JUDGMENT OF THE COURT OF FIRST INSTANCE (Sixth Chamber)

7 October 2009 (*)

(Plant protection products – Active substance chlorothalonil – Amendment of the entry in Annex I to Directive 91/414/EEC – Directive 2006/76/EC – Retroactivity – No transitional period – Legal certainty – Legitimate expectations – Principle of equal treatment)

In Case T-380/06,

Vischim Srl, established in Cesano Maderno (Italy), represented by C. Mereu and K. Van Maldegem, lawyers,

applicant,

v

Commission of the European Communities, represented by L. Parpala and B. Doherty, acting as Agents,

defendant,

APPLICATION for the annulment of the second paragraph of Article 2 of Commission Directive 2006/76/EC of 22 September 2006 amending Council Directive 91/414/EEC as regards the specification of the active substance chlorothalonil (OJ 2006 L 263, p. 9),

THE COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES (Sixth Chamber),

composed of A.W.H. Meij, President, F. Dehousse and V. Vadapalas (Rapporteur), Judges,

Registrar: C. Kantza, Administrator,

having regard to the written procedure and further to the hearing on 25 September 2008,

gives the following

Judgment

Legal context

Directive 91/414/EEC

1 As provided in Article 4(1)(a) of 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), 'Member States shall ensure that a plant protection product is not authorised unless its active substances are listed in Annex I and any conditions laid down therein are fulfilled'.

2 Article 5(1) of Directive 91/414 states that, 'in the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the … conditions' which are then set out and relate to the products not being harmful for human or animal health or the environment.

3 By virtue of the first and second indents of Article 5(4) of Directive 91/414, an active substance's inclusion may be subject to requirements relating to 'the minimum degree of purity of the active substance' and to 'the nature and maximum content of certain impurities'.

4 Article 6(1) of Directive 91/414 provides:

'Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 19.

The following shall also be decided in accordance with that procedure:

– any conditions for inclusion,

– amendments to Annex I, where necessary,

…’

5 The first subparagraph of Article 8(2) of Directive 91/414 provides that, ‘by way of derogation from Article 4 …, a Member State may, during a period of 12 years following the notification of this Directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive’.

6 The second subparagraph of Article 8(2) of Directive 91/414 states that within the same 12-year period the Commission is to commence a programme of work for the gradual examination of those active substances.

7 According to the fourth subparagraph of Article 8(2), ‘during [that] period … it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I’. This provision adds that ‘the Member States shall ensure that the relevant authorisations are granted, withdrawn or varied, as appropriate, within a prescribed period’.

8 Article 19 of Directive 91/414, as amended by Council Regulation (EC) No 806/2003 of 14 April 2003 (OJ 2003 L 122, p. 1), provides that the Commission is to be assisted by a regulatory committee, the Standing Committee on the Food Chain and Animal Health (‘the Committee’).

9 As regards the active substance chlorothalonil, the period referred to in Article 8(2) of Directive 91/414, which was to expire on 26 July 2003, was extended, initially until 31 December 2005, by Commission Regulation (EC) No 2076/2002 of 20 November 2002 (OJ 2002 L 319, p. 3), then until 31 December 2006, by Commission Regulation (EC) No 1335/2005 of 12 August 2005 (OJ 2005 L 211, p. 6), unless a decision on its inclusion in Annex I to Directive 91/414 was taken before that date.

Regulation (EEC) No 3600/92

10 Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414 (OJ 1992 L 366, p. 10) sets out the procedure for the assessment of a number of active substances, including chlorothalonil, with a view to their possible inclusion in Annex I to that directive.

11 Article 4(1) of Regulation No 3600/92 states that ‘any producer wishing to secure the inclusion of an active substance … in Annex I to … Directive [91/414] shall so notify the Commission within six months of the date of entry into force of this Regulation’.

12 Article 7(1) and (2) of Regulation No 3600/92, as amended by Commission Regulation (EC) No 1199/97 of 27 June 1997 (OJ 1997 L 170, p. 19), governs the manner in which the dossiers submitted by notifiers are examined.

13 The fourth subparagraph of Article 8(3) of Regulation No 3600/92, as amended, states:

‘After the examination … the Commission shall … present to the Committee:

(a) a draft directive to include the active substance in Annex I to … Directive [91/414], setting out where appropriate the conditions, including the time-limit, for such inclusion;

…’

Background to the dispute

Inclusion of chlorothalonil in Annex I to Directive 91/414

14 On 8 July 1993 the applicant, Vischim Srl, an Italian company producing chlorothalonil, informed the Commission of its wish to secure the inclusion of that active substance in Annex I to Directive 91/414.

15 Only two notifiers in respect of chlorothalonil submitted their dossiers within the deadline, namely ISK Biotech Europe (which was replaced in the course of the assessment procedure by Zeneca Agrochemicals, which in turn became Syngenta) and the applicant.

16 On 16 September 2005, after those dossiers had been examined, the Commission adopted Directive 2005/53/EC amending Directive 91/414 to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ 2005 L 241, p. 51).

17 By virtue of Article 1 of Directive 2005/53 and the annex thereto, chlorothalonil was included under No 102 in the table in Annex I to Directive 91/414. The fourth column of that table, headed ‘Purity’, states: ‘Hexachlorobenzene: not more than 0.01g/kg’.

18 It is apparent from the review report for chlorothalonil (document SANCO/4343/2000 final of 14 February 2005; 'the review report') that that condition relating to the maximum content of hexachlorobenzene (HCB) was laid down having regard to the specification for chlorothalonil adopted by the FAO (Food and Agriculture Organisation of the United Nations) in February 2005.

19 Under Article 3(1) of Directive 2005/53, the Member States were obliged, where necessary, to amend or withdraw existing authorisations for plant protection products containing chlorothalonil by 31 August 2006, verifying whether the conditions in Annex I to Directive 91/414 were met and whether the holder of the authorisation had, or had access to, a dossier satisfying the requirements of Annex II to Directive 91/414 in accordance with the conditions of Article 13 of that directive.

20 Directive 2005/53 entered into force on 1 March 2006. Under the first and second paragraphs of Article 2, the Member States had to adopt and publish the provisions necessary in order to comply with Directive 2005/53 by 31 August 2006 at the latest, and to apply them from 1 September 2006.

21 On 25 November 2005, the applicant brought an action for, inter alia, the annulment of Directive 2005/53 (Case T-420/05).

22 In the context of that action, the applicant made two successive applications for interim measures, which were dismissed by orders of the President of the Court of First Instance of 4 April 2006 in Case T-420/05 R *Vischim* v *Commission*, not published in the ECR, and of 13 October 2006 in Case T-420/05 R II *Vischim* v *Commission* [2006] ECR II-4085, the latter order being upheld by order of the President of the Court of Justice of 3 April 2007 in Case C-459/06 P(R) *Vischim* v *Commission*, not published in the ECR.

Amendment of the entry in Annex I to Directive 91/414

23 In December 2005, the FAO published, on the basis of the information submitted by the applicant, a new specification for chlorothalonil increasing the maximum HCB content to 0.04g/kg.

24 The applicant informed the Commission of that new specification by letter of 16 December 2005.

25 In March 2006, the Commission asked the rapporteur Member State to evaluate the various versions of chlorothalonil conforming to the new FAO specification, including the applicant's product.

26 Simultaneously, the Commission staff sent the Member States an email in the following terms:

''[The rapporteur Member State] has undertaken to examine the equivalence of the different sources (including Vischim's). If the conclusion is that these are as safe as the reference source, the Commission would consider amending [Directive 91/414] as regards the purity levels for HCB. In this scenario, it might be difficult to amend the text formally before 1 September 2006, so some degree of administrative flexibility might be required around that date. It would be unfortunate if products were withdrawn from a national market only to be reauthorised shortly afterwards. It is obvious that a withdrawal of authorisations is still required when it is shown that the outcome of the examination of the dossier is clearly unfavourable or when the necessary administrative provisions have not been met.'

27 When the rapporteur Member State completed its assessment in April 2006, it found that chlorothalonil containing 0.04g/kg of HCB did not involve risks additional to those already taken into consideration when Directive 2005/53 was adopted. Accordingly, it proposed an amendment to the specification for chlorothalonil provided for by Directive 2005/53.

28 On 13 and 14 July 2006 that amendment was approved by the Committee. As regards the period relating to the introduction of the amended specification, the minutes of the meeting of the Committee state inter alia as follows:

'There was a general agreement on modifying the concerned specification and [the Commission] promised to propose the draft for adoption without delay … As regards the question raised on a possible extension of the 6-months period for the submission of missing studies, it seems inappropriate to do so. This could set a precedent and would expose [the Commission] to criticism as regards [unequal] treatment between notifiers … For the above reasons, it is considered inopportune to deviate from the standard period foreseen … by the inclusion directive … [The United Kingdom] asks to extend the date of compliance in this case in order to allow Vischim to start an arbitration procedure under national law in order to get access to vertebrate studies after the vote on inclusion of the substance'.

29 By letter of 27 July 2006, the applicant stated to the Commission that, 'in order to ensure its effectiveness in relation to [the applicant's] registrations, the amendment [had to], first, enter into force before 31 August 2006 and second, set a new period for the Member States to verify compliance with the Annex I inclusion conditions'. The Commission did not reply to that letter.

30 Between July and September 2006, the applicant received letters from the competent authorities in the United Kingdom of Great Britain and Northern Ireland, the Kingdom of Belgium and Ireland informing it of their intention to withdraw its product from the market.

31 In particular, the letter sent to the applicant by the United Kingdom authorities, dated 28 July 2006, is in the following terms:

'[Your product] is compliant with the new [purity] specifications … as amended by the [Committee on] 13-14 July 2006 [but] you have not yet demonstrated appropriate access to Annex II data to support your existing approved chlorothalonil-

containing products ... Therefore a Notice of Intent to revoke your existing chlorothalonil products is enclosed with this letter.'

32 On 22 September 2006, the Commission adopted Directive 2006/76/EC amending Directive 91/414 as regards the specification of the active substance chlorothalonil (OJ 2006 L 263, p. 9; 'the contested directive').

33 Pursuant to Article 1 of the contested directive, the specification laid down for chlorothalonil when it was included in Annex I to Directive 91/414 was replaced by the annexed table. The fourth column of that table, headed 'Purity', states: 'Hexachlorobenzene: not more than 0.04g/kg'.

34 The contested directive entered into force on 23 September 2006. Under Article 2, the Member States had to adopt and publish the provisions necessary in order to comply with the contested directive by 31 August 2006 at the latest, and to apply them from 1 September 2006.

Procedure and forms of order sought

35 By application lodged at the Registry of the Court of First Instance on 15 December 2006, the applicant brought the present action.

36 By a separate document lodged on the same day, the applicant applied for an expedited procedure pursuant to Article 76a of the Rules of Procedure of the Court of First Instance. This request was rejected by decision of the President of the Fourth Chamber of the Court of First Instance of 24 January 2007.

37 On 27 February 2007 the Commission lodged, in a separate document, an objection of inadmissibility. After the applicant had submitted its observations, consideration of the objection of inadmissibility was reserved for the final judgment by order of the Court of First Instance of 27 June 2007.

38 When the defence had been lodged, the Court decided, in accordance with Article 47(1) of the Rules of Procedure, that a second exchange of pleadings was unnecessary.

39 Upon a change in the composition of the Chambers of the Court, the Judge-Rapporteur was assigned to the Sixth Chamber, to which the present case was consequently allocated.

40 As a member of the Chamber was unable to sit, the President of the Court of First Instance designated another Judge to complete the Chamber pursuant to Article 32(3) of the Rules of Procedure.

41 After the parties had been heard, the present case and Case T-420/05 were joined for the purposes of the oral procedure.

42 Upon hearing the report of the Judge-Rapporteur, the Court decided to open the oral procedure and, by way of measures of organisation of procedure, put certain questions in writing to the parties, which replied to them by letters of 16 June and 7 and 14 July 2008.

43 The parties presented oral argument and replied to the questions put by the Court at the hearing on 25 September 2008.

44 The applicant claims that the Court should:

– partially annul the contested directive, in particular the second paragraph of Article 2 thereof;

– order the Commission to provide for accurate, reasonable and legally acceptable prospective time-limits regarding the contested directive;

– order the Commission to pay the costs.

45 The Commission contends that the Court should:

– dismiss the action as inadmissible or, in the alternative, as unfounded;

– order the applicant to pay the costs.

Law

Admissibility

46 In relation, first, to the applicant's request that the Court order the Commission to provide for accurate, reasonable and legally acceptable prospective time-limits regarding the contested directive, it is to be recalled that, when reviewing legality on the basis of Article 230 EC, the Community judicature is not entitled to issue directions to the institutions (Case T-155/04 *SELEX Sistemi Integrati* v *Commission* [2006] ECR II-4797, paragraph 28).

47 Accordingly, that request, set out in the applicant's second head of claim, is inadmissible.

48 Next, the Commission contends that the request that the Court annul the second paragraph of Article 2 of the contested directive is inadmissible, first, pleading that the partial annulment sought by the applicant is impossible and, second, invoking the legislative nature of the contested directive.

49 The applicant maintains that its request is admissible.

50 As regards the Commission's first plea of inadmissibility, it is settled case-law that partial annulment of an act is possible only if the elements whose annulment is sought may be severed from the remainder of the act. That requirement of severability is not satisfied where the partial annulment would have the effect of altering the substance of the contested act (see Case C-540/03 *Parliament* v *Council* [2006] ECR I-5769, paragraphs 27 and 28, and the case-law cited).

51 Under the second paragraph of Article 2 of the contested directive, the Member States were to apply the provisions adopted to comply with that directive from 1 September 2006, and thus retroactively.

52 The applicant maintains that its action does not seek the total annulment of the contested directive, which is essentially favourable to it, but concerns only the directive's temporal effects, which are defined in particular in the provision at issue.

53 The Commission contends that the provision in question, defining the temporal scope of the contested directive, is not severable from it, because if the provision were annulled the contested directive would become inapplicable.

54 It is to be observed that there is nothing to prevent the legality of a Community act from being put in issue only as regards its temporal effects and, in particular, its retroactive effect (see, to this effect, Case C-368/89 *Crispoltoni* [1991] ECR I-3695 and Joined Cases C-260/91 and C-261/91 *Diversinte and Iberlacta* [1993] ECR I-1885).

55 Also, in an action whose purpose is not to secure the removal of a substantive provision favourable to the applicant but only to have the provision defining its temporal effects annulled, the Community judicature may decide, under the second paragraph of Article 231 EC, to maintain the contested act as it stands until the competent institutions have adopted the measures necessary to comply with the judgment (see, to this effect, Case T-7/99 *Medici Grimm* v *Council* [2000] ECR II-2671, paragraphs 93 and 94, and the case-law cited). Furthermore, while the second paragraph of Article 231 EC refers only to regulations, the scope of that provision must extend to acts of the institutions which, although they are not in the form of a regulation, nevertheless produce similar effects (see, to this effect, Case C-295/90 *Parliament* v *Council* [1992] ECR I-4193, paragraph 26).

56 Accordingly, the plea of inadmissibility relied upon by the Commission to the effect that the contested directive's partial annulment, limited to the second paragraph of Article 2 defining its temporal effects, is not possible should be dismissed.

57 As regards the Commission's second plea of inadmissibility, concerning the legislative nature of the contested directive, it is to be remembered that the fact that the fourth paragraph of Article 230 EC makes no express provision regarding the admissibility of actions brought by natural or legal persons for annulment of a directive is not sufficient to render such actions inadmissible (Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335, paragraph 63, and order in Case T-223/01 *Japan Tobacco and JT International* v *Parliament and Council* [2002] ECR II-3259, paragraph 28).

58 The applicant, as a notifier and a holder of existing authorisations for plant protection products containing chlorothalonil, is directly and individually concerned by the inclusion of that active substance in Annex I to Directive 91/414 as provided for by Directive 2005/53 and, therefore, by the contested directive amending the conditions of its inclusion. Moreover, the contested directive was adopted following an assessment requested by the applicant and relating inter alia to its product.

59 It is clear from the foregoing that the applicant is entitled to seek the annulment of the contested directive as regards the temporal effects defined by the second paragraph of Article 2 thereof.

Substance

Arguments of the parties

60 The first plea advanced by the applicant in support of its action alleges a failure to state reasons. The contested directive does not contain reasoning justifying its retroactive effect. The Commission did not explain how, de jure and de facto, its retroactivity was to operate so as to enable the amended specification to be applied effectively.

61 The applicant's second plea alleges breach of Article 8(2) of Directive 91/414 and Article 8(3)(a) of Regulation No 3600/92. In its submission, those provisions require the Commission to set, in a directive relating to the inclusion of an active substance in Annex I to Directive 91/414, a transitional period for the review of existing national authorisations. The existence of that obligation is confirmed by the Commission's practice. To have any purpose and effect that transitional period needs to be prospective, that is to say from the date upon which the contested directive entered into force. By not prescribing such a transitional period in the present case, the Commission thus infringed an essential procedural requirement imposed upon it by Directive 91/414 and Regulation No 3600/92.

62 While continuing to centre its arguments around the absence of a prospective transitional period in the contested directive, the applicant pleads, next, breach of the principles of non-retroactivity, legal certainty, the protection of legitimate

expectations and equal treatment.

63 The applicant recalls the case-law according to which a Community measure cannot apply retroactively save in exceptional cases, where the purpose of the measure so requires and the legitimate expectations of those concerned are respected. Neither of those conditions is met here.

64 The retroactive effect of the contested directive cannot be justified by the need to avoid application of the stricter specification laid down by Directive 2005/53. That directive has already produced legal effects, namely the withdrawal of the authorisations held by the applicant. In those circumstances, the retroactive amendment would only have an effect if coupled with a prospective transitional period during which compliance with the new specification can be demonstrated.

65 Moreover, the failure to prescribe a new transitional period is contrary to economic operators' legitimate expectations created by the applicable legislation and the Commission's practice. In particular, in the absence of a new transitional period, the retroactive effect of the contested directive thwarted the applicant's legitimate expectations, inasmuch as it was not in a position to rely on the rights resulting from the amendment of the specification for chlorothalonil.

66 In the absence of a transitional period, the applicant could not 'turn back the clock' to submit its dossier to the national authorities, for them to check its product's compliance with regard to the amended specification introduced by the contested directive. The Member States, for their part, could not comply with their obligations in the light of the new applicable provisions, in particular assess or re-assess the applicant's national authorisations in the light of the new specification. Thus, the contested directive is devoid of practical effect and infringes the principle of legal certainty.

67 Nor has the Commission treated the applicant in the same way as the producers concerned by other measures adopted in the same field, which have provided for a transitional period following the inclusion of the active substances in Annex I to Directive 91/414, and in particular in the same way as the other notifier of chlorothalonil, Syngenta, which benefited from such a period under Directive 2005/53.

68 The Commission contests the applicant's arguments.

Findings of the Court

69 It is appropriate to consider first the alleged failure to comply with Article 8(2) of Directive 91/414 and Article 8(3)(a) of Regulation No 3600/92 and to observe previous Commission practice, then breach of the various general principles of law relied upon by the applicant, and finally breach of the duty to state reasons.

– The alleged failure to comply with Article 8(2) of Directive 91/414 and Article 8(3)(a) of Regulation No 3600/92 and to observe previous Commission practice

70 As regards, in the first place, the provisions allegedly infringed, neither of them imposes an obligation upon the Commission to prescribe a transitional period for the purpose of reviewing existing national authorisations.

71 First, Article 8(2) of Directive 91/414 prescribes a programme of work with various periods for the examination of active substances already on the market two years after the date of notification of the directive, with a view to their possible inclusion in Annex I thereto. Article 8(2) of Directive 91/414 therefore does not deal in the slightest with the prescribing by the Commission of a transitional period after the inclusion of an active substance in Annex I.

72 Second, Article 8(3)(a) of Regulation No 3600/92 provides that, in a draft directive to include an active substance in Annex I to Directive 91/414, the Commission is to set out where appropriate the conditions, including the time-limit, for such inclusion. This provision accordingly concerns certain detailed rules governing the phase of inclusion of an active substance in Annex I to Directive 91/414. It does not reveal an obligation on the Commission to prescribe a transitional period for review of existing national authorisations after the substance's inclusion.

73 That is all the more true in the present case because the contested directive does not repeal Directive 2005/53, but merely amends Annex I to Directive 91/414 so far as concerns the specification for the substance at issue. The contested directive therefore does not in any way affect the entire procedure for the inclusion of that substance in Annex I to Directive 91/414. It was in the course of that procedure that the applicant had to submit a summary dossier and a complete dossier, in accordance with Article 2 of Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Regulation No 3600/92 (OJ 1994 L 107, p. 8), as amended by Commission Regulation (EC) No 2230/95 of 21 September 1995 (OJ 1995 L 225, p. 1), and Article 6 of Regulation No 3600/92, as supplemented by Commission Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27). At the end of that procedure Directive 2005/53 was adopted, which included the substance in question in Annex I to Directive 91/414 and prescribed a transitional period before its inclusion took effect. In the present case, the inclusion of chlorothalonil in Annex I to Directive 91/414 was thus duly followed by a transitional period allowing the national authorities to examine existing national authorisations.

74 Accordingly, the fact that the contested directive does not prescribe such a transitional period does not constitute a breach of the provisions relied upon by the applicant.

75 As regards, in the second place, the applicant's argument relating to the Commission's practice, it is to be noted that a mere administrative practice that is not contrary to the legislation in force and does not involve the exercise of discretion may give rise to a legitimate expectation on the part of the persons concerned (see Case T-310/00 *MCI* v *Commission* [2004]

ECR II-3253, paragraph 112, and the case-law cited).

76 In the present case, the Commission states that its consistent practice is that it requires the Member States to take certain measures within a period of six months from an active substance's inclusion in Annex I to Directive 91/414.

77 The Commission's practice of prescribing such a period in order to permit the parties concerned to prepare themselves to meet the new requirements and the Member States to review existing authorisations is also apparent from recitals 9 and 10 in the preamble to Directive 2005/53.

78 However, such a practice, first, relates above all to the Member States, upon which it confers obligations, in particular as regards the period for review available to them, and second, concerns the initial inclusion of an active substance in Annex I to Directive 91/414.

79 It is accordingly clear that the applicant is also wrong in relying upon the Commission's practice in order to assert that the Commission was under an obligation to prescribe in the present case a transitional period for the purpose of reviewing existing national authorisations. The practice to which the applicant refers does not concern the case in point.

80 Consequently, in not prescribing a transitional period in the contested directive for the purpose of review of existing national authorisations, the Commission infringed neither Article 8(2) of Directive 91/414 nor Article 8(3)(a) of Regulation No 3600/92 and did not depart from its previous practice.

– The alleged breach of the principles of non-retroactivity, legal certainty, the protection of legitimate expectations and equal treatment

81 The principle of legal certainty requires Community rules binding on individuals to be clear and precise so that they may know without ambiguity what their rights and obligations are and are in a position to take steps accordingly (Case 169/80 *Gondrand and Garancini* [1981] ECR 1931, paragraph 17).

82 Also, as a general rule, the principle of legal certainty precludes a Community measure from taking effect from a point in time before its publication, save exceptionally where the purpose to be achieved so demands and where the legitimate expectations of those concerned are duly respected (Case 98/78 *Racke* [1979] ECR 69, paragraph 20; see also, with regard to the retroactive effect of a directive, Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 45).

83 It is accordingly to be established in the present case, first, whether the purpose to be achieved justifies the retroactivity of the contested directive and, second, whether the applicant's legitimate expectations were duly respected and whether the applicant was able to know without ambiguity what its rights and obligations were and to take steps accordingly.

84 As regards the first condition, it is clear from recitals 1 and 2 in the preamble to the contested directive that the Commission amended the specification for chlorothalonil in order to take account of the new FAO specification, published after Directive 2005/53 was adopted. This FAO specification, repealing the specification which had been in force on the date when Directive 2005/53 was adopted, amended the requirement relating to the HCB content, increasing the limit from 0.01 to 0.04 g/kg.

85 The Commission indicated in recital 4 in the preamble to the contested directive that, 'since Directive 2005/53 … require[d] Member States to apply its Article 2 from 1 September 2006, the amended specification for chlorothalonil should also apply from this date'.

86 It is apparent from those statements that, in providing that the amended specification was to have retroactive effect, the Commission intended to prevent the Member States from being required to apply, even if only very briefly, the stricter specification prescribed by Directive 2005/53. Given this objective, it had to be laid down that the amended specification for chlorothalonil would be applicable from the date laid down for application of the initial specification.

87 It must therefore be concluded that, in the present case, the first condition laid down by the case-law cited in paragraph 82 above is met, that is to say, the purpose to be achieved demanded that the contested directive provide for retroactive application of the new, less strict, specification. Nor does the applicant challenge the retroactivity of the contested directive in so far as it set a new specification that is less strict.

88 As regards the second condition, namely that the legitimate expectations of those concerned are respected, it should be pointed out at the outset that, since the amended specification laid down by the contested directive had the effect solely of making the conditions upon which chlorothalonil was included less exacting, its retroactive effect, as such, was not capable of interfering with the legitimate expectations of the economic operators concerned.

89 However, the applicant submits that the contested directive infringes the principles of legal certainty and of the protection of legitimate expectations in that it does not set a transitional period enabling the applicant to adapt to the new requirements and entailing an obligation on the Member States to review existing national authorisations.

90 In that regard, it is to be remembered (see paragraphs 70 to 80 above) that neither the applicable provisions nor the Commission's practice require the Commission to prescribe such a transitional period here.

91 Nor has the applicant adduced evidence or arguments such as to prove that the Commission caused it to entertain legitimate

expectations that amendment of the specification would be followed by the establishment of a new transitional period. Inasmuch as the applicant is itself at the origin of that amendment (see paragraphs 23 and 24 above) which reduces the requirements for authorisation of its products, it cannot be contrary to the principles of legal certainty and of the protection of legitimate expectations not to prescribe a transitional period in order to enable the applicant to adapt to the new requirements.

92 Here, any product complying with the specification under Directive 2005/53 meets, a fortiori, the specification under the contested directive, so that adaptation, on the part both of the Member States and of the applicant, to the new requirements does not seem to demand particular measures or efforts justifying a legitimate expectation that a transitional period would be laid down for that purpose.

93 More specifically from the point of view of compliance with the principle of legal certainty, Directive 2005/53 and the clear and precise provisions applicable at the time, which were not repealed by the contested directive, enabled the applicant to know without ambiguity the extent of the obligations which they imposed upon it. It could take steps accordingly and, in particular, if it wished to retain its existing authorisations, submit a complete dossier compiled in accordance with the requirements of Annex II to Directive 91/414. During the transitional period which followed the adoption of Directive 2005/53, it was clearly in the applicant's interest to submit such a dossier or to demonstrate access to such a dossier in order to be able to retain its existing authorisations.

94 Pursuant to Article 3(1) of Directive 2005/53, the applicant was forewarned that if it did not satisfy that obligation, which is independent of the obligation relating to a product's conformity to the Community specification, its authorisations would be withdrawn.

95 Secondarily and having more specific regard to the context, it is also apparent from the facts of the case that the applicant was aware of the fact that the Commission was envisaging amending the specification for chlorothalonil to take account of the specification adopted by the FAO in December 2005 and that that amendment would come within the framework of the review conducted in accordance with Article 3(1) of Directive 2005/53.

96 The procedure which preceded the adoption of the contested directive had been initiated on the basis of the information provided by the applicant on 16 December 2005 and the applicant was informed both of the conclusions of the report drawn up by the rapporteur Member State in April 2006, proposing that the specification established by Directive 2005/53 be amended, and of the adoption of the proposal to this effect by the Committee on 13 and 14 July 2006.

97 It is apparent from the letter sent by the authorities of the United Kingdom of Great Britain and Northern Ireland of 28 July 2006 (see paragraph 31 above), adduced by the applicant, and from the letters sent by the authorities of Ireland of 30 August 2006 and the Kingdom of Belgium of 7 September 2006, adduced by the Commission, that the applicant had certain authorisations withdrawn not for want of conformity with the specification for chlorothalonil prescribed by Directive 2005/53, but because it failed to submit a dossier satisfying the requirements of Annex II to Directive 91/414 or demonstrate access to such a dossier.

98 The applicant cannot therefore claim a right to fill the gaps in its dossier in a fresh examination of its authorisations during a fresh transitional period, when it could fully appreciate the interest in submitting a dossier that complied with the requirements of Annex II to Directive 91/414 during the transitional period which followed the adoption of Directive 2005/53. It is to be noted in this regard that the requirements relating to the submission of that dossier remained unchanged. Any dossier compliant with the requirements of Annex II to Directive 91/414 was so under Directive 2005/53 and remained so under the contested directive. As regards both the specification and possession of a compliant dossier, therefore, the Commission had no reason, when adopting the contested directive, either to oblige the Member States to undertake a fresh examination of existing authorisations or to prescribe a transitional period for that purpose.

99 It follows that the retroactive application of the new specification introduced by the contested directive does not infringe the principles of legal certainty and of the protection of legitimate expectations. It should be added that, contrary to the applicant's assertions, the contested directive is not devoid of practical effect either. It enables existing authorisations for products conforming to the new specification which it introduces to be maintained, provided that the holder of the authorisation has satisfied the other requirements laid down by Directive 2005/53.

100 As regards the principle of equal treatment, this principle is breached only where comparable situations are treated differently or different situations are treated in the same way, unless a distinction is objectively justified (Case C-174/89 *Hoche* [1990] ECR I-2681, paragraph 25).

101 In the present case, the applicant's arguments essentially amount to a comparison of different situations. The inclusion of a substance in Annex I to Directive 91/414 is not comparable with mere amendment of the specification for that substance, which has already been included in the annex, and it was thus not obligatory for the contested directive to lay down the same transitional arrangements as Directive 2005/53, which moreover was not repealed.

102 Furthermore, since the applicant could, like other producers, benefit from the transitional period which ensued after the adoption of Directive 2005/53 and thus after the inclusion of chlorothalonil in Annex I to Directive 91/414 and in particular submit, in this context, a dossier that complied with the requirements of Annex II to Directive 91/414 to the national authorities, it cannot plead unequal treatment vis-à-vis other producers of that substance or any other substance at the time of its inclusion in Annex I to that directive. Nor has the applicant shown that transitional periods have been laid down by the Commission in favour of other producers when the specification for a substance already included in Annex I to Directive 91/414 has been amended.

103 Consequently, the Commission did not infringe the principle of equal treatment by not prescribing a transitional period in the contested directive for the purposes of the review of existing authorisations that is provided for in Article 3(1) of Directive 2005/53.

104 It follows that no breach of the general principles of law that are referred to by the applicant can be found.

– The alleged breach of the duty to state reasons

105 It is settled case-law that the statement of reasons required by Article 253 EC must disclose in a clear and unequivocal fashion the reasoning followed by the Community authority which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure for the purpose of defending their rights and to enable the Community judicature to exercise its power of review (see Case T-89/00 *Europe Chemi-Con (Deutschland)* v *Council* [2002] ECR II-3651, paragraph 65, and the case-law cited).

106 As regards an alleged failure to state reasons that relates to the provision of the contested directive establishing its temporal application, first, recitals 1, 2 and 4 in the preamble to the contested directive, which are cited in paragraphs 84 and 85 above, indicate clearly the reasons why the Commission gave the amended specification retroactive effect.

107 Second, the Commission was not obliged to state the reasons why it did not prescribe a transitional period for the review of national authorisations. As is apparent from the foregoing findings, the Commission was not required to prescribe such a transitional period by the applicable provisions, its previous practice or any of the general principles of law relied upon by the applicant.

108 Accordingly, the applicant is wrong in its contention that the contested directive is vitiated by a failure to state reasons.

109 In view of all the foregoing, this action must be dismissed.

Costs

110 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

On those grounds,

THE COURT OF FIRST INSTANCE (Sixth Chamber)

hereby:

1. Dismisses the action;

2. Orders Vischim Srl to pay the costs.

Meij Dehousse Vadapalas

Delivered in open court in Luxembourg on 7 October 2009.

[Signatures]

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* Language of the case: English.