JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)

28 June 2005 *

In Case T-158/03,

Industrias Químicas del Vallés, SA, established in Mollet del Vallés (Spain), represented initially by C. Fernández Vicién, J. Sabater Marotias and P. González-Espejo, and subsequently by C. Fernández Vicién, J. Sabater Marotias and I. Moreno-Tapia Rivas, lawyers,

applicant,

v

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

defendant,

* Language of the case: Spanish.

ACTION 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 COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Second Chamber),

composed of J. Pirrung, President, N.J. Forwood and S. S. Papasavvas, Judges,

Registrar: J. Palacio González, Principal Administrator,

having regard to the written procedure and further to the hearing on 8 December 2004,

gives the following

Judgment

Relevant provisions

1 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) introduces, inter alia, the Community system for the granting and withdrawal of authorisation for plant protection products. Article 4 of Directive 91/414 provides that 'Member States

shall ensure that a plant protection product is not authorised unless ... its active substances are listed in Annex I'. The conditions for the inclusion of active substances in Annex I are laid down in Article 5 of Directive 91/414. Inclusion is not possible unless, in the light of current scientific and technical knowledge, it may be expected that plant protection products containing the active substance will fulfil certain conditions ensuring that they are not harmful for human and animal health or the environment.

2 Active substances which are not included in Annex I to Directive 91/414 may, under certain conditions, enjoy transitional derogating measures. Article 8(2) of Directive 91/414 provides therefore that '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.' That period of 12 years, which expired on 26 July 2003, was extended in the case of some substances 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/EEC 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). Under that regulation, the time period of 12 years is extended until 31 December 2005 'unless a decision has been taken or is taken before that date to include or not include the active substance in Annex I to Directive 91/414.'

3 Article 8(2) of Directive 91/414 provides that during that transitional period the active substances concerned must be subjected to an evaluation programme, at the end of which they may either be included in Annex I to Directive 91/414 or not be included in it if those substances do not meet the safety requirements set out in Article 5 of Directive 91/414 or the information and data needed for the evaluation have not been submitted 'within the prescribed period'. Lastly Article 8(2) of Directive 91/414 provides that the details of the evaluation programme are to be set out in a Commission regulation.

4 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 Council Directive 91/414/EEC (OJ 1992 L 366, p. 10) lays down the evaluation procedure for several substances with a view to their possible inclusion in Annex I to Directive 91/414. One of those substances is metalaxyl, used in the manufacture of fungicides for the control of several diseases affecting crops.

5 The procedure introduced by Regulation No 3600/92 begins with a notification of interest, provided for under Article 4(1) of that regulation, according to which 'any producer wishing to secure the inclusion of an active substance referred to in Annex I hereto, or any salts, esters or amines thereof, 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'. The ninth recital in the preamble to Regulation No 3600/92 states that 'in order to avoid duplication of work, and in particular experiments involving vertebrate animals, specific provisions have to be provided to stimulate producers to submit collective dossiers'.

6 Following the examination of the notifications of interest, Article 5(2)(b) of Regulation No 3600/92 provides that a rapporteur Member State is to be appointed in order to evaluate each of the active substances concerned. In the present case the Portuguese Republic was appointed as the rapporteur Member State with regard to metalaxyl, under 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 Commission Regulation (EEC) No 3600/92 (OJ 1994 L 107, p. 8). The Portuguese Republic appointed as the competent authority for that purpose the Direcção-Geral de Protecção das Culturas (Department for the Protection of Crops, 'DGPC') of the Ministry of Agriculture, Rural Development and Fisheries.

7 Once the rapporteur Member State has been appointed, Article 6(1) of Regulation No 3600/92 provides that it is for the notifiers to send a 'summary dossier' and a

'complete dossier', as defined in Article 6(2) and (3), to that State. The summary dossier includes a copy of the notification, the recommended conditions for use, the available summaries and results of trials for each point of Annex III to Directive 91/414 relevant to the assessment of the criteria referred to in Article 5 of the Directive. That information relates to one or more preparations which are representative of the recommended conditions for use in connection with inclusion of the active substance in Annex I to the directive. The complete dossier includes the protocols and the complete study reports concerning all the information referred to above. Under Article 6(2)(b) of Regulation No 3600/92, as supplemented by Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27), 'it has to be demonstrated by the notifier that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the requirements of Directive [91/414] in relation to the criteria referred to in Article 5 thereof can be met'.

8 The notifiers are to send the summary dossier and the complete dossier to the rapporteur Member State within a time-limit set by the Commission. In the case of metalaxyl the time-limit for submitting the dossiers was set at 30 April 1995 under Regulation No 933/94, and extended until 31 October 1995 by Commission Regulation (EC) No 2230/95 of 21 September 1995 amending Regulation No 933/94 (OJ 1995 L 225, p. 1). Article 6(1) of Regulation No 3600/92 provides that the notifiers must also send the summary dossier and the complete dossier to experts of other Member States accepted by the Commission with a view to further consultation.

9 The rapporteur Member State then examines the summary dossier and the complete dossier and, under Article 7(1)(b) of Regulation No 3600/92, must 'immediately after examining a dossier, ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission'. Article 7(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) provides that from the start of its examination

'the rapporteur Member State may request the notifiers to improve their dossiers, or add to them', and 'may ... 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'.

10 The rapporteur Member State then prepares and sends a report on its assessment of the dossiers to the Commission within 12 months of the receipt of the dossiers, under Article 7(1)(c) of Regulation No 3600/92. That report must contain in particular a recommendation on whether it is appropriate to include the active substance concerned in Annex I to Directive 91/414.

11 Furthermore, Directive 91/414 includes two provisions, Articles 13 and 14, under the heading 'Data requirements, data protection and confidentiality'.

12 Article 13 of Directive 91/414 relates to applications for authorisation to place on the market plant protection products containing active substances already included in Annex I to that directive, and provides that use may be made of the information of another applicant only with the agreement of that applicant. Thus Article 13(3) provides, inter alia, that 'in granting authorisations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants unless the applicant has agreed with the first applicant that use may be made of such information'. Moreover, under Article 13(7) 'the holder or holders of previous authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.'

13 Also in relation to applications for authorisation to place products on the market, Article 14 of Directive 91/414 provides that 'Member States and the Commission shall, ... , ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant wishing to have an active substance included in Annex I or the applicant for authorisation of a plant protection product so requests, and if the Member State or the Commission accepts that the applicant's request is warranted.' That confidentiality is limited, since Article 14 goes on to provide:

'Confidentiality shall not apply to:

— the names and content of the active substance or substances and the name of the plant protection product,

— ...

— physico-chemical data concerning the active substance and plant protection product,

— any ways of rendering the active substance or plant protection product harmless,

— a summary of the results of the tests to establish the substance's or product's efficacy and harmlessness to humans, animals, plants and the environment,

— recommended methods and precautions to reduce handling, storage, transport, fire or other hazards,

— methods of analysis referred to in Articles 4(1)(c) and (d) and 5(1),

— ...

If the applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority.'

14 The report sent by the rapporteur Member State to the Commission may then be subject to an opinion from experts from the Member States, and the Commission may consult some or all of the notifiers under Article 7(3) of Regulation No 3600/92, as amended by Regulation No 1199/97. The consultation of experts from the Member States is considered as 'peer review'. The coordination and administration work relating to that review was entrusted to ECCO (European Commission Coordination) on the basis of a contract concluded with the Commission. During that review, the dossier and the rapporteur Member State's report are examined by experts from several Member States for the purpose of confirming the rapporteur Member State's analysis and identifying information which is missing. That procedure can last from six to nine months. After the review and the obtention of any missing information, the rapporteur Member State's report is examined by the Standing Committee on the Food Chain and Animal Health ('the Committee') under the same provision, as amended by Article 62(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

15 Article 7(3A) of Regulation No 3600/92, as added by Regulation No 1199/97, provides that after that examination, the Commission is to present to the Committee either a draft directive to include the active substance in Annex I to Directive 91/414, or a draft decision to withdraw the authorisations of plant protection products containing the active substance, or a draft decision relating to such a withdrawal with the option of reconsidering inclusion of the active substance in Annex I to the Directive after submission of the results of additional trials or of additional information, or finally a draft decision to postpone inclusion of the active substance pending the submission of the results of additional trials or information.

16 However, Article 7(4), first indent, of Regulation No 3600/92, as supplemented by Regulation No 2266/2000, provides that where, following the Committee's examination, the submission of the results of certain additional trials or of additional information is required, the Commission is to determine the time-limit within which the results or information concerned must be submitted. The provision states:

'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.'

17 Article 7(5) of Regulation No 3600/92 states that 'the Commission shall submit to the Committee a draft decision for non-inclusion in Annex I ... in accordance with the final subparagraph of Article 8(2) of Directive [91/414], where ... 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.'

18 Article 8 of Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that after receiving the results of the additional trials or the additional information, the rapporteur Member State must finalise its examination, ensure that the summary of the additional trials and the results of those trials or the additional information are sent by the notifier to the other Member States and to the Commission, and communicate as quickly as possible, and 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.

19 Pursuant to Article 8(3) of Regulation No 3600/92, as amended by Regulation No 2266/2000, after the Commission has received the report drawn up by the rapporteur Member State, it is to refer it to the Committee for examination. That provision provides that 'before referring the dossier and report to the Committee, 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.' It is added that 'the 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', specifying that 'the rapporteur Member State shall provide the necessary technical and scientific assistance during these consultations.' After examination by the Committee, the Commission finally submits to the Committee either a draft decision to include or not include the substance in Annex I to Directive 91/414.

Facts

20 The applicant, Industrias Químicas del Vallés, SA ('IQV' or 'the applicant'), is a company governed by Spanish law whose activities include the production and marketing of plant protection products, animal feed and chemicals. Since February 1994 IQV has imported metalaxyl into Spain and marketed products containing that active substance in Italy, Spain, Greece and Portugal, and also in several States outside the Community. Rallis India Ltd ('Rallis') produces the metalaxyl which IQV imports.

21 The applicant and Ciba Geigy AG (which later became Novartis AG then Syngenta AG; 'Syngenta'), an undertaking which at the time also marketed products containing metalaxyl, each notified the Commission of their intention to submit a dossier with a view to the inclusion of that substance in Annex I to Directive 91/414. Before making that notification, IQV and Syngenta expressed their interest in submitting a collective dossier. They then exchanged correspondence and organised meetings 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. IQV stated that Syngenta had been hostile from the outset to the idea of putting together a collective dossier.

22 Syngenta and the applicant finally submitted separate dossiers to the Portuguese authorities on 19 April 1995 and 26 April 1995 respectively, that is to say, before the 31 October 1995 deadline set by Regulation No 2230/95.

23 After studying those documents, the Portuguese authorities considered that the dossier submitted by Syngenta was 'substantially complete', but that the one submitted by IQV was not. IQV was informed of this by a letter from DGPC of 22

March 1996 and then undertook to complete its dossier according to a timetable approved by the Portuguese authorities. On 12 April 1996, IQV indicated to the Portuguese authorities that most of the data identified as missing would be available before the end of June 1996. On 27 May 1996 the Portuguese authorities informed IQV that they agreed to the time-limit for the submission of the information still to be supplied, stressing at the same time the need to set a time-limit for the submission of certain other information.

24 On 3 June 1997 the Portuguese authorities sent a letter to IQV stating that its dossier could still not be regarded as complete. DGPC explained that essential studies were missing in almost all the areas provided for by Directive 91/414, namely analytical methods on residues, toxicology, residues, intended use and behaviour in the environment, ecotoxicology. DGPC explained what those studies were and identified the missing information.

25 On 30 September 1997 IQV informed the Portuguese authorities that it should be possible to provide most of the information required within nine months, that is, in June 1998 at the latest.

26 On 11 May 1998 Syngenta informed the Portuguese authorities that it was withdrawing from the procedure for the evaluation of metalaxyl. Syngenta also requested, on 15 May 1998, that the summary dossier and the complete dossier it had submitted during the procedure should be returned to it. IQV was therefore the only undertaking participating in the procedure for the evaluation of metalaxyl, but at that stage it had not yet completed its dossier. After its withdrawal from the procedure, Syngenta obtained registration of metalaxyl-M, an active substance with characteristics very similar to those of metalaxyl, on 15 July 2002.

27 On 27 July 1998 IQV was informed of Syngenta's withdrawal from the procedure for the evaluation of metalaxyl.

28 By letter of 15 January 1999, IQV informed DGPC that it was obliged to make use of all the information and documents submitted by all of the notifiers. Moreover, IQV stated that, if it was asked for a complete dossier, an additional period had to be granted to enable it to produce and synthesise all the information required. IQV added that it wished DGPC would keep the Commission informed of its position.

29 By letters of 5 February 1999 and 15 March 1999 respectively, DGPC and IQV asked the Commission for its view on the use by the rapporteur Member State of studies submitted by a notifier which later withdrew from the procedure for the evaluation of an active substance. IQV also informed the Commission that its dossier was not complete and that, if it was asked to supply a complete dossier, it should be granted additional time.

30 By letter of 19 July 1999 the Commission informed the Portuguese authorities that, in its view, the fact that a notifier had withdrawn from the procedure for the examination of an active substance did not preclude the Member State responsible for investigating the dossier from taking into account all the information available to it, including the information supplied by that notifier. Point 6 of that letter stated as follows:

'However, the notifier [in this case the notifer continuing its notification] is required to give a number of guarantees to the rapporteur Member State:

— it takes responsibility for submitting to the rapporteur Member State, the other Member States, the Commission and 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 during preparation of its assessment report and [later] during the examination of that report by the Commission in accordance with Article 7(2) of Regulation No 3600/92.'

31 On 28 October 1999 the Portuguese authorities informed IQV that they were prepared to draw up an assessment report on metalaxyl on the basis of all the available information, including the dossier supplied by Syngenta. The Portuguese authorities stated, however, that if additional questions were raised during the evaluation or additional data were required, the questions and requests for additional information would be addressed to IQV. The Portuguese authorities stated that they would ask Syngenta for confirmation of the list of information regarded as protected.

32 On 26 January 2001, pursuant to Article 7 of Regulation No 3600/92, the Portuguese authorities sent the Commission the report on their assessment of metalaxyl, drawn up on the basis of the dossiers sent by Syngenta and IQV. In their report the Portuguese authorities stated that certain additional information was required in order to complete the evaluation of that substance and that it was not possible for them at that stage to propose the inclusion of the substance in Annex I to Directive 91/414.

33 By letter of 9 February 2001, ECCO asked IQV to fill in a table on the progress of the studies. IQV completed column C of that table by electronic mail on 9 March 2001. That table, updated to 14 October 2002, showed that certain information requested would not be available until September 2004 (suspension stability of the substance), and that certain additional studies relating to the residues in the soil, water and air could not be submitted until May 2003. Moreover, other studies would not be

available until the end of December 2002 (for example, toxicity for aquatic organisms and honeybees) or May 2003 (for example, toxicity for terrestrial micro-organisms).

34 By letters of 2 and 15 February 2001, the Portuguese authorities asked IQV to send to the Member States and the Commission, before 15 March 2001, an updated summary dossier pursuant to Article 7(1)(b) of Regulation No 3600/92 and, should it be requested, a complete dossier on metalaxyl.

35 On 26 March 2001 the Commission informed IQV that since it had not sent the updated summary dossier within the required time-limit it was not possible for the Commission and the Member States to carry out an appropriate examination and draw a conclusion about metalaxyl. The Commission stated that Article 6(1) of Regulation No 3600/92 required the notifiers to send a summary dossier and a complete dossier at the request of the competent authority of each Member State. However, the Commission stated that since those dossiers had not been sent, it intended to present a draft decision not to include metalaxyl in Annex I to Directive 91/414.

36 By letter of 4 May 2001 addressed to the Commission, IQV stated that it was analysing the cost and the time required to reproduce certain studies submitted by Syngenta with a view to ensuring compliance with the time-limit, which expired in May 2002. IQV stated that its intention at that time was to obtain only the Syngenta studies which were protected. In addition, IQV asked the Commission whether the Portuguese Republic was responsible for circulating the documentation to the Member States at IQV's expense.

37 In a letter of 7 June 2001 addressed to the Commission, IQV listed the studies in Syngenta's file which were protected. It also stated that it was unlikely that Syngenta would agree to sell its studies to it. IQV also stated that those studies could be reproduced by the time-limit which expired in May 2002.

38 In order to compile a complete dossier, on 7 June 2001 IQV contacted Syngenta with a proposal to buy certain studies it had carried out in connection with its notification (studies contained in its summary dossier and its complete dossier).

39 In a letter dated 11 July 2001 the Commission let it be known that if IQV did not have the complete dossier it could probably not reply within a reasonable period to questions about metalaxyl raised by the experts from the Member States or the Commission. Further, the Commission stated that a final decision on metalaxyl had to be taken before July 2003. As regards the question of the Portuguese Republic circulating the documentation to the Member States, the Commission took the view that that was possible if such circulation was only an administrative task for the rapporteur Member State.

40 On 10 September 2001 Syngenta sent a letter to IQV in which it informed the latter that it was not willing to sell it the studies carried out for its dossier on metalaxyl.

41 On 26 September 2001 the Portuguese authorities informed IQV that they were not willing to circulate Syngenta's summary or complete dossier to the Member States and the Commission.

42 On 15 October 2001 the Commission informed IQV that, due to Syngenta's refusal to sell its studies to IQV and the Portuguese authorities' refusal to copy and circulate the dossier, it was impossible for it to consult experts from the Member States in regard to metalaxyl.

43 In a letter of 8 March 2002, the Commission informed IQV that the non-inclusion of metalaxyl in Annex I to Directive 91/414 seemed to be the only conceivable course of action. It stated that it would not extend the deadline of 25 July 2003 provided for in Directive 91/414. The Commission referred to the impossibility of carrying out the examination by the national experts effectively. It stated that it was sure, owing to its experience, that in the peer review new studies or clarifications would be demanded. The peer review was blocked in so far as IQV did not have the information contained in Syngenta's dossier. IQV would therefore have to carry out new studies, which would give rise to further delays and some uncertainty. That uncertainty was due to the fact that, despite submitting new studies to fill the gaps in its dossier (namely, by providing the studies not already in Syngenta's file), IQV would not be able to reply to the experts' questions on the studies in Syngenta's dossier of which it had no knowledge. Furthermore, the Commission added that the Portuguese authorities considered that it was not for them to reply to the questions raised during the examination by the national experts.

44 By letter of 1 April 2002, IQV informed the Commission that it was willing to carry out all the studies necessary to apply for the registration of metalaxyl provided it was granted a new transitional period during which that substance would not be withdrawn from the market.

45 On 12 April 2002 IQV sent the Commission an updated summary dossier and confirmed its decision to compile a new complete dossier.

46 By a letter of 6 June 2002 the Commission informed IQV that only those active substances in respect of which full data were available by 31 December 2003 at the latest could have their deadline for evaluation extended beyond the end of 2003. In the Commission's view, it was clear that IQV's complete dossier could not be ready by that date and Syngenta's withdrawal from the notification process did not warrant metalaxyl being treated any differently from other active substances. Accordingly, the Commission stated that it was forced to propose that metalaxyl should not be included in Annex I to Directive 91/414. It indicated, however, that IQV could file a dossier for the purpose of registering metalaxyl as a new active substance.

47 By letter of 14 June 2002, IQV stated that it was continuing the studies necessary to fill the gaps identified in the report of the Portuguese authorities. IQV stated that those studies should be finished 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 the undertaking to compile that dossier was a major financial investment. Therefore IQV concluded that it would complete such a dossier provided the Commission guaranteed it would authorise metalaxyl for a transitional period so it would not lose market share during the evaluation procedure.

48 Following a request from ECCO on 9 February 2001, IQV completed a table, prepared on the basis of the rapporteur Member State's report and incorporating the information requested. IQV then completed that table so that the information was updated to 14 October 2002 (see paragraph 33 above).

49 At its meeting of 18 and 19 October 2002, the Committee approved a draft decision not to include metalaxyl in Annex I to Directive 91/414. In its report the Committee stated, inter alia, that IQV did not have a dossier which was sufficiently complete to enable it to participate in the detailed evaluation of metalaxyl under Article 7(3) of

Regulation No 3600/92. IQV would be unable to reply to the questions raised by the Member States regarding Syngenta's studies and to submit additional studies.

50 On 2 May 2003 the Commission adopted Decision 2003/308/EC concerning the non-inclusion of metalaxyl in Annex I to Directive 91/414/EEC (OJ 2003 L 113, p. 8) ('the contested decision').

Proceedings

51 By application lodged at the Registry of the Court of First Instance on 9 May 2003, the applicant brought an action for annulment of the contested decision.

52 By a separate document lodged at the Registry of the Court of First Instance on the same day, the applicant brought an application under Article 242 EC to suspend application of the contested decision.

53 By order of 5 August 2003 in Case T-158/03 R *Industria Químicas del Vallés* v *Commission* [2003] ECR II-3041, the President of the Court dismissed the application for suspension of application, reserving the decision on costs.

54 By application lodged at the Court Registry on 22 August 2003, IQV appealed against the order in *Industria Químicas del Vallés* v *Commission*, cited above, under Article 225 EC and the second paragraph of Article 57 of the Statute of the Court of Justice.

55 By order of 21 October 2003 in Case C-365/03 P(R) *Industria Químicas del Vallés* v *Commission* [2003] ECR I-12389, the President of the Court set aside the order of 5 August 2003 in *Industria Químicas del Vallés* v *Commission*, cited above, and ordered the suspension of application of the contested decision, reserving the decision on costs.

56 Upon hearing the report of the Judge-Rapporteur, the Court of First Instance decided to open the oral procedure. In the course of measures of organisation of procedure, on 12 October 2004 the Court asked the parties to reply to written questions. The applicant and the defendant submitted their replies to the questions on 5 and 8 November 2004 respectively.

57 The parties presented oral argument at the hearing which took place on 8 December 2004. On 22 February 2005 the President of the Second Chamber closed the oral procedure.

Forms of order sought

58 The applicant claims that the Court should:

— annul the contested decision;

— order the Commission to pay the costs, including the costs relating to the interlocutory proceedings.

59 The Commission contends that the Court should:

— dismiss the present action as unfounded,

— order the applicant to pay the costs.

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Law

60 In support of its action, the applicant puts forward three pleas. The first plea is based on the illegality of the contested decision in so far as it is the result of an incorrect and inconsistent interpretation of Directive 91/414 and Regulation No 3600/92. The second plea relates to infringement of the principle of proportionality. The third plea relates to misuse of powers.

1. *The first plea: incorrect and inconsistent interpretation of Directive 91/414 and Regulation No 3600/92*

61 The applicant divides this plea into three parts. First, IQV claims that there is a conflict between the contested decision and the provisions of Directive 91/414 and Regulation No 3600/92 and their implementing rules. Secondly, IQV submits that the contested decision is contrary to the spirit and purpose of the system for re-evaluating active substances. Those two parts will be examined together. Thirdly, IQV submits that there is a conflict between the contested decision and the

interpretation given by the Commission on the question of use of the studies submitted by Syngenta for the purpose of preparing the rapporteur Member State's report. Moreover, the Court considers it appropriate to group some of the applicant's arguments together in a fourth part, based on the fact that the Commission relied on an unjustified presumption and infringed applicable legislation.

Conflict between the contested decision and (i) the provisions of Directive 91/414, Regulation No 3600/92 and their implementing rules, and (ii) the spirit and purpose of the system for re-evaluating active substances

IQV's obligation to compile a complete dossier

— Arguments of the parties

62 The applicant claims that it is an infringement of Community law for the Commission to require a complete dossier from each of the notifiers where there are collective notifications of active substances. In particular, that requirement is incompatible with the submission, preferably, of collective dossiers under Article 6 (1) of Regulation No 3600/92. It is also incompatible with the ninth recital in Regulation No 3600/92 which refers to avoiding duplication of studies and experiments involving vertebrate animals (see paragraph 5 above).

63 The applicant adds that the most obvious means of avoiding duplication of work is to set up a transparent mechanism requiring both large and smaller undertakings to submit their data and studies, such as that in the United States and in several Member States, including the Kingdom of Spain.

64 IQV also refers to Article 13(7) of Directive 91/414 which, in its opinion, pursues the same objective (see paragraph 12 above).

65 As regards the implementing rules published by the Commission on certain aspects of the re-evaluation procedure, the applicant refers to a working document dated 1 June 2002 concerning the number of copies of the summary dossier and complete dossier requested by each Member State. The applicant states that, according to that document, the Member States do not all request a copy of a complete dossier for each active substance. Accordingly, it is not essential to the re-evaluation procedure of an active substance to make a copy of the complete dossier available to all the Member States.

66 The applicant states in its reply that, in the letter of 19 July 1999 (see paragraph 30 above) the Commission had stated, relying in particular on Article 7 of Regulation No 3600/92, that the rapporteur Member State could make use of all the data available, and not only the data submitted by the notifiers or the interested parties, to prepare the evaluation report on metalaxyl. The applicant submits that, in its letter of 28 October 1999, DGPC did not insist that IQV reproduce the studies in Syngenta's complete dossier. It merely indicated that IQV would be the sole point of contact for replies to questions and submission of further information.

67 The applicant believes that that requirement is contrary to the spirit and purpose of the system for re-evaluating active substances. The objective of the latter is to ensure that active substances available on the European market are not harmful and do not present any risk either to the health of humans and animals or to the environment. To achieve that result, it is necessary to carry out a series of scientific studies on the active substance evaluated. It is essential to have a complete dossier, but neither Directive 91/414 nor Regulation No 3600/92 are specifically concerned with the origin or ownership of those studies.

68 According to IQV, the objective pursued by the system for re-evaluating active substances cannot be to favour only large multinationals which were or are owners of industrial property rights in those active substances. Only those multinationals have complete dossiers enabling them to put the case for each active substance. Those undertakings hold patents compensating them for their invention and the studies carried out on a particular active substance. The system for re-evaluating active substances cannot be turned into a tool to perpetuate legal monopolies based on patent ownership. The legal monopoly of the patent should be limited in time and, where appropriate, should then benefit other traders on the market.

69 The applicant adds that it is contrary to the spirit of the evaluation system to require a complete dossier from IQV in the context of this case, since that principally favours large undertakings to the detriment of smaller undertakings and helps to maintain the legal monopolies given to them by their patents. The applicant makes several references to metalaxyl-M, an active substance very similar to metalaxyl which was the subject of a notification by Syngenta and was included in Annex I to Directive 91/414 in 2002. IQV submits that the authorisation of metalaxyl-M, which is a substitute for metalaxyl, enables Syngenta to acquire a dominant position on the market for curative fungicides.

70 The Commission contests all the arguments put forward by the applicant. It states that the contested decision is based on the fact that, since IQV did not have a complete dossier on metalaxyl, Syngenta's withdrawal from the evaluation procedure and its refusal to sell the studies in its own dossier to IQV made it impossible to finalise the evaluation of metalaxyl. Moreover, according to the Commission, IQV was not in a position to submit the additional information requested on the basis of the rapporteur Member State's report or to complete its dossier within the prescribed time-limits, in breach therefore of the series of undertakings it had given.

— Findings of the Court

71 First of all it must be stated that in this case IQV and Syngenta did not make a collective notification. There were two separate notifications because the attempt to make a collective notification failed. The existence of a collective notification presupposes a previous agreement between the parties. However, in this case IQV and Syngenta did not reach an agreement by which they could combine their efforts to make the evaluation of the active substance metalaxyl possible. Therefore the provisions on collective notifications do not have to be applied in this case.

72 The existence of two separate notifications means that a complete dossier is required from each notifier. In that connection, Regulation No 3600/92 lays down specific provisions.

73 Article 6(1) of Regulation No 3600/92 provides that, within the time-limit referred to in Article 5(4), the notifiers must send to the rapporteur Member State the summary dossier and the complete dossier. It follows from that provision and from Article 6(2)(b) and Article 7(1)(b) that each notifier is responsible for preparing a summary dossier and a complete dossier. The fact that Syngenta withdrew from the procedure does not alter IQV's obligations. That assessment is not called into question by the fact that Regulation No 3600/92 states a preference for the submission of collective dossiers. Article 6(1) of Regulation No 3600/92 does not impose an obligation to submit collective dossiers but seeks only to encourage their submission. That finding also makes it possible to discount the applicant's argument based on the ninth recital in Regulation No 3600/92. Therefore the applicant's argument relating to the obligation to submit collective dossiers must be rejected.

74 As for the applicant's argument based on Article 13(7) of Directive 91/414, that provision relates only to authorisations of plant protection products containing active substances already included in Annex I to Directive 91/414. That article does not therefore apply in this case.

75 IQV's argument relating to the Commission's working document of 1 June 2002, cited above, is also irrelevant. The Commission stated, without contradiction, that in practice the Member States generally request a copy of the complete dossier. Further, that document cannot alter the obligation laid down in the regulation to submit a complete dossier.

76 As regards the spirit and purpose of the re-evaluation system, at issue is an assessment of the harmful effects of active substances on the health of humans and animals and on the environment. Nevertheless, as the Commission rightly states, the burden of proof that the active substance is not harmful lies with the notifier, who has the obligation to submit the summary dossier and the complete dossier. Since IQV did not have access to Syngenta's dossier, as the latter refused to sell it its studies, the only course of action open to IQV was to submit such studies itself in order to create a complete dossier.

77 In respect of the applicant's argument relating to legal monopolies based on patent ownership, neither Directive 91/414 nor Regulation No 3600/92 makes reference to the need to protect competition and avoid the perpetuation of legal monopolies. Moreover, that legislation contains no legal basis allowing the Commission to require undertakings to share their studies or information.

78 It follows from the foregoing that the applicant's arguments challenging the obligation to submit a complete dossier must be rejected.

Unlawful time-limits granted to IQV for submitting its dossier

— Arguments of the parties

79 The applicant states that it is unlawful for the Commission to require IQV's complete dossier to be notified in the time-limit provided for in Article 6(1) of Regulation No 3600/92. According to the applicant, the Commission itself placed IQV in a situation in which it was impossible to comply with that time-limit. At first, in the letter of 19 July 1999 sent to DGPC (see paragraph 30 above) the Commission explained that it was possible for the rapporteur State to make use of all the information available to carry out its evaluation. Following that letter, on 28 October 1999 DGPC informed IQV that it would continue the evaluation on the basis of all the information available and that IQV would be the sole point of contact for answering questions and communicating additional information. IQV was therefore convinced that it would not subsequently be asked for a new complete dossier since it had itself informed the Commission during March 1999 that its dossier was not complete. However, subsequently, in February 2001, the Commission and DGPC asked IQV for a complete dossier. By changing its approach, the Commission made it impossible to comply with the time-limit provided for by Article 6(1) of Regulation No 3600/92.

80 The applicant submits that it is contrary to the spirit of the legislation to require a complete dossier to be submitted in a time-limit with which it is impossible to comply and to refuse to extend it. In that connection, the Commission's adoption of Regulation No 2076/2002 was telling since it was tangible proof that the Commission could have made the procedural time-limits more flexible by extending them, as it had done so for other active substances.

81 Furthermore, Syngenta's withdrawal from the procedure created an exceptional situation which Regulation No 3600/92, the guidelines and the policy documents on the re-evaluation procedure had not envisaged. The Commission's refusal to extend the time-limit laid down in Regulation No 2076/2002 was discriminatory.

82 Finally, IQV complains that the Commission did not inform it that Regulation No 2076/2002 applied to metalaxyl and that it was therefore possible to extend the time-limit up to 31 December 2005.

83 The Commission replies that the procedure for evaluating existing active substances is subject to time-limits with which the notifiers, the rapporteur Member State and the Commission are required to comply. Moreover, in 2001, in a report to the European Parliament, the Commission undertook to ensure that the greatest number of decisions possible would be adopted before July 2003 and that any extension of the time-limit proving necessary would be as short as possible.

84 The Commission challenges the argument that IQV was not in a position to comply with the time-limits prescribed by the Community legislation due to an alleged change in Commission policy. According to the Commission, DGPC pointed out to IQV several times in the evaluation procedure that it had to complete the dossier submitted because important studies were missing. Moreover, IQV had undertaken several times to carry out the studies necessary to complete its dossier. However, the time-limits given had never been complied with.

85 In the Commission's view, IQV had known since 1998 that it was the only notifier and since 1999 that the Commission and DGPC had emphasised its information and evidential obligations in that regard. If IQV had begun preparing the complete dossier when Syngenta had officially announced its withdrawal in 1998, or even when it had received confirmation that the review would continue in 1999, all the information could have been gathered, according to the calculation accepted by the applicant, at the latest by 2002 or 2003, and therefore within the time-limits laid down by the legislation.

86 The Commission submits that IQV did not have a complete dossier on metalaxyl in May 2002 and still did not have one at the time when it drafted its defence, although that was an essential condition for adoption of a decision by 2005 at the latest.

87 The Commission submits, lastly, that IQV's position is inconsistent. IQV claims that it is an exceptional situation which the Commission ought to have taken into account, but then seeks to compare the position of metalaxyl with that of other active substances covered by Regulation No 2076/2002. As regards alleged discrimination, the Commission notes that more than 400 active substances have been withdrawn on grounds related to the evaluation procedure, in particular owing to failure to notify or submit a complete dossier within the time-limits laid down.

— Findings of the Court

88 As the Commission rightly points out, there are specific legislative provisions concerning the duration of the general procedure for evaluating active substances and the time-limits for submitting a complete dossier and additional information.

89 Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that those time-limits expire, as a general rule, on 25 May 2002, as regards the submission of the results of additional trials, and on 25 May 2003, as regards long-term studies.

90 The transitional period for authorisation to place on the market plant protection products based on active substances was to be completed, in principle, by July 2003, but was extended until 31 December 2005 by Regulation No 2076/2002, unless a decision has been taken or was taken before that date to include or not include the active substance in Annex I.

91 It is necessary to determine whether the Commission was entitled to refuse to extend the time-limit with a view to continuing the procedure for evaluating metalaxyl.

92 In that regard, it is apparent from Article 7(4) of Regulation No 3600/92 (see paragraph 16 above) that the Commission is able to extend the time-limit only in exceptional cases, namely where it has not been possible for the rapporteur Member State and the Commission, by 25 May 2001, to identify the long-term studies necessary for examining the dossier. In addition, the notifier must supply 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.

93 The exceptional nature of a situation depends on the circumstances of the case and its assessment is a matter for the Commission's discretion. In this case, the applicant knew that it would be asked for a complete dossier pursuant to Article 6(1)(b) of Regulation No 3600/92. DGPC informed it as early as 3 June 1997 (see paragraph 24 above) that its dossier was incomplete. IQV was informed of Syngenta's withdrawal in July 1998, which did not in any way alter its obligation to submit a complete dossier within the time-limit. That conclusion cannot be affected by the fact that there is no provision governing the situation in which one of the two notifiers withdraws. Further, following the Commission's communication in May 2002 that it intended to submit to the Committee a draft proposal not to include metalaxyl in

Annex I to Directive 91/414, IQV suspended on its own initiative all the studies it could and, in particular, those costing the most. In those circumstances, IQV's position cannot be regarded as being exceptional.

94 The applicant's argument that it is not possible to comply with the time-limits following a change in the Commission's position is irrelevant. The 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 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. Accordingly, IQV's position cannot be described as exceptional by virtue of the Commission's conduct.

95 The power to grant an extension is similar to a discretion in regard to an assessment which depends on the circumstances of the case. It should be noted that in matters concerning the common agricultural policy, as is the case here, the Community institutions enjoy a broad discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action. In that regard, review by the Community judicature of the substance of the relevant act must be confined to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion (Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraphs 177 to 180). It must be determined whether, by refusing to extend the time-limit, the Commission made a manifest error of assessment.

96 An indefinite extension of the time-limit for evaluating an active substance would be contrary to the objectives pursued by Directive 91/414 of ensuring a high level of protection of the health of humans and animals and the environment. It is true that the Commission has already granted extensions of time-limits for evaluating active substances and IQV has claimed that the lack of an extension regarding metalaxyl

was discriminatory. However, as the Commission explained, the extension of the time-limit granted for other active substances never went beyond 31 December 2003. According to the table showing the progress of IQV's studies, updated to 14 October 2002, some studies had been completed only in September 2004.

97 Furthermore, account should be taken of the fact that, in 2001 in a report addressed to the European Parliament, the Commission had undertaken to ensure that the largest possible number of decisions would be taken before July 2003 and that any extension of the time-limit proving necessary would be as short as possible. In light of those factors, the Commission did not make a manifest error of assessment by refusing to grant the extension for metalaxyl.

98 So far as concerns the applicant's argument that the rapporteur Member State ought to have taken care of the circulation of Syngenta's complete dossier in order to gain time and make it possible to open the stage of review by the national experts (peer review), it is sufficient to point out that there are no legislative provisions requiring the rapporteur Member State to do that distribution. Further, Article 7(1)(b) of Regulation No 3600/92 provides for circulation of dossiers by the notifier.

99 In so far as the applicant pleads the spirit and lawful purpose of the re-evaluation system to challenge the time-limit given to it for submitting a complete dossier, it is the legislation in force which specifies the time-limits and that extension is merely an option available to the Commission (see paragraphs 95 to 97 above).

100 It follows that the applicant's arguments challenging the time-limits are not well-founded and must be rejected. The first and second parts of the first plea are therefore not well-founded.

Conflict between the contested decision and the Commission's position regarding the use of the studies submitted by Syngenta for the purpose of compiling the rapporteur Member State's report

Arguments of the parties

101 The applicant complains that the Commission displayed inconsistency by stating in its letter of 19 July 1999 that there was nothing to preclude the rapporteur Member State from compiling its report on the basis of all the information available to it, while requiring IQV to produce a complete dossier, entailing the purchase of Syngenta's studies or the duplication of existing studies. In the applicant's view, the Commission knew from the outset that IQV did not have a complete dossier and that to have one it had to duplicate the studies in Syngenta's dossier.

102 In the applicant's opinion, having regard to the gaps in the applicable legislation, the Commission should have chosen one of several approaches to authorise IQV to continue the work of re-evaluating metalaxyl: first, use of the existing dossier to the extent possible for the purpose of re-evaluating metalaxyl, entrusting IQV with the task of replying to the questions asked of it and carrying out new or additional studies essential for reassuring the Member States in respect of the active substance in question; secondly, failing that, identification of the protected studies in Syngenta's dossier which it was necessary to duplicate to put the case for metalaxyl and which IQV had stated it was willing to duplicate; thirdly, authorisation for IQV to carry out those studies within a time-limit which was acceptable in practice, which it had done for other active substances.

103 The Commission believes that the contested decision is consistent with the interpretation of the applicable legislation referred to in the Commission's letter of

19 July 1999. In that letter, the Commission stated that that there was nothing to preclude the rapporteur Member State from compiling its report on the basis of all the information available to it. However, in the Commission's view, given that the notifier has the burden of proof, it is for that notifier to submit all the information necessary to demonstrate the absence of harmful or unacceptable effects of that active substance.

Findings of the Court

104 It suffices to note that the Commission's position on that question has not changed (see paragraph 94 above). The Commission did not contradict itself by requiring a complete dossier in 2001, since, as early as July 1999, the legal opinion addressed to DGPC referred to that obligation.

105 Article 7(1)(a) of Regulation No 3600/92 provides that the rapporteur Member State must 'examine the dossiers referred to in Article 6(2) and (3) [that is, the summary dossier and the complete dossier] ... and any other available information'. The Commission's interpretation in its opinion of 19 July 1999 is not incompatible with Regulation No 3600/92. In addition, the fact that in the legislation the Commission did not expressly lay down the consequences in a particular case where an application for authorisation to place a substance on the market is withdrawn but another application for authorisation of that same substance is maintained, does not constitute a lacuna in the law. The applicant's argument must therefore be rejected and that part of the first plea dismissed in its entirety.

Unlawful presumption by the Commission

Arguments of the parties

106 The applicant maintains that the Commission relied on a presumption which is unjustified and not in accordance with the rules. It had been presumed that IQV was not in a position to reply to the experts' questions asked during the peer review or to submit information relating to certain questions. The applicant states that in the preamble to the contested decision the Commission states that the information was inadequate for the purposes of the evaluation whereas, first, IQV submitted studies which the Commission did not take into account and filled the gaps in the dossier over a period of several years with new studies, secondly, IQV has always been willing to submit the necessary studies and, thirdly, the Commission was itself not able to determine and define which studies it considered essential in respect of the active substance and the protected studies in Syngenta's dossier.

107 Moreover, IQV submits that the Commission should have taken account of the fact that it was acting as a screen for the undertaking producing the metalaxyl it imported (Rallis). Owing to the technical competence and in-depth experience of Rallis, it would have been exceptionally well-placed to reply to the majority of questions which could be raised on metalaxyl. Finally, the applicant states that the Commission's presumption is based on its experience of re-evaluation procedures. However, the re-evaluation procedure of each active substance is different and raises separate and distinct questions in each case.

108 The Commission asserts that certain vital questions, particularly the ecotoxicity of metalaxyl and its constituents, remained unanswered. Further, IQV contradicted itself by undertaking to complete its dossier but then distinguishing between essential studies which it had to carry out and those protected in Syngenta's dossier.

109 The Commission emphasises that, contrary to IQV's claims, the dossier submitted by Syngenta for the purposes of preparing the report by the rapporteur Member State was not complete. That report of DGPC found important gaps in Syngenta's dossier. Furthermore, IQV did not have access to the studies in that dossier and it could not therefore refer the participants in the evaluation to those studies, of which it had no knowledge, and deal with the questions and criticisms of the experts from the Member States. The Commission adds that neither the rapporteur Member State nor another undertaking, such as Rallis, had the burden of proof. In any event, if Rallis had the relevant information, nothing prevented it from sending it to the applicant.

Findings of the Court

110 In light of the information in the dossier and its relevant practice, the Commission rightly found that IQV, without access to the studies in Syngenta's dossier, was not in a position to answer the experts' questions on those studies. In the seventh recital in the contested decision, the Commission refers to the insufficient information for carrying out the evaluation. Moreover, the Portuguese authorities, which held Syngenta's dossier, believed that it was not for them to reply to the questions raised during the national experts' examination.

111 Inasmuch as the applicant states that it has always been willing to submit the necessary studies, it should again be noted that several times it did not comply with the time-limits for completing its dossier. As the Commission rightly points out, IQV therefore contributed to its situation by not complying with the time-limits for submitting the additional information and, therefore, to its failure to submit a complete dossier.

112 It should be added that, even if were relevant to allow that Rallis was exceptionally well-placed to reply to most of the questions during the experts' review, it is common ground that IQV still did not have a complete dossier and that certain essential questions, including in particular those on the ecotoxicity of metalaxyl and its constituents, were still unanswered. In that regard, all the essential studies which were missing in IQV's dossier were not in Syngenta's dossier (see also paragraph 137 below).

113 Finally, the applicant itself stated in its letter of 4 May 2001 addressed to the Commission that it was having difficulty replying to the Member States' questions since it did not have access to Syngenta's studies.

114 The argument that the Commission's presumption was unlawful must therefore be rejected.

115 It follows that the first plea must be dismissed in its entirety.

2. *The second plea: infringement of the principle of proportionality*

Arguments of the parties

116 The applicant submits that the Commission infringed the principle of proportionality by deciding not to include the active substance metalaxyl in Annex I to Directive 91/414 and to withdraw all plant protection products containing metalaxyl

from the market (Articles 1 and 2 of the contested decision). According to the applicant, the objective pursued by Directive 91/414 and Regulation No 3600/92 is the re-evaluation of all the active substances which undertakings wish to support, but on the basis that there are studies which make that possible and that only harmless substances should remain on the market. The applicant breaks its plea down into three parts, which will be dealt with together by the Court.

Contested decision inadequate and inappropriate for attaining the objective pursued

117 The applicant claims that the contested decision infringes the principle of proportionality as it withdrew a substance from the European market before its scientific analysis was completed. That withdrawal was ordered despite the fact that the rapporteur Member State had all the studies necessary to evaluate the active substance in question and there was an undertaking, IQV, wishing to market that active substance and willing to participate in the re-registration work. The contested decision was the result of the Commission's inability to use a logical approach to resolve a problem for which Regulation No 3600/92 did not lay down a clear and obvious solution.

118 In addition, the applicant considers that the Commission does not have a serious ground to justify adoption of the contested decision. It alleges that an active substance very similar to metalaxyl, metalaxyl-M, was recently included in Annex I to Directive 91/414 and was promoted by Syngenta by using studies 80% of which match those necessary to put the case for metalaxyl. In fact, metalaxyl was marketed worldwide without any difficulty for several years and without any public health issues being raised.

119 In the applicant's view, the Commission's decision is the result of the haste it displayed in completing as quickly as possible the re-evaluation of substances under the first phase of the re-registration programme for active substances. The applicant states that the contested decision was taken on procedural and administrative grounds which are certainly not irrefutable. By expediting the re-evaluation work on active substances, the Commission added to the list of active substances which are to disappear from the market.

120 The applicant adds that the decision is inappropriate because it does not benefit health or the general interest or the European market. In fact the contested decision is nothing but detrimental to the market, consumers (reduction in choice) and competition. Metalaxyl is thus replaced by metalaxyl-M, a perfect substitute, owned by Syngenta, the multinational. Metalaxyl's withdrawal enables Syngenta to acquire a dominant position on the market for curative fungicides. The applicant adds that other producers and owners of substances regarded by the Commission as substitutes for metalaxyl, for example Bayer and Aventis, have not taken advantage of adoption of the contested decision to promote their products and take that part of the market hitherto reserved to metalaxyl.

121 The applicant states that Syngenta's plan to implement the same monopolistic strategy of excluding metalaxyl from the market and dominating that market by using metalaxyl-M was rejected by the American authorities, which have a system which is sufficiently flexible to control or prevent that type of problem.

122 The Commission states that the objectives pursued by the directive are neither the protection of the market or of competition, but the protection of human and animal health and the environment (fourth and ninth recitals in Directive 91/414). That objective is consistent with the precautionary principle as defined by the case-law, which has upheld the primacy of the protection of health and the environment over economic interests.

123 The Commission adds that the applicant was informed that essential studies had been missing from its dossier since 1996. The applicant claimed, in June 2002, that it needed at least three years to enable it to prepare a complete dossier. The Commission therefore concludes that its decision was not hasty or adopted as a matter of urgency.

Possibility of attaining the objective pursued by adopting a less restrictive measure

124 The applicant claims that the Commission could have chosen different approaches with less serious consequences before reaching a decision not to include metalaxyl in Annex I to Directive 91/414 and completely to withdraw from the market plant protection products containing it. The Commission could have:

— continued the re-evaluation work by requiring the Portuguese authorities to circulate the complete dossier on metalaxyl to the Member States which requested it, entrusting the applicant with the task of carrying out the additional studies necessary to remove doubts about the active substance;

— stated which studies were essential and those which were protected (or the rapporteur Member State could have done this);

— granted the applicant sufficient time to duplicate the studies.

125 The applicant states that the Commission should have set out in its decision the reason for which it decided not to grant an extension beyond 2003 in respect of metalayxl whereas Regulation No 2076/2002 allowed an extension until December 2005.

126 Finally, the applicant states that the opening of a procedure for inclusion of metalaxyl as a new substance was not a viable solution.

127 The Commission submits that the objective of the evaluation system introduced by Directive 91/414 is adequately to evaluate the active substances in question on the basis of the information supplied by the notifier.

Infringement of the principle of proportionality in the strict sense

128 First, the applicant submits, essentially, that the contested decision does not satisfy the requirement of proportionality in the strict sense, in so far as the harm caused to the rights of individuals greatly outweighs the advantages created in the general interest. The substance was to be eliminated from the market when it had not been proven that the substance raised difficulties or gave rise to the slightest risk to public health.

129 Secondly, the applicant adds that the Commission's decision gives rise to a reduction in competition (reduction in imports of agricultural products treated with products containing metalaxyl) and in choice for consumers.

130 Thirdly, according to the applicant, Syngenta is the only party to benefit from the withdrawal of metalaxyl, since it markets metalaxyl-M, the obvious substitute for metalaxyl. Moreover, at no time did Syngenta seek to turn consumers' attention towards products other than metalaxyl-M, also owned by it and considered by the Commission to be substitutes for metalaxyl.

131 The Commission rejects those arguments, taking the view that it is the directive itself which, by laying down strict evidentiary obligations on notifiers, subordinated the notifiers' individual interest to the general interest. At issue is the authorisation of substances and products which do not present risks to human and animal health or the environment.

132 According to the Commission, the effects which non-inclusion in Annex I to Directive 91/414 could have on the imports in question do not stem from the contested decision, but are the subject-matter of an ongoing procedure which entails consultation with the Committee on Sanitary and Phytosanitary Measures of the World Trade Organisation.

Findings of the Court

133 Contrary to the applicant's claims, the sixth recital in the preamble to Regulation No 2076/2002 does not refer to the protection of competition. As the Commission states, the objectives to be pursued by Directive 91/414 are not the protection of the market or of competition, but the protection of human and animal health and the environment. That objective is consistent with the precautionary principle and reflects the case-law upholding the primacy of the protection of health and the environment over economic interests.

134 It is settled case-law that the importance of the objective pursued, namely the protection of human health, may justify adverse economic consequences, even those which are substantial, for certain traders. The protection of public health must take precedence over economic considerations (Order in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 93, and Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraphs 456 and 457).

135 The Court has consistently held that the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, inter alia, Case 137/85 *Maizena* [1987] ECR 4587, paragraph 15, and *Pfizer*, cited above, paragraph 411).

136 None the less, in matters concerning agriculture, being a question of measures taken under Article 43 of the EC Treaty (now, after amendment, Article 37 EC), judicial review of the principle of proportionality is special, inasmuch as the Court acknowledges the Community legislature's wide discretion in that sphere as it entails choices of a political, economic and social nature and complex assessments (Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 61). Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate in relation to the objective which the competent institution is seeking to pursue (Case C-189/01 *Jippes and Others* [2001] ECR I-5689, paragraph 82, *Pfizer*, cited above, paragraph 412, and *Alpharma*, cited above, paragraphs 177 to 180).

137 In this case, the legal basis of Directive 91/414 is Article 43 of the EC Treaty. Therefore it must be examined whether the Commission adopted a decision manifestly inappropriate to attain the objective envisaged by the re-evaluation system implemented by that directive, namely the protection of human and animal health and the environment. Since it did not have access to Syngenta's studies, IQV could not have replied to the questions raised in the peer review. It was not therefore possible to prove that the active substance was not harmful and the objective of protecting human and animal health and the environment could therefore not be attained. Even though the applicant stated, in response to a written question of the Court, that only two studies ('laboratory studies to cover the effects of metalaxyl [on] non-target arthropods other than bees') and ('more medical data on surveillance and manufacturing plant personnel, clinical cases and poisoning incidents') were not covered by its studies or those of Syngenta, and that those studies were finished by the time the contested decision was adopted, it should be noted that at the hearing it admitted that only draft reports rather than definitive studies had been completed by the date of adoption of the contested decision in May 2003.

138 The applicant's argument that the contested decision is contrary to the principle of proportionality in so far as it is inadequate and inappropriate for attaining the objective of protection of competition must be rejected.

139 In the light of the foregoing, none of the three parts of the plea regarding infringement of the principle of proportionality are well-founded and the plea must be dismissed.

3. *The third plea: misuse of powers*

Arguments of the parties

140 The applicant takes the view, essentially, that the contested decision is a misuse of powers in so far as, by taking that decision, the Commission pursued objectives completely extraneous to the objectives laid down by the Community legislation on re-registration of active substances.

141 More specifically, the applicant takes the view that the contested decision is the result of pressure exerted by Syngenta on the Commission and that its purpose is to favour that undertaking.

142 The applicant sets out three arguments to that effect. First, the contested decision has no scientific basis and was taken when all the studies making the evaluation of metalaxyl possible were in existence and IQV was willing to take responsibility for its marketing within the European Union and complete the re-registration likely to be required (by carrying out the necessary additional studies and replying to the questions of the Member States and the Commission). Secondly, the Commission thought it better to withdraw metalaxyl by choosing one of the most restrictive courses of action without even taking serious account of other less restrictive options such as extension of the time-limit. Thirdly, during the procedure the Commission changed its opinion and interpretation on the use of the studies submitted by Syngenta.

143 The Commission states that it did not take the contested decision in the interests of Syngenta but in accordance with the Community legislation in force, namely Directive 91/414 which provides for non-inclusion of an active substance when the necessary information has not been supplied in sufficient time.

144 The Commission believes that it is apparent from the exchange of correspondence between IQV and the Portuguese authorities that there is no inconsistency in the assessment relating to IQV's dossier by the rapporteur Member State from the time it was submitted. There was also no inconsistency in the approach of the Commission, which always made a clear distinction between the dossiers on the basis of which DGPC was to compile its report and IQV's obligations on the submission of information.

145 According to the Commission, IQV thanked the Commission several times for its cooperation and efforts in seeking a suitable solution. Finally, IQV acknowledged in its correspondence that the Commission had proposed alternatives, stating that it was still possible to apply for the inclusion of metalaxyl in Annex I to Directive 91/414 in accordance with the procedure applicable to authorisation of new active substances.

Findings of the Court

146 It is settled case-law that the concept of misuse of powers has a specific meaning in Community law and refers to a situation in which an administrative authority uses its powers for the purpose of achieving an end other than that for which they were granted. A decision amounts to a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken to achieve an end other than that stated (Case C-285//94 *Italy* v *Commission* [1997] ECR I-3519, paragraph

52, and Case C-48/96 P *Windpark Groothusen* v *Commission* [1998] ECR I-2873, paragraph 52; Case T-254/97 *Fruchthandelsgesellschaft Chemnitz* v *Commission* [1999] ECR II-2743, paragraph 76, and Case T-612/97 *Cordis* v *Commission* [1999] ECR II-2771, paragraph 41).

147 In this case, the applicant requests that the Court adopt measures of organisation of procedure with a view to proving misuse of powers but does not explain in what way pressure could have been exerted by Syngenta. Moreover, the applicant has not adduced any conclusive evidence to show that the Commission adopted the decision under such pressure. It is not for the Court to adduce evidence of such vague claims. Further, the documents requested of the Court are not relevant for the outcome of the proceedings. Accordingly, the plea of misuse of powers must be rejected.

148 It follows from the foregoing that the applicant's application for annulment must be dismissed in its entirety.

Costs

149 Under Article 87(2) of the Rules of Procedure of the Court of First Instance, 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, and the Commission has applied for costs, the applicant must be ordered to pay the costs, including those relating to the interlocutory proceedings.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Industrias Químicas del Vallés, SA to pay the costs, including those relating to the interlocutory proceedings.**

Pirrung Forwood Papasavvas

Delivered in open court in Luxembourg on 28 June 2005.

H. Jung

Registrar

J. Pirrung

President

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