



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 11 April 2011 (14.04)
(OR. fr)**

8970/11

LIMITE

**JUR 172
INST 203**

OPINION OF THE LEGAL SERVICE (*)

Subject : **Application of Articles 290 (delegated acts) and 291 (implementing acts)
TFEU**

I. Introduction

1. This opinion of the Legal Service responds to a need for clarification, expressed by various Council Working Parties, regarding the application of Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
2. A number of questions relating to these articles are dealt with in this opinion, in particular their respective scopes, the distinction between the essential and non-essential elements of an act, the conditions to which delegation is subject and the possible mechanisms for control under those provisions.
3. Before examining aspects relating to the application of the two articles separately, we make a number of preliminary comments that apply to both articles.

* **This document contains legal advice protected under Article 4(2) of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, and not released by the Council of the European Union to the public. The Council reserves all its rights in law as regards any unauthorised publication.**

II. Comments applicable to both provisions

4. The conferral of delegated or implementing powers on the Commission must be carried out in accordance with Articles 290 and 291 TFEU. The possibility of conferring such powers on the Commission has to be assessed on a case-by-case basis in the framework and in the light of the treaty system. It should be noted that the legislature is entitled to establish not only the essential elements of an act, but also, if considered appropriate and subject to the principle of subsidiarity, all the rules of law for a specific area.
5. As was already the case before the entry into force of the Lisbon Treaty, only the power to adopt non-essential rules may be conferred on the Commission. The first subparagraph of Article 290(1) TFEU stipulates that the legislature may delegate to the Commission the power to supplement or amend "*non-essential elements of the legislative act*" and the second subparagraph adds that "*[t]he essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power*".
6. Article 291 TFEU makes no explicit reference to this point only because it is obvious that the implementation of a basic act cannot affect its essential elements¹.
7. The legislature has a considerable margin of discretion in determining the essential and non-essential elements of the acts it adopts. However, the case law of the Court of Justice has defined the limits of the concept. The classification of "essential" "*must be reserved for provisions which are intended to give concrete shape to the fundamental guidelines of Community policy*"². Accordingly, the modification of the material³, geographical or temporal

¹ The distinction made in the past by the case law of the Court of Justice between "*...rules which, since they are essential to the subject-matter envisaged, must be reserved to the Council's power, and those which, being merely of an implementing nature, may be delegated to the Commission*" (Judgment of 27 October 1992, Germany v Commission "German sheepmeat", C-240, ECR 1992, p. I 5383, paragraph 36 of the judgment, underlining added) remains applicable to implementing acts adopted by the Commission pursuant to Article 291 TFEU.

² See German sheepmeat case referred to above, paragraph 37 of the judgment.

³ See paragraphs 64 et seq. of the judgment of 23 October 2007, Parliament v Commission, C-403/05. See in this respect the opinion of the Legal Service of 21 September 2007 (13150/07, paragraph 7).

scope of a basic act constitutes an essential element of that act, which the legislature cannot in principle confer on the Commission under either Article 290 or Article 291 TFEU. No exception can be made unless the powers conferred on the Commission are so strictly circumscribed that its margin of discretion is either non-existent or extremely limited. The Legal Service has already expressed the view that the power to alter the temporal scope of an act would certainly interfere with its essential elements, unless it is strictly circumscribed⁴.

8. Likewise, the obligations imposed under an act and the consequences of any violation are essential elements which the basic act should define, at least with respect to their general nature⁵.
9. When the Commission is granted the power to update the basic act, without any margin of discretion, in the light of scientific data which may become available over time, unless those scientific data are in themselves crucial to the choices made by the legislature in the basic act, it may be considered that such power does not affect the essential elements of the basic act.
10. With regard to the respective scope of the two provisions, an initial observation must be made. In terms of procedure, there is a manifest difference between the delegation of legislative powers and the granting of implementing powers. However, it is just as clear that in use, the two procedures are not exclusive categories, but overlap considerably. While there are certain measures which can come only under Article 290 or under Article 291, there are many others which, depending on how they are presented, can constitute either acts that supplement "*certain non-essential elements of the legislative act*" or rules establishing "*uniform conditions for implementing*" basic acts. There are thus many cases in which it is not possible to determine by means of legal analysis, in a non-arbitrary way, that it is essential to choose Article 290 as the legal basis rather than 291 TFEU.

⁴ See the opinion of the Legal Service of 31 March 2010 (8177/10, paragraph 14).

⁵ See the opinion of the Legal Service of 17 March 2010 (7635/10), paragraphs 18-19.

III. Delegation of powers to the Commission pursuant to Article 290 TFEU

A. General considerations

11. Pursuant to Article 290 TFEU, the legislature may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the basic legislative act⁶ ("delegated acts"). Thus, the definition of a delegated act is similar to that of the measures which could be adopted under the regulatory procedure with scrutiny (PRAC) pursuant to Article 5a of the 1999 Decision on Committee Procedure (as amended in 2006)⁷. It should, however, be borne in mind that it is not possible to automatically replace all the existing provisions providing for the regulatory procedure with scrutiny with provisions providing for the power to adopt delegated acts. It is for the legislature to establish on a case-by-case basis, in the light of the provisions concerned, whether the measures in question come under the scope of Article 290 TFEU⁸ or Article 291 TFEU⁹. The legislature may also in all cases decide to incorporate in the basic act any provisions which were subject to the regulatory procedure with scrutiny, rather than making use of either Article 290 or 291 TFEU.

⁶ The procedure applicable within the Council for the implementation of Council prerogatives arising from Article 290 TFEU was the subject of a note of 25 February 2011 from the Secretary-General to the Directors-General of the GSC, of which all delegations received a copy.

⁷ Accordingly, the opinions delivered by the Legal Service distinguishing the scope of the regulatory procedure with scrutiny from that of other the committee procedures remain valid (see in particular 12336/06, 12813/06, 15038/06, 5658/07, 14179/09, 16323/09). It should also be noted that the new Regulation on Committee Procedure does not repeal Article 5a (PRAC) of Decision 1999/468/EC. In the statements accompanying the new Regulation on, the Commission undertakes to submit, by 2014, proposals amending basic acts containing the regulatory procedure with scrutiny to align them with the new provisions of the Lisbon Treaty.

⁸ Moreover, the legislature must make a choice concerning the objectives, content, scope and duration of the delegation of power (Article 290(1), second paragraph, TFEU), as well as the conditions to which the delegation is subject (article 290(2), TFEU).

⁹ See also Article 13(4) of the Regulation on Committee Procedure, which establishes that the automatic alignment of the previous committee procedures with the new procedures must not prejudice the nature of the acts concerned, i.e. their classification as delegated acts or implementing acts.

12. According to the case law of the Court of Justice, "[...] *when the Community legislature wishes to delegate its power to amend aspects of the legislative act at issue, it must ensure that that power is clearly defined and that the exercise of the power is subject to strict review in the light of objective criteria [...]*"¹⁰. The second subparagraph of Article 290(1) TFEU states that the "[...] *objectives, content, scope and duration of the delegation of power shall be explicitly defined*" in the basic legislative act.
13. In the light of the above, the delegation of powers to the Commission must be strictly circumscribed and the use of words such as "in particular" and other not clearly defined formulas for delegating powers¹¹ should be avoided.

B. Scope of Article 290 TFEU

14. Only measures of general application fall within the scope of Article 290 TFEU. Where the legislature wishes to confer powers on the Commission to adopt individual measures (e.g. individual authorisations to be granted to one or more Member States¹²), it may not do so by reference to Article 290 TFEU.

¹⁰ Judgment of 12 July 2005, Alliance for Natural Health and others, C-154/04 and C-155/04, ECR 2005, p. I-6451, paragraph 90.

¹¹ See *mutatis mutandis* the opinion of the Legal Service of 6 October 2009 (14179/09), paragraphs 4 and 8.

¹² It should be noted, however, that the Court of First Instance held that derogations from the general arrangements provided for under a Directive can, in certain circumstances, concern its general nature, "*given that they are addressed in abstract terms to undefined classes of persons and apply to objectively defined situations.*" (see Order of the Court of First Instance of 11 July 2000, Fédération nationale d'agriculture biologique des régions de France and others v Council, T 268/99, ECR p. II-2893, paragraphs 37 and 38, confirmed by the Order of the Court of Justice of 10 May 2001, Fédération nationale d'agriculture biologique des régions de France and others v Council, C 345/00 P ECR. p. I-3811; Order of the Court of First Instance of 16 February 2005, Fost Plus VZW. v Commission, T 142/03, paragraph 47).

15. Moreover, only legally binding measures may be delegated under Article 290¹³. The delegated acts which the Commission can adopt are acts which supplement or amend elements of legislative act. There are thus of a quasi-legislative nature and cannot take the form of mere recommendations or guidelines.
16. As already pointed out by the Legal Service in relation to the regulatory procedure with scrutiny, the term "amend" has a precise meaning. It means to make changes to a text by deleting, replacing or adding non-essential elements. The procedure provided for under Article 290 TFEU thus applies where the legislature envisages the basic act being amended by the addition of new non-essential elements or by the replacement or deletion of non-essential elements in the basic act itself (whether in an article of the basic act or in an annex).
17. The meaning of the term "supplement" is more complex, and relates to a grey area between the scope of Article 290 and that of Article 291 TFEU. To determine whether an act to be adopted by the Commission actually "supplements" the basic act, the legislature must in principle evaluate whether the future measure will add new (non-essential) rules which expand the legislative framework of the basic act, particularly by leaving a considerable margin of discretion to the Commission. If the answer is affirmative, then it could be considered, depending on the specific circumstances, that the measure "supplements" the basic act. Conversely, measures intended solely to give effect to existing rules in the basic act¹⁴, without adding new elements to the act, or to implement aspects already clearly defined by the legislature, would fall more under the scope of Article 291 TFEU than of Article 290 TFEU.

¹³ See *mutatis mutandis* the opinion of the Legal Service of 19 November 2009 (16323/09).

¹⁴ The Legal Service has already held that the implementing powers conferred on the Commission for the adoption of annual work programmes are not designed to make changes to the text of the basic instrument by deleting or replacing certain of its elements, or by supplementing the basic act by the addition of new non-essential elements. On the contrary, they are designed to implement specific existing rules in the basic act without allowing the Commission to add new elements and thus "supplement" it (Opinion of 26 January 2007, 5658/07, paragraph 6).

18. It is for the legislature to decide whether the text of the basic act needs to be "supplemented" and, if so, by what. The basis for the assessment must be given in the statement of reasons. While the legislature is entitled to regulate an entire area without providing for implementing measures, it may also regulate just a part of that area, leaving it to the Commission to "supplement" the rules by delegated acts on non-essential aspects¹⁵, provided of course that such delegation is properly defined and restricted.

C. Conditions and procedures for the delegation of powers

19. The Legal Service notes that the legislature has three options regarding the two *conditions* for the delegation of powers set out in Article 290 TFEU: first, it may decide not to impose conditions on the delegation of powers (i.e. not provide for any right to revoke the delegation nor any right to express objections to the delegated act); second, it may provide for a single condition; third, it may provide for both conditions cumulatively, in the basic legislative act.

¹⁵ Some recent examples of measures that "supplement" the basic act:

- The adoption of criteria and conditions to be fulfilled by categories of persons established by the basic act (see Article 12(4)(a) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45);
- The adoption of specifications relating to the conditions required for the addition of a species to an Annex to the basic act (see Article 1(6) of Regulation (EU) No 304/2011 of the European Parliament and of the Council of 9 March 2011 amending Council Regulation (EC) No 708/2007 concerning use of alien and locally absent species in aquaculture, OJ L 88, 4.4.2011, p. 1);
- The establishment of essential characteristics for which the manufacturer must declare the performance of the product when it is placed on the market or the setting of threshold levels for the performance in relation to the essential characteristics to be declared (see Article 3(3) of Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, text with EEA relevance, OJ L 88, 4.4.2011, p. 5);
- The adoption of supplementary procedural rules for drafting documents provided for by the basic act (see Article 19(3) of Regulation No 305/2011).

20. As the Legal Service has already stated¹⁶, the legislature may not lay down conditions different from those provided for by Article 290(2), i.e.: revocation of the delegation of powers, or objection. This does not preclude the legislature from making the Commission's exercise of delegated powers subject to the existence of objective triggering circumstances of law or of fact. The "conditions" mentioned in Article 290 are in fact procedural requirements for the use of delegation, not prerequisites determining when delegated powers come into play. However, this right cannot make it obligatory that there be prior intervention (e.g. through consultation) by EU institutions, their preparatory bodies or other bodies operating under a committee procedure.
21. On the other hand, there is nothing to prevent the legislature from providing, besides such objective circumstances considered as prerequisites, for the Commission to consult, at the preparatory stage of delegated acts, experts from e.g. Member States or interested parties (industry, NGOs, etc.), provided that that consultation is not a compulsory element of the delegated act¹⁷ and that its outcome does not bind the Commission¹⁸. Note too that in the financial services field, Declaration 39 annexed to the Final Act of the IGC which adopted the Lisbon Treaty spells out "*the Commission's intention to continue to consult experts appointed by the Member States in the preparation of draft delegated acts in the financial services area, in accordance with its established practice.*"

¹⁶ See in particular the abovementioned Legal Service opinion 8177/10, point 13.

¹⁷ The *Common Understanding* agreed by the European Parliament, the Council and the Commission on the procedural requirements for application of Article 290 TFEU in fact provides for the inclusion of such consultation in recitals (not in the enacting terms) of legislative acts conferring on the Commission powers to adopt delegated acts.

¹⁸ However, note that the legislative acts belonging to the financial supervision package define precisely the ways the Commission can diverge from draft delegated acts drawn up by the authorities instituted by the package (see in particular Article 10 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC, OJ L 331, 15.12.2010, p. 84).

22. Although not provided for by Article 290 TFEU, the delegation of powers can be tacitly (or automatically) extended. That extension is not a new condition of the Commission's exercise of its delegated powers. It represents a procedure linked to the delegation that the Commission proposed in its communication of December 2009¹⁹, it being understood that the delegation can be revoked at any time. The legislature has also included it in a number of acts²⁰.
23. Finally, it should be pointed out that the introduction of an "urgency procedure" in the basic legislative act to allow the Commission to adopt a delegated act that comes into force without delay raises reservations as regards its compatibility with Article 290 TFEU. The *Common Understanding* agreed by the three institutions provides for the use of such a procedure only in exceptional cases of urgency. Although the *Common Understanding* does not define the exceptional cases in which the procedure applies, restricting itself to listing certain fields by way of example (public health, security, international relations, including humanitarian crises), the Legal Service considers that use of the urgency procedure should be confined to cases where there are imperative or overriding general-interest requirements, in line with the case law of the Court²¹.

¹⁹ COM(673)2009, 9 December 2009.

²⁰ See in particular Article 1(7) of Regulation (EU) No 438/2010 of the European Parliament and of the Council of 19 May 2010 amending Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals, OJ L 132, 29.5.2010, p. 3, and Article 25(1) of Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ L 207, 6.8.2010, p. 14. See also point 9 of the *Common Understanding*.

²¹ See inter alia the judgments of 20 February 1979, *Rewe v Bundesmonopolverwaltung für Branntwein* (120/78, ECR 1979, p. 649), of 29 November 1983, *Roussel Laboratoria and others* (181/82, ECR 1983, p. 3849), and of 9 July 1992, *Commission v Belgium* (C-2/90, ECR 1992, p. I-4331).

IV. Conferral of implementing POWERS on the Commission under Article 291 TFEU

A. General considerations

24. While Article 290 TFEU is an innovation, Article 291 is in line with previously existing provisions (see Article 202 TEC and, before the Amsterdam Treaty, Article 145 TEC).
25. The Treaty first recalls one of the main features of the Union's legal system, namely that it is primarily for Member States to implement Union law (Article 291(1) TFEU)²². It then states that, where uniform conditions for implementing legally binding Union acts are needed, the legislature will confer on the Commission²³ the power to adopt implementing measures at Union level²⁴.

²² On this point see pages 2 and 3 of the Legal Service's opinion of 19 October 1998 (11987/98) and point 7 of the Legal Service's opinion of 2 February 2006 (5923/06).

²³ It should be noted that the Commission also has certain implementing powers conferred directly by the treaties. See for instance, in relation to competition rules, Article 106(3) TFEU: "*The Commission shall ensure the application of the provisions of this Article and shall, where necessary, address appropriate directives or decisions to Member States.*"

²⁴ It should be noted that Article 291(2) TFEU still provides for the possibility of conferring on the Council implementing powers for legally binding acts of the Union in duly justified cases. As was the case in applying Article 202 TEC, reasons must be given for such a decision; thus, the legislature must duly justify, on the basis of the nature and content of the basic act to be implemented, any exception to the rule that, in the treaty system, when it is necessary to take implementing measures at Union level for a basic act, it is for the Commission to exercise that power (*mutatis mutandis*, see point 8 of the Legal Service's opinion of 30 July 2009, 12506/09). The Court has already judged adequate a justification contained in relatively general recitals which, analysed in the context of the adoption of the act, showed clearly the grounds justifying the reservation of powers to the Council (see judgment of 18 January 2005, C-257/01, *Commission v Council*, paragraphs 53 to 59).

In conferring such powers on the Council, the legislature may provide that the latter act on a proposal of the Commission (on this, see points 10 and 11 of the Legal Service's opinion of 4 February 2011, 6134/11) or without a proposal from the Commission.

26. Although in its *Vreugdenhil* judgment²⁵ the Court acknowledged that "*the concept of implementation must be given a wide interpretation*", it also rejected generalising that ruling, emphasising that "*such a wide interpretation of the Commission's powers can be accepted only in the specific framework of the rules on agricultural markets*".
27. The basic act must in any case define the implementing powers conferred on the Commission, by spelling out inter alia the purpose of the powers conferred on the Commission²⁶, the reasons for which Commission intervention is necessary, whether or not it must²⁷ be accompanied by procedures for control by Member States (in that case applying the Regulation on Committee Procedure) and, when the latter option is used, what type of procedure the Commission is to use for the adoption of the implementing acts concerned.

²⁵ Judgment of 29 June 1989, *Vreugdenhil and others v Minister van Landbouw en Visserij* (22/88, ECR 1989, p. 2049), paragraph 17.

²⁶ As the Legal Service has stated, criteria should be established in the basic act to govern the exercise of the power to adopt the implementing measures conferred on the Commission. These criteria may be general and the purpose of their insertion would include enabling economic operators to be aware of the conditions in which, for instance, they could be the subject of an implementing measure adopted pursuant to the basic act (see point 12 of the opinion of 28 September 2009, 13772/09 + COR 1).

²⁷ It will be recalled that, as was the case under Article 202 TEC, the legislature still retains the right to decide that control by the Member States of implementing powers conferred on the Commission is not necessary. In that case, the Commission can adopt implementing measures without a committee procedure. Article 1 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, hereinafter "*the Regulation on Committee Procedure*") also states that it applies "*where a legally binding Union act (hereinafter a "basic act") identifies the need for uniform conditions of implementation and requires that the adoption of implementing acts by the Commission be subject to the control of Member States*" (our emphasis).

B. Scope of Article 291 TFEU

28. In contrast to Article 290 TFEU, Article 291 TFEU does not restrict the possibility of conferring implementing powers on the Commission solely to legislative acts. Any legally binding Union act may thus confer implementing powers on the Commission (or the Council) ²⁸.
29. As ruled by the Court and as provided by the Regulation on Committee Procedure, the concept of implementation for the purposes of Article 291 comprises both the drawing up of implementing rules (in the form of acts of general scope) and the application of rules to specific cases by means of acts of individual application²⁹.

²⁸ To make this note more readable, the term "the legislature" is used to refer to the author of legally binding acts conferring implementing powers on the Commission, even if the acts in question are not only legislative acts within the meaning of Article 289 TFEU.

²⁹ Judgment of 24 October 1989, *Commission v Council* 16/88, ECR 3457, paragraph 11. Examples of implementing powers that a basic act may confer on the Commission pursuant to Article 291 TFEU:

- defining the format or content of a report or a notification the submission of which by Member States is made obligatory by the basic act;
- granting (general) authorisations to produce/use/place on the market a given product or substance;
- verifying data provided by Member States, transmission of which is made obligatory by a basic act;
- drawing up studies, analyses and reports;
- establishing a list of projects eligible for EU funding, following verification that they meet all the conditions and criteria set out by the basic act;
- adopting decisions of individual application, e.g. granting individual authorisations to one or more Member States pursuant to the basic act;
- adopting guidelines essentially designed to provide a practical guide for submitting projects eligible for EU funding;
- drawing up guidelines on the application of the basic act, including strategic guidelines or strategy papers (in particular within the broader category of "external financial instruments").

C. Regulation on Committee Procedure

30. Under Article 291(3) TFEU, rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers are laid down by Parliament and the Council acting in accordance with the ordinary legislative procedure. The Legal Service notes that the Regulation on Committee Procedure, like Decision 1999/468/EC which preceded it, is "supra-legislative" in nature as the legislature is subject to the Regulation when exercising its legislative powers. Only those mechanisms for control laid down in advance in the Regulation in accordance with Article 291(3) TFEU may be used by the legislature³⁰.
31. The Regulation on Committee Procedure, which came into force on 1 March 2011, follows the same logic as that on which Decision 1999/468/EC was based. It does, however, introduce a number of significant changes in relation to the previous system, including the following in particular:
- it applies to all Union policies³¹;
 - the three previous procedures (advisory, management and regulatory) are replaced by two new procedures (advisory and examination);

³⁰ However, whilst it may happen that legislative acts impose an obligation on the Commission to consult agencies, specific committees, specialised bodies or even Member States designated in general in connection with the exercise of the implementing powers conferred on it, the involvement of such agencies, committees (not being those referred to in the Regulation on Committee Procedure) or bodies cannot form part of the committee procedure itself. If and when such committees or bodies are involved, their role should be limited to purely advisory functions prior to the committee procedure (see in this regard the opinions of the Legal Service of 21 November 2008 (16204/08, point 4) and of 30 July 2009 (12506/09, point 11)). Note, however, that in the legislative acts forming part of the financial supervision package referred to in the footnote on page 18, it is the authorities themselves that draw up the draft implementing acts which are then adopted by the Commission; the Commission may not change the content of a draft implementing technical standard prepared by an authority without prior coordination with that authority (see in particular Article 15 of Regulation (EU) No 1095/2010 referred to above).

³¹ Regarding competition law, recital 22 of the Regulation on Committee Procedure states that "*[t]he Commission's powers, as laid down by the TFEU, concerning the implementation of the competition rules are not affected by this Regulation*". Concerning the common commercial policy, trade defence measures are now included in the scope of the Regulation on Committee Procedure, though a number of arrangements are provided for to take account of their specific characteristics.

- matters are no longer referred to the Council in committee procedures, and an appeal committee made up of representatives of the Member States has been set up;
- in certain cases, the Commission may adopt measures even if the appeal committee delivers a negative opinion (or if no opinion is delivered)³².

32. The Legal Service considers it necessary at this stage to clarify certain aspects relating to the application of the new Regulation as regards the selection of procedures, the use of the option envisaged in point (b) of the second subparagraph of Article 5(4) or of that envisaged in Article 8, and the transition between Decision 1999/468/EC and the new Regulation.

(i) *Selection of procedures*

33. Article 2 of the Regulation on Committee Procedure lays down general criteria for the selection of procedures, while allowing the legislature some flexibility depending on the nature or the impact of the measure to be adopted by the Commission.

34. The scope of the examination procedure is very broad: in addition to measures in the areas set out in Article 2(2)(b)³³, it applies to the adoption of measures of general scope, regardless of area³⁴. Furthermore, the list of implementing acts to which the examination procedure applies (Article 2(2)) is not exhaustive.

35. The advisory procedure applies in principle to all individual measures in areas other than those referred to in Article 2(2)(b).

³² See Article 7 of the Regulation on Committee Procedure.

³³ The examination procedure applies in principle to external financial instruments. Such measures fall within the scope of Article (2)(2)(b)(i). Moreover, according to recital 12 of the Regulation on Committee Procedure, "[p]rovided that the basic act confers implementing powers on the Commission relating to programmes with substantial budgetary implications or directed to third countries, the examination procedure should apply."

³⁴ See Article 2(2)(a) of the Regulation on Committee Procedure.

36. Any decision by the legislature to deviate from the criteria set out in Article 2 must be duly justified.
- (ii) *Use of the option envisaged in point (b) of the second subparagraph of Article 5(4) of the Regulation on Committee Procedure*³⁵
37. The purpose of Article 5(4) of the Regulation on Committee Procedure is to make provision, as part of the examination procedure, for the consequences of an absence of an opinion from the committee to which the Commission refers a draft implementing act. The first subparagraph of this provision enables the Commission to adopt the draft implementing act in the absence of an opinion from the committee. However, three exceptions are set out in the second subparagraph and one of them (point (b)) allows the legislature to stipulate in the basic act that the draft implementing act may not be adopted by the Commission where no opinion is delivered by the committee.
38. In the light of the specific features of each case, it is therefore up to the legislature to determine whether or not to avail itself, in the basic act, of the option made available by point (b) of the second subparagraph of Article 5(4) of the Regulation on Committee Procedure, thus preventing the Commission from adopting a draft implementing act in the absence of an opinion from the committee. No legal considerations limit the use of this option. Unlike other provisions of the Regulation on Committee Procedure³⁶, Article 5(4) requires no specific justification for this choice.
39. Regarding the recasting or amendment of acts which referred to the regulatory procedure provided for in Decision 1999/468/EC, it should be noted that the procedure in the new Regulation on Committee Procedure which is closest to that old procedure is the one referred to in point (b) of the second subparagraph of Article 5(4). This interpretation is confirmed by the fact that the transitional provisions in Article 13(1)(c) of the Regulation provide for the automatic substitution of the procedure in Article 5 for the regulatory procedures which existed on 1 March 2011.

³⁵ Points 37 to 40 are taken from the opinion of the Legal Service of 4 March 2011 (7325/11).

³⁶ See, in particular, Article 8(1), which states: "*a basic act may provide that, on duly justified imperative grounds of urgency, this Article is to apply*" (our emphasis).

40. Naturally, the decision on whether or not to use point (b) of the second subparagraph of Article 5(4) is entirely a matter for the legislature. This also applies to the old regulatory procedures, the old advisory procedures and the old management procedures.

(iii) Use of the option provided for in Article 8 of the Regulation on Committee Procedure

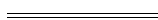
41. Article 8 of the Regulation on Committee Procedure allows the legislature to make provision, in the basic act, for what could be referred to as an "urgency" procedure to apply where there are duly justified imperative grounds of urgency³⁷. This is not a self-standing procedure but an arrangement that is possible as part of an advisory or examination procedure.

42. Use of the urgency procedure and the situations in which it is possible must be set out explicitly in the basic act. It is therefore up to the legislature to determine the circumstances under which the urgency procedure will apply. Although the Regulation on Committee Procedure does not define cases of imperative urgency, the Legal Service considers that use of the urgency procedure should be limited to cases where there are imperative or overriding general-interest requirements, in line with the case law of the Court. The main characteristic of this procedure is that the implementing act is adopted by the Commission without first referring the matter to a committee. The adopted act comes into force immediately and remains in force for a period not exceeding six months, unless the basic act provides otherwise. If, under the examination procedure, the committee delivers a negative opinion on an act adopted by the urgency procedure, the Commission is required to repeal that act immediately. The matter is not referred to the appeal committee.

³⁷ This should not be confused with the option available to the Commission under Article 7 of the Regulation on Committee Procedure, in the context of the examination procedure, to adopt an implementing act despite a negative opinion (or in the absence of an opinion) by the committee where the act needs to be adopted without delay in order to avoid creating a significant disruption of the markets in the area of agriculture or a risk for the financial interests of the Union within the meaning of Article 325 TFEU. The legislature does not have to make provision for this option in the basic act; its use by the Commission is made possible directly by the Regulation on Committee Procedure.

(iv) *Transition between Decision 1999/468/EC and the new Regulation on Committee Procedure*

43. As set out in Article 13(1) of the Regulation on Committee Procedure, from 1 March 2011 onwards, the advisory procedure provided for under the Regulation on Committee Procedure applies where reference is made to the advisory procedure under Decision 1999/468/EC, while the examination procedure applies where reference is made to the management or regulatory procedures under the same Decision³⁸. Even where texts originating before the entry into force of the Regulation on Committee Procedure are not formally amended, application of the new procedures does not require the adoption of a particular act.
44. Under Article 14, the Regulation on Committee Procedure does not affect ongoing procedures in which a committee has already delivered an opinion under Decision 1999/468/EC. This provision also covers cases where no opinion is delivered, provided that the vote in committee that led to the absence of an opinion was held before 1 March 2011. In such situations, the matter would still be referred to the Council under the relevant provisions of Decision 1999/468/EC.



³⁸ Specific arrangements on the replacement of the old management and regulatory procedures by the new examination procedure are set out in Article 13(1)(b) and (c).