Reports of Cases

JUDGMENT OF THE COURT (Grand Chamber)

13 March 2018*

(Appeal — Plant protection products — Implementing Regulation (EU) 2015/408 — Placing on the market of plant protection products and establishing a list of candidates for substitution — Inclusion of active substance metalaxyl in that list — Action for annulment — Admissibility — Article 263, fourth paragraph, TFEU — Regulatory act that does not entail implementing measures — Individually concerned person)

In Case C-244/16 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 27 April 2016,

Industrias Químicas del Vallés SA, established in Mollet del Vallés (Spain), represented by C. Fernández Vicién, C. Vila Gisbert and I. Moreno-Tapia Rivas, abogadas,

appellant,

the other party to the proceedings being:

European Commission, represented by I. Galindo Martín and P. Ondrůšek, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, A. Tizzano, Vice-President, R. Silva de Lapuerta, T. von Danwitz, J.L. da Cruz Vilaça, A. Rosas, C.G. Fernlund and C. Vajda, Presidents of Chambers, C. Toader, M. Safjan, D. Šváby, M. Berger, A. Prechal, E. Jarašiūnas and E. Regan (Rapporteur), Judges,

Advocate General: M. Wathelet,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 6 June 2017,

after hearing the Opinion of the Advocate General at the sitting on 6 September 2017,

gives the following

* Language of the case: Spanish.

Judgment

1 By its appeal, the appellant, Industrias Químicas del Vallés SA, seeks the annulment of the order of the General Court of the European Union of 16 February 2016, *Industrias Químicas del Vallés* v *Commission* (T-296/15, not published, 'the order under appeal', EU:T:2016:79), by which the General Court rejected as inadmissible its action seeking the partial annulment of Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ 2015 L 67, p. 18) ('the regulation at issue').

Legal context

Directive 91/414

2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) as last amended by Commission Directive 2011/34/EU of 8 March 2011 (OJ 2011 L 62, p. 27) ('Directive 91/414'), provided, in Annex I, a list of active substances the inclusion of which was authorised in plant protection products.

3 In accordance with Article 1 and the Annex to Commission Directive 2010/28/EU of 23 April 2010 amending Council Directive 91/414/EEC to include metalaxyl as active substance (OJ 2010 L 104, p. 57), the list in Annex I to Directive 91/414 was amended to add that substance.

Regulation (EC) No 1107/2009

4 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 (OJ 2009 L 309, p. 1), provides, in Article 14, entitled 'Renewal of approval', which is in subsection 3, entitled 'Renewal and review', of Section 1, entitled 'Active substances' of Chapter II of that regulation, entitled 'Active substances, safeners, synergists and co-formulants':

'1. On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

…

2. The renewal of the approval shall be for a period not exceeding 15 years. ...'

5 Article 20, entitled 'Renewal Regulation', which is also in subsection 3 of Regulation No 1107/2009 is worded as follows:

'1. A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

(a) the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or

(b) the approval of an active substance is not renewed.

…'

6 Article 24, entitled 'Candidates for substitution', which is in subsection 4, entitled 'Derogations', of Section 1 of Chapter II of Regulation No 1107/2009, provides:

'1. ... By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding seven years.

2. Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in the Regulation referred to in Article 13(4).'

7 Article 41, entitled 'Authorisation', which is in subsection 3, entitled 'Mutual recognition of authorisations', of Section 1, entitled 'Authorisation', of Chapter III of that regulation, entitled 'Plant protection products', provides as follows:

'1. The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies.

2. By way of derogation from paragraph 1, the Member State may authorise the plant protection product where:

…

(b) it contains a candidate of substitution;

…'

8 Article 50, entitled 'Comparative assessment of plant protection products containing candidates for substitution', which is in subsection 5, entitled 'Special cases', of Section 1 of Chapter III of the regulation provides:

'1. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

…

4. For plant protection products containing a candidate for substitution Member States shall perform the comparative assessment provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, Member States shall maintain, withdraw or amend the authorisation.

…'

9 Article 80, entitled ‘Transitional measures’, which is in Chapter XI of the same regulation entitled ‘Transitional and final provisions’, provides, in paragraph 7:

‘By 14 December 2013, the Commission shall establish a list of substances included in Annex I to Directive [91/414] which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply.’

Implementing regulations

Implementing Regulation (EU) No 540/2011

10 According to recital 1 and Article 1 of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation No 1107/2009 as regards the list of approved active substances (OJ 2011 L 153, p. 1), active substances included in Annex I to Directive 91/414 are to be deemed to have been approved under Regulation No 1107/2009.

The regulation at issue

11 Article 1 of the regulation at issue, entitled ‘Candidates for substitution’, is worded as follows:

‘Active substances included in Annex I to Directive [91/414] which fulfil the criteria set out in point 4 of Annex II to Regulation [No 1107/2009] shall be as set out in the list in the Annex to this Regulation.

…’

12 The list in the annex to that regulation includes metalaxyl.

Background to the dispute

13 The background to the dispute, as described in paragraphs 1 to 6 of the order under appeal, may be summarised as follows.

14 The appellant is a company established under Spanish law whose activities include the manufacture, sale, distribution, representation and marketing of plant protection products, animal feed products, and other chemical products. It imports, in particular, an active chemical substance, metalaxyl, into Spain and markets plant protection products containing that active substance in a number of Member States.

15 In April 1995, the appellant and another company submitted a request to the competent authorities in the Portuguese Republic to include metalaxyl in the list in Annex I to Directive 91/414.

16 By Decision 2003/308/EC of 2 May 2003 concerning the non-inclusion of metalaxyl in Annex I to Directive 91/414 and the withdrawal of authorisations for plant-protection products containing that active substance (OJ 2003 L 113, p. 8), the Commission rejected that request and invited the Member States to withdraw authorisations granted for plant protection products containing metalaxyl and not to grant any new authorisations.

17 By judgment of 28 June 2005, *Industrias Químicas del Vallés* v *Commission* (T-158/03, EU:T:2005:253), the General Court dismissed the action for annulment brought by the appellant, which was directed against Decision 2003/308.

18 By judgment of 18 July 2007, *Industrias Químicas del Vallés* v *Commission* (C-326/05 P, EU:C:2007:443), the Court upheld the appeal brought by the appellant against the judgment of 28 June 2005, *Industrias Químicas del Vallés* v *Commission* (T-158/03, EU:T:2005:253), and set it aside. Considering that the state of the proceedings permitted a final ruling to be made, the Court, pursuant to the second sentence of the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, ruled on the merits of the case and annulled Decision 2003/308.

19 On 23 April 2010, the Commission adopted Directive 2010/28 to add metalaxyl to the list of active substances set out in Annex I to Directive 91/414.

20 By the regulation at issue, the Commission added metalaxyl to the list of candidates for substitution, annexed to that regulation, on the ground that that substance contained a significant proportion of non-active isomers, within the meaning of point 4 of Annex II to Regulation No 1107/2009.

The proceedings before the General Court and the order under appeal

21 By application lodged at the Registry of the General Court on 5 June 2015, the appellant brought an action for partial annulment of the regulation at issue.

22 By the order under appeal, the General Court dismissed that action as inadmissible on the ground, first, that the appellant was not individually concerned by the regulation at issue and, second, that that regulation was a regulatory act that entailed with regard to the appellant implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU. The General Court also dismissed the appellant's argument that, if its action were rejected as inadmissible, it would be denied effective judicial protection.

Forms of order sought

23 By its appeal, the appellant claims that the Court should:

– set aside the order under appeal;

– declare its action for annulment brought against the regulation at issue to be admissible;

– refer the case back to the General Court for judgment; and

– order the Commission to pay the costs relating to the appeal proceedings.

24 The Commission asks the Court to dismiss the appeal and order the appellant to pay the costs.

The appeal

The first ground of appeal

Arguments of the parties

25 By its first ground of appeal, the appellant contests paragraphs 39 to 41, 43 to 46, 48 to 50, 58 and 59 of the order under appeal and criticises the General Court for having concluded that the regulation at issue entails implementing measures, within the meaning of the final limb of the fourth paragraph of Article 263 TFEU.

26 According to the appellant, in order to assess whether a regulatory act entails implementing measures it is necessary to assess it by reference to, first, the position of the person pleading the right to bring proceedings under the fourth paragraph of Article 263 TFEU and, second, the subject matter of the action. In the latter regard, in the event that the appellant seeks only the partial annulment of an act, it is appropriate to take into consideration solely any implementing measures of the part of the act of which annulment is sought.

27 As regards, first, the appellant's position, it is the proprietor of the European registration for metalaxyl and national registrations for plant protection products containing that substance.

28 As regards, second, the subject matter of the action brought before the General Court, the appellant recalls that it sought the partial annulment of the regulation at issue in so far as it classifies metalaxyl as a candidate for substitution, thus submitting it to the regime applicable to such substances laid down in Regulation No 1107/2009. The appellant also raised the plea of the illegality of certain provisions of that regulation.

29 According to the appellant, the order under appeal, in particular in paragraphs 23, 35 and 36, contains too short a description of the subject matter of the action which is based on an equally limited description of the regulation at issue. The purpose of the latter is not only to establish a list of candidates for substitution, but also to subject those substances to the substantive provisions contained in Regulation No 1107/2009, which is, according to the appellant, an immediate and direct effect of the application of the regulation at issue and does not require any implementing measure. In other words, that regulation would produce, by itself, in a manner which is both definite and immediate, concrete effects on the appellant's legal situation.

30 In that regard, the appellant observes, first, that, as is clear from paragraphs 39 to 41 of the order under appeal, it is true that the renewal of approval of metalaxyl, under Regulation No 1107/2009, will take place in the future and that the Commission must adopt a new act upon the request for renewal that the appellant will submit. It submits, however, that that act will be an implementing measure not of the regulation at issue but of Article 14 et seq. of Regulation No 1107/2009, which govern the procedure for the renewal of approval of an active substance.

31 The appellant emphasises that that act will have no effect of completing or changing the legal status of candidates for substitution and will not contribute to defining or clarifying the substantive rules applicable to them.

32 The appellant also highlights the fact that the regulation at issue has the effect of subjecting metalaxyl to approval every 7 years at least, and not every 15 years as is the case for active substances which are not candidates for substitution.

33 The appellant submits, secondly, that as regards the national authorisation of plant protection products containing metalaxyl of which the appellant is a proprietor, the regulation at issue has the immediate effect of subjecting those products and their use to the comparative assessment referred to in Article 50 of Regulation No 1107/2009. In that regard, contrary to the General Court's finding made in paragraph 45 of the order under appeal, Member States make the companies concerned bear the costs not only of the comparative assessment but also of carrying out the assessment itself, since the national authorities merely adopt a decision on the application for renewal of the authorisation for the plant protection product in question. Thus, the appellant is required to meet the obligations resulting from the comparative assessment irrespective of the final result of that assessment.

34 In finding, in paragraph 43 of the order under appeal, that the performance of that comparative assessment has no bearing on the fact that marketing authorisations are granted or refused, renewed, withdrawn or amended by the Member States, the General Court fails to take account of the fact that the effect of the regulation at issue is unconnected with any decision taken by a national authority.

Article 50(4) of Regulation No 1107/2009 requires Member States to perform the comparative assessment regularly and, at the latest, at renewal or amendment of the authorisation. Therefore, no application for authorisation or renewal of an authorisation would be necessary for the Member State concerned to carry out a comparative assessment of metalaxyl, which would be the direct consequence of its classification as a candidate for substitution.

35 Thirdly, in the appellant's opinion, a similar conclusion must be reached as regards the principle of mutual recognition, between Member States, of plant protection products. As a result of the adoption of the regulation at issue, mutual recognition of a product containing a candidate for substitution is no longer automatic, as is the case, by contrast, for all other active substances.

36 Fourthly, in the same way as the Commission's act on the renewal of approval of metalaxyl, measures adopted by Member States on a request for mutual recognition or national authorisation have no effect either on the classification of metalaxyl as a candidate for substitution or on the regime applicable to it under Regulation No 1107/2009.

37 The appellant adds that, in the same way as the acts that will be adopted by the Commission, those that will be adopted by Member States in order to implement the specific rules applicable to metalaxyl will be implementing measures not of the regulation at issue, but of Regulation No 1107/2009.

38 The Commission disputes the appellant's arguments.

Findings of the Court

39 It must be recalled at the outset that the admissibility of an action brought by a natural or legal person against an act which is not addressed to them, in accordance with the fourth paragraph of Article 263 TFEU, is subject to the condition that they be accorded standing to bring proceedings, which arises in two situations. First, such proceedings may be instituted if the act is of direct and individual concern to those persons. Second, such persons may bring proceedings against a regulatory act not entailing implementing measures if that act is of direct concern to them (see, inter alia, judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraphs 59 and 91).

40 In the context of the examination of the second situation, made in paragraphs 30 to 49 of the order under appeal, the General Court found, in paragraphs 31 to 33 of that order, that the regulation at issue is a regulatory act within the meaning of the final limb of the fourth paragraph of Article 263 TFEU, which is not contested by the parties in the present appeal.

41 Consequently, the question that must be examined is whether, as the appellant submits, the General Court erred in law in finding, in paragraphs 34 to 49 of the order under appeal, that the regulation at issue entails implementing measures in respect of the appellant.

42 In that regard, it must be recalled that the expression 'which … does not entail implementing measures', within the meaning of the final limb of the fourth paragraph of Article 263 TFEU, must be interpreted in the light of the objective of that provision, which is, as is apparent from its drafting history, to ensure that individuals do not have to break the law in order to have access to a court. Where a regulatory act directly affects the legal situation of a natural or legal person without requiring implementing measures, that person could be denied effective judicial protection if he did not have a legal remedy before the European Union judicature for the purpose of challenging the legality of the regulatory act. In the absence of implementing measures, natural or legal persons, although directly concerned by the act in question, would be able to obtain a judicial review of that

act only after having infringed its provisions, by pleading that those provisions are unlawful in proceedings initiated against them before the national courts (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 29 and the case-law cited).

43 By contrast, where a regulatory act entails implementing measures, judicial review of compliance with the European Union legal order is ensured irrespective of whether those measures were adopted by the European Union or the Member States. Natural or legal persons who are unable, because of the conditions governing admissibility laid down in the fourth paragraph of Article 263 TFEU, to challenge a regulatory act of the European Union directly before the European Union judicature are protected against the application to them of such an act by the ability to challenge the implementing measures which the act entails (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 30 and the case-law cited).

44 Where responsibility for the implementation of such acts lies with the institutions, bodies, offices or agencies of the European Union, natural or legal persons are entitled to bring a direct action before the European Union judicature against the implementing acts under the conditions stated in the fourth paragraph of Article 263 TFEU, and to plead in support of that action, pursuant to Article 277 TFEU, the illegality of the basic act at issue. Where that implementation is a matter for the Member States, those persons may plead the invalidity of the basic act at issue before the national courts and tribunals and cause the latter to request a preliminary ruling from the Court of Justice, pursuant to Article 267 TFEU (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 31 and the case-law cited).

45 As the Court has already held, whether a regulatory act entails implementing measures should be assessed by reference to the position of the person pleading the right to bring proceedings under the final limb of the fourth paragraph of Article 263 TFEU. It is therefore irrelevant whether the act in question entails implementing measures with regard to other persons (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 32 and the case-law cited).

46 Furthermore, in the context of that assessment, it is necessary to refer exclusively to the subject matter of the action and, where an applicant seeks only the partial annulment of an act, it is solely any implementing measures which that part of the act may entail that must, where appropriate, be taken into consideration (judgment of 10 December 2015, *Kyocera Mita Europe* v *Commission*, C-553/14 P, not published, EU:C:2015:805 paragraph 45, and the case-law cited).

47 Moreover, it is entirely irrelevant, in that regard, whether those measures are of a mechanical nature (judgments of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraphs 41 and 42, and of 10 December 2015, *Kyocera Mita Europe* v *Commission*, C-553/14 P, not published, EU:C:2015:805, paragraph 46).

48 In the present case, it is necessary, in the first place, to reject the appellant's argument that the General Court did not properly take into consideration the subject matter of the action brought before it, in particular the fact that that action sought the annulment of the regulation at issue in so far as it subjects metalaxyl to certain substantive rules laid down by Regulation No 1107/2009, as unfounded.

49 It is clear from paragraphs 35 to 38 of the order under appeal that, after recalling that the purpose of the regulation at issue was to establish a list of candidates for substitution, the General Court noted that Regulation No 1107/2009 provided for the application, to those substances, of particular rules that derogate from those applicable to other active substances. The General Court stated, in paragraph 38 of the order under appeal, that those particular rules concern, first, the approval of

candidates for substitution and the renewal of that approval, secondly, the marketing authorisations for plant protection products containing such substances and the renewal and amendment of those authorisations and, thirdly, the mutual recognition between Member States of those authorisations.

50 It is also clear from paragraphs 39 to 49 of the order under appeal that the General Court carried out a detailed examination of those particular rules and concluded that they were only capable of producing their effects on the appellant's legal situation through acts adopted by the Commission or the Member States.

51 In the second place, it is necessary to examine the appellant's arguments challenging the correctness of that conclusion.

52 In that regard, it must be observed that the fact that a regulatory act of the European Union entails implementing measures, within the meaning of the final limb of the fourth paragraph of Article 263 TFEU, such that certain legal effects of the regulation only materialise through those measures, does not exclude that that regulation produces, in the legal situation of a natural or legal person, other legal effects, which do not depend on the adoption of implementing measures.

53 In the present case, it is necessary therefore to take into account the three categories of particular rules applicable to metalaxyl that are set out in paragraph 49 above and upon which the appellant relies in support of its appeal, in order to determine whether the regulation at issue, owing to the fact that it subjects metalaxyl to those rules, produces effects on the legal situation of the appellant which do not depend upon any sort of implementing measure.

54 As regards, first, the rules in respect of the approval of candidates for substitution and renewal of that approval, it is necessary, first, to recall, as the General Court observed in paragraph 39 of the order under appeal, that metalaxyl was the object of an approval before the adoption of the regulation at issue. Second, as the Commission submitted at the hearing before the Court of Justice, the expiry date of that approval was not affected by the regulation at issue.

55 It follows, as the General Court also noted in paragraph 39 of the order under appeal, without that point being challenged in this appeal, that only the procedure for the renewal of approval of candidates for substitution, as provided for in Regulation No 1107/2009, is relevant as regards the appellant.

56 In that regard, as is stated in paragraph 39 of the order under appeal, without the appellant contesting the point, Article 24(1) of Regulation No 1107/2009 provides that the approval of a candidate for substitution is renewable for a maximum period of 7 years, unlike the approval of other active substances which may be renewed for a maximum period of 15 years, pursuant to Article 14(2) of that regulation. Therefore, the fact of including metalaxyl in the list annexed to the regulation at issue, as a candidate for substitution, the renewal of its approval could be granted for a period of only seven years and not for a longer maximum period, as would have been the case if that substance were not included in that list.

57 However, the legal effects of the regulation at issue on the duration of the validity of the renewal of approval of metalaxyl will only materialise, in respect of the appellant, through the intermediary of implementing measures.

58 It follows from the provisions of Regulation No 1107/2009, in particular, Article 24(2) thereof, that, as the General Court stated in paragraphs 39 and 40 of the order under appeal, without it being contested in the appeal, the classification of metalaxyl as a candidate for substitution, by the regulation at issue, is without prejudice to the application of the procedure for the renewal of approval of that substance.

That procedure requires, in the same way as the procedure for the renewal of approval of an active substance which is not included on the list annexed to the regulation at issue, the adoption of a regulation by the Commission, pursuant to Article 20(1) of Regulation No 1107/2009.

59 It follows, as the General Court correctly held in paragraph 41 of the order under appeal, that the effects of the regulation at issue on the duration of the validity of the renewal of approval of metalaxyl will be deployed with respect to the appellant only by the possible adoption, on the basis of Article 20(1) of Regulation No 1107/2009, to which Article 24(2) of that regulation refers, of a regulation renewing for a maximum period of seven years the approval of that substance.

60 Thus, if the potential additional burden on the appellant connected to the necessity of renewing the approval of metalaxyl more frequently may be regarded as an effect of the adoption of the regulation at issue, that effect will materialise not by the adoption of that regulation, but by the adoption, should it occur, by the Commission of a regulation on the renewal of approval of that substance.

61 Therefore the General Court did not commit any error of law in finding, in paragraph 41 of the order under appeal, that a Commission regulation on the renewal of approval of candidates for substitution such as metalaxyl, is an implementing measure of the regulation at issue, within the meaning of the final limb of the fourth paragraph of Article 263 TFEU.

62 As regards, secondly, the rules on marketing authorisations for plant protection products containing candidates for substitution and on renewal and amendment of those authorisations, it is true, as the appellant observes, that the regulation at issue has the effect of subjecting those plant protection products containing metalaxyl to the comparative assessment procedure, laid down in Article 50 of Regulation No 1107/2009, in the context of which the health or environmental risks of the plant protection product concerned are compared with risks of same nature connected with a replacement product or a non-chemical pest control or prevention method.

63 However, the appellant cannot successfully submit that it bears the responsibility of performing that comparative assessment, and the potential costs incurred in carrying out the assessment, in order to demonstrate that the adoption of the regulation at issue had effects for it irrespective of the adoption of implementing measures. As the General Court correctly held in paragraph 42 of the order under appeal, it is clear from Article 50(1) and (4) of Regulation No 1107/2009 that it is the Member States that are required to perform the comparative assessment.

64 As regards the appellant's argument that the national authorities of certain Member States require the proprietors of national registrations of plant protection products containing metalaxyl to provide them with a comparative assessment, there is no support for its thesis that the regulation at issue would produce effects on its legal situation that do not depend upon implementing measures. The obligations alleged to be borne by those proprietors are the result, not of the regulation at issue but of a decision by the competent national authorities.

65 Moreover, as the General Court correctly held in paragraph 43 of the order under appeal, without it being contested by the appellant, the performance of the comparative assessment referred to in Article 50 of Regulation No 1107/2009 has 'no influence on the fact that, pursuant to Article 36(2), Article 43(1), Article 44(3) and Article 45(1) of Regulation No 1107/2009, marketing authorisations for plant protection products containing active substances may, as appropriate, be granted or refused, renewed, withdrawn or amended by the Member States'.

66 In those circumstances, the General Court also did not err in law in holding, in paragraph 44 of that order, that the effects of the regulation at issue on the performance, by the Member States, of a comparative assessment of the health or environmental risks of plant protection products containing metalaxyl compared with a substitute product or a non-chemical method of pest control or prevention 'will not be made with respect to the [appellant] except through the intermediary of measures taken by

the competent authorities of the Member States' and that 'such acts constitute, therefore, implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU'.

67 Thirdly, as regards the rules on mutual recognition between Member States of marketing authorisations of plant protection products containing candidates for substitution, it is true that Article 41(2)(b) of Regulation No 1107/2009 provides that a Member State that receives, under the mutual recognition procedure, an application for marketing authorisation for plant protection products containing a candidate for substitution may authorise those plant protection products, whereas, outside the other hypotheses covered by Article 41(2), and without prejudice to the application of Article 36(3) of that regulation, the Member State is required, under Article 41(1) of that regulation, to issue such an authorisation in accordance with the conditions laid down in that latter provision.

68 However, even if the adoption of the regulation at issue had the effect of reducing the likelihood that a Member State would grant an application for marketing authorisation of a plant protection product containing metalaxyl under the mutual recognition procedure, it remains the case that the Member State before which such an application is brought is required to make a decision on it. In that regard, it must be recalled that, as follows from paragraph 47 above, it is irrelevant whether such a decision is mechanical or not.

69 Consequently, the General Court was correct to hold, in paragraph 48 of the order under appeal, that the effects of the regulation at issue in respect of the procedure for the mutual recognition of marketing authorisations for plant protection products containing a substance that is a candidate for substitution 'concern only the margin of discretion available to Member States in ruling on an application to that effect' and that 'those effects will not arise, if they do arise, as regards the applicant except by the intermediary of measures by national authorities ruling on the applications for mutual recognition lodged by the applicant'.

70 Having regard to paragraphs 52 to 69 above, it is necessary to conclude that while it is certainly true that by including metalaxyl in the list of candidates for substitution the regulation at issue subjected that substance to specific rules set out in paragraph 49 above and therefore produced legal effects in that it alters the EU legal regime applicable to metalaxyl, it remains the case that the appellant has not demonstrated that that alteration had, on its legal situation, effects that did not depend upon the adoption of implementing measures, within the meaning of the final limb of the fourth paragraph of Article 263 TFEU. Therefore, the General Court was correct in law to hold that the appellant did not have standing to bring an action on that basis.

71 That conclusion is not called into question by the appellant's argument, set out in paragraphs 30 and 37 above, that the measures adopted by the Commission or the Member States in order to implement the specific rules applicable to metalaxyl, in particular the act by which the Commission will renew the approval of that substance, are implementing measures not of the regulation at issue but of Regulation No 1107/2009.

72 Contrary to what the appellant appears to imply in its submissions, the wording of the final limb of the fourth paragraph of Article 263 TFEU does not require, for a measure to be classified as an implementing measure of a regulatory act, that that act is the legal base of that measure. The same measure may be an implementing measure both of the act the provisions of which constitute its legal base and of a different act, such as, in the present case, the regulation at issue, where all or part of the legal effects of the latter act will be produced, vis-à-vis the applicant, only through the intermediary of that measure (see, by analogy, judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 40).

73 In the present case, it is clear from paragraphs 54 to 70 above that the acts that will be adopted by the Commission or by the Member States in order to implement the specific rules applicable to metalaxyl, laid down in Regulation No 1107/2009, will produce the legal effects of the regulation at issue vis-à-vis the appellant and will therefore constitute implementing measures of the latter regulation.

74 The conclusion reached in paragraph 70 of this judgment is also not undermined by the argument set out in paragraphs 31 and 36 above, that the measures that may be adopted by the Commission or by the Member States in order to give effect to the application, to metalaxyl, of the specific rules set out in paragraph 49 above, will have no effect either on the classification of metalaxyl as a substance that is a candidate for substitution or on the legal regime applicable to that substance established by Regulation No 1107/2009.

75 That argument is not capable of overturning the finding that the effects of the application to metalaxyl of the specific rules laid down by Regulation No 1107/2009 will only be produced, vis-à-vis the appellant's legal situation, through the intermediary of the implementing measures of the regulation at issue.

76 Having regard to all the foregoing considerations, the General Court was fully entitled to conclude in paragraph 49 of the order under appeal that the regulation at issue entails, vis-à-vis the appellant, implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU.

77 Consequently, the first ground of appeal must be rejected as unfounded.

The third ground of appeal

Arguments of the parties

78 By its third ground of appeal, which it is appropriate to examine second, the appellant challenges the General Court's ruling, in paragraphs 28 and 29 of the order under appeal, that it was not individually concerned by the regulation at issue.

79 The appellant submits that it was the only author of a notification to the Commission seeking the inclusion of metalaxyl in Annex I to Directive 91/414. It also brought actions before the General Court and the Court of Justice, which led to the annulment of the first negative Commission decision and the adoption of Directive 2010/28 by which metalaxyl was included in Annex I to Directive 91/414.

80 The appellant alleges that since it was the only company to have asked for the inclusion of metalaxyl in Annex I to Directive 91/414 and therefore the only entity responsible for that inclusion — upon which, furthermore, all the national registrations in force for plant protection products containing metalaxyl depend — it is individually concerned by the regulation at issue. That fact differentiates it, as regards metalaxyl, from all other persons.

81 The appellant adds that it is clear from recital 4 of the regulation at issue that it was adopted on the basis, in particular, of the assessment reports on active substances and that one of those reports refers to the fact that it was the only author of the notification referred to in paragraph 79 above. The appellant submits that it is therefore individually concerned by that regulation.

82 The appellant considers that the order under appeal must, therefore, be set aside, and that the Court has all the information necessary to examine whether it is, moreover, directly concerned by the regulation at issue.

83 In that regard, the appellant submits, first, that the submission of metalaxyl to the substantive provisions laid down in Regulation No 1107/2009 requires the application to that substance of more restrictive conditions than those applicable to active substances that are not candidates for substitution. It observes, second, that that fact is the direct result of the regulation at issue and that neither the Commission nor the national authorities have any margin of discretion, when adopting measures implementing the specific rules applicable to metalaxyl, as regards the classification of metalaxyl as a candidate for substitution.

84 The Commission submits that the third ground of appeal is inadmissible since the appellant merely recalls that it brought an application that led to the inclusion of metalaxyl in the list of active substances in Annex I to Directive 91/414. The appellant does not raise arguments capable of demonstrating that the General Court wrongly held that that fact was not, in itself, capable of distinguishing it and does not specifically contest the General Court's finding that a person's intervention in the process leading to the adoption of a European Union act is capable of distinguishing him in relation to the act in question where the European Union legislation gives him certain procedural guarantees.

85 The Commission adds that this ground is, in any event, unfounded.

Findings of the Court

86 Without it being necessary to rule on the admissibility of the argument advanced by the appellant in the context of this ground of appeal, for the purpose of demonstrating that it is individually concerned by the regulation at issue, that argument must, in any event, be rejected as unfounded.

87 According to settled case-law, recalled by the General Court in paragraph 25 of the order under appeal, persons other than those to whom a decision is addressed may claim to be individually concerned, within the meaning of the fourth paragraph of Article 263 TFEU, only if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of those factors distinguishes them individually just as in the case of the person addressed by such a decision (see, inter alia, judgments of 15 July 1963, *Plaumann* v *Commission*, 25/62, EU:C:1963:17, p. 223, and of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 93).

88 In that regard, it is also clear from settled case-law, recalled by the General Court in paragraph 26 of the order under appeal, that the possibility of determining more or less precisely the number, or even the identity, of the persons to whom a measure applies by no means implies that it must be regarded as being of individual concern to them as long as that measure is applied by virtue of an objective legal or factual situation defined by it (judgment of 19 December 2013, *Telefónica* v *Commission*, C-274/12 P, EU:C:2013:852, paragraph 47 and the case-law cited).

89 The fact that the Council of the European Union or the Commission was obliged, pursuant to specific provisions, to take into account the consequences of the act that they proposed to adopt on the situation of certain individuals could be capable of distinguishing those persons, where it is proven that they are prejudiced by that act owing to a factual situation that differentiates them from all other persons (see, to that effect, judgment of 10 April 2003, *Commission* v *Nederlandse Antillen*, C-142/00 P, EU:C:2003:217, paragraphs 71 to 76 and the case-law cited).

90 In the present case, the mere fact, assuming it is established, that the appellant had participated in the procedure that led to the inclusion of metalaxyl in Annex I to Directive 91/414, in the way set out in paragraphs 79 to 81 above, is not capable of distinguishing it, within the meaning of the case-law recalled in paragraphs 87 to 89 above, as regards the regulation at issue.

91 In particular, the appellant has not demonstrated that that participation was capable of calling into question the finding, in paragraph 28 of the order under appeal, that it is only concerned by the regulation at issue because of its objective quality as importer of metalaxyl and seller of products containing that substance, on the same basis as any other economic operator that is, actually or potentially, in an identical situation. It is also common ground that, when the regulation at issue was adopted, the inclusion of metalaxyl on the list of substances that are candidates for substitution was decided not by taking into account the appellant's particular qualities, but, as is clear from paragraph 9 of that order, on the ground that that substance contained a significant proportion of non-active isomers, within the meaning of point 4 of Annex II to Regulation No 1107/2009 (see, by analogy, judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 66).

92 It follows that the appellant's arguments advanced under the present ground, do not demonstrate that the General Court committed any error of law in deciding, in paragraph 29 of the order under appeal, that the appellant was not individually concerned by the regulation at issue.

93 Finally, given that, first, the General Court did not err in law in finding that the appellant was not individually concerned by the regulation at issue and, second, the conditions of both direct concern and individual concern by the European Union regulatory act of which annulment is sought are cumulative (see, to that effect, judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 76), the arguments set out in paragraphs 82 and 83 above on the question of whether the appellant is directly concerned by the regulation at issue are ineffective and must therefore be rejected.

94 It follows that the third ground of appeal must be rejected as in part unfounded and in part ineffective.

The second ground of appeal

Arguments of the parties

95 By its second ground of appeal, the appellant criticises the General Court for having considered, in paragraphs 50 to 58 of the order under appeal, that the rejection of its action as inadmissible would not deprive it of effective judicial protection.

96 The appellant submits that it would not be able to challenge either a national measure implementing the regulation at issue or call into question the effects of that regulation. In particular, for so long as the substitution of metalaxyl remains undecided by a national authority, that substance must be the object of periodic comparative assessments that the appellant would not be able to contest for lack of a legitimate interest in challenging an act that is favourable to it. The Tribunal Supremo (Supreme Court, Spain) and the Tribunal Constitucional (Constitutional Court, Spain) have held that an applicant has no interest or standing to bring proceedings, where the decision that he contests causes him no prejudice.

97 The appellant would therefore be forced to provoke the adoption of a negative decision by the national authorities in order to be able to bring an action against that decision and to challenge, in the context of that action, the classification of metalaxyl as a candidate for substitution.

98 The Commission submits that the second ground of appeal is inadmissible, since the appellant merely repeats the arguments it presented at first instance to the effect that it would be deprived of effective judicial protection without, however, criticising the General Court's response to those arguments, as set out in paragraphs 50 to 59 of the order under appeal.

99 In the alternative, the Commission submits that the second ground of appeal is unfounded.

Findings of the Court

100 Without it being necessary to rule on the admissibility of this ground of appeal, it is necessary, in any event, to reject it as unfounded.

101 In particular, it must be recalled that the conditions for admissibility laid down in the fourth paragraph of Article 263 TFEU must be interpreted in the light of the fundamental right to effective judicial protection without, however, setting aside those conditions, which are expressly laid down in that Treaty (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 44 and the case-law cited).

102 However, judicial review of compliance with the European Union legal order is ensured, as can be seen from Article 19(1) TEU, not only by the Court of Justice but also by the courts and tribunals of the Member States. The FEU Treaty has established, by Articles 263 and 277, on the one hand, and Article 267, on the other, a complete system of legal remedies and procedures designed to ensure judicial review of the legality of European Union acts, and has entrusted such review to the European Union judicature (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 45 and the case-law cited).

103 In that context, it must be emphasised that, in proceedings before the national courts, individual parties have the right to challenge before the courts the legality of any decision or other national measure relative to the application to them of a European Union act of general application, by pleading the invalidity of such an act (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 46 and the case-law cited).

104 It follows that references on validity constitute, like actions for annulment, means for reviewing the legality of European Union acts (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 47 and the case-law cited).

105 In that regard, it must be borne in mind that where a national court or tribunal considers that one or more arguments for invalidity of a European Union act, put forward by the parties or, as the case may be, raised by it of its own motion, are well founded, it is incumbent upon it to stay proceedings and to make a reference to the Court for a preliminary ruling on the act's validity, the Court alone having jurisdiction to declare a European Union act invalid (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 48 and the case-law cited).

106 As regards persons who do not fulfil the requirements of the fourth paragraph of Article 263 TFEU for bringing an action before the Courts of the European Union, it is for the Member States to establish a system of legal remedies and procedures which ensure respect for the fundamental right to effective judicial protection (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 49 and the case-law cited).

107 That obligation of the Member States was reaffirmed by the second subparagraph of Article 19(1) TEU, which states that Member States 'shall provide remedies sufficient to ensure effective judicial protection in the fields covered by Union law'. Such an obligation also follows from Article 47 of the Charter of Fundamental Rights of the European Union as regards measures taken by the Member States to implement Union law within the meaning of Article 51(1) of that Charter (judgment of 28 April 2015, *T & L Sugars and Sidul Açúcares* v *Commission*, C-456/13 P, EU:C:2015:284, paragraph 50 and the case-law cited).

108 In the present case, as follows from paragraphs 48 to 76 above, the General Court was fully entitled to conclude that the regulation at issue entails, vis-à-vis the appellant, implementing measures within the meaning of the final limb of the fourth paragraph of Article 263 TFEU.

109 Consequently, and having regard to the case-law recalled in paragraphs 101 to 107 above and set out by the General Court in paragraphs 51 to 57 of the order under appeal, the General Court also did not err in law in deciding, in paragraph 58 of that order, that the appellant's argument that the rejection, as inadmissible, of its action for annulment of the regulation at issue would infringe its right to effective judicial protection. Even if, owing to the conditions for admissibility laid down in the fourth paragraph of Article 263 TFEU, the appellant cannot directly attack the regulation at issue before the European Union judicature, it can, by contrast, in the context of an action brought before a national court against an act by a Member State which is an implementing measure of the regulation, plead the invalidity of the latter and cause that court to refer questions to the Court of Justice pursuant to Article 267 TFEU (see, by analogy, judgment of 19 December 2013, *Telefónica* v *Commission*, C-274/12 P, EU:C:2013:852, paragraph 59).

110 Moreover, the appellant could, if necessary, challenge a Commission regulation on renewal of the approval of metalaxyl before the European Union courts under the conditions laid down in the fourth paragraph of Article 263 TFEU, and, in the context of that action, challenge the validity of the regulation at issue by means of an objection of illegality pleaded against the latter, in accordance with the case-law cited in paragraph 44 above, with a view, in particular, to challenging the duration of the validity of the renewal of approval of metalaxyl.

111 The second ground of appeal must therefore be rejected as unfounded.

112 In view of all the foregoing considerations, the appeal must be dismissed in its entirety.

Costs

113 Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to costs. Under Article 138(1) of those rules, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

114 Since the Commission has applied for costs to be awarded against the appellant and the latter has been unsuccessful, the appellant must be ordered to pay the costs.

On those grounds, the Court (Grand Chamber) hereby:

1. Dismisses the appeal;

2. Orders Industrias Químicas del Vallés SA to pay the costs.

[Signatures]