animals, so as to ensure a high level of protection of human and animal health, provide adequate information for users and strengthen the effective functioning of the internal market in the agriculture field, Articles 43 and 168(4)(b) TFEU constitute the appropriate legal basis for the Regulation.

With regards to Article 43 TFEU, it seems worthwhile to note that according to settled case-law of the Court of Justice, this article is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex I to the Treaty which contributes to the achievement of one or more of the objectives of the common agricultural policy set out in Article 39 of the Treaty. In this connection, it is also well-established case-law that where a legislative act constitutes an essential means of increasing agricultural productivity (an objective laid down in Article 39(1)(a) of the Treaty), it must be adopted on the basis of Article 43 of the Treaty even though, in addition to applying essentially to products falling within Annex I, it also covers incidentally other products not included in that annex[1].

The proposed Regulation aims at contributing to the objectives of the common agriculture policy laid down by Article 39 TFEU, namely (a) increasing agriculture productivity by promoting technical progress and by ensuring the rational development of agriculture production and the optimum utilisation of the factor of production, in particular labour; (b) thus ensuring a fair standard of living for the agricultural community, in particular by increasing the individual earnings of persons engage in agriculture; (c) stabilising markets; (d) assuring the availability of supplies, and (e) ensuring that supplies reach consumers at reasonable prices.

Article 43 TFEU has five paragraphs, two of which are legal bases. Paragraph 2 of the said article empowers the European Parliament and the Council to establish, in accordance with the ordinary legislative procedure, the common organisation of agricultural markets provided for in Article 40(1) and the other provisions necessary for the pursuit of the objectives of the

---

[1] Case C-180/96 *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities* [1998], ECR *I-02265*, and case-law cited therein; Case C-11/88 *Commission v Council (Undesirable substances and products in animal nutrition — Legal basis)* [1989] ECR 3799, paragraph 15, summary publication, which states as follows: "Article 43 of the Treaty is the appropriate legal basis for any legislation concerning the production and marketing of agricultural products listed in Annex II to the Treaty which contributes to the achievement of one or more of the objectives of the common agricultural policy set out in Article 39 of the Treaty. Even where such legislation is directed both to objectives of agricultural policy and to other objectives which, in the absence of specific provisions, are pursued on the basis of Article 100 of the Treaty, it may involve the harmonization of provisions of national law in the latter field without there being any need to have recourse to Article 100. In view of the precedence which Article 38(2) of the Treaty gives to specific provisions in the agricultural field over general provisions relating to the establishment of the common market, Article 100 cannot be relied on as a ground for restricting the field of application of Article 43 (see judgments of 23 February 1988 in Cases 68/86 and 131/86 *United Kingdom* v *Council* [1988] ECR 855 and 905). Although Directive 87/519 amending Directive 74/63 on undesirable substances and products in animal nutrition, may refer incidentally to certain products not included in Annex II, it applies essentially to products within that annex; furthermore, it is an essential factor in increasing agricultural productivity, which is the stated objective of Article 39(1)(a) of the Treaty."

common agriculture policy and the common fisheries policy. For its part, paragraph 3 authorises the Council to adopt, on a proposal from the Commission, measures on fixing prices, levies, aid and quantitative limitations and on the fixing and allocation of fishing opportunities.

It is apparent from the content of the proposed Regulation that it does not incorporate any element relating to paragraph 3 of Article 43 TFUE and that this paragraph is thus irrelevant for the purposes of the proposal. Paragraph 2 of Article 43 TFUE covers all aspects of the common agriculture policy included in the proposal. Therefore, a correction to the legal basis in order to restrict it to paragraph 2 of Article 43 TFUE would be appropriate. This conclusion was also reached by the Legal Service of the Parliament[1].

Moving on to Article 168(4)(b) TFEU, it is clear from the recitals and the content of the proposed Regulation that it also aims at protecting public health by means of the adoption of measures in the veterinary and phytosanitary fields. The proposed Regulation purports to regulate the manufacture, placing on the market and use of medicated feed, which should be produced only with authorised veterinary medicinal products, the compatibility of which should be ensured for the purpose of safety and efficacy of the product.

According to the case law on legal bases mentioned above, a dual legal basis is possible only where it can be determined that a measure has several contemporaneous objectives or components which are indissolubly linked with each other without one being secondary and indirect in respect of the others. This seems to be the case with the present proposal. In fact, it can be concluded that the proposal has two main objectives intimately linked, namely to ensure a high level of protection of human and animal health and to strengthen the effective functioning of the internal market, neither of which seems to take precedence over each other.

Besides, both provisions provide for the ordinary legislative procedure so no issue of incompatibility between both legal bases arises.

VI. Conclusion and recommendation

At its meeting of 13 July 2015 the Committee on Legal Affairs accordingly decided by 21votes in favour and 2 votes against[2] that Articles 43(2) and 168(4)(b) TFEU constitute the appropriate legal bases for the proposal and therefore to recommend to the Committee on Agriculture and Rural Development to modify the reference to Article 43 TFEU and to restrict it to paragraph 2 of that article.

[1] See the note of the Legal Service of 19 June 2015.

[2] The following were present for the final vote: Pavel Svoboda (Chair), Jean-Marie Cavada (Vice-Chair), Axel Voss (Vice-Chair), Mady Delvaux (Vice-Chair), Max Andersson, Joëlle Bergeron, Marie-Christine Boutonnet, Kostas Chrysogonos, Angel Dzhambazki, Rosa Estaràs Ferragut, Evelyne Gebhardt, Heidi Hautala, Sylvia-Yvonne Kaufmann, Dietmar Köster, Gilles Lebreton, António Marinho e Pinto, Emil Radev, Julia Reda, Evelyn Regner, Virginie Rozière, József Szájer, Tadeusz Zwiefka, Ángela Vallina (for Jiří Maštálka, pursuant to Rule 200(2)), Bogdan Brunon Wenta (for Therese Comodini Cachia, pursuant to Rule 200(2)).

Yours sincerely,

Pavel Svoboda