JUDGMENT OF THE COURT (Third Chamber)

18 July 2007 *

In Case C-326/05 P,

APPEAL under Article 56 of the Statute of the Court of Justice, brought on 26 August 2005,

Industrias Químicas del Vallés, SA, established in Mollet del Vallés (Spain), represented by C. Fernández Vicién, I. Moreno-Tapia Rivas and J. Sabater Marotias, abogados,

appellant,

the other party to the proceedings being:

Commission of the European Communities, represented by B. Doherty and S. Pardo Quintillán, acting as Agents, with an address for service in Luxembourg,

defendant at first instance,

* Language of the case: Spanish.

THE COURT (Third Chamber),

composed of A. Rosas, President of the Chamber, A. Tizzano (Rapporteur), A. Borg Barthet, U. Lõhmus and A. Ó Caoimh, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 27 September 2006,

after hearing the Opinion of the Advocate General at the sitting on 30 November 2006,

gives the following

Judgment

1 By its appeal, Industrias Químicas del Vallés, SA ('IQV') is asking the Court to set aside the judgment delivered by the Court of First Instance of the European Communities on 28 June 2005 in Case T-158/03 *Industrias Químicas del Vallés* v *Commission* [2005] ECR II-2425 ('the judgment under appeal'), by which the Court of First Instance dismissed the action brought by IQV for annulment of Commission

Decision 2003/308/EC of 2 May 2003 concerning the non-inclusion of metalaxyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance (OJ 2003 L 113, p. 8, 'the contested decision').

Legal context

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) establishes the Community rules governing the granting of authorisation to place plant protection products on the market and the withdrawal of such authorisation. Under Article 4 of Directive 91/414, Member States are to authorise the placing on the market only of those plant protection products of which 'the active substances are listed in Annex I'. Article 5 of the directive sets out the conditions required for the inclusion of substances in that annex. Those conditions are designed to protect human and animal health and the environment.

3 Article 6 of Directive 91/414 provides:

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

...

2. A Member State receiving an application for the inclusion of an active substance in Annex I shall without undue delay ensure that a dossier which is believed to satisfy the requirements of Annex II is forwarded by the applicant to the other Member States and to the Commission together with a dossier complying with Annex III on at least one preparation containing that active substance. The Commission shall refer the dossier to the Standing Committee on Plant Health referred to in Article 19 for examination.

3. Without prejudice to the provisions of paragraph 4, at the request of a Member State, and within three to six months after the date of referral to the committee mentioned in Article 19, it shall be established by the procedure laid down in Article 20 whether the dossier has been submitted in accordance with the requirements of Annexes II and III

4. If the assessment of the dossier referred to in paragraph 2 shows that further information is necessary, the Commission may ask the applicant to submit such information. The applicant or his authorised representative may be asked by the Commission to submit his remarks to it, in particular whenever an unfavourable decision is envisaged.

...'

4 Article 8 of Directive 91/414 provides for transitional measures and derogations for active substances not listed in Annex I, but already on the market two years after the date of notification of that directive. The placing on the market of those active substances may be authorised by Member States for a provisional period of 12 years. During that transitional period, the active substances concerned must undergo a programme of assessment after which 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'.

5 That transitional period, which was initially due to expire on 26 July 2003, was extended until 31 December 2005 by Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Directive 91/414 and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (OJ 2002 L 319, p. 3). It was then extended — by Commission Regulation (EC) No 1335/2005 of 12 August 2005 amending Regulation No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Directive 91/414 and the continued use of certain substances not included in its Annex I (OJ 2005 L 211, p. 6) — until 31 December 2006, except in cases where a decision had been taken before that date regarding the inclusion of a particular active substance in Annex I to Directive 91/414.

6 Article 19 of Directive 91/414 provides:

'Where the procedure laid down in this Article is to be followed, matters shall be referred without delay by the chairman, either on his own initiative or at the request of a Member State, to the Standing Committee on Plant Health ...

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter ...

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.'

7 Directive 91/414 also contains provisions on confidentiality. Article 13 concerns applications for authorisation to place on the market plant protection products containing active substances already included in Annex I to that directive, and permits the use of information supplied by another applicant provided that the latter has agreed to such use.

8 Article 14 of Directive 91/414 provides:

'Member States and the Commission shall ... ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant ... so requests, and if the Member State or the Commission accepts that the applicant's request is warranted.

...'

9 By 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), as amended by Commission Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27) ('Regulation No 3600/92'), the Commission implemented the assessment procedure for a number of substances, with a view to their possible inclusion in Annex I to Directive 91/414. Metalaxyl was among those substances.

10 Article 4(1) of Regulation No 3600/92 provides that '[a]ny producer wishing to secure the inclusion of an active substance referred to in Annex I hereto ... in Annex I to the Directive [91/414], shall so notify the Commission within six months of the date of entry into force of this Regulation'.

11 Article 5 of Regulation No 3600/92 provides that:

'1. The Commission shall examine with the [Standing] Committee [on Plant Health] the notifications ...

2. Following the examination referred to in paragraph 1, decisions shall be adopted on the following, according to the procedure under Article 19 of the Directive [91/414], in the form of a regulation:

(a) the list of active substances adopted for assessment with a view to their possible inclusion in Annex I to Directive [91/414];

(b) designation of a rapporteur Member State for each active substance included in the list referred to in (a).

...

4. For each substance adopted for assessment, the regulation referred to in paragraph 2 shall give:

...

— the deadline for the submission to the rapporteur Member State of the dossiers referred to in Article 6 hereof, generally laying down a period of 12 months for the compilation of the documents, and for the submission by any interested parties of technical or scientific information with regard to the potentially dangerous effects of the substance or its residues on human and/or animal health and/or on the environment.

...'

12 Article 6 of Regulation No 3600/92 provides:

'1. Within the time-limit referred to in the third indent of Article 5(4), the notifiers specified in the regulation referred to in that Article must, individually or collectively, send to the designated authority of the rapporteur Member State, for any given active substance:

(a) the summary dossier referred to in paragraph 2 hereof; and

(b) the complete dossier referred to in paragraph 3 hereof.

...

Where for any substance the regulation as envisaged in Article 5(4) indicates several notifications, the notifiers concerned shall take all reasonable steps to present collectively the dossiers referred to in the first subparagraph. Where a dossier was not presented by all notifiers concerned, it shall mention the efforts made and the reasons why certain producers have not participated.

...

4. Where, for any given active substance, the dossiers referred to in paragraph 1 are not sent within the time-limit laid down in Article 5(4) or where the dossiers sent clearly do not satisfy the requirements laid down in paragraphs 2 and 3 hereof, the rapporteur Member State shall inform the Commission, giving the reasons pleaded by the notifiers.

5. On the basis of the report of the rapporteur Member State referred to in paragraph 4, the Commission shall present to the Committee a draft decision not to include the active substance in Annex I, in accordance with the final subparagraph of Article 8(2) of the Directive [91/414], unless:

— a new time-limit has been granted for the submission of a dossier fulfilling the requirements of paragraphs 2 and 3; a new time-limit will only be granted where

the delay is proved to have been caused by efforts to present collective dossiers, or by additional efforts to be made by the notifier (or notifiers) on account of a decision to designate another rapporteur Member State in accordance with Article 5(5), [or by force majeure,]

...'

13 Article 7 of Regulation No 3600/92 provides:

'1. For each active substance for which it has been designated rapporteur, the Member State shall:

(a) examine the dossiers referred to in Article 6(2) and (3), ... as well as any information as referred to in the third indent of Article 5(4) and any other available information ...;

(b) immediately after examining a dossier, ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission;

(c) send the Commission, as quickly as possible and at the latest 12 months after receipt of a dossier as referred to in Article 6(2) and (3), a report of its assessment of the dossier, including a recommendation:

— to include the active substance in Annex I to the Directive, stating the conditions for its inclusion, or

— to remove the active substance from the market,

...

2. From the start of the examination referred to in paragraph 1, the rapporteur Member State may request the notifiers to improve their dossiers, or add to them. Moreover, the rapporteur Member State may, from the start of this examination, consult with experts from other Member States, and may request additional technical or scientific information from other Member States in order to assist the evaluation.

3. After receiving the summary dossier and the report referred to in paragraph 1, the Commission shall refer the dossier and the report to the [Standing] Committee [on Plant Health] for examination.

Before referring the dossier and report to the Committee, the Commission shall circulate the rapporteur's report to the Member States for information ...

Before the dossier and report are referred to the Committee, a consultation of experts from the Member States may be organised ...

3A. After the examination referred to in paragraph 3, the Commission shall ... present to the Committee:

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

(b) a draft decision addressed to the Member States to withdraw the authorisations of plant protection products containing the active substance, pursuant to the fourth subparagraph of Article 8(2) of the Directive, whereby that active substance is not included in Annex I to the Directive;

(c) a draft decision addressed to the Member States to suspend plant protection products containing the active substance from the market, with the option of reconsidering the inclusion of the active substance in Annex I to the Directive after submission of the results of additional trials or of additional information; or

(d) a draft decision to postpone inclusion of the active substance in Annex I to the Directive pending the submission of the results of additional trials or information.

4. However, where, following the examination referred to in paragraph 3, the submission of the results of certain additional trials or of additional information is required, the Commission shall determine:

— the time-limit within which the results or information concerned must be submitted to the rapporteur Member State and the experts designated according to paragraph 2 above, this time limit will be 25 May 2002 unless an earlier time-limit is established by the Commission for a particular active substance except for the results of long-term studies, identified as being

necessary by the rapporteur Member State and the Commission during the examination of the dossier and which are not expected to be fully completed by the deadline established, provided that the information submitted contains evidence that such studies have been commissioned and that their results will be submitted at the latest on 25 May 2003. In exceptional cases, where it has not been possible for the rapporteur Member State and the Commission to identify such studies by 25 May 2001, an alternative date may be established for the completion of such studies, provided the notifier supplies the rapporteur Member State with evidence that such studies have been commissioned within three months of the request to undertake the studies, and with a protocol and progress report of the study by 25 May 2002,

— the time-limit within which the notifiers concerned must communicate to the rapporteur Member State and to the Commission their undertaking to submit the required results or information within the time-limit laid down in the first indent.

...

5. The Commission shall submit to the Committee a draft decision for non-inclusion in Annex I to the Directive [91/414] in accordance with the final subparagraph of Article 8(2) thereof, where

— the notifiers concerned have not communicated their undertaking to submit the required results within the time-limit referred to in the second indent of paragraph 4,

— the rapporteur Member State has informed the Commission that the results referred to in the first indent of paragraph 4 have not been submitted within the time-limit laid down.

— ...'

14 Pursuant to Article 8(1) of Regulation No 3600/92, after receiving the results of the additional trials or the additional information, the rapporteur Member State must examine those results or the additional information, ensuring that the results or the additional information are sent by the notifier to the other Member States and to the Commission. Further, the rapporteur Member State must communicate, within six months at the latest following receipt of the results or information, a report of its assessment of the whole dossier including a recommendation whether or not to include the active substance in Annex I to Directive 91/414.

15 Under Article 8(3) of Regulation No 3600/92, '[b]efore referring the dossier and report to the [Standing] Committee [on Plant Health], the Commission shall circulate the rapporteur's report to the Member States for information and may organise a consultation of experts from one or several Member States'. The same provision states that '[t]he Commission may consult some or all of the notifiers of active substances on the report or parts of the report on the relevant active substance' and, for those purposes, '[t]he rapporteur Member State shall provide the necessary technical and scientific assistance during these consultations'.

16 After the examination by the Standing Committee on Plant Health, the Commission is to prepare a draft measure including the substance in Annex I to Directive 91/414, or concerning the non-inclusion of that substance. The draft measure is then presented to that Committee for approval in accordance with the procedure laid down in Article 19 of the directive.

The facts and the contested decision

17 IQV is a company governed by Spanish law, the activities of which include the production and marketing of chemical products and plant protection products. In

particular, IQV imports metalaxyl into Spain and markets products containing that active substance in a number of Member States.

18 In April 1995, IQV and the German undertaking Ciba Geigy AG (later Syngenta AG, 'Syngenta') both submitted to the Direcção-geral de Protecção das Culturas (Directorate general for the protection of crops, 'the DGPC') an application for inclusion of metalaxyl in Annex I to Directive 91/414. Portugal had been designated as the rapporteur Member State in respect of that active substance.

19 Before making the notification required under Article 4(1) of Regulation No 3600/92, IQV and Syngenta entered into contact with a view to setting up a task force to compile a single collective dossier. However, Syngenta then decided not to make a collective notification. Consequently, Syngenta and IQV submitted separate dossiers to the Portuguese authorities, on 19 and 26 April 1995 respectively.

20 After examination of those dossiers, the DGPC considered that the dossier produced by Syngenta was complete, but that information was missing from the dossier lodged by IQV. Accordingly, by letter of 22 March 1996, the DGPC asked IQV to fill in the gaps in its dossier, in accordance with a strict timetable.

21 Over the following months, the Portuguese authorities and IQV exchanged correspondence concerning the need for IQV to provide the information missing from its dossier, as well as the period of time to be allowed for that purpose.

22 On 11 May 1998, Syngenta informed the DGPC that it was withdrawing from the procedure for assessing metalaxyl. IQV therefore remained the sole company which was party to the procedure.

23 By letter of 15 January 1999, IQV informed the Portuguese authorities that they were under an obligation to make use of all the information and all the documents submitted by all the notifiers and stating that, if IQV was to be asked for a complete dossier, an additional period of time ought to be granted to enable it to produce and summarise all the information required.

24 By letters of 5 February and 15 March 1999 respectively, the DGPC and IQV asked the Commission for its opinion on the use by rapporteur Member States of studies submitted by notifiers which subsequently withdraw from the procedure for assessment of the active substance concerned.

25 By letter of 19 July 1999 ('the letter of 19 July 1999'), the Commission replied to the DGPC, annexing an opinion prepared by the Commission Legal Service, worded as follows:

'...

2. ... There is no doubt that [Syngenta] has ceded its rights over the studies to the rapporteur so that the latter can use them in accordance with the rules governing the assessment procedure. The question which remains to be addressed, therefore, is whether those rules allow the rapporteur to use data after the notifier who supplied them has withdrawn from the procedure.

3. The legislation is not very clear on this point ... The rapporteur is to examine the dossiers submitted and ... may use "all information", not only that supplied by the notifiers or the interested parties.

4. Both Directive 91/414 and Regulation No 3600/92 are designed to encourage the joint participation of the various producers in the assessment procedure ... That does not alter the fact that several notifiers may participate without reaching an agreement. In such a case, the rapporteur is to take account of all the studies provided. Thus, the active substance is included even if the data supplied by one producer are incomplete, and the studies carried out by one notifier are of benefit to the producers as a whole even in the absence of an agreement.

5. Under the system set up by Directive 91/414, inclusion of an active substance in Annex I is not linked exclusively to the producer who has applied for its inclusion and inclusion may even be applied for independently by a Member State. In return for its efforts, the undertaking which has carried out the scientific studies has the exclusive right to rely on those studies when the Member States authorise products containing the active substance in question ... It seems therefore that, even if the other producers all benefit where the active substance is included thanks to studies carried out by their competitors, they will not be able to obtain authorisation for products containing that substance unless they carry out the studies again or obtain the right to use them from the author of those studies.

It would be rather odd, therefore, if different rules and different rights were to apply where a notifier withdraws from the procedure, and paradoxical, almost, to offer a producer which abandons the market for an active substance better protection than a producer which is in competition on that market with the other notifiers. Moreover, the legislation makes no distinction between the two situations in terms of the protection offered to the studies supplied by the producers. In consequence, it would appear that the same set of rules must apply.

6. However, the notifier is required to give a number of guarantees to the rapporteur Member State:

— it takes responsibility for submitting to the rapporteur Member State, to the other Member States, to the Commission and to the experts referred to in Article 7(2) (peer review), a summary dossier and, if necessary, a complete dossier in accordance with Article 6(1) of Regulation No 3600/92;

— it must reply appropriately to the requests of the rapporteur Member State to improve or add to the dossier ...

It follows that the intention of the legislature was clearly to set up a system of close cooperation between the rapporteur Member State and the notifier, under which the provision of technical support ... and the possibility of obtaining any useful information ... must be guaranteed by the notifier.

7. In conclusion, ... consideration of the matter indicates to the Commission that the withdrawal of a notifier from participation in the work programme should not prevent the rapporteur Member State from examining the data provided and issuing the assessment report, particularly where another notifier in respect of the same substance has expressed an interest in that assessment being completed.

...'

26 On 28 October 1999, the DGPC informed IQV that it was prepared to draw up the assessment report for metalaxyl on the basis of all the information available, including the information in the dossier submitted by Syngenta. It was also stated in that letter that if additional questions were raised during the assessment, or if additional data were required, those questions and requests for additional information would be addressed to IQV.

27 On 26 January 2001, pursuant to Article 7 of Regulation No 3600/92, the DGPC sent the Commission its assessment report on metalaxyl, drawn up on the basis of the dossiers provided by IQV and by Syngenta. In the report, the DGPC stated that certain additional information was necessary in order to complete the assessment and that, in consequence, it was not possible at that stage to propose the inclusion of metalaxyl in Annex I to Directive 91/414.

28 By letters of 2 and 15 February 2001, the Portuguese authorities asked IQV to send an updated summary dossier to the Member States and to the Commission before 15 March 2001 and, should it be requested, a complete dossier.

29 On 26 March 2001 the Commission informed IQV that, since IQV had not sent the updated summary dossier within the time-limits specified, it was not possible to carry out an appropriate examination of metalaxyl and to arrive at a finding in respect of that substance. The Commission pointed out that, under Article 6(1) of Regulation No 3600/92, the notifiers were under an obligation to send both a summary dossier and a complete dossier to the competent authority of the rapporteur Member State. Accordingly, since those dossiers had not been sent, the Commission intended to propose the adoption of a decision not to include metalaxyl in Annex I to Directive 91/414.

30 By letter of 4 May 2001 addressed to the Commission, IQV explained that it intended to purchase those of Syngenta's studies which were protected. IQV also asked the Commission to let it know whether the Portuguese authorities had been given responsibility for circulating the necessary documentation to the Member States, and offered to meet the expenses of such distribution itself. Subsequently, in a letter of 7 June 2001 to the Commission, IQV provided the list of the studies in Syngenta's dossier which were protected, and pointed out that it was unlikely that Syngenta would agree to sell those studies to IQV.

31 In that letter of 7 June 2001, IQV also attempted to identify — from among the protected Syngenta studies — those which it would need in order to complete its own dossier. IQV explained that those studies could be replicated before the May 2002 deadline. However, IQV asked the Commission to confirm the list so that it could be sure of being able to meet that deadline. On the same day, in order to compile a complete dossier, IQV contacted Syngenta with a proposal to purchase certain studies carried out in connection with Syngenta's notification.

32 By letter of 11 July 2001, the Commission told IQV that it had to complete its dossier by 25 May 2002, since the Commission services had to arrive at a final decision regarding metalaxyl before the end of July 2003. The Commission also stated that if IQV did not have the complete dossier it would probably be unable to reply within a reasonable period to questions raised by the experts from the Member States or by the Commission.

33 By letter of 26 September 2001, the DGPC informed IQV that it was not willing to circulate Syngenta's dossier to the Member States and the Commission.

34 By letter of 15 October 2001, the Commission informed IQV that Syngenta's refusal to sell its studies to IQV and the Portuguese authorities' refusal to circulate Syngenta's dossier meant that it was impossible for the Commission to organise effectively the consultation of the experts (the 'peer review' mechanism) with regard to metalaxyl.

35 By letter of 1 April 2002, IQV told the Commission that it was willing to carry out all the studies necessary to obtain the inclusion of metalaxyl in Annex I to Directive 91/414. On 12 April 2002, IQV sent the Commission an updated summary dossier and confirmed its decision to compile a complete dossier.

36 By letter of 6 June 2002, the Commission informed IQV that only those active substances in respect of which full data would be available by 31 December 2003 at the latest could have their deadline for assessment extended beyond that date. The Commission stated in that letter its opinion that IQV could not produce a complete dossier by that date. Accordingly, the Commission stated that it was forced to propose that metalaxyl should not be included in Annex I to Directive 91/414. The Commission pointed out, however, that IQV could file a dossier for the purpose of registering metalaxyl as a 'new active substance'.

37 By letter of 14 June 2002 to the Commission, IQV stated that it was continuing to carry out the studies necessary to fill the gaps identified in the report from the Portuguese authorities, and undertook to submit those studies by May 2003. Regarding the submission of a dossier for the registration of metalaxyl as a new active substance, IQV stated that the compilation of such a dossier would not be possible before the end of 2005. IQV added that since the compilation of such a dossier entailed a major financial investment, it could only be envisaged if the Commission guaranteed that metalaxyl would be authorised for a transitional period so that IQV would not lose market share during the assessment procedure.

38 In June 2002 the Commission placed a draft decision not to include metalaxyl before the Standing Committee on Plant Health. After the Committee had approved the draft decision at its meeting of 18 and 19 October 2002, the Commission adopted the contested decision on 2 May 2003.

The proceedings before the Court of First Instance and the judgment under appeal

39 By application lodged at the Registry of the Court of First Instance on 9 May 2003, IQV brought an action for annulment of the contested decision. On the same day, IQV also applied for the suspension of application of that decision.

40 By order of 5 August 2003 in Case T-158/03 R *Industrias Químicas del Vallés* v *Commission* [2003] ECR II-3041, the President of the Court of First Instance dismissed the application for interim measures brought by IQV. IQV then filed an appeal against that order.

41 By order of 21 October 2003 in Case C-365/03 P(R) *Industrias Químicas del Vallés* v *Commission* [2003] ECR I-12389, the President of the Court, on finding that the President of the Court of First Instance had erred in law in the balancing of the interests involved and that the conditions relating to a prima facie case and to urgency were satisfied, set aside the order of 5 August 2003 in *Industrias Químicas del Vallés* v *Commission*, and ordered the suspension of operation of the contested decision.

42 By the judgment under appeal, the Court of First Instance ruled on the substance of the case and rejected the three pleas in law relied on by IQV. By those pleas in law, IQV alleged the incorrect application to the facts of the case of Directive 91/414 and Regulation No 3600/92, infringement of the principle of proportionality and misuse of powers.

43 Firstly, the Court of First Instance held that the Commission had not contravened either the rules relevant to the assessment of active substances or its own interpretation of the provisions relating to the use of studies submitted, before its withdrawal, by another notifier. Whatever the circumstances, IQV should have submitted to the rapporteur Member State a complete dossier within the time-limits laid down in Regulation No 3600/92. The Court of First Instance also held that the presumption relied on by the Commission — that, since IQV did not have access to the studies submitted by Syngenta, IQV would be unable to reply to the questions which would arise in the course of the peer review — was justified.

44 Further, the Court of First Instance considered that the contested decision did not infringe the principle of proportionality since, in the circumstances of the case, the withdrawal from the market of plant protection products containing metalaxyl represented the only means of ensuring that the objective of protecting human and animal health and the environment would be met.

45 Lastly, the Court of First Instance rejected the plea in law alleging misuse of powers, on the ground that IQV had not adduced any evidence to show that the Commission had adopted the contested decision as a result of pressure exerted by Syngenta.

Proceedings before the Court of Justice and the forms of order sought by the parties

46 By application lodged at the Registry of the Court on 26 August 2005, IQV brought the present appeal against the judgment under appeal, together with a fresh application for suspension of operation of the contested decision. The latter application was dismissed by order of the President of the Court of 15 December 2005 in Case C-326/05 P-R *Industrias Químicas del Vallés* v *Commission* (not published in the ECR).

47 IQV claims that the Court should:

— declare that the present appeal is admissible and well founded;

— set aside the judgment under appeal;

— grant the application made at first instance, seeking annulment of the contested decision;

— in the alternative, refer the case back to the Court of First Instance for judgment;

— order the Commission to pay the costs incurred both at first instance and on appeal and, if appropriate, those incurred as a result of the proceedings relating to interim measures.

48 The Commission contends that the Court should:

— dismiss the appeal as inadmissible or, in the alternative, as unfounded, as regards the first to third grounds of appeal, the first and third parts of the fourth ground of appeal, the first part of the fifth ground of appeal, the seventh ground of appeal and the assertions made in paragraphs 108 and 109 of the appeal which relate to the content of certain statements made by the legal representative of IQV in the course of the hearing before the Court of First Instance;

— dismiss the appeal, for the rest, as unfounded;

— order IQV to pay the costs.

The appeal

49 In its appeal, the appellant relies on seven grounds of appeal in order to have the judgment under appeal set aside and the contested decision annulled or, in the alternative, to have the case referred back to the Court of First Instance for a new ruling.

The first ground of appeal

Arguments of the parties

50 By its first ground of appeal, the appellant submits that the Court of First Instance distorted the clear sense of the evidence before it in order to conclude, in paragraphs 94 and 104 of the judgment under appeal, that the Commission had not in any way changed, in the course of the procedure, its position as to the requirement that IQV submit a complete dossier.

51 According to IQV, it is clear from the letter of 19 July 1999 — as well as from other documents, which the Court of First Instance did not take into account — that, initially, the Commission and the DGPC had thought it possible to carry out the assessment of metalaxyl not only on the basis of the dossier lodged by IQV, but also

in the light of all the information available, including the studies submitted by Syngenta. Only subsequently did the Commission demand a complete dossier from the appellant, thereby changing its approach and making it impossible in practice to produce such a dossier within the period of time allowed.

52 IQV alleges in particular that, by referring to a single passage in the letter of 19 July 1999, without considering the entire contents, the Court of First Instance misconstrued the meaning of that letter. According to IQV, a reading of the whole letter reveals that, in 1999, the Commission did not consider that the submission of a complete dossier by IQV was necessary, whether for proceeding with the assessment of metalaxyl or for the possible inclusion of that substance in Annex I to Directive 91/414.

53 IQV adds that, in analysing the letter of 19 July 1999, the Court of First Instance did not take into account either the facts or the documents subsequent to that letter. On that point, IQV relies principally on a letter from the DGPC dated 28 October 1999 (according to IQV, the only document of which it was aware at the material time) in which, on the one hand, no mention was made of the possibility that IQV might be asked to produce a complete dossier and, on the other, it was stated that the procedure would be conducted on the basis of all the information available.

54 The Commission contends that this ground of appeal is inadmissible, since the appellant has not demonstrated any distortion of the clear sense of the evidence submitted to the Court of First Instance.

55 The Commission also contends that this ground of appeal is unfounded. It maintains that it never changed its approach in the course of the assessment procedure: on the contrary, it always insisted that IQV submit a complete dossier. That is clear from the very wording of the letter of 19 July 1999, as the Court of First Instance rightly pointed out.

Findings of the Court

56 First, the Commission's preliminary plea of inadmissibility must be examined.

57 In that regard, it must be pointed out that, in accordance with the case-law of the Court of Justice, complaints based on findings of fact and on the assessment of those facts in the judgment under appeal are admissible on appeal where the appellant submits that the Court of First Instance has made findings of fact which the documents in the file show to be substantially incorrect or that it has distorted the clear sense of the evidence before it (see, to that effect, Case C-82/01 P *Aéroports de Paris* v *Commission* [2002] ECR I-9297, paragraph 56, and Case C-229/05 P *PKK and KNK* v *Council* [2007] ECR I-439, paragraph 35).

58 That is indeed the case here. The ground of appeal set out by the appellant refers in some detail to a manifest error committed by the Court of First Instance in its reading of the documents before it.

59 In those circumstances, the first ground of appeal must be held to be admissible.

60 As to whether the ground of appeal is well founded, it should be recalled that there is distortion of the clear sense of the evidence where, without recourse to new evidence, the assessment of the existing evidence appears to be clearly incorrect (*PKK and KNK* v *Council*, paragraph 37, and, to that effect, see also Case C-551/03 P *General Motors* v *Commission* [2006] ECR I-3173, paragraph 54).

61 In the light of that criterion, the Court finds that the Court of First Instance relied on the content both of the letter of 19 July 1999 and of a letter of 28 October 1999 from the DGPC to IQV in order to conclude that the Commission had in no way changed its position on the need for IQV to submit a complete dossier and that, consequently, the Commission was justified in refusing to extend the period of time allowed for that submission.

62 Thus, in paragraph 94 of the judgment under appeal, the Court of First Instance stated that '[t]he language of the letter of 19 July 1999 concerning IQV's obligations is very clear: "[The notifier] has responsibility for submitting to the rapporteur Member State, the other Member States and the experts referred to in Article 7(2) (peer review) a summary dossier, and, where necessary, a complete dossier." Even though the DGPC's letter to IQV of 28 October 1999 did not repeat that passage, it is clear that the Commission's position did not change at all'. In paragraph 104 of the judgment under appeal, the Court of First Instance added that 'the Commission's position on that question has not changed ... The Commission did not contradict itself by requiring a complete dossier in 2001, since, as early as July 1999, the legal opinion addressed to the DGPC referred to that obligation.'

63 However, as was pointed out by the Advocate General in points 68 to 72 of his Opinion, the inferences drawn by the Court of First Instance from those letters are not consistent with the meaning and implications of the letters read as a whole.

64 While it is true that, according to paragraph 6 of the letter of 19 July 1999, IQV was required to submit 'if necessary, a complete dossier', the fact remains that, elsewhere in that letter, the Commission stated to the DGPC:

— '[t]here is no doubt that [Syngenta] has ceded its rights over the studies to the rapporteur so that the latter can use them in accordance with the rules governing the assessment procedure' (paragraph 2);

— '[t]he rapporteur is to examine the dossiers submitted and ... may use "all information", not only that supplied by the notifiers or the interested parties' (paragraph 3);

— '[where several notifiers participate in an assessment procedure without reaching an agreement,] the rapporteur is to take account of all the studies provided. Thus, the active substance is included even if the data supplied by one producer are incomplete, and the studies carried out by one notifier are of benefit to the producers as a whole even in the absence of an agreement' (paragraph 4)

— '[u]nder the system set up by Directive 91/414, inclusion of an active substance in Annex I is not linked exclusively to the producer who has applied for its inclusion and inclusion may even be applied for independently by a Member State' (paragraph 5);

— '[i]n conclusion, ... consideration of the matter indicates to the Commission that the withdrawal of a notifier from participation in the work programme should not prevent the rapporteur Member State from examining the data provided and issuing the assessment report, particularly where another notifier in respect of the same substance has expressed an interest in that assessment being completed' (paragraph 7).

65 It is clear therefore from the terms of the letter of 19 July 1999 read as a whole that, although the Commission mentioned the possibility that production of a complete dossier might be required, it primarily confirmed to the Portuguese authorities that the assessment procedure for the active substance had to be carried out by reference to all the data available and that, in any event, the fact that IQV's dossier was incomplete did not as such represent an obstacle either to proceeding with the assessment procedure or to the possible inclusion of metalaxyl in Annex I to Directive 91/414.

66 Furthermore, the meaning of that letter is also clear from the letter sent to IQV on 28 October 1999 — after the DGPC had acquainted itself with the opinion of the Commission — in which the DGPC stated, without mentioning any possibility whatsoever that production of a complete dossier might be required, that it would take account of the dossier submitted by Syngenta and that only additional information could be requested from IQV. Moreover, as the Commission stated in point 5 of the grounds of the contested decision, the metalaxyl assessment report sent by the Portuguese authorities on 26 January 2001 was drawn up on the basis of information supplied by both notifiers.

67 Lastly, it must also be observed that, while the Commission referred in its letter of 26 March 2001 both to the obligation to produce a summary dossier and to the obligation to submit a complete dossier, it indicated that the latter obligation would arise only 'if requested'.

68 Consequently, it must be held that the findings of fact set out in paragraphs 94 and 104 of the judgment under appeal, to the effect that the Commission had in no way changed its position on the need for the applicant to produce a 'complete dossier' in support of its application for registration of metalaxyl, are incorrect and amount to a distortion of the clear sense of the evidence submitted to the Court of First Instance.

69 Accordingly, the first ground of appeal must be upheld and the judgment under appeal must be set aside, without it being necessary to rule on the other grounds of appeal relied on by IQV.

The action before the Court of First Instance

70 In accordance with the second sentence of the first paragraph of Article 61 of the Statute of the Court of Justice, if the decision of the Court of First Instance is set aside the Court of Justice may give final judgment in the matter where the state of the proceedings so permits.

71 It is appropriate in the present case for the Court to avail itself of that possibility, since it has all the information necessary to rule on the substance of the case.

72 By the second and third parts of the first plea in law — which should be examined first — IQV submitted in essence that the Commission made a manifest error of assessment in requiring a complete dossier to be lodged before the deadline specified and in refusing to defer that deadline. By its contradictory behaviour, the Commission itself made it impossible for IQV to meet that obligation in the time allowed.

73 The Commission has maintained that it correctly assessed the facts of the case, that it correctly applied the legislation, and that it did not behave in a contradictory manner with regard to the need for IQV to submit a complete dossier so that the assessment procedure for metalaxyl could be completed.

74 The Court notes however that, as is clear from Recitals 5, 6 and 9 in the preamble thereto, Directive 91/414 seeks to remove barriers to intra-Community trade in plant products, while maintaining a high level of protection of the environment and of human and animal health (see also Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-8339, paragraph 43).

75 In that context, as the Court of First Instance rightly held in paragraph 95 of the judgment under appeal, if the Commission is to be able to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion.

76 However, the exercise of that discretion is not excluded from review by the Court. The Court has consistently held that in the context of such a review the Community judicature must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of powers (Case 98/78 *Racke* [1979] ECR 69, paragraph 5, and Case C-16/90 *Nölle* [1991] ECR I-5163, paragraph 12).

77 In particular, where a party claims that the institution competent in the matter has committed a manifest error of appraisal, the Community judicature must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case, facts which support the conclusions reached (see, inter alia, Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14).

78 It must therefore be determined whether the contested decision was adopted in accordance with the principles set out above.

79 On that point, it must be stated that the letters referred to above, written in 1999 by the Commission and by the DGPC, could well have led IQV to believe — as is clear from paragraphs 61 to 67 of the present judgment — that the assessment of metalaxyl would be carried out on the basis of all the information available (including the studies contained in the dossier submitted by Syngenta) and that the competent authorities would, if necessary, ask it to provide no more than clarification or additional data. Moreover, the letters from the DGPC, which are referred to in paragraph 28 of the present judgment, also bear witness to somewhat inconsistent behaviour on the part of the DGPC towards IQV.

80 It must accordingly be held that the appellant found itself in an unforeseen and complicated situation, account being taken in particular of the time and effort needed to organise the required scientific studies when the Commission asked it to produce a complete dossier.

81 Thus, while IQV stated in its letter of 7 June 2001 that it could complete its dossier within the time allowed — that is, before May 2002 — if the Commission could confirm the list set out in Syngenta's dossier of the studies necessary for that purpose, the Commission did no more in its letter of 11 July 2001 than emphasise that the deadline for completion of the dossier was 25 May 2002 and that a final decision on metalaxyl had to be adopted before the end of July 2003. It is common ground that the Commission never confirmed the list of studies set out in IQV's letter of 7 June 2001.

82 As emerges from the letters from IQV referred to in paragraphs 35 to 37 of the present judgment, and particularly from the letter of 14 June 2002, IQV nevertheless continued clearly to express its intention of submitting to the Commission the studies missing from its dossier, undertaking to produce them for May 2003.

83 It is common ground, however, that the Commission took no account of that undertaking in that it did not reply to the letter of 14 June 2002 and at the same time placed a draft decision before the Standing Committee on Plant Health for the non-inclusion of metalaxyl.

84 It follows that the appellant has rightly submitted that the impossibility of lodging a complete dossier before the specified deadline of 25 May 2002 was attributable, at least in part, to the contradictory behaviour of the competent authorities. It is also obvious that the Commission did not in any way take that circumstance into account when it decided to adopt the contested decision and to refuse to defer the deadline until May 2003, as IQV had requested.

85 That finding is not affected by the argument relied on by the Commission that the circumstances of the case precluded the setting of new deadlines for IQV so as to enable it to submit the missing information. As the Advocate General pointed out in points 77 to 84 of his Opinion, it was perfectly possible under the rules in force at

the material time to defer the deadline for completion of the dossier, since the Commission had done so in the context of similar assessment procedures for other active substances. The Commission acknowledged, moreover, in the defence submitted at first instance that the deferral until 31 December 2005 of the deadline for assessment of active substances 'also applied to metalaxyl'.

86 In addition, the Commission itself had confirmed — in the letter to IQV referred to in paragraph 36 of the present judgment — that it could as a general rule use any information submitted to it before 31 December 2003, in other words, at a date several months after the May 2003 date proposed by IQV and refused by the Commission.

87 It should be noted, furthermore, that the Commission has not disputed, even at the hearing, the absence of evidence indicating that the use of metalaxyl may present any risk whatsoever to public health or to the environment.

88 It follows that the Commission committed a manifest error of appraisal in refusing to grant IQV a deferral of the deadline for production of the studies missing from its dossier and in deciding as a consequence not to include metalaxyl in Annex I to Directive 91/414 on the sole ground that the appellant had failed to submit a complete dossier before that deadline.

89 The contested decision is therefore vitiated by an error in law and must be annulled.

Costs

90 Under Article 69(2) of the Rules of Procedure, which applies to appeal proceedings by virtue of Article 118 thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since IQV has applied for costs and the Commission has been unsuccessful in its pleadings, the Commission must be ordered to pay the costs of the present proceedings and of the proceedings at first instance, including costs relating to the proceedings for interim measures before both the Court of Justice and the Court of First Instance.

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

1. **Sets aside the judgment of the Court of First Instance of the European Communities of 28 June 2005 in Case T-158/03 *Industrias Químicas del Vallés* v *Commission*;**

2. **Annuls Commission Decision 2003/308/EC of 2 May 2003 concerning the non-inclusion of metalaxyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance;**

3. **Orders the Commission of the European Communities to pay the costs of the present proceedings and of the proceedings at first instance, including those relating to the proceedings for interim measures before both the Court of Justice and the Court of First Instance.**

[Signatures]