JUDGMENT OF THE COURT OF FIRST INSTANCE
(Second Chamber, Extended Composition)

11 July 2007 *

In Case T-229/04,

Kingdom of Sweden, represented by A. Kruse, acting as Agent,

applicant,

supported by

Kingdom of Denmark, represented by J. Molde, A. Jacobsen and J. Bering Liisberg, acting as Agents,

by

Republic of Austria, represented by E. Riedl, acting as Agent,

and by

Republic of Finland, represented by T. Pynnä and E. Bygglin, acting as Agents,

interveners,

* Language of the case: Swedish.

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

defendant,

APPLICATION for annulment of Commission Directive 2003/112/EC of 1 December 2003 amending Council Directive 91/414/EEC to include paraquat as an active substance (OJ 2003 L 321, p. 32),

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

composed of J. Pirrung, President, A.W.H. Meij, N.J. Forwood, I. Pelikánová and S. Papasavvas, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 3 October 2006,

gives the following

Judgment

Legal framework

I — *Provisions of the Treaty*

1 Article 6 EC states that environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities referred to in Article 3 EC, in particular with a view to promoting sustainable development.

2 Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.

3 Article 174(2) EC states that Community policy on the environment is to aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. That provision also provides that Community environmental policy is to be based on the precautionary principle.

4 According to Article 174(3) EC, in preparing its policy on the environment, the Community is to take account of available scientific and technical data.

II — *Directive 91/414/EEC*

5 The ninth recital in the preamble to 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) states that the provisions governing the authorisation of plant protection products must ensure a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment have not been the subject of appropriate research. That recital also indicates that the objective of improving plant production should not take priority over the protection of human health and the environment.

6 Article 2 of Directive 91/414 defines plant protection products as, inter alia, active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, and which are intended to destroy undesired plants. That article defines active substances as substances or micro-organisms including viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

7 Article 4(1) of Directive 91/414 states:

'Member States shall ensure that a plant protection product is not authorised unless:

(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, unless:

(b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:

...

(iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;

(iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;

(v) it has no unacceptable influence on the environment, having particular regard to the following considerations:

— ...

— its impact on non-target species;

...'

8 According to Article 5(1) of Directive 91/414:

'In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the following conditions:

(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;

(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4(1)(b)(iv) and (v).'

9 Article 5(4) of Directive 91/414 provides that '[i]nclusion of an active substance in Annex I may be subject to requirements such as [inter alia] restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question [and] the manner of use'.

10 Article 6 of Directive 91/414 provides, inter alia, that inclusion of an active substance in Annex I is to be decided in accordance with the procedure laid down in Article 19 of that directive. Article 19 of Directive 91/414, as amended by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority) (OJ 2003 L 122, p. 1), provides that the Commission is to be assisted by a regulatory committee, the Standing Committee on the Food Chain and Animal Health ('the Standing Committee').

11 Article 8 of Directive 91/414 provides that a gradual assessment is to be made of certain active substances in the context of a Commission programme of work.

12 Annex II to Directive 91/414 sets out the conditions to be fulfilled in order to submit a dossier for the inclusion of an active substance in Annex I to Directive 91/414. It is indicated in the introduction to Annex II that the information to be provided is to include a technical dossier supplying, on the one hand, the information necessary for

evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for humans, animals and the environment and, on the other, results of certain studies referred to subsequently, and a full and impartial report on the studies conducted, together with a full description of those studies or, where particular data or information do not seem necessary or cannot be supplied, a justification which is acceptable to the competent authority.

13 It can be seen from point 5.7 of Part A of Annex II to Directive 91/414 that delayed neurotoxicity studies, the aim of which is to provide sufficient data to evaluate whether the active substance could provoke delayed neurotoxicity after acute exposure, must be carried out for substances of similar or related structures to those capable of inducing delayed neurotoxicity, such as organophosphates.

14 Annex VI to Directive 91/414 ('Annex VI') contains uniform principles to ensure that the Member States apply the requirements laid down in Article 4(1)(b) to (e) of that directive in an equivalent manner and at the high level of protection of human and animal health and the environment sought by the directive. In accordance with Article 18(1) of Directive 91/414, the uniform principles were initially adopted in Council Directive 94/43/EC of 27 July 1994 establishing Annex VI (OJ 1994 L 227, p. 31). That directive was annulled by judgment of the Court of Justice in Case C-303/94 *Parliament* v *Council* [1996] ECR I-2943. The Council subsequently adopted Council Directive 97/57/EC of 22 September 1997 establishing Annex VI (OJ 1997 L 265, p. 87).

15 Point A 2(c) of Annex VI states:

'In evaluating applications and granting authorisations Member States shall ... take into consideration other relevant technical or scientific information they can

reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its residues.'

16 According to point C 2.4.1.1 of Annex VI, '[n]o authorisation shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the [acceptable operator exposure level]'.

17 Point C 2.5.2.1 of Annex VI provides, inter alia, that where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorisation is to be granted if the acute and short-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that no unacceptable impact occurs after use of the plant protection product in accordance with the proposed conditions of use.

III — *Regulation (EEC) No 3600/92*

18 Article 4 of 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) provides, inter alia, that any producer wishing to secure the inclusion of an active substance referred to in Annex I to Directive 91/414 is to notify the Commission accordingly.

19 Under Article 5(2) of Regulation No 3600/92, the Commission is to draw up the list of active substances notified for assessment and to designate a rapporteur Member State for the assessment of each active substance.

20 Article 6 of Regulation No 3600/92 provides, essentially, that the notifiers specified in Article 4 thereof must, for any given active substance, send a summary dossier and a complete dossier to the designated authority of the rapporteur Member State.

21 It can be seen from Article 6(2) of Regulation No 3600/92 that the summary dossier is to include: (i) a copy of the notification; (ii) the recommended conditions of use, to be considered in relation to inclusion of the active substance in Annex I to Directive 91/414; (iii) the available summaries and results of trials and the name of the person or institute that has carried out the trials in respect of each point of Annex II to Directive 91/414, and in respect of each point of Annex III to Directive 91/414 relevant to the assessment of the criteria referred to in Article 5 thereof and for one or more preparations which are representative for the recommended conditions of use.

22 Article 6(2) of Regulation No 3600/92 also provides that where the summaries or results of trials are not available, the dossier must include: either the scientific or technical reasons demonstrating that the information is not necessary for the assessment of the active substance according to the criteria referred to in Article 5 of Directive 91/414, in accordance with the introductory provisions of Annexes II and III thereto; or an undertaking by the producer or producers submitting the dossier that the missing information will be sent at a later date, in accordance with a detailed timetable.

23 Article 6(3) of Regulation No 3600/92 states that the complete dossier is to contain the protocols and the complete study reports concerning all the information referred to in Article 6(2)(c) of that regulation.

24 Article 7(1)(a) of Regulation No 3600/92 states that, for each active substance for which it has been designated rapporteur, the Member State is to examine, inter alia, the dossiers referred to in Article 6(2) and (3) of that regulation. Under Article 7(1)(b), the rapporteur Member State, immediately after examining a dossier, is to ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission.

25 Article 7(1)(c) of Regulation No 3600/92 requires the rapporteur Member State to send the Commission a report of its assessment of the dossiers referred to in Article 6(2) and (3) of that regulation, including a recommendation to include the active substance in Annex I to Directive 91/414, stating the conditions for its inclusion; or to remove the active substance from the market; or to suspend the active substance from the market, with the option of reconsidering the inclusion of the active substance in Annex I after submission of the results of additional trials or of additional information specified in the report; or to postpone any decision on possible inclusion pending the submission of the results of additional trials or information specified in the report.

26 Under Article 7(2) of Regulation No 3600/92, the rapporteur Member State may, from the start of its examination, request the notifiers to improve their dossiers, or add to them. Moreover, the rapporteur Member State may, from the start of that 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.

27 Article 7(3) of Regulation No 3600/92 states that after receiving, inter alia, the rapporteur Member State's report, the Commission is to refer the dossier and the report to the Standing Committee for examination. That provision also states that, before referring the dossier and report to the Standing Committee, the Commission is to circulate the rapporteur Member State's report to the Member States for information.

28 Article 8(1) of Regulation No 3600/92 provides, in substance, that, after receiving the results of the additional trials or the additional information, the rapporteur Member State must examine that data and 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 to the Commission its evaluation of the dossier as an addendum to the evaluation report. That report is also to be referred to the Standing Committee.

Background to the dispute

I — *Procedure leading to the adoption of Directive 2003/112/EC*

29 Paraquat is an active substance. It is contained in one of the three most widely used weedkillers in the world. It acts as a non-selective herbicide with a broad spectrum of activity particularly active against weeds. It destroys the green parts of the plant through desiccation of the foliage. It does not attack the roots. Its abortive and destructive action is restricted to the site of the application of the product. It is used on more than 50 plant varieties in more than 120 countries and has been marketed as a weedkiller for about 60 years.

30 Paraquat is prohibited in 13 countries, including Sweden, Denmark, Austria and Finland.

31 In July 1993, a number of producers of paraquat — including Zeneca, whose rights were later taken over by Syngenta ('the notifier') — notified the Commission, under Article 4 of Regulation No 3600/92, of their desire to have that active substance listed in Annex I to Directive 91/414.

32 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 Regulation No 3600/92 (OJ 1994 L 107, p. 8), the United Kingdom of Great Britain and Northern Ireland was designated as rapporteur Member State for paraquat ('the rapporteur').

33 The notifier submitted a file to the rapporteur concerning the inclusion of paraquat and, on 31 October 1996, the rapporteur submitted a draft assessment report to the Commission ('the Draft Report'). In that report, the rapporteur proposed that the decision on the inclusion of paraquat in Annex I to Directive 91/414 be postponed pending receipt of further data, particularly on the effects of paraquat on bird reproduction and its toxicity to hares. Furthermore, the rapporteur proposed certain conditions for the inclusion of paraquat in Annex I to Directive 91/414.

34 The Commission transmitted the Draft Report to the Member States and to the notifier to enable them to submit their observations.

35 The Draft Report and the dossier also underwent examination by a group of experts, the European Commission Coordination (ECCO), set up by the Commission in 1996. That examination took the form of consultations with technical experts from certain Member States, organised by the Commission between April and July 1997. The experts were asked for their opinion on various aspects of paraquat. The points of view considered and the result of the meetings of the group of experts were set out in a report ('the ECCO report'). That report was transmitted to the Member States and to the notifier for comment and/or explanations.

36 In May 2000, the rapporteur drew up an addendum to the Draft Report containing, inter alia, its observations on the exposure of users, hares and birds to paraquat.

37 The dossier, the Draft Report with its addendum, the ECCO report and the comments and explanations received were transmitted to the Standing Committee for its assessment. The Standing Committee's assessment was carried out from June 2000 to July 2003.

38 The Commission also chose to transmit the documents referred to in the preceding paragraph to the Scientific Committee on Plants, set up by Commission Decision 97/579/EC of 23 July 1997 setting up scientific committees in the field of consumer health and food safety (OJ 1997 L 237, p. 18; 'the Scientific Committee'), with a view, inter alia, to obtaining its opinion on the risks for operators, particular account being taken of exposure through inhalation or contact with the skin, and the risks of the uses envisaged for bird reproduction and hares. The Scientific Committee delivered its opinion on 20 December 2001. Following that opinion, the notifier furnished additional data.

39 In September 2002, the rapporteur submitted a report containing its comments on the Scientific Committee's opinion and on the further data furnished by the notifier ('the rapporteur's second report').

40 During the procedure for assessing paraquat, certain comments and findings received from various contributors were synthesised and integrated into an evaluation table.

41 The procedure for assessing paraquat with a view to its inclusion in Annex I to Directive 91/414 was closed at a meeting of the Standing Committee on 3 October 2003. The conclusions reached at that meeting appear in the Commission's review report.

II — *Directive 2003/112/EC*

42 On 1 December 2003, the Commission adopted Directive 2003/112/EC amending Directive 91/414 to include paraquat as an active substance (OJ 2003 L 321, p. 32; 'the contested directive'). Recital 4 in the preamble to the contested directive reads as follows:

'The report on paraquat and further information were also submitted to the Scientific Committee ... The Committee was asked to comment on ... the risk for operators, taking into particular account potential inhalatory and dermal exposure, ... and on the risks the intended uses might pose to reproducing birds and hares. ... Based on the field exposure studies, corroborated by information on health surveys on operators, the Committee found that when paraquat is used as a plant protection product as recommended under prescribed good working practices, its use does not

pose any significant health risk for the operators. ... Furthermore, the Scientific Committee concluded that available studies indicate a hazard to ground-breeding birds but further information on realistic exposures is needed for a definitive assessment of the risk. This information was subsequently provided and the evaluation within the Standing Committee ... concluded that there are several situations where exposure to ground-nesting birds is negligible. However, there are also scenarios where exposure may occur. The evaluation within the Standing Committee ... concluded that the risk would be acceptable, provided appropriate risk-mitigation measures are applied. Finally, the Scientific Committee concluded that paraquat may be expected to cause lethal and sublethal effects for hares, but the available data are inadequate to estimate the proportion of hares affected. The views of the Scientific Committee were taken into consideration when drafting this Directive and the review report. The evaluation within the Standing Committee ... concluded that the risk would be acceptable if appropriate risk-mitigation measures were applied.'

43 Recital 5 in the preamble to the contested directive is drafted in the following terms:

'It has appeared from the various examinations made that there are uses of plant protection products containing paraquat which may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, provided appropriate risk-mitigation measures and restrictions are applied. It is therefore appropriate to include paraquat in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive. However some uses of plant protection products containing paraquat pose an unacceptable risk and should therefore not be authorised. Moreover, it is considered appropriate to ensure that Member States impose that the notifier and any other authorisation holder of paraquat establish a stewardship programme particularly for operator safety, and that they report to the Commission yearly on incidences of

operator health problems as well as possible impacts on hares. This should enable a verification of whether the risk-mitigation measures imposed by Member States really limit the possible risks for operators and hares to an acceptable level, and, if appropriate, a re-evaluation, in line with scientific progress, of the properties and potentially related risks to humans and the environment.'

44 Article 1 of the contested directive states 'Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive'. In addition to including paraquat in Annex I to Directive 91/414, the annex to the contested directive states, under the heading 'Specific provisions':

'Only uses as herbicide may be authorised.

The following uses must not be authorised:

— knapsack and handheld applications in home gardening, neither by amateur nor by professional users,

— use via broadcast air-assisted application equipment,

— ultra low volume applications.

For the implementation of the uniform principles of Annex VI, the conclusions of the [Commission's] review report on paraquat, and in particular Appendices I and II there[to], as finalised in the Standing Committee ... on 3 October 2003, shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of:

— operators, in particular for knapsack and handheld applications,

— ground-nesting birds. Where use scenarios indicate the potential for exposure of eggs a risk assessment should be conducted and, where appropriate, risk mitigation applied,

...

— hares. Where use scenarios indicate the potential for exposure of hares, a risk assessment should be conducted and, where appropriate, risk mitigation applied.

Member States shall ensure that the authorisation holders report at the latest on 31 March each year until 2008 on incidences of operator health problems and impact on hares in one or more representative areas of use, which should be supplemented by sales data and a survey of use patterns, so that a realistic picture of the toxicological and ecological impact of paraquat can be obtained.

Member States must ensure that technical concentrates shall contain an effective emetic. Liquid formulations shall contain an effective emetic, blue/green colourants and stenching or other olfactory alerting agent or agents. Other safeners, such as thickeners, may also be included.

In doing so they shall take account of the FAO specification.'

Procedure

45 By application lodged at the Registry of the Court of Justice on 27 February 2004, the Kingdom of Sweden brought the present action. It was registered as Case C-102/04.

46 By decision of the Court of Justice of 8 June 2004, the case was referred to the Court of First Instance pursuant to Council Decision 2004/407/EC, Euratom of 26 April 2004 amending Articles 51 and 54 of the Protocol on the Statute of the Court of Justice (OJ 2004 L 132, p. 5). The case was then registered as Case T-229/04.

47 By documents lodged at the Registry of the Court of First Instance on 17 June 2004, the Kingdom of Denmark and the Republic of Finland applied for leave to intervene in the proceedings in support of the form of order sought by the Kingdom of Sweden. The same application was made by the Republic of Austria in a document lodged at the Registry of the Court of First Instance on 21 June 2004. By order of 15 December 2004, the President of the Second Chamber of the Court of First Instance granted those applications. The interveners submitted their statements in intervention and the other parties submitted their observations thereon within the prescribed time-limit.

48 Pursuant to Article 14(1) of the Rules of Procedure of the Court of First Instance and on the proposal of the Second Chamber, the Court, after hearing the parties, decided to refer the case to the Second Chamber, Extended Composition, in accordance with Article 51 of the abovementioned rules.

49 Upon hearing the report of the Judge-Rapporteur, the Court of First Instance (Second Chamber, Extended Composition) decided to open the oral procedure.

50 In the context of the measures of organisation of procedure provided for in Article 64 of the Rules of Procedure, the Court, on the application of the Kingdom of Sweden, called upon the Commission to produce a document entitled 'the French study' and also put written questions to the parties, calling upon them to answer certain of those questions in writing before the hearing. The Commission complied with the Court's request to produce the French study. The parties submitted their written answers to the questions within the prescribed time-limit.

51 The parties presented oral argument and answered written and oral questions put by the Court at the hearing on 3 October 2006.

Forms of order sought

52 The Kingdom of Sweden, supported by the Kingdom of Denmark, the Republic of Austria and the Republic of Finland, claims that the Court should:

— annul the contested directive;

— order the Commission to pay the costs.

53 The Commission contends that the Court should:

— dismiss the application;

— order the Kingdom of Sweden, the Kingdom of Denmark, the Republic of Austria and the Republic of Finland to pay the costs.

Law

54 In support of its application, the Kingdom of Sweden, supported by the interveners, relies on two sets of pleas in law. The first set of pleas, of a procedural nature, alleges infringement of Article 7 of Regulation No 3600/92, Article 5 of Directive 91/414 and Article 174(3) EC. The second set of pleas alleges: (i) infringement of Article 5 of Directive 91/414; (ii) breach of the principle of the need for integration; (iii) breach of the principle that a high level of protection of the environment and human health is to be ensured; and (iv) breach of the precautionary principle.

55 The Commission contends that neither of those sets of pleas is well founded.

56 The parties also submitted comments on the scientific dossier concerning paraquat which the Kingdom of Sweden indicated at the hearing, without being contradicted by the Commission, would provide a factual basis for the pleas and arguments put forward in the written pleadings.

I — *The state of the scientific dossier concerning paraquat*

A — *Generalities*

57 The Kingdom of Sweden claims that paraquat is the substance most dangerous to health — in terms of acute toxicity — ever included in Annex I to Directive 91/414, since the lesions caused by it are incurable. The World Health Organisation (WHO) states that when paraquat is introduced into the body or is spread in concentrated form on the skin, it will, after a certain lapse of time, produce serious, even fatal, effects.

58 The Kingdom of Sweden points out that ingestion of 2 centilitres of concentrated paraquat is fatal. A study of poisoning deaths in England and Wales between 1980 and 1991 ('the Thompson study') shows that fatal accidents took place during that period notwithstanding the measures to reduce risks taken by the notifier from the 1980s. Those measures thus leave an unacceptable risk of exposure to the substance which could lead to incurable lesions or to the victim's death.

59 With regard to risks linked to inhalation of the substance, the Kingdom of Sweden claims that a study carried out with very precise methods of measuring has shown that normal use of paraquat over a long period can affect capacity to absorb oxygen ('the Dalvie study').

60 The Kingdom of Sweden adds that fatal poisonings by absorption through the skin have been noted. A study ('the Wesseling study') has indicated that a user can suffer a fatal exposure after three and a half hours of spraying with apparatus which is not

watertight. The Republic of Finland points to a case of an operator whose trousers were stained with paraquat while transferring the substance from one receptacle to another and who waited 48 hours before cleaning the stain in question. Ten days after the incident, his lungs ceased to function and he died on the 15th day after the incident. The Wesseling study also indicated that there is a relationship between prolonged use of paraquat and skin cancer.

61 The Commission replies that, far from being the most poisonous substance included in Annex I to Directive 91/414, paraquat is regarded as a mildly toxic substance by the WHO.

62 With regard to the risks linked to ingestion of paraquat, it can be seen from the data concerning such cases in the United Kingdom between 1980 and 1991, which are in the Draft Report and to which the Kingdom of Sweden refers, that the number of unintentional ingestions and deaths has constantly diminished and that, with the exception of two doubtful cases in 1987, no death has been reported in the United Kingdom since 1983, even though the volume of sales of products containing paraquat has constantly increased. It adds that the Thompson study merely indicates that 33 deaths out of 3 978 were caused by pesticides containing paraquat and the majority of those were cases of suicide.

63 With regard to the consequences of inhaling paraquat, the Commission points out that normal lung tests have revealed effects, not on breathing in cases of prolonged use of paraquat, but on the capacity to consume oxygen. It adds that it can be seen from the Dalvie study that the effects on the respiratory passages of long exposure to small doses of paraquat have not yet been fully established and that that study does not establish a link between long-term exposure to paraquat and the symptoms mentioned.

64 Finally, with regard to the consequences of exposure to paraquat through the skin, the Commission contends that the Wesseling study makes clear that paraquat is one of the most widely used pesticides in the world, that it is used without restriction in most countries and that it is regarded as safe by the majority of supervisory authorities. That study refers to a fatal accident in which a knapsack containing paraquat was not watertight. The Commission contends that, in the Community, it is compulsory to wear protective equipment when plant protection products containing paraquat are being applied. The Wesseling study is thus irrelevant in this case because it deals with an atypical situation. That study also does not show that use of paraquat over a long period is linked to skin cancer. In addition, the WHO does not regard paraquat as a substance which causes cancer.

B — *The link between exposure to paraquat and Parkinson's disease*

65 The Kingdom of Sweden claims that there are indications, in the literature concerning the neurotoxicity of paraquat, of a link between use of that substance and the appearance of Parkinson's disease, a neuro-degenerative illness in humans, although the existence of that link has not been established with certainty. A 2002 study of mice ('the McCormack study') revealed that paraquat can provoke lesions of the nervous system regarded as characteristic of Parkinson's disease. In addition, a study carried out in the 1990s ('the Hertzman study') drew attention to the importance of the link between exposure to paraquat and the appearance of Parkinson's disease.

66 The Commission contends, essentially, that a possible link between paraquat and Parkinson's disease has never been established. The Hertzman study is a retrospective study which looked for risk factors linked to the environment in the

case of Parkinson's disease and showed that the risk increases for persons who have worked with fruit plants or in planing mills.

67 The McCormack study concerned newborn mice, raised to be sensitive to Parkinson's disease, into which a massive dose of paraquat was injected. That study is not relevant, from a toxicological point of view, to human health, because it does not reflect a realistic exposure, even in the most unfavourable use scenario. With regard to the latter point, the Commission contends that the doses injected were 1 000 times higher than the average daily dose and 2 000 times above the acceptable operator exposure level ('the AOEL'). That study was more concerned with assessing the danger that paraquat represents than with assessing the risks to which a user is exposed under normal conditions of use.

68 In addition, a study of the existing literature shows that there is no link between the use of paraquat and Parkinson's disease. The Commission refers in that regard, in particular, to a review of the scientific literature carried out in 2001 for the United Kingdom's Advisory Committee on Pesticides ('the Dewhurst study'). The same can also be seen from epidemiological studies mentioned in a note drawn up by the notifier and circulated at the Standing Committee meeting in July 2003.

C — *The mathematical models and field studies concerning the risk to operators arising from the use of paraquat*

69 The Kingdom of Sweden claims that the mathematical models and field studies concerning the use of paraquat show that such use is a source of risk.

70 It claims, first of all, that the models show without ambiguity that the exposure of users to paraquat exceeds the AOEL. It states that, according to the two models used to calculate the exposure of professional users to paraquat, taking account of the presence or absence of personal protective equipment and different ways of using the substance (knapsack or tractor-mounted sprays), the exposure of such users exceeds by 4 to 100 times the threshold laid down. The values are 20 to 100 times higher than the AOEL for workers using a knapsack but not wearing protective clothing whereas they are 60 times higher than the AOEL where gloves are used when handling or spraying the substance. Finally, even with gloves, breathing equipment, overalls, wide-brimmed hats and solid shoes, the level of exposure is above the AOEL.

71 Secondly, the Kingdom of Sweden claims that the field studies show the existence of exposures exceeding the AOEL.

72 A study carried out in Sri Lanka, in which users did not wear protective equipment, showed, according to rudimentary methods of analysis, that the quantities absorbed by the skin were 8 to 18 times higher than the AOEL. The corresponding evaluation based on a urine analysis showed exposure levels 2 to 8 times above the AOEL.

73 A study carried out in 1996 in Guatemala on 20 persons who had used protective equipment ('the Guatemalan study') showed that one of the users had suffered an exposure level equivalent to 118% of the AOEL notwithstanding the fact that he was wearing protective equipment. It is also mentioned therein that another user wearing protective equipment suffered an exposure level equivalent to 92.8% of the limit notwithstanding the fact that, according to the study, the user applied the product carefully.

74 The Guatemalan study is relevant since the spraying method used is applicable in Europe. The Kingdom of Sweden argues that even if the high level of exposure shown by that study is due to the fact that the user concerned sprayed the product on sloping land, such a case could arise in Europe where paraquat is used in vineyards and olive groves, about 2.5 million hectares of which are located on sloping land.

75 A study carried out in 1997 in a citrus orchard in Spain involving 20 users with protective equipment ('the Spanish study') showed that the average exposure was 15% of the limit and the 75th percentile corresponded to 48% of the limit, that the highest dose was 81% of the limit and that 4 users had an exposure level above 50% of the limit.

76 A French study referred to by the Commission in the course of the procedure before the Court revealed an unacceptable level of exposure. According to the minutes of a meeting of the Standing Committee's working group in December 2002, that study reaches the conclusion that the use of hand tools can make the exposure level of operators unacceptable. It can also be seen from the same minutes that the French study recommends prohibiting the use of paraquat in the gardens of private individuals and carrying out checks on users.

77 Finally, with regard to the information submitted by the Italian Republic and the Portuguese Republic, which was referred to by the Commission in its written pleadings before the Court and according to which the risks associated with paraquat were properly managed in those Member States, the Kingdom of Sweden argues that no scientific evidence has been produced in support of that claim, which rests solely on the experience of the Member States concerned.

78 The Commission contends, first of all, that the mathematical models concerning exposure must be followed by field studies where, as in this case, they reveal the existence of problems. It adds that, as the Scientific Committee pointed out in its opinion, the field studies showed that the theoretical models overestimated real exposure in a work situation.

79 The Commission contends that the studies carried out in Sri Lanka, Spain and Guatemala were commented on by the rapporteur in the addendum to the Draft Report and it can be seen from those comments that the AOEL will not be exceeded if the proposed conditions for the use of paraquat are complied with.

80 It adds that the French study concluded that the exposure level can be made acceptable by using tractor-mounted appliances, whereas hand appliances make it unacceptable, and the same study recommends prohibiting the use of paraquat in the gardens of private individuals and carrying out checks on users. It also argues that the data transmitted by the Italian Republic and the Portuguese Republic indicate that the risks related to the use of paraquat can be properly managed.

D — *The effects of paraquat on animal health*

81 It is common ground between the parties that the field studies show that paraquat may be regarded as harmful and fatal to hares. It is also common ground that exposure of eggs to paraquat can constitute a danger to avian embryos.

II — *The set of pleas alleging the infringement, in the processing of the dossier, of Article 7 of Regulation No 3600/92, Article 5 of Directive 91/414 and Article 174(3) EC*

A — *Arguments of the parties*

82 The Kingdom of Sweden claims that the way in which the application for the inclusion of paraquat was dealt with is vitiated by several serious defects which infringe the procedures laid down in Regulation No 3600/92, Directive 91/414 and Article 174(3) EC.

83 First of all, the manner in which the application for inclusion was dealt with infringes the procedures laid down in those provisions concerning consideration of the link between paraquat and Parkinson's disease.

84 In support of that claim, the Kingdom of Sweden alleges, first, that the question of a link between paraquat and Parkinson's disease was never mentioned, whether by the notifier, the rapporteur or the Commission, in the assessment of the risks, although there is evidence in the scientific literature, and in particular in the Hertzman and McCormack studies, that paraquat affects the nervous system.

85 The Kingdom of Sweden claims, in particular, that the McCormack study contains essential information on the capacity of paraquat to damage, or even destroy, nerve cells in the brain (in particular, in the dopaminergic neurons in the *substantia nigra*

pars compacta) and that the lesions affecting those nerve cells are generally recognised as the primary cause of Parkinson's disease in humans.

86 Secondly, the Kingdom of Sweden claims that in order to conclude that the documentation concerning the relationship between the use of paraquat and Parkinson's disease has been taken into account and considered, the minutes of the Standing Committee would, first of all, have to refer to it. However, although certain information, and in particular, the Hertzman and McCormack studies, was distributed and discussed at the meeting of the working group of the Standing Committee in July 2003, the discussions on that point are not mentioned in the minutes of the meeting. In addition, the documentation concerning the relationship between the use of paraquat and Parkinson's disease should have been the subject of a written assessment by the rapporteur, which was not the case. Finally, the rapporteur should have given the other Member States an opportunity to comment on its assessment, which also did not happen in this case.

87 Thirdly, the Kingdom of Sweden claims that the articles concerning the absence of a link between paraquat and Parkinson's disease, to which the Commission refers in its written pleadings before the Court, were not available during the procedure leading to the adoption of the contested directive inasmuch as, contrary to other documents of which account was taken in assessing the active substance at issue, those documents were not available on the Commission's internal website 'Communication & Information Resource Centre Administrator (CIRCA)'. In particular, the content of those articles was not referred to or discussed in the course of dealing with the application for the inclusion of paraquat. With regard to that last point, the Commission's written pleadings before the Court do not make it possible to determine clearly the context in which the Commission analysed and assessed the documents to which it refers.

88 Fourthly, the Kingdom of Sweden claims that the question of a link between the use of paraquat and Parkinson's disease is complex. Consequently, an adequate consideration of the question of including paraquat in Annex I to Directive 91/414 also required that the Scientific Committee be consulted. By failing to

consult that committee, the Commission committed a manifest error in dealing with the dossier, contrary to Article 174(3) EC, Article 5(1) of Directive 91/414, point A 2(a) of Annex VI to Regulation No 3600/92 and to Article 7(1) thereof.

89 In its second argument, the Kingdom of Sweden claims that the Commission failed to follow the procedures laid down in Regulation No 3600/92 in regard to consideration of the French study and the data transmitted by the Italian Republic and the Portuguese Republic.

90 The Kingdom of Sweden claims, first, that it was only upon reading the defence, that it became aware of the importance of those studies and that data for the Commission's assessment.

91 The Kingdom of Sweden also claims that the information that the risks associated with use of paraquat were properly managed in Portugal and Italy was communicated orally at two meetings of the working group of the Standing Committee, without any reference to a study or a scientific report. In order to take account of the data in an assessment of risks, they should be presented in a written scientific dossier which could be the subject of discussion.

92 In addition, the Kingdom of Sweden states that the French study was presented orally and in summary fashion at a meeting of the Standing Committee's working group in December 2002 and that it was not made available to the Member States. Moreover, the rapporteur did not indicate whether that study had been in any way considered. In so far as the study was taken into account, the rapporteur should have ensured that, in accordance with the provisions of Regulation No 3600/92, the other Member States were able to take cognisance of it before any decision was adopted.

93 Finally, the Kingdom of Sweden claims that the French study should have been available in written form and should, in accordance with the provisions of Regulation No 3600/92, have given rise to a discussion and a common assessment before concluding that the risks were acceptable in the context of a particular use. In addition, because the French study referred to unacceptable risks in regard to certain uses of paraquat, the Scientific Committee should have been asked to give its opinion on it.

94 The Republic of Finland adds, in essence, that neither the Scientific Committee nor the Standing Committee had available to it studies concerning the effects of paraquat on aquatic organisms.

95 The Commission contends, first of all, that, in accordance with Article 7(1) of Regulation No 3600/92, it is the rapporteur which must examine all the available information. The Commission is certainly responsible for coordinating the processing of the dossier, making the final assessment and the adoption of the decision at Community level. However, the Member States have a significant influence on the management of the dossier.

96 With regard to a possible relationship between paraquat and Parkinson's disease, the Commission contends that all the information to which the Kingdom of Sweden refers, and more besides, was taken into account both by it and by the rapporteur. It emphasises that the Kingdom of Sweden itself admits that some information on the link between paraquat and Parkinson's disease was circulated and discussed at the meeting of the Standing Committee in July 2003. The Hertzman and McCormack studies, for example, were cited in the bulletin of the Pestizid Aktions-Netzwek eV (PAN), which was available at the Standing Committee meeting in July 2003.

97 The Commission also contends that, as can be seen from an e-mail from a competent authority in the rapporteur Member State to the Commission, dated 23 May 2003, the rapporteur assessed the relevance of the documents which cited paraquat in connection with Parkinson's disease and reached the conclusion that there were not sufficient grounds to take account of them when considering the question whether paraquat should be included in Annex I to Directive 91/414. Moreover, the Commission contended at the hearing that the rapporteur's assessment was based on the Dewhurst study.

98 It adds that there is no obligation on the Commission to include in its evaluation report all the information or documents which have been discussed during the assessment since it is not required to discuss all the issues of fact and of law which have been raised by every party during the administrative proceedings.

99 With respect to the French study and the information transmitted by the Italian Republic and the Portuguese Republic, the Commission contends, primarily, that the complaints alleging irregularities in the procedure in regard to consideration of that study and of the information were raised out of time, having regard to Article 48(2) of the Rules of Procedure, inasmuch as they were raised only in the reply. However, the matters raised in the reply were known to the Kingdom of Sweden at the time of the examination of the dossier and should therefore have been raised in the application.

100 In the alternative, the Commission denies being in breach of essential procedural requirements in regard to the French study and the information transmitted by the Italian Republic and the Portuguese Republic. It reiterates, first of all, the argument that Article 7(1) of Regulation No 3600/92 is addressed to the rapporteur, not to the Commission. It also contends that the provision in question does not impose any obligation that the entire assessment dossier must be of a scientific nature, in writing, and based on written documentation. Moreover, the Commission is not subject to a general obligation to consult the Scientific Committee, all the more so in

this case, as the information transmitted by the Member States was not of such a technical complexity that there was any particular reason to consult the Scientific Committee. Finally, the information transmitted by the Italian Republic and the Portuguese Republic, like the French study, confirmed the findings of the rapporteur, the Standing Committee and the Scientific Committee, with the result that the Commission had no particular reason further to consult the Scientific Committee.

101 Finally, with regard to the Republic of Finland's argument that neither the Scientific Committee nor the Standing Committee had available to it studies concerning the effects of paraquat on aquatic organisms, the Commission contends, essentially, that the studies required by Directive 91/414 were taken into account and analysed and if a Member State considered that certain important information should be included in the assessment dossier, it should have indicated that fact during the assessment procedure, something the Republic of Finland did not do.

B — *Findings of the Court*

102 The complaint alleging irregularities in the processing of the dossier in regard to a possible link between exposure to paraquat and Parkinson's disease should be considered first.

103 It should be pointed out, first of all, that the Commission's evaluation report states that there is no indication that paraquat is neurotoxic.

104 In considering this plea, it is sufficient to examine whether the procedure which led the Commission to make that statement is in accordance with the procedural requirements laid down in the provisions which the Kingdom of Sweden alleges have been infringed.

105 It should be borne in mind that, under Article 7(1)(a) and (c) of Regulation No 3600/92, the rapporteur is to examine the dossier referred to in Article 6(2) of that regulation and to send the Commission a report thereon. Article 6 of Regulation No 3600/92 provides that the notifier must send to the competent authority of the rapporteur a summary dossier containing the available summaries and results of trials in respect of each point in Annex II to Directive 91/414 or, where the summaries and results of trials are not available, either the reasons demonstrating that the information is not necessary for the assessment of the substance in accordance with the criteria referred to in Article 5 of Directive 91/414 or an undertaking that the missing information will be sent at a later date. Point 5.7 of Part A of Annex II to Directive 91/414 provides that delayed neurotoxicity studies must be carried out for substances of similar or related structures to those capable of inducing delayed neurotoxicity such as organophosphates.

106 It should be pointed out, as the Kingdom of Sweden does, that, in this case, the question of the relationship between paraquat and Parkinson's disease was never raised by the notifier. Moreover, it can be seen from the Draft Report that the notifier provided the rapporteur with no data concerning the neurotoxicity of paraquat, without giving any reason why information on that point was not necessary. In addition, although Article 7(2) of Regulation No 3600/92 permits the rapporteur to request notifiers to improve their dossiers, or add to them, the rapporteur did not avail itself of that possibility. In its Draft Report, the rapporteur expressly indicates that the information supplied by the notifier in regard to the toxicological aspects of paraquat was sufficient to permit inclusion of that substance in Annex I to Directive 91/414.

107 Admittedly, the Commission contends in the course of these proceedings that the rapporteur did in fact assess the relevance of the documents citing paraquat in connection with Parkinson's disease on the basis of the Dewhurst study and reached the conclusion that there were not sufficient grounds to take account of those documents when considering the question whether paraquat should be included in Annex I to Directive 91/414 (see paragraph 97 above).

108 However, even if it is accepted that such an assessment actually took place — as the e-mail of 23 May 2003, referred to by the Commission and the Dewhurst study and in the case-file tends to suggest — the Court finds that that assessment does not fulfil the requirements laid down in Article 7 of Regulation No 3600/92. As the Kingdom of Sweden claims (see paragraph 65 above), without being contradicted on that point by the Commission, there are, in the literature concerning the neurotoxicity of paraquat, indications of a link between use of that substance and the appearance of Parkinson's disease. Consequently, if the rapporteur had assessed the literature concerning the possibility of a link between use of paraquat and Parkinson's disease, that assessment would have been carried out in the context of an assessment of paraquat's neurotoxicity. Article 7(1)(c) of Regulation No 3600/92 requires that the rapporteur's examination of an active substance be followed by a report to the Commission, which, by virtue of Article 7(3) of the regulation, must be referred to the Standing Committee and to the other Member States for information.

109 In the present case, however, as the Kingdom of Sweden has, essentially, pointed out (see paragraph 86 above) without being contradicted on that point by the Commission, the rapporteur's reports contain no assessment of the literature concerning possible links between paraquat and Parkinson's disease. Moreover, the Commission has not established, nor even alleged, that such an assessment was transmitted to the Standing Committee.

110 In the light of the foregoing, it must be concluded that the claim made in the Commission's evaluation report that there is no indication that paraquat is neurotoxic flows from a consideration of the dossier which does not satisfy the

procedural requirements laid down in Article 7 of Regulation No 3600/92. The allegation of procedural irregularity in the consideration of a possible link between paraquat and Parkinson's disease must therefore be accepted, without there being any need to rule on the other arguments put forward in support of that plea.

111 Secondly, the allegation of procedural irregularity in the consideration of the French study and the information transmitted by the Italian Republic and the Portuguese Republic must be considered.

112 The preliminary plea of inadmissibility raised by the Commission against that allegation must first be considered.

113 Under Article 48(2) of the Rules of Procedure, no new plea in law may be introduced in the course of proceedings unless it is based on matters of law or of fact which have come to light in the course of the procedure.

114 As the Commission points out (see paragraph 99 above), by claiming in its reply that the data transmitted by the Italian Republic and the Portuguese Republic, as well as the French study, should have been available in writing and transmitted to the Scientific Committee, the Kingdom of Sweden is putting forward pleas which were not in the application and are consequently new within the meaning of Article 48(2) of the Rules of Procedure.

115 Moreover, it is common ground that the information supplied by the Italian Republic and the Portuguese Republic was communicated orally at meetings of the

working group of the Standing Committee and that the French study was mentioned in the minutes of meetings of the same group in December 2002 and February 2003. The existence of that information, and the study, is not something which came to light during the oral procedure before the Court.

116 However, it should be pointed out that the Kingdom of Sweden puts forward the new pleas mentioned in paragraph 114 above only in so far as the Commission alleges, in its defence, that the information supplied by the Italian Republic and the Portuguese Republic as well as the French study were attributed some importance in relation to accepting the inclusion of paraquat in Annex I to Directive 91/414.

117 It must be considered that the circumstances under which the information and the study in question were taken into account in no way indicate the importance which the Commission attached to them in regard to the inclusion of paraquat in Annex I to Directive 91/414. As the Kingdom of Sweden has pointed out (see paragraph 77 above) without being contradicted by the Commission on that point, the information supplied by the Italian Republic and the Portuguese Republic consisted in the mere assertion that, in the experience of those two Member States, the risks associated with paraquat can be properly managed, without any study or written document capable of supporting that assertion being produced. Moreover, it is common ground that the French study was the subject of an oral and summary presentation in the Standing Committee and that it was not made available to the representatives of the Member States on that committee. In the light of those circumstances, it must be concluded that the alleged importance of the information and the study at issue in relation to accepting the inclusion of paraquat in Annex I to Directive 91/414 is a matter of fact which came to light in the course of the procedure before the Court. Consequently, the claims put forward in regard to the way in which the French study and the information supplied by the Italian Republic and the Portuguese Republic were handled must be regarded as admissible under Article 48(2) of the Rules of Procedure.

118 In order to determine whether those claims are well founded, the claims put forward in regard to the French study must first be considered.

119 It should be pointed out, first of all, that the Commission refers to the French study as an important factor in the assessment of paraquat and emphasises that the study reaches the conclusion that the use of tractor tools can make the exposure level of operators acceptable whereas the use of hand tools can make it unacceptable and that it recommends prohibiting the use of paraquat in the gardens of private individuals and carrying out checks on users.

120 It should also be pointed out that the parties agree that there is no written assessment dossier on the French study and that the Scientific Committee's opinion was not sought on it. In addition, as the Kingdom of Sweden points out, nothing in the dossier establishes that the rapporteur took cognisance of the French study and considered it before a decision on the inclusion of paraquat in Annex I to Directive 91/414 was adopted.

121 Since it is not established that a report by the rapporteur on the French study was transmitted to the Standing Committee, it must be concluded that the way in which that study was dealt with — a study which the Commission claims was important in its assessment of paraquat — is not in accordance with the procedural requirements laid down in Article 7 of Regulation No 3600/92. More specifically, as has been pointed out in paragraph 108 above, Article 7(1)(c) of Regulation No 3600/92 requires that the rapporteur's examination be followed by a report to the Commission, which, by virtue of Article 7(3) of the regulation, must be referred to the Standing Committee and to the other Member States for information.

122 In addition, the way in which the French report was dealt with differs significantly from the treatment of the studies carried out in Sri Lanka, Guatemala and Spain

concerning the level of exposure of operators to paraquat. Those studies, the first two of which mention cases in which the level of exposure of operators to paraquat was above the AOEL, were all considered by the rapporteur. The rapporteur's consideration of them was the subject of a written summary either in the Draft Report or in the addendum thereto. Moreover, those reports were submitted to both the Standing Committee and the Scientific Committee.

123 Since the French study was, according to the Commission, of some importance for the assessment of paraquat, it should have undergone an evaluation procedure similar to that applied to the Sri Lankan, Guatemalan and Spanish studies, including consideration by the Scientific Committee.

124 With regard, secondly, to the way in which the information supplied by the Italian Republic and the Portuguese Republic was dealt with, it should be pointed out that the dossier contains no indication that that information, which the Commission regards as important, was the subject of a report on the part of the rapporteur. For the reasons already set out in paragraphs 108 and 121 above, the absence of such a report constitutes a failure to comply with the provisions of Article 7 of Regulation No 3600/92.

125 Consequently, the claims of irregularities in the procedure followed in regard to the French study and the information supplied by the Italian Republic and the Portuguese Republic must be accepted.

126 In view of the foregoing, the plea alleging infringement of Article 7 of Regulation No 3600/92 in regard to the way in which the dossier was dealt with must be accepted without there being any need to consider the other procedural pleas, claims or arguments put forward by the parties.

III — *The set of pleas alleging infringement of Article 5 of Directive 91/414; breach of the principle of the need for integration; breach of the principle that a high level of protection is to be ensured; and breach of the precautionary principle*

127 This set of pleas is divided into two branches, the first of which concerns the protection of human health and the second of which concerns the protection of animal health.

128 In addition, the parties have put forward a number of arguments — concerning the principle of integration, the precautionary principle and the principle that a high level of protection is to be ensured — which, as the Kingdom of Sweden indicated at the hearing, without being contradicted on that point by the Commission, serve merely to support pleas and arguments expressly raised elsewhere.

A — *The first branch, concerning the protection of human health*

1. Arguments of the parties

129 The Kingdom of Sweden, supported by the interveners, claims that, when considering the risks to human health caused by the use of paraquat, the Commission failed to have regard to the precautionary principle, the principle that a high level of protection is to be ensured, the need for integration, Article 5 of Directive 91/414 and the specific requirements of Annex VI. To that extent, it manifestly exceeded the limits of its discretion. The Kingdom of Sweden, supported by the interveners, essentially puts forward three principal submissions which the Commission contests.

(a) The submission alleging that operator exposure is above the AOEL

130 The Kingdom of Sweden, supported by the Kingdom of Denmark, states, first of all, that when examining an active substance under Article 5 of Directive 91/414, the uniform principles laid down in Annex VI to which the Member States refer in the course of national authorisation procedures for plant protection products are applicable.

131 In that regard, Article 5 of Directive 91/414 refers, at least indirectly, to the criteria in Annex VI. By virtue of Article 5(1)(b) of Directive 91/414, the essential requirements laid down in Article 4(1)(b)(iv) and (v) of the directive are therefore applicable when assessing an active substance. However, it is not possible to assess compliance with those fundamental requirements without applying the principles in Annex VI, which determine the content of those provisions.

132 The applicability of the uniform principles in Annex VI also follows from a Commission practice according to which, in the absence of specific guidelines concerning compliance with the requirements laid down in Article 5 of Directive 91/414, the criteria in Annex VI are always applied.

133 Secondly, the Kingdom of Sweden claims that the models and field studies clearly show that, in the present case, the level of protection does not meet the requirements set out in point C 2.4.1.1 of Annex VI, which provides that the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, may not exceed the AOEL. Given that the AOEL has been exceeded, the Commission, when it examined paraquat, failed to comply with Annex VI, Article 5 of Directive 91/414 and the principle that a high level of protection is to be ensured.

134 The Republic of Finland adds that account should have been taken of the neurological effects of paraquat, to be found in the scientific studies used to fix the AOEL, and the acceptable daily dose for operators. In its view, because the studies concerning the neurological effects of paraquat were not taken into account, the AOEL and the acceptable daily dose for operators used in assessing risks to operators were too high.

135 The Commission contests the claim that it should have applied the uniform principles in Annex VI when it assessed paraquat.

136 First of all, Article 5(1)(b) of Directive 91/414 refers to Article 4(1)(b)(iv) and (v) of that directive, which does not mention Annex VI. Consequently, the Commission is not formally required to apply the uniform principles in that annex when it assesses an active substance. It also states, essentially, that although the Commission is not bound by those principles, it may none the less take them into account when assessing an active substance.

137 The Commission contends that the risk of arbitrariness, which, in the view of the Kingdom of Sweden, would follow from non-application of the principles in Annex VI, does not seem very likely, given the scale of the assessment measures to which an active substance is subjected in accordance with the legislation on plant protection products.

138 With regard to the Republic of Finland's argument that the safety factors represented by the AOEL and the acceptable daily dose were fixed at too high a level because the neurological effects of paraquat were not taken into account, the Commission argues that, in its view, there was no need to evaluate the effects of paraquat on Parkinson's disease and no Member State made such a request.

(b) The submission that the scientific dossier does not contain enough evidence to conclude that paraquat does not pose a significant risk to human health

139 The Kingdom of Sweden contests the Commission's view that the scientific dossier shows that paraquat does not represent a significant risk to human health.

140 The Kingdom of Sweden, supported by the Kingdom of Denmark, argues, first of all, that it follows from Article 5(1) of Directive 91/414 that a substance may not be included in Annex I until it has been proved beyond a reasonable doubt that a product containing that active substance can be used with complete safety in at least one representative type of use. Such proof must rest on an assessment of the risks, supported by a scientific dossier.

141 The Kingdom of Denmark challenges the argument that, under Article 5(1) of Directive 91/414, the Commission is subject to such a low standard of proof that the mere possibility, uncertain or theoretical, that a product containing an active substance might be acceptable is sufficient to permit inclusion of that substance in Annex I to that directive. If there is evidence that a certain substance could represent a particular type of risk to human health or the environment, then, before deciding to include the substance in Annex I, enough information should be gathered to assess the risk in a scientific manner and the effectiveness of possible restrictions on use should be assessed with the same scientific rigour.

142 In the applicant's view, the scientific dossier in this case does not support the conclusion that paraquat satisfies all the requirements laid down in Article 5 of Directive 91/414.

143 First of all, the mathematical models show unambiguously that exposure of users to paraquat is higher than the limit fixed. The Guatemalan and French studies show an unacceptable level of exposure for users and only the Spanish study concludes that the level of exposure is acceptable.

144 Moreover, according to the applicant, neither the Guatemalan nor the French studies were adequately taken into account. Thus, although the Guatemalan study indicates that a person using protective equipment suffered exposure above the AOEL, the Scientific Committee concluded that, in its opinion, only persons who had not followed the recommended work procedure had shown levels of exposure close to the limit. In addition, although the French study indicated that the use of knapsack sprayers should be prohibited and the use of paraquat in private individuals' gardens was inadvisable, the contested directive merely prohibited the use of knapsack and handheld sprayers in 'home gardening'.

145 The Commission contends that the scientific dossier provides sufficient evidence to justify the inclusion of paraquat in Annex I to Directive 91/414.

146 It relies, first of all, on the scope of Article 5 of Directive 91/414. It contests the interpretation of Article 5 according to which, before an active substance is included in Annex I, it must be proved beyond a reasonable doubt that a product containing that active substance has been used with complete safety in at least one representative type of use, taking all possible risks into account.

147 On the one hand, such a requirement is close to zero tolerance. However, according to case-law, a preventive measure cannot properly be based on a purely hypothetical

approach to the risk, founded on mere conjecture which has not been scientifically verified. In particular, the Court has decided that the Community institutions may not base their decisions on a 'zero-risk' (Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 152).

148 On the other hand, such a requirement is contrary to the terms of Directive 91/414 and the evidence which it requires for inclusion of an active substance. Thus, by using the expression 'if it may be expected', rather than, for example, 'if it can be shown', the legislature accepted that it was impossible to foresee every possible and imaginable situation in which a plant protection product containing an active substance could be used and that the environmental conditions to be taken into account in regard to the use of a plant protection product can vary considerably from one Member State to another, which is the reason why the legislation concerning plant protection products also gives an active role to the Member States.

149 The Commission denies that it must be verified in a scientific manner that the restrictions on use laid down in Article 5(4) of Directive 91/414 really reduce risks. It points out that Article 5(1) of the directive provides that in the 'light' of current scientific and technical knowledge, it must be determined whether 'it may be expected' that the conditions for inclusion in Annex I to the directive will be fulfilled.

150 Secondly, the Commission denies that the scientific dossier is insufficient to support the inclusion of paraquat in Annex I to Directive 91/414.

151 There exists sufficient scientific documentation to support the view that, independently of the risks which the use of paraquat may represent, the risks assessed were acceptable having regard to the measures introduced to reduce them, such as the prohibition on the use by private individuals of plant protection products containing paraquat and the imposition of conditions on the professional use of that substance.

152 Moreover, the mathematical models indicating that the AOEL had been exceeded are irrelevant. The Commission argues that if the models reveal the existence of problems, they must be followed by field studies. In the present case, the rapporteur considered, in the addendum to the Draft Report, that the AOEL would not be exceeded if the conditions of use envisaged for paraquat were complied with. In addition, the Scientific Committee reached the same conclusion as the rapporteur in finding that even if the models of exposure indicated that the AOEL might possibly be exceeded, field studies in various countries showed that the models had overestimated real exposure in a work situation.

153 In addition, the Commission denies that it relied only on the Spanish study when forming its opinion. It points out that the rapporteur, the Scientific Committee and the experts from ECCO considered that the studies which had been submitted were sufficient to reach the general conclusion that, in cases of use in accordance with the proposed conditions, paraquat did not represent a significant risk to health.

154 With regard to the alleged failure to take account of the Guatemalan study in the procedure leading to the adoption of the contested directive, the Commission contends that it can be seen from the opinion of the Scientific Committee that the Committee was in possession of the addendum to the Draft Report, in which the Guatemalan study appeared. Also, in its second report, the rapporteur indicated that the Scientific Committee based its opinion on field studies. Thus, there is nothing to indicate that the Scientific Committee did not take account of the Guatemalan study.

155 The Commission also denies that the conditions for the use of paraquat laid down in the contested directive do not reflect the conclusions of the French study. It points out that the contested directive does not generally authorise handheld tools and that the grant of authorisation to use a plant protection product will be conditional upon compliance with good practice.

(c) The submission alleging a reduction in the level of protection

156 The Kingdom of Sweden, supported by the Republic of Austria, argues, essentially, that by accepting the inclusion of paraquat in Annex I, the Commission infringed the principle that a high level of protection of human health must be ensured.

157 Thus, the fact that the contested directive requires the establishment of stewardship programmes for operator safety and that a report must be submitted to the Commission yearly on incidences of the use of paraquat on operator health shows that the Commission is hesitant as to the risks of paraquat. No other active substance included in Annex I requires yearly reports. Consequently, in the present case, the Commission tried a sort of experiment, contrary to Directive 91/414, to the precautionary principle and to the principle that a high level of protection of human health must be ensured.

158 By authorising paraquat, the most toxic substance that exists, as an active substance, the Commission therefore seriously reduced the level of protection governing the choice of substances which may be included in Annex I. For that reason, it has manifestly failed to have regard to the objective of the provisions at issue, which is to ensure a high level of protection, and the terms of the preamble to Directive 91/414, according to which the objective of improving plant production should not take priority over the protection of human health and the environment.

159 The Commission replies that it cannot understand why the Kingdom of Sweden is complaining because the Commission requires holders of an authorisation for a plant protection product containing paraquat to establish stewardship programmes for operator safety and to report yearly on possible health or pollution problems linked to the use of paraquat.

2. Findings of the Court

(a) The assessment framework

160 Article 5(1) of Directive 91/414 provides that, for an active substance to be included in Annex I to that directive, it must be possible to expect that, in the light of current scientific and technical knowledge, use of plant protection products containing that active substance, consequent on application consistent with good plant protection practice, will not have any harmful effects on human health as provided for in Article 4(1)(b)(iv) and (v) of that directive.

161 It follows from that provision, interpreted in combination with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414. The precautionary principle is designed to prevent potential risks. By contrast, purely hypothetical risks, based on mere hypotheses that have not been scientifically confirmed, cannot be accepted (Case T-392/02 *Solvay Pharmaceuticals* v *Council* [2003] ECR II-4555, paragraph 129).

162 In order to determine whether the requirements laid down in Article 5(1) of Directive 91/414 have been fulfilled in regard to human health, that provision refers back to Article 4(1)(b)(iv) of the directive which provides, in essence, that it must be established that a plant protection product has no harmful effect on human health, directly or indirectly, or on groundwater.

163 It should be pointed out, however, that it can be seen from Article 4(1)(a) of Directive 91/414 that in order to fulfil the requirements laid down in Article 4(1)(b) of that directive, the uniform principles provided for in Annex VI must be applied. Moreover, the second recital in the preamble to Directive 97/57, fixing the content of Annex VI, states that that annex must lay down uniform principles to ensure the application of the requirements of Article 4(1)(b), (c), (d) and (e) of Directive 91/414 in a uniform manner and as stringently as is sought by the directive.

164 It follows that Article 4(1)(b)(iv) of Directive 91/414, to which Article 5(1)(b) of that directive expressly refers, requires compliance with the uniform principles laid down in Annex VI.

165 In addition, if the reference made by Article 5(1)(b) of Directive 91/414 did not imply the application of the uniform principles set out in Annex VI, the reference would have no real utility. In such a case, for the purpose of assessing the harmful effect on human health under Article 5(1)(b) of the directive, the reference in that provision would be limited to the application of an almost identical criterion concerning the absence of any 'harmful effect on human ... health, directly or indirectly (e.g. through drinking water, food ...) or on groundwater'.

166 Finally, it should be pointed out that the Commission admitted, at the hearing, that it had already applied the criteria in Annex VI when evaluating certain active substances under Article 5(1) of Directive 91/414.

167 In the light of the foregoing, it must be concluded that when the Commission evaluates an active substance with a view to its inclusion in Annex I to Directive 91/414, it follows from Article 5(1)(b) of that directive that the criteria in Annex VI are to be applied.

168 More specifically, point C 2.4.1.1 of Annex VI states that no authorisation is to be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.

169 The effect of Article 5(4) of Directive 91/414, which provides that inclusion of an active substance in Annex I may be subject to restrictions on use, is to permit inclusion of active substances which do not fulfil the requirements of Article 5(1) of the directive subject to certain restrictions which exclude problematic uses of the substance involved.

170 Since that provision is to be regarded as a limitation on Article 5(1) of Directive 91/414, it must be interpreted in the light of the precautionary principle. Consequently, before including a substance in Annex I to that directive, it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid down in Article 5(1) of Directive 91/414.

171 The various submissions made under the present heading must be considered in the light of the rules set out above.

(b) The submissions put forward

172 The first two submissions, alleging, respectively, that the AOEL is exceeded and that there is not sufficient evidence in the dossier to justify inclusion of paraquat in Annex I to Directive 91/414, must be considered together.

173 In regard to those two submissions, it is common ground between the parties that the Standing Committee fixed the AOEL for short-term exposure to paraquat at 0.005 milligrams per kilogram of body weight.

174 It is also common ground between the parties that the mathematical models show an exposure to paraquat 4 to 100 times higher than the AOEL. However, as the Commission rightly points out, the Scientific Committee indicated in its opinion that field studies in various countries showed that the mathematical models had very seriously overestimated real exposure in a work situation. Consequently, it must be considered that in the circumstances of the present case, the mathematical models do not, in themselves, constitute solid evidence which may reasonably raise doubts as to the safety of paraquat.

175 With regard to the field studies, the Guatemalan study, in which it was found that one of the operators taking part in the study suffered exposure to paraquat equal to 118% of the AOEL, must be considered first.

176 It can be seen from the notifier's observations on the Guatemalan study, as set out in the addendum to the Draft Report, that the operators with the highest potential and systematic exposure do not appear to have mixed or applied the product, or loaded the sprayer tanks, differently from others participating in the study. The addendum to the Draft Report also indicates that all the workers covered by the study generally followed the label recommendations for mixing the product and loading the sprayer tanks, and appear to have demonstrated reasonable hygiene standards during mixing of the product at issue.

177 The addendum to the Draft Report also states that spraying at chest or head height into drainage gullies caused significant contamination of operators' clothing and that the worker whose exposure was 118% of the AOEL had applied the product to irrigation canals, which led him to hold the spray lance at head height.

178 It is true that the addendum to the Draft Report states that the circumstances under which the operator suffered exposure higher than the AOEL in the Guatemalan study must be considered unrepresentative of application practice in Europe. However, the fact remains that the addendum to the Draft Report gives no reason why the application of paraquat in an irrigation canal, causing the operator to hold the spray lance at head height, is unrepresentative of conditions of use in Europe. The Kingdom of Sweden, on the other hand, argues, without being contradicted on that point by the Commission, that the use of paraquat on sloping land is one of the uses envisaged for paraquat in Europe (see paragraph 75 above).

179 Moreover, it should be pointed out that no restriction adopted under Article 5(4) of Directive 91/414 prohibits the use of paraquat in the circumstances which led to exposure of an operator at a level higher than the AOEL in the Guatemalan study. It

can be seen from the contested directive that the only express restriction on the use of portable sprayers to apply products containing paraquat concerns 'home gardening', where such use is prohibited. In addition, the fact that the specific provisions of the contested directive require Member States to pay particular attention to the protection of operators — particularly in the case of knapsack and handheld sprayers — does not entail the prohibition of uses such as the one which gave rise to the AOEL being exceeded in the Guatemalan study. Finally, Annexes I and II to the Commission's evaluation report, to which the specific provisions of the contested directive refer, do not mention a prohibition of the problematic use. It must therefore be held that the Guatemalan study takes account of a problematic use of paraquat in regard to which there is nothing to suggest that it could not occur in Europe.

180 It should be pointed out that the Scientific Committee's statement that only persons who had not followed the recommended work procedure had shown levels of exposure close to the limit is not corroborated, in regard to the Guatemalan study, by anything else in the dossier. On the other hand, as was pointed out in paragraph 176 above, the addendum to the Draft Report indicates that the operators in the Guatemalan study generally followed the recommendations and complied with hygiene standards. It must therefore be held that the study is recounting a case where exposure to paraquat was problematic even though the recommended work procedures had been followed.

181 In the light of the foregoing, the Guatemalan study appears to constitute solid evidence which may reasonably raise doubts as to the safety of paraquat for operators applying it.

182 Since the Guatemalan study attests to a level of exposure higher than the AOEL in cases where paraquat was used in accordance with the recommended conditions, the requirement laid down in point C 2.4.1.1 of Annex VI, which prohibits any

exceeding of the AOEL, has not been fulfilled. However, for the reasons set out in paragraphs 162 to 168 above, the criteria in Annex VI must be applied when evaluating an active substance under Article 5(1)(b) of Directive 91/414. Consequently, the contested directive infringes the requirement, laid down in Article 5(1)(b) of Directive 91/414, to protect human health. The submission that operators are exposed to an extent higher than the AOEL must therefore be accepted.

183 Secondly, it should be pointed out that, following production of the French study by the Commission in the context of measures of organisation of procedure, it became clear that the document is not so much a field study as an assessment, by the French Commission d'étude de la toxicité (Commission for the Study of Toxicity; 'the CET'), of the exposure of operators to paraquat as revealed by various studies. Thus, the CET assessed the exposure of operators in the case of an application of paraquat carried out with a tractor. That assessment took account of exposure calculations made on the basis of a mathematical model and a field study carried out in the United States. The CET also assessed the exposure of operators in the case of an application of paraquat carried out with a knapsack sprayer. That evaluation took account of exposure calculations made on the basis of a mathematical model and the Sri Lankan, Guatemalan and Spanish studies. As a conclusion to its study, the CET stated that it 'remained opposed to the authorisation of paraquat-based preparations for any uses requiring application with a knapsack sprayer'. It adds that it 'approves authorisation of paraquat-based preparations for all uses requiring application to plants exclusively by means of a tractor'.

184 It should be pointed out that the contested directive prohibits the use of knapsack or handheld sprayers only in regard to 'home gardens', which means that applications with knapsack sprayers outside 'home gardens' are permitted, even though the CET indicated in the French study that it was against such applications.

185 Since the Commission states that the French study played an important role in its decision to include paraquat in Annex I to Directive 91/414, it must be held, for the purposes of these proceedings, that the study's unfavourable conclusion in regard to uses requiring a knapsack sprayer constitutes solid evidence which may reasonably raise doubts as to the safety of such a use of paraquat.

186 In the light of the foregoing, the submissions alleging exposure above the level of the AOEL and the lack of sufficient evidence in the dossier to justify inclusion of paraquat in Annex I to Directive 91/414 must be accepted.

187 With regard to the submission alleging a reduction in the level of protection of human health, it should be borne in mind that Article 5(4) of Directive 91/414 permits the Commission to make the inclusion of an active substance in Annex I thereto subject to certain restrictions. Consequently, the mere fact that the contested directive lays down specific requirements cannot be regarded as contrary to Article 5 of Directive 91/414.

188 Moreover, the fact that the specific requirements laid down in the contested directive consist, inter alia, in the obligation on Member States to ensure that the authorisation holders report at the latest on 31 March each year until 2008 on incidences of operator health problems and that that information should be supplemented by sales data and a survey of use patterns, so that a realistic picture of the toxicological and ecological impact of paraquat can be obtained, does not, in itself, indicate that the Commission has compromised the principle that a high level of protection for human health should be ensured.

189 Thus, contrary to the Kingdom of Sweden's argument, which the interveners support, those specific requirements for paraquat do not, in themselves, indicate that the Commission was hesitant as to the risks posed by that substance, nor that it decided to observe, after the event, the consequences of paraquat rather than to carry out a prior assessment.

190 Consequently, the third submission must be rejected.

191 It follows from all of the foregoing that the first branch concerning the protection of human health must be accepted, except for the third submission.

B — *The second branch, concerning the protection of animal health*

1. Arguments of the parties

(a) The submission alleging that the scientific dossier contains insufficient evidence

192 The Kingdom of Sweden claims, essentially, that the Commission accepted the inclusion of paraquat in Annex I to Directive 91/414 on the basis of a dossier with gaps concerning the harmful effects of paraquat on the health of hares and avian embryos and the effectiveness of the measures envisaged to attenuate those effects, which is contrary to Article 5 of Directive 91/414, taken in conjunction with the precautionary principle and the requirement of a high level of protection of the environment, and demonstrates the arbitrary nature of the Commission's conclusion that paraquat could be included in Annex I to Directive 91/414.

193 With regard to hares, the Kingdom of Sweden argues, first, that it can be seen from the statement of the reasons on which the contested directive is based and from the dossier on which it is based that paraquat has lethal and sublethal effects on those mammals.

194 It points out, secondly, that the reasons on which the contested directive is based, the opinion of the Scientific Committee and the Commission's evaluation report indicate that the available information did not make it possible to establish what proportion of hares would be affected by paraquat.

195 It also argues that the rapporteur, in its second report, envisaged a scenario for the use of paraquat in stubble fields in the United Kingdom which showed that about 2% of the total hare population could be exposed in the worst hypothesis, which, according to the Kingdom of Sweden, represents 16 000 hares per year in the territory of the United Kingdom. That estimate is based on the hypothesis that 0.4% of the total cereal area will be sprayed, whereas no country has yet found it appropriate to limit in practice the surfaces which may be treated with pesticides.

196 In addition, and with the support of the interveners, the Kingdom of Sweden states that animals such as rabbits, moles, voles and shrews are exposed to the same risks as hares and that account was not taken of such mammals in determining the measures designed to attenuate the risks. The fact that so many animals are in danger of dying or suffering serious lesions is unacceptable.

197 It adds that the rapporteur's assessment clearly shows that it was not possible to find a use for paraquat which is safe for hares. On the one hand, instead of examining the areas of use proposed by the notifier, the rapporteur concluded that the risks to hares should be assessed at the level of the Member States. On the other hand, even if the rapporteur were to recommend a particular use of paraquat, that would be

valid only for its use in stubble fields since the rapporteur relied on a scenario concerning only use in that domain. However, the notifier envisaged several domains of use and, before including paraquat in Annex I to Directive 91/414, the risks in each of those domains should have been assessed.

198 The Kingdom of Sweden also states that, in its opinion, the Scientific Committee mentioned measures which might be capable of reducing the risks to hares but, in the absence of scientific data showing the likely effects of the measures in question, the Committee had no choice but to conclude that, in the light of the data submitted, paraquat could cause lesions to, or even the death of, certain individual hares. In its view, the data collected in the field studies in which hares were exposed to the substance show that the risks are real but that it is not possible to estimate the number of animals affected. On the other hand, no new scientific data were presented in support of the notifier's claim that measures capable of reducing the risks to hares had been effective. In accordance with the usual practice in regard to inclusion of active substances in Annex I, the information concerning the possible effects of the proposed measures should have been presented in writing and accompanied by a scientific evaluation so as to serve as a basis for the assessment made in the present case.

199 With regard to avian embryos, the Kingdom of Sweden claims, first, that the statement of the reasons on which the contested directive is based and the Commission's evaluation report indicate that paraquat has harmful effects on bird reproduction. More specifically, it claims that the Scientific Committee concluded that the study of exposures carried out shows that paraquat could be a threat to avian embryos but that additional information from realistic studies would have to be obtained in order to assess the risks.

200 In the Kingdom of Sweden's view, the notifier provided additional information consisting of three estimates, based on laboratory tests, of the doses of paraquat

which would damage birds' eggs and of various claims regarding the places and times at which ground-nesting birds nest, including the claim that it was unlikely that birds which reproduce on the ground would nest in orchards, olive groves or vineyards. That new information did not include a realistic field study of exposure and was not supported by evidence. It is therefore misleading and incomplete, and did not provide an answer to the Scientific Committee's questions. The Kingdom of Sweden also adds that the fact that the Commission relied only on that dossier, with gaps in it, when authorising the inclusion of paraquat in Annex I shows that its assessment infringes the precautionary principle.

201 The Kingdom of Sweden also states that, in its second report, the rapporteur indicates that the risk of exposure for ground-nesting birds is low in lucerne fields in autumn and winter. The Kingdom of Sweden argues that, on the basis of the available data, that is the only acceptable use from the point of view of birds and that only that use should therefore have been authorised. It claims, consequently, that the Commission has not in any way shown at a more general level that there is a use for paraquat in which the risk of exposure for ground-nesting birds is acceptable.

202 The Commission denies that the dossier does not contain sufficient evidence in regard to animal health to justify the inclusion of paraquat in Annex I to Directive 91/414.

203 With regard to hares, the Commission contends, first of all, that the ECCO experts indicated that additional information was necessary in order to assess the effect of the product on hares and, as a result, the notifier completed the dossier.

204 It then points out that the Scientific Committee stated that the information available did not make it possible to evaluate the number of hares which could be affected but that there were measures which make it possible to reduce the risks to those animals.

205 It states that, in its second report, the rapporteur indicated that the Scientific Committee and the notifier proposed to reduce the risks to hares (spraying in the early morning, since hares are active at night; adding a repellent; spraying from the centre of the field outwards; not spraying the whole field on the same day). It also states that, in view of the fact that the situation varies from one Member State to another, it is appropriate to permit the Member States to prescribe appropriate conditions of use when plant protection products are authorised.

206 The Commission adds that, in the light of the uncertainty as to the number of hares concerned, the rapporteur envisaged a scenario for the use of paraquat in stubble fields in the United Kingdom. In the Commission's view, the choice of scenario was justified by the facts that such use had provoked incidents in the 1960s, that data for the United Kingdom were available and that the notifier had envisaged that use of paraquat.

207 It also contends that it can be seen from the evaluation table that the notifier states that the restrictive measures proposed by the Scientific Committee had been effective. It contends, in addition, that the evaluation table indicates that the rapporteur and the Scientific Committee considered that the available information was sufficient.

208 Finally, it states that a special condition concerning hares was included in the contested directive.

209 With regard to birds, the Commission contends, first of all, that the Scientific Committee merely indicated that dipping an egg into paraquat for 30 seconds clearly went beyond the most unfavourable realistic scenario and that, consequently, in order to reach a conclusion as to the risks, more realistic studies — based, for example, on spraying — were necessary.

210 It also points out that the notifier provided additional information. It denies that that information was inaccurate and insufficient and that it did not answer the Scientific Committee's questions. With regard to the latter point, the Kingdom of Sweden does not specify — according to the Commission — which of the Scientific Committee's questions remained unanswered. Secondly, it contends that, in its second report, the rapporteur took account of the effects of spraying eggs and considered that, in many situations, exposure of ground-nesting birds was negligible and, consequently, the risk was acceptable, but that where exposure was possible, the risk needs to be determined, if possible at Member State level.

211 The Commission further argues that, in the addendum to the Draft Report, the rapporteur emphasises that the initial assessment of the risks remains acceptable; that the information supplied by the notifier had undergone a critical assessment; that the information was reliable and appropriate for use in a Europe-wide risk assessment; and that there will be no unacceptable impact on ground-nesting birds following use of paraquat in accordance with the proposed conditions of use.

212 It adds that it can be seen from the evaluation table that the ECCO experts considered that the risk to birds could be reduced by the conditions of use. It can also be seen from that table that the rapporteur, which had assessed the additional information furnished by the notifier, considered that the data supplied were reliable and relevant because they provide a basis for a more robust consideration of the

actual risk posed to ground-nesting birds. Finally, the table shows that there will be no unacceptable impact on ground-nesting birds if the proposed conditions of use are complied with.

213 In addition, it points out that the contested directive expressly provides, in regard to ground-nesting birds, that where use scenarios indicate the potential for exposure of eggs, a risk assessment must be conducted and, where appropriate, risk mitigation applied.

214 Finally, the Commission argues that although it is true that the contested directive does not contain any particular measure for mammals other than hares, that is due to the impossibility of taking into account the possible risks to each mammal and, for that reason, a pragmatic and realistic approach led to the assessment concentrating on the most exposed animals. However, the dossier shows that information concerning other mammals, such as voles and rats, was also considered. Moreover, it contends that when a Member State has to decide whether to grant an authorisation for a plant protection product containing an active substance included in Annex I, it must comply with the provisions of Annex VI, point B 2.5.2.1 of which requires it to evaluate the possibility of exposure of birds and other terrestrial vertebrates to the plant protection product and, if this possibility exists, they are to evaluate the extent of the short-term and long-term risk to be expected for those organisms (including their reproduction), after use of the plant protection product in accordance with the proposed conditions of use. That provision is therefore adapted to the specific conditions which may prevail in a particular Member State in regard to a precise method of use. In addition, the Member State may make the authorisation subject to particular conditions, such as the addition of a repellent.

(b) The submission that the long-term toxicity/exposure ratio is inadequate having regard to point C 2.5.2.1 of Annex VI

215 The Kingdom of Sweden claims, in substance, that point C 2.5.2.1 of Annex VI indicates that, where there is a possibility of birds or other non-target terrestrial vertebrates being exposed, a special upper limit and a margin of safety — in accordance with which the long-term toxicity/exposure ratio is to be 5 or above — must be applied. However, the studies on which the Commission based its assessment of paraquat show that the ratio in question was only 2. It adds that the Commission has not shown that there is a use for paraquat in which the risk of exposure for ground-nesting birds would be acceptable. It follows that the Commission cannot conclude, on the basis of the existing dossier, that there are no unacceptable risks.

216 The Commission contends, essentially, that it is for the Member States, and not for the Commission, to apply Annex VI when authorising a plant protection product.

(c) The submission that the assessment and management of possible risks have been left to the Member States

217 The Kingdom of Sweden, supported by the Republic of Austria and the Kingdom of Denmark, claims that the conditions laid down in the contested directive show that the Commission has chosen to leave risk assessment to the Member States, together with the fundamental assessment as to whether it is possible to attain an acceptable level of risk. Such laissez-faire is contrary to Directive 91/414.

218 The Commission denies that it transferred risk assessment to the Member States and left it to them to make the fundamental assessment as to whether or not it is possible to attain an acceptable level of risk. It contends, essentially, that there was a Community assessment. It states that, in regard to hares, the rapporteur and the assessment group of the Standing Committee both considered that the available information was sufficient for the purposes of assessing the risks and that the contested directive provides that where use scenarios indicate a potential for exposure of hares, a risk assessment must be conducted and, where appropriate, risk mitigation applied.

219 With regard to birds, it indicates that, in its second report, the rapporteur considered that in many situations exposure of ground-nesting birds was negligible and, consequently, the risk was acceptable, but that, in cases where exposure was possible, the risk should be assessed, if possible, at Member State level. It also relies on the conclusion to the addendum to the Draft Report, which states that there will be no unacceptable impact on ground-nesting birds if paraquat is used in accordance with the proposed conditions of use. Finally, it relies on the evaluation table, which shows that, according to the ECCO evaluation report, the risk to birds could be reduced by the conditions of use.

(d) The submission that animals exposed suffer unacceptable pain

220 The Kingdom of Sweden claims, first of all, that Article 5(1)(b) of Directive 91/414 provides that for inclusion of an active substance in Annex I to the directive, the substance must fulfil the requirements laid down in Article 4(1)(b)(iv) and (v) of that directive and that under the second indent of Article 4(1)(b)(v), use of the plant protection product in question must have no unacceptable influence on the environment, having regard to its impact on non-target species. The latter provision must be interpreted as meaning that the use of the plant protection product

concerned may not cause unnecessary suffering and pain to non-target species since, in regard to vertebrates to be controlled, Article 4(1)(b)(iii) of the directive prohibits such suffering and pain.

221 It also contends that it is known that persons exposed to paraquat undergo considerable pain and severe suffering and that it can be seen from the scientific dossier that it may be supposed that the same is true of other mammals. Consequently, the contested directive is contrary to the requirements of Article 5(1)(b) of Directive 91/414.

222 The Commission did not express its view on this submission in its written pleadings. At the hearing, it denied the relevance of the second indent of Article 4(1)(b)(v) of Directive 91/414 to the assessment of an active substance.

2. Findings of the Court

(a) The assessment framework

223 With regard to the protection of animal health, Article 5(1) of Directive 91/414 provides that for an active substance to be included in Annex I to that directive, it must be possible to expect that, in the light of current scientific and technical knowledge, use of plant protection products containing the active substance, consequent on application consistent with good plant protection practice, will not

have any harmful effects on animal health as provided for in Article 4(1)(b)(iv) of the directive.

224 For reasons similar to those set out in regard to the first branch of the present plea, concerning the protection of human health (see paragraph 161 above), the above provision, taken in combination with the precautionary principle, implies that, in the domain of animal health, the existence of solid evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414.

225 For the reasons set out in paragraphs 162 to 167 above, the uniform principles laid down in Annex VI must be applied when assessing whether the requirements of Article 5(1) of Directive 91/414 concerning the protection of animal health are fulfilled.

226 More specifically, point C 2.5.2.1 of Annex VI provides, in substance, that where there is a possibility of birds or other non-target terrestrial vertebrates being exposed, no authorisation is to be granted if the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that no unacceptable impact occurs after use of the plant protection product in accordance with the proposed conditions of use.

227 Finally, for the reasons set out in paragraphs 169 and 170 above, before including a substance in Annex I to Directive 91/414, it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved, imposed under Article 5(4) of that directive, make it possible to ensure that use of that substance will be in accordance with the requirements of Article 5(1) thereof.

228 The various submissions made under this branch must be considered in the light of the rules which have just been set out.

(b) The submissions

The first submission, alleging that the dossier does not contain sufficient evidence to conclude that paraquat has no harmful effects on animal life

229 It must be considered, first, whether, where the Commission examines an active substance under Article 5(1)(b) of Directive 91/414, it is required to assess all representative uses for the substance at issue, as communicated by the notifier.

230 It should be pointed out that according to recital 2 in the preamble to the contested directive, the effects of paraquat have been assessed in accordance with the provisions laid down in Regulation No 3600/92 for a range of uses proposed by the notifier.

231 In addition, in reply to a question from the Court at the hearing, the Commission stated that it was required to consider the use of paraquat as a herbicide for the 14 uses mentioned in Annex IV to the Commission's assessment report, that is to say, the use of paraquat on citrus fruit, treenuts and hazelnuts, apples, grapes, strawberries, olives, tomatoes and cucumbers, beans, potatoes, lucerne and fields of

autumn stubble, in spring land preparation, forestry and ornamentals and on non-crop land.

232 Consequently, it must be considered in the present case that the Commission based its conclusion that paraquat had no harmful effect on animal health on an assessment of the 14 uses envisaged by the notifier.

233 However, in assessing the effects of paraquat on hares and avian embryos, only two areas of use were considered: use in fields of autumn stubble with regard to hares and in fields of lucerne in autumn and winter with regard to birds.

234 Moreover, the Commission provides no reason why it was unnecessary to consider the other 12 representative uses of paraquat in order to assess the impact of that substance on hares and avian embryos.

235 Under those circumstances, the claim that the dossier did not contain sufficient evidence to conclude that paraquat had no harmful effect on the health of hares and avian embryos must be accepted.

236 Secondly, it must be considered whether it has been sufficiently established that the measures referred to by the Commission actually made it possible to reduce the risks of paraquat to the health of hares, something the Kingdom of Sweden contests.

237 The Commission alleges that the Scientific Committee and the notifier identified the measures likely to reduce the risks to hares, that the notifier claimed that those measures had been effective and that the rapporteur and the Standing Committee considered that the available information was sufficient to assess the impact of paraquat on the health of hares.

238 Those factors alone are not enough to support a finding that the effectiveness of the alleged measures has been established to the requisite legal standard.

239 It should be pointed out that the conclusion which the Scientific Committee draws in its opinion is that paraquat is likely to have lethal or sublethal effects on hares and that that was confirmed by the field studies. It should also be pointed out that the Scientific Committee reached that conclusion after taking account of the measures which the Commission contends will reduce the identifiable risk. Consequently, the effectiveness of the measures relied on may be sufficiently established only on the basis of new scientific data, different from those taken into account by the Scientific Committee. However, it must be stated that the Commission did not refer to any such data. It must therefore be considered that the Commission has failed to establish the effectiveness of the measures to which it refers.

240 It should also be pointed out that the measures which the Commission alleges are appropriate to reduce risks to hares — such as spraying paraquat early in the morning, adding a repellent, spraying from the centre of the field outwards or not spraying the whole field on the same day — are mentioned neither directly nor indirectly in the contested directive as specific provisions under Article 5(4) of Directive 91/414.

241 More specifically, the fact that the annex to the contested directive requires Member States to pay particular attention to the protection of hares and to carry out, if necessary, a risk and a risk management assessment cannot be regarded as a restriction on the use of paraquat under Article 5(4) of Directive 91/414 which has been shown, beyond a reasonable doubt, to enable it to be ensured that that substance is used in accordance with the requirements of Article 5(1) of Directive 91/414.

242 It follows that the submission must also be accepted in so far as it alleges that the Commission relied on a dossier which does not establish, to the requisite legal standard, that the measures cited will reduce the identifiable risks to hares.

243 Thirdly, the submission that the dossier contained insufficient evidence concerning the measures envisaged to reduce the risks to the health of birds will be considered together with the second and third submissions relied on under the present branch (see paragraph 252 below).

The second and third submissions, alleging, respectively, that the long-term toxicity/exposure ratio is inadequate, having regard to point C 2.5.2.1, and that the evaluation and management of risks to the health of avian embryos have been left to the Member States

244 In regard, first, to the long-term toxicity/exposure ratio, it can be seen from the Kingdom of Sweden's answer to a written question from the Court, which the Commission has not contested, that the expressions 'long-term toxicity/exposure ratio' and 'safety margin' mean the same thing. It may also be seen from that answer that, when assessing the risks to ground-nesting birds, the Commission relied upon studies which revealed negative effects on the hatching of eggs where those eggs had been exposed to a dose of paraquat corresponding to 2.24 kilograms of the substance per hectare sprayed, whereas the maximum recommended by the notifier is 1.1 kilogram of the substance per hectare. The Kingdom of Sweden concludes, without being contradicted by the Commission on that point, that the latter based itself on a safety margin of 2 and not 5, as required by point C 2.5.2.1 of Annex VI.

245 However, the choice of a safety margin lower than 5 is contrary to point C 2.5.2.1 of Annex VI only if it appears that no appropriate risk assessment has been carried out, establishing specifically that no unacceptable impact occurs after use of the plant protection product containing paraquat in accordance with the proposed conditions of use.

246 It must therefore be considered whether the Commission has shown that there is a use for paraquat in regard to which the risk of exposure for ground-nesting birds is acceptable, something which the Kingdom of Sweden contests both in the submission concerning failure to comply with point C 2.5.2.1 and in the first submission, alleging that the dossier contains insufficient evidence.

247 It its opinion, the Scientific Committee indicated that paraquat could be a threat to avian embryos but that additional information from realistic studies would have to be obtained in order to assess the risks.

248 It can be seen from the rapporteur's second report that additional information was provided by the notifier in the form of three studies dealing with the consequences of spraying paraquat on the eggs of Japanese quail (*Coturnix coturnix japonica*), mallard ducks and pheasants (*Phasianus colchicus*).

249 The rapporteur states in its second report that the studies mentioned in the previous paragraph indicate that spraying the eggs of mallard duck and pheasant with paraquat at twice the application rate resulted in an overall reduction in the egg hatchability for those eggs. The rapporteur also states that some of the uses envisaged by the notifier pose a negligible risk to avian embryos due to the period of use or the improbability of nesting in the forms of cultivation to which paraquat might be applied, but that some of the forms of cultivation envisaged may constitute a suitable habitat for ground-nesting birds. However, the rapporteur makes clear that it has no information available to it to indicate whether such forms of cultivation are in fact used by ground-nesting birds or to what extent. The rapporteur adds that such information will be specific to each Member State and hence the risk should be determined at Member State level.

250 The contested directive expressly indicates that the evaluation within the Standing Committee concluded that the risk would be acceptable, provided that appropriate risk-mitigation measures were applied.

251 In the light of the foregoing, it must be held that the Commission has relied on no specific measure which can be shown to justify, beyond a reasonable doubt, the inclusion of paraquat in Annex I to Directive 91/414 while complying with the requirements of Article 5(1)(b) of that directive in regard to bird health.

252 It follows that, at the time when paraquat was included in Annex I to Directive 91/414, it had not yet been specifically established that paraquat did not have an unacceptable impact on the health of avian embryos, since only measures yet to be adopted by the Member States could render that risk acceptable. The submission alleging failure on the Commission's part to comply with the requirements of point C 2.5.2.1 of Annex VI must therefore be accepted. The same is true in regard to the submission that the dossier contained insufficient evidence to justify the inclusion of paraquat in Annex I to Directive 91/414 while complying with the requirements of Article 5(1)(b) of that directive in regard to bird health. Finally, it also follows from the foregoing that the submission that, contrary to Article 5 of Directive 91/414, assessment and management of the risks to avian embryos were left to the Member States, must be accepted.

The fourth submission, alleging unacceptable suffering caused to animals exposed to paraquat

253 It should be pointed out that the Kingdom of Sweden starts from the premiss that the second indent of Article 4(1)(b)(v) of Directive 91/414, which requires that there should be no unacceptable influence on the environment, having particular regard to the impact of a product containing the active substance on non-target species, is

relevant for the purposes of assessing whether the requirements laid down in Article 5(1)(b) of that directive have been fulfilled in regard to animal health.

254 However, that is not the case. Article 5(1) of Directive 91/414 draws a distinction between, on the one hand, human or animal health, in respect of which the existence of harmful effects is not tolerated, and, on the other, the environment, in respect of which only unacceptable influences are excluded. Similarly, Article 4(1)(b) of Directive 91/414 deals separately with the question of harmful effects on human or animal health (Article 4(1)(b)(iv) of the directive) and the question of unacceptable influence on the environment (Article 4(1)(b)(v) of the directive). It follows from the structure of Articles 4 and 5 of Directive 91/414 that where an active substance is to be assessed from the point of view of the protection of animal health under Article 5(1)(b) of that directive, the reference which that provision makes to Article 4(1)(b) applies only to the provisions of Article 4(1)(b) which deal specifically with animal health, namely Article 4(1)(b)(iv).

255 Consequently, by reason of the fact that Article 4(1)(b)(iv) of Directive 91/414 already deals specifically with the question of the effects of a product containing the active substance on animal health, the second indent of Article 4(1)(b)(v) thereof, concerning the absence of an unacceptable influence on the environment having regard to the impact on non-target species, is not relevant when assessing whether a substance fulfils the requirements of Article 5(1)(b) of the directive in regard to the impact on non-target species.

256 It should be added that, in any event, even supposing that the second indent of Article 4(1)(b)(v) of Directive 91/414 applied to an assessment as to whether the requirements of Article 5(1)(b) of the directive in regard to animal health are satisfied, Sweden's submission cannot be accepted.

257 It is true that if the second indent of Article 4(1)(b)(v) of Directive 91/414 applied, it would be necessary to consider whether that provision required that no unnecessary suffering or pain be caused to non-target species by the product containing the active substance in question. Once it is accepted, as the Kingdom of Sweden claims, that Article 4(1)(b)(iii) of Directive 91/414 prohibits a product which causes unnecessary suffering and pain to vertebrates to be controlled then, a fortiori, animals which the product in question is not intended to control must enjoy at least equivalent protection.

258 However, the Kingdom of Sweden has not put forward a single argument leading to the conclusion that paraquat causes unnecessary suffering and pain to hares and merely indicates that since paraquat causes such pain and suffering in humans, it must be deemed to cause identical effects on mammals such as hares, on which it is common ground that paraquat causes lethal or sublethal effects.

259 Even if it is probable that animals exposed to fatal doses of paraquat endure great pain and severe suffering, it does not necessarily follow that that pain and suffering prove that the provisions of Article 4 expressly relied on by the Kingdom of Sweden in connection with this claim have been infringed. Unlike Article 4(1)(b)(iv) of Directive 91/414, which permits no harmful effects, whether direct or indirect, to be caused to animal health by the product containing the active substance, Article 4(1)(b)(iii) and (v) of that directive merely prohibits suffering and pain which are of an unacceptable character. It follows that those provisions are infringed only if it is established that the limits of what is acceptable have been exceeded, something which the Kingdom of Sweden has not established in this case. Thus, the Kingdom of Sweden has neither indicated the limit beyond which suffering or pain becomes unacceptable nor that that limit has been exceeded in the present case.

260 Consequently, in the absence of any factor supporting the claim that exposure to paraquat causes unacceptable suffering or pain to hares, the fourth submission cannot be accepted.

261 It follows that, with the exception of the fourth submission, the second branch concerning the protection of animal health must be accepted.

262 In the light of the foregoing and of the conclusion drawn in paragraph 191 above, both branches of the set of pleas in law alleging infringement of Article 5 of Directive 91/414, breach of the principle of integration, breach of the precautionary principle and breach of the principle that a high level of protection should be ensured must be substantially accepted.

263 Since both sets of pleas in law have been upheld, at least in part, the contested directive must be annulled.

Costs

264 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In addition, under Article 87(4) of the Rules of Procedure, the Member States which intervened in the proceedings are to bear their own costs.

265 Since the Commission has been unsuccessful, it must be ordered to bear its own costs and to pay those of the Kingdom of Sweden in accordance with the latter's pleadings.

On those grounds,

THE COURT OF FIRST INSTANCE
(Second Chamber, Extended Composition)

hereby:

1. Annuls Commission Directive 2003/112/EC of 1 December 2003 amending Council Directive 91/414/EEC to include paraquat as an active substance;

2. Orders the Commission to bear its own costs and to pay those of the Kingdom of Sweden;

3. **Orders the Kingdom of Denmark, the Republic of Austria and the Republic of Finland to bear their own costs.**

Pirrung Meij Forwood

Pelikánová Papasavvas

Delivered in open court in Luxembourg on 11 July 2007.

E. Coulon J. Pirrung

Registrar President

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