

RULING BY THE TRIBUNAL [COURT OF FIRST INSTANCE] (Second Chamber, Extended Composition)

11 July 2007*

"Directive 91/414/EEC – Phytopharmaceutical products – Active substance '*paraquat*' – Authorisation to place on market – Authorisation procedure – Protection of human and animal health"

In Case No. T-229/04,

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

the Petitioner,

supported by

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

by

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

and by

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

the Intervening Parties,

versus

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

the Defendants,

*Language of the proceedings: Swedish

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RULING DATED 11 JULY 2007 – CASE T-229/04

in dealing with a request to declare null and void the Commission's Directive 2003/112/CD dated 1 December 2003, which amended Council Directive 91/414/EEC by registering the active substance *paraquat* therein (JO L 321, p. 32),

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

composed of Messrs. J. Pirrung, the Presiding Judge, A. W. H. Meij, N. J. Forwood, Ms. I. Pelikánová and Mr. S. Papsavvas, Judges,

The Registrar: Ms. C. Kristensen, Administrator,

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

has issued this

Ruling

Legal background

I - Treaty provisions

- 1 Article 6 EC stipulates that environmental protection requirements must be integrated into the Community's definition and implementation of the policies and actions stipulated in Article 3 EC, particularly with regard to promoting sustainable development.
- 2 Article 152, Paragraph 1 EC provides that a high level of protection for human health must be ensured in the definition and implementation of all the Community's policies and actions.
- 3 Article 174, Paragraph 2 EC stipulates that the Community's environmental policy is aimed at providing a high level of protection, taking into account the differing circumstances in different parts of the Community. This provision likewise states that the Community's environmental policy is based on the Precautionary Principle.
- 4 According to Article 174, Paragraph 3 EC, the Community must consider available scientific and technical data in developing its environmental policy.

II - Directive 91/414/EEC

- 5 Preamble, Recital 9 of Council Directive 91/414/EEC dated 15 July 1991 concerning the bringing to market of phytopharmaceutical products (JO L 230, p. 1), declares that the provisions governing the authorisation

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of phytopharmaceutical products must ensure a high level of protection; in particular, this means that authorisation should not be given to those phytopharmaceutical products on which no relevant analyses of the attendant risks to health, groundwater and the environment have been performed. This preamble recital likewise indicates that the goal of improving crop production may not take priority over human health and the environment.

- 6 Article 2 of Directive 91/414 defines as phytopharmaceutical products, in particular, those active substances and preparations containing one or more active substances that are presented in the form in which they are supplied to the user and which are intended to destroy undesired plants. This article defines the active substances as substances or microorganisms with a general or specific effect on pests or plants, parts of plants or plant products.

- 7 Article 4, Paragraph 1 of Directive 91/414 stipulates:

"The Member States shall ensure that a phytopharmaceutical product is authorised only:

- a) if the active substances are listed in Annex I and if the conditions applying to said Annex have been met and, with respect to Points b), c), d) and e), the uniform principles listed in Annex VI shall apply;
- b) if the existing scientific and technical know-how, as well as the results of an analysis of the data package, as stipulated in Annex III, establish that, when administered in accordance with the provisions of Article 3, Paragraph 3 and with regard to all normal conditions under which it might be used and the ramifications of its use:

[...]

- iii) it will not lead to unacceptable pain and suffering by the vertebrates it is designed to combat;
- iv) it does not produce any direct or indirect harmful effects on human or animal health (for example via drinking water or food destined for human or animal consumption) or on groundwater;
- v) it does not have an unacceptable impact on the environment, in particular with regard to the following effects:
 - [...]
 - its impact on non-target species;

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[...]"

8 Under the terms of Article 5, Paragraph 1 of Directive 91/414:

"1. Given the existing scientific and technical know-how, an active substance shall be registered in Annex I for an initial period not to exceed ten years, if it is expected that the phytopharmaceutical products containing this active substance will meet the following conditions:

- a) when administered in accordance with phytosanitary best practices, their residue will not produce any harmful effects on human or animal health or on groundwater or have an unacceptable impact on the environment and, to the extent they may be significant from a toxicological or environmental standpoint, they can be measured using current methods;
- b) when administered in accordance with phytosanitary best practices, they will not produce any harmful effects on human or animal health or have an unacceptable impact on the environment, in accordance with Article 4, Paragraph 1, subsection b), iv) and v)."

9 Article 5, Paragraph 4 of Directive 91/414 provides that "[1] Registration of an active substance in Annex I may be subject to requirements such as [notably...] limitations resulting from the analysis of the data mentioned in Article 6, taking into account farming conditions, phytosanitary conditions and environmental conditions, including climatic conditions and the conditions examined, [...] and] the type of use."

10 Article 6 of Directive 91/414 provides, in particular, that the registration of an active substance in Annex I to said Directive shall be decided in accordance with the procedure stipulated in Article 19 of the same Directive. Article 19 of Directive 91/414, as amended by Council Regulation (EC) No. 806/2003 dated 14 April 2003, concerning an adjustment to reflect Decision 1999/468/EC on the provisions relating to the committees assisting the Commission in exercising the implementing powers conferred on the Commission by legislative acts of the Council adopted in accordance with the consultation procedure (qualified majority) (JO L 122, p. 1), provides that the Commission shall be assisted by a regulatory committee, the Standing Committee on Food Chain and Animal Health (hereinafter referred to as the "Standing Committee").

11 Article 8 of Directive 91/414 specifies that the Commission shall undertake a program of work for the gradual examination of certain active substances.

12 Annex II to Directive 91/414 defines the conditions that must be met in order to submit the data package relating to registration of an active substance in Annex I to Directive 91/414. The introduction to this Annex II indicates that the required information includes, in particular, a technical specifications data package containing, on the one hand,

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the information necessary for assessing the foreseeable, immediate or more long-term risks that the substance may pose to humans, animals and the environment and, on the other hand, the results of the studies, several of which are mentioned below, and a complete and impartial report on the studies conducted, along with a complete description of them, or, if certain data or specific pieces of information appear to be unnecessary or cannot be provided, this must be substantiated in a way acceptable to the competent authority.

- 13 It follows from Point 5.7 of Part A of Annex II to Directive 91/414 that studies of delayed-type neurotoxicity – designed to provide sufficient data to examine whether the active substance could cause delayed neurotoxicity following acute exposure – should be carried out on substances that have a similar structure or which are likely to induce delayed neurotoxicity, such as organophosphates.
- 14 Annex VI to Directive 91/414 (hereinafter referred to as "Annex VI") contains uniform principles to ensure that the Member States apply the requirements stipulated in Article 4, Paragraph 1, subsections b) through e) of said Directive consistently and with the level of vigour intended by this same Directive to protect human and animal health and the environment. Pursuant to Article 18, Paragraph 1 of Directive 91/414, the uniform principles were originally adopted by Council Directive 94/43/EC dated 27 July 1994, which established Annex VI (JO L 227, p.31). This Directive was annulled by a Court of Justice ruling on 18 June 1996, *Parliament versus Council* (in Case C-303/94, ECR p. I-2943). The Council then adopted Directive 97/57/EC dated 22 September 1997, establishing Annex VI (JO L 265, p. 87).
- 15 Point A2, subsection c) of Annex VI stipulates:

"In evaluating applications and granting authorisations, Member States shall [...] take into account other technical or scientific information which may reasonably be expected to be available to them that is relevant to the performance of the phytopharmaceutical product or to the potentially harmful effects of the phytopharmaceutical product, its components or its residues."
- 16 Under the terms of Point C 2.4.1.1 of Annex VI, "it shall not be authorised if the level of operator exposure when handling and administering the phytopharmaceutical product under the proposed conditions for use (and, in particular, the dose and application method) exceeds the [acceptable operator exposure level]".
- 17 In particular, Point C 2.5.2.1 of Annex VI stipulates that no authorisation shall be granted in the event of potential exposure of non-target birds and other terrestrial vertebrates if the long-term toxicity/exposure ratio is below 5, unless a suitable risk assessment specifically determines that there is no unacceptable

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impact following use of the phytopharmaceutical product under the proposed conditions.

III – Regulation (EEC) No. 3600/92

- 18 Article 4 of Commission Regulation (EEC) No. 3600/92 dated 11 December 1992, which established the methods for implementing Phase 1 of the work programme stipulated by Article 8, Paragraph 2 of Directive 91/414 (JO L 366, p.10) provides, in particular, that all manufacturers wishing to have an existing active substance included in Annex I to Directive 91/414 must notify the Commission of such wish.
- 19 Under Article 5, Paragraph 2 of Regulation No. 3600/92, the Commission shall establish a list of the active substances for which analysis applications have been filed and shall designate a "Rapporteur Member State" to evaluate each active substance.
- 20 In essence, Article 6 of Regulation No. 3600/92 provides that the Notifying Parties submitting the notification stipulated in Article 4 of the same Regulation must send a summary data package and a complete data package to the Rapporteur Member State's designated authority for a defined active substance.
- 21 It follows from Article 6, Paragraph 2 of Regulation No. 3600/92 that the summary data package shall include, in particular, a copy of the notification, the conditions for use recommended as part of the registration of the active substance in Annex I of Directive 91/414 and the available test summaries and test results, as well as the name of the person or the institute that performed the tests, on the one hand, for each point in Annex II to Directive 91/414 and, on the other hand, for each point in Annex III to this same Directive that is relevant to assessing the criteria mentioned in Article 5 of said Directive; this applies to one or more preparations that is/are typical under the recommended conditions for use.
- 22 Article 6, Paragraph 2 of Regulation No. 3600/92 further specifies that, if the test summaries or test results are not available, the data package must contain either the scientific or technical items proving that such data are not necessary to evaluate 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 to this Directive, or a commitment by the manufacturer or manufacturers submitting the data package to forward the missing information later, in accordance with a detailed schedule.
- 23 Article 6, Paragraph 3 of Regulation No. 3600/92 indicates that the complete data package must contain the minutes and the complete study reports relating to all the data referred to in Article 6, Paragraph 2, subsection c) of Regulation No. 3600/92.
- 24 Subsection a) of Article 7, Paragraph 1 of Regulation No. 3600/92 stipulates that, for each active substance for which a Member State has been designated as a Rapporteur Member State,

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the latter must, in particular, examine the data packages referred to in Article 6, Paragraphs 2 and 3 of Regulation No. 3600/92. Pursuant to Point b) of this same paragraph, immediately after examining a data package, the Rapporteur Member State shall see to it that the authors of the data package submit an updated summary data package to the other Member States and to the Commission.

- 25 Article 7, Paragraph 1, subsection c) of Regulation No. 3600/92 requires that the Rapporteur Member State send to the Commission an evaluation report on the data packages referred to in Article 6, Paragraphs 2 and 3 of Regulation 3600/92; the report must either recommend that the active substance be registered in Annex I to the Directive and indicate the conditions for such an entry, or recommend that the active substance be withdrawn from the market, or recommend that the active substance be temporarily withdrawn from the market, with the possibility of reviewing the inclusion of said substance in Annex I following notification of the results of additional tests or additional information specified in the report, or recommend once again postponing any decision concerning a possible registration pending notification of the additional test results or information specified in the report.
- 26 Pursuant to Article 7, Paragraph 2 of Regulation No. 3600/92, as soon as it has initiated its investigation, the Rapporteur Member State may ask the Notifying Parties to improve or add to their data packages. In addition, from the start of such investigation, the Rapporteur Member State may consult with experts from other Member States or request that they provide additional scientific or technical data to facilitate the evaluation.
- 27 Article 7, Paragraph 3 of Regulation No. 3600/92 stipulates that, once it has received the report from the Rapporteur Member State, in particular, the Commission shall confer on the Standing Committee the assignment to examine the data package and the report from the Rapporteur Member State. This provision also indicates that, before sending the data package and the report to the Standing Committee, the Commission must distribute the report from the Rapporteur Member State to the other Member States, for their information.
- 28 In essence, Article 8, Paragraph 1 of Regulation No. 3600/92 provides that, once it has received the additional test results or additional information, the Rapporteur Member State must examine these data, ensure that the Notifying Party sends a summary of the additional tests and the results of these tests or the additional data to the other Member States and to the Commission and must itself send to the Commission its evaluation of these data in the form of an addendum to the evaluation report. This report must also be submitted to the Standing Committee.

Background to the dispute

I – Proceeding that led to the adoption of Directive 2003/112/EC

- 29 *Paraquat* (Translator's Note: toxic herbicide) is an active substance. It is a constituent part of one of the three most widely used herbicides in the world. It acts as a broad-spectrum, non-selective herbicide which is particularly active against weeds. It destroys the green parts of the plant by drying out the foliage. It does not attack the root system. The abortive, destructive action is localised to the spot where it is applied to the product. It is used on more than 50 crop types in more than 120 countries and has been sold as an herbicide for more than 60 years.
- 30 This substance has been banned in thirteen countries, including Sweden, Denmark, Austria and Finland.
- 31 In July 1993, several manufacturers of *paraquat*, including the Zeneca Company, the rights and obligations of which were later assumed by the Syngenta Company (hereinafter referred to as the "Notifying Party"), notified the Commission that they wished to have this active substance registered in Annex I to Directive 91/414, pursuant to Article 4 of Regulation No. 3600/92.
- 32 Pursuant to Commission Regulation (EC) No. 933/94 dated 27 April 1994, which established the list of active substances in phytopharmaceutical products and designated the Rapporteur Member States to enforce Regulation No. 3600/92 (JO L 107, p.8), the United Kingdom of Great Britain and Northern Ireland was designated as the Rapporteur Member State (hereinafter referred to as the "RMS") for the active substance *paraquat*.
- 33 The Notifying Party sent to the RMS a data package relating to the registration of *paraquat* and on 31 October 1996, the RMS submitted a preliminary report on its investigation to the Commission (hereinafter referred to as "preliminary report"). In this preliminary report, the RMS suggested that the decision on including *paraquat* in Annex I to Directive 91/414 be suspended until it received the additional data relating, in particular, to the impact of the active substance on bird reproduction and on the toxicity to hares of the active substance. In addition, the RMS proposed certain conditions concerning the possible registration of *paraquat* in Annex I to Directive 91/414.
- 34 The Commission sent the preliminary report to the Member States and to the Notifying Party, requesting their comments.
- 35 Both the preliminary report and the data package were examined by a group of experts, the European Commission Co-ordination (ECCO), created by the Commission in 1996. This examination took the form of consultations with technical experts from certain Member States which were held by the Commission between April and July of 1997. These experts were asked for their opinions on various aspects of the

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substance *paraquat*. The viewpoints investigated and the results of this group's meetings were recorded in a report (hereinafter referred to as the "ECCO investigation report"). This report was sent to the Member States and to the Notifying Party for comments and, where applicable, for clarifications.

- 36 In May 2000, the RMS set up an addendum to the preliminary report that specifically contained its observations concerning the exposure to *paraquat* of the users, hares and birds.
- 37 The data package, the preliminary report, including its addendum, the ECCO investigation report and the comments and clarifications received were sent to the Standing Committee for its assessment. The Standing Committee conducted its investigation from June 2000 until July 2003.
- 38 The Commission likewise chose to send the documents mentioned in the preceding point to the Scientific Committee on Plants created by its Decision 97/579/EC on 23 July 1997, which established scientific committees covering consumer health and food safety (JO L 237, p. 18, hereinafter referred to as the "Scientific Committee"), with the aim, in particular, of obtaining its opinion on operator risks, especially considering exposure through inhalation and skin contact, as well as concerning the risks such use posed to bird and hare reproduction. The Scientific Committee issued its opinion on 20 December 2001. Following this opinion, the Notifying Party sent some additional data.
- 39 In September 2002, the RMS presented a report containing its comments on the Scientific Committee's report and on the additional data sent by the Notifying Party (hereinafter referred to as the "RMS's second report").
- 40 During the *paraquat* evaluation process, some of the comments and arguments submitted by the various Intervening Parties were synthesised and incorporated into an evaluation table.
- 41 The *paraquat* evaluation procedure aimed at including *paraquat* in Annex I to the Directive was closed when the Standing Committee met on 3 October 2003. The conclusions reached at that meeting are described in the Commission's investigation report.

II – Directive 2003/112/EC

- 42 On 1 December 2003, the Commission adopted Directive 2003/112/EC, amending Directive 91/414 by registering the active substance *paraquat* (JO L 321, p. 32, hereinafter referred to as the "disputed Directive"). Preamble, Recital 4 of the disputed Directive is worded as follows:

"The report on the *paraquat* and the additional data were [...] submitted to the Scientific Committee [...] [This] committee was asked to draw up an opinion

on [...] operator risk, in particular taking into account possible skin exposure and exposure through inhalation, [...] and the risk that the proposed uses could pose for bird and hare reproduction [...] Based on the studies relating to ground exposure, substantiated by information derived from the medical supervision of the operators, the Committee determined that when the *paraquat* is used as a phytopharmaceutical product following recommended best practices, its use does not pose any significant risk to the operators' health [...] Moreover, the Scientific Committee decided that the available studies do indicate a risk to ground-nesting birds, but that additional data concerning realistic exposure were required in order to make a definitive risk assessment. This information was then submitted to the Standing Committee, whose own assessment [...] concluded that, in many cases, the exposure for ground-nesting birds was negligible. However, there are also some scenarios in which exposure may occur. The assessment conducted by the Standing Committee [...] concluded that the risk might be acceptable, provided that appropriate steps were taken to mitigate the risks. Finally, the Scientific Committee determined that the *paraquat* could cause lethal and sublethal effects on hares, but that the available data were not adequate to evaluate the percentage of hares affected. The Scientific Committee's observations were taken into account in drawing up this Directive and the investigation report. The assessment carried out by the Standing Committee [...] concluded that the risk might be acceptable, provided that appropriate steps were taken to mitigate the risks."

43 Preamble, Recital 5 of the disputed Directive reads as follows:

"The various investigations conducted have shown that certain uses of phytopharmaceutical products containing *paraquat* may, in general, meet the requirements stipulated in Article 5, Paragraph 1, subsections a) and b) of Directive 91/414, provided that appropriate steps and restrictions are taken to mitigate the risks. Therefore, it is advisable that *paraquat* be registered in Annex I in order to guarantee that all Member States authorise pharmaceutical products containing this active substance in accordance with the provisions of the Directive. However, certain uses of phytopharmaceutical products containing *paraquat* may pose an unacceptable risk and consequently may not be authorised. Moreover, it was considered appropriate to ensure that the Member States require that the Notifying Party and any other entity holding a permit for *paraquat* set up a management programme, in particular to cover operator safety and to report to the Commission annually concerning negative effects on operator health, as well as any effects on hares. This should make it possible to determine whether the measures imposed by the Member States to mitigate the risks are actually limiting possible risks to operators and hares to an acceptable level and, where applicable, to conduct a

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re-assessment of the properties and associated potential risks to humans and the environment, in line with scientific progress.

- 44 Under the terms of Article 1 of the disputed Directive, "Article [1] of Directive 91/414 has been amended in accordance with the Annex to this Directive". Besides including *paraquat* in Annex I to Directive 91/414, the annex to the disputed Directive states, under the heading "Specific Provisions":

"Only uses as an herbicide may be authorised.

The following uses may not be authorised:

- home-gardening applications using knapsack and hand-held sprayers, whether carried out by amateurs or professionals;
- applications using hydraulic sprayers, air-blast sprayers and lateral hydraulic sprayers;
- ultra-low-volume applications.

When implementing the uniform principles stipulated in Annex VI, consideration shall be given to the conclusions contained the investigation report [from the Commission] concerning *paraquat* and, in particular, in Annexes I and II to the report, in the form finalised by the Standing Committee [...] on 3 October 2003. As part of this general assessment, the Member States must pay special attention to protecting:

- operators, particularly in applications using knapsack and hand-held sprayers;
- ground-nesting birds [;] when the usage scenarios indicate potential exposure of eggs, a risk assessment must be performed and, where necessary, steps must be taken to mitigate the risks;

[...]

- hares [;] when the usage scenarios indicate potential exposure of hares, a risk assessment must be carried out and, where necessary, steps must be taken to mitigate the risks.

The Member States shall see to it that the permit holders report negative effects on operator health and any effects on hares within one or more typical usage areas by 31 March of each year, at the latest, until 2008; these data must be supplemented by sales data and a survey of the types

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of use, in order to provide a realistic picture of the toxicological and environmental impact of *paraquat*.

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

At the same time, they must take into account the FAO specifications."

Procedure

- 45 The Kingdom of Sweden initiated this action in a petition filed with the Court Registry on 27 February 2004. This action was registered with the Court Registry under Number C-102/04.
- 46 In a ruling dated 8 June 2004, the Court of Justice remanded the case to the Court of First Instance (Tribunal), citing Council Decision 2004/407/EC, Euratom, dated 26 April 2004, concerning the amendment of Articles 51 and 54 to the Protocol of the Statute of the Court of Justice (JO L 132, p.5). The case was then registered with the Tribunal's Registry under Number T-229/04.
- 47 In applications filed with the Tribunal's Registry on 17 June 2004, the Kingdom of Denmark and the Republic of Finland asked to intervene in this procedure in support of the submissions by the Kingdom of Sweden. The Republic of Austria presented the same request in an application filed with the Tribunal's Registry on 21 June 2004. The Presiding Judge of the Tribunal's Second Chamber issued an order on 15 December 2004 allowing these interventions. The Intervening Parties filed their written statements and the other parties filed their comments regarding these within the established time limits.
- 48 Under Article 14, Paragraph 1 of the Tribunal's Rules of Procedure and at the suggestion of the Second Chamber, the Tribunal decided, after hearing the Parties, and in line with Article 51 of said Rules of Procedure, to remand the case to the Second Chamber, Extended Composition.
- 49 After reading the report of the Judge-Rapporteur, the Tribunal (Second Chamber, Extended Composition) decided to open the oral proceeding.
- 50 As part of the organisational steps for the proceeding stipulated in Article 64 of the Rules of Procedure, the Tribunal, pursuant to a request to that effect from the Kingdom of Sweden, asked the Commission to produce a document which the latter has labelled the "French Study" and also submitted written questions to the Parties asking them to respond to certain of these questions, in writing, before the hearing. The Commission complied with the request to conduct the French Study.

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The Parties submitted their written answers to the questions within the established time limits.

- 51 The Parties' pleadings and their responses to the written questions and the oral questions posed by the Tribunal at the hearing on 3 October 2006 have been heard.

Forms of order sought by the Parties

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

- annul the disputed Directive;
- order the Commission to pay the expenses incurred.

- 53 The Commission claims that the Tribunal should:

- reject the application;
- order the Kingdom of Sweden and the Kingdom of Denmark, the Republic of Austria and the Republic of Finland to pay the expenses incurred.

In law

- 54 To support its petition, the Kingdom of Sweden, supported by the Intervening Parties, is making two groups of arguments. The arguments in the first group are procedural in nature and are based on the violation of Article 7 of Regulation No. 3600/92, Article 5 of Directive 91/414 and Article 174, Paragraph 3 EC. The arguments in the second group are based on the violation of Article 5 of Directive 91/414, the integration requirement principle, the requirement for a high level of protection of the environment and human health and the Precautionary Principle.

- 55 The Commission disputes the validity of each of these groups of arguments.

- 56 Moreover, the Parties have also pressed claims concerning issues surrounding the scientific data package relating to *paraquat*, whereby the Kingdom of Sweden indicated at the hearing that these served as a factual basis for the pleas and arguments explicitly raised in the written statements – and this point was not contradicted by the Commission.

I – Regarding the scientific dossier relating to paraquat

A – General points

- 57 The Kingdom of Sweden wishes to argue that paraquat is the most dangerous substance to health – in terms of acute toxicity – that has ever been added to appendix 1 of directive 91 / 414, as the lesions caused by this substance are irreversible. With regard to this point, WHO states that when paraquat enters the body or is disseminated in a concentrated form through the skin, it will, after a certain period of time, cause serious, if not lethal side effects.
- 58 The Kingdom of Sweden wishes to stress the fact that the ingestion of 2 centilitres of a concentrated paraquat solution is lethal. A study relating to deaths from pesticide poisoning in England and Wales between 1980 and 1991 (hereinafter referred to as the “ Thompson study ”) would tend to show that fatal accidents took place during that period as of 1980 in spite of the risk prevention measures taken by the author of the notification. These measures would therefore fail to eliminate an unacceptable risk of exposure to the substance which, in turn, could lead to irreversible lesions or the death of the victims.
- 59 With regard to the risks associated with the inhalation of the substance, the Kingdom of Sweden maintains that the study carried out by using very accurate measuring methods has shown that normal long-term use of paraquat could affect the capacity to absorb oxygen (referred to hereinafter as “ the Dalvie study ”) .
- 60 The Kingdom of Sweden wishes to add that these lethal intoxications via skin exposure have been recorded. For example, a study indicates that a user can suffer fatal exposure after spraying with a non-waterproof device for three and a half hours (hereinafter the “ the Wesseling study ”) . On this matter, the Republic of Finland puts forward the case of an operator whose trousers were stained with paraquat while he was transferring the liquid. He waited for 48 hours to wash off the stain. Ten days after the incident his pulmonary activity ceased altogether and he died on the fifteenth day after the incident. The Wesseling study also indicates that there are correlations between the long-term use of paraquat and skin cancer.
61. The Commission responds that far from being the most toxic substance included in annex 1 of Directive 91/414, Paraquat is considered to be a substance which the WHO considers to be moderately toxic.
- 62 With regard to the risks associated with the ingestion of this substance, it appears that, on the basis of the data relating to cases of ingestion in the United Kingdom between 1980 and 1991, and which are listed in the preliminary report and to which the Kingdom of Sweden refers, the number of unintentional ingestions and deaths has steadily decreased and, except for two suspicious cases in 1987, no deaths have been recorded in the United Kingdom since 1983 although sales volumes of products containing

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paraquat have steadily increased. The study continues to show that the Thompson study limits itself to point out that 33 deaths out of 3,978 cases were caused by pesticides containing paraquat and that most of the cases in question were suicides.

- 63 As for the consequences of inhaling paraquat, the Commission notes that routine pulmonary function tests have made it possible to show that the side effects do not concern the respiratory function in case of long-term exposure to paraquat, but, in fact, paraquat affects the capacity to absorb oxygen. It goes on to show that according to the results deduced from the Dalvie study, the effects on the respiratory tract in the case of long - term exposure to low concentrations of paraquat have not yet been demonstrated and that this study has not made it possible to establish a link between long-term exposure to paraquat and the symptoms in question.
- 64 Finally, with regard to the consequences of skin exposure to paraquat, the Commission sustains that the Wesseling study clearly states 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 considered safe by most of the control authorities. This study refers to a fatal accident whereby the rucksack containing paraquat was not waterproof. In respect of this, the Commission argues that within the European Community, it is mandatory to wear protective clothing while spraying phytopharmaceutical products containing paraquat. Therefore the Wesseling study loses its relevance in this case, as it refers to an atypical situation. This study does not indicate either that there is a link between the use of paraquat over a long period of time and skin cancer. Moreover, WHO does not consider paraquat as a cancerogenic substance.

B – Regarding the link between exposure to paraquat and Parkinson's disease

- 65 The Kingdom of Sweden wishes to argue that, in the literature concerning the neurotoxicity of paraquat, there are indications that there is a link between the use of this substance and the onset of Parkinson's disease, which is a neurodegenerative disease in humans, even if the existence of an undisputed link between the use of paraquat and this disease has not been proved. Thus, a study carried out on mice in 2002 indicates that paraquat can cause lesions to the nervous system and that these lesions are considered to be characteristic of Parkinson's disease (hereinafter referred to as the “ McCormack ” study). Moreover, a study carried out in the nineties highlights the link between exposure to paraquat and the onset of Parkinson's disease (hereinafter referred to as “ the Hertzman study ”).
- 66 The Commission maintains that, in fact, no possible or potential link between paraquat and Parkinson's disease has ever been established. Therefore, the Hertzman study constitutes a retrospective study that looked for risk factors linked to the environment in the case of Parkinson's disease and that indicated that the

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risk factor increases in the case of persons who have worked in fruit orchards or planing mills.

- 67 The McCormack study concerns newly-born mice brought up with a view to them being prone to developing Parkinson's disease, and which were injected with massive doses of paraquat. This study is not relevant, from a toxicology point of view, to human health as it does not reflect a realistic exposure, even from the perspective of the most unfavourable scenario involving the use of paraquat. In respect of the above-mentioned, the Commission maintains that the injected doses were a thousand times higher than the average daily dose and two thousand times higher than the acceptable exposure levels for operators (hereinafter referred to as " NAEO "). This study, which was conceived to assess the risk to which users are exposed while using paraquat under realistic conditions, actually focuses more on the assessment of the danger that paraquat may pose rather than on risk assessment.
- 68 Moreover, a close look at existing literature shows that there is no link between the use of paraquat and Parkinson's disease. On this point, the Commission specifically refers to a study of scientific literature carried out in 2001 for the Advisory Committee on Pesticides (United Kingdom) (hereinafter referred to as " the Dewhurst examination "). This is also found in other epidemiology studies mentioned in a memorandum produced by the author of the notification and which was circulated during the meeting of the standing committee in July 2003.

C – Regarding the mathematical modelization and the field studies relating to the risk arising from the use of paraquat by operators

- 69 The Kingdom of Sweden maintains that the mathematical modelizations and field studies relating to the use of paraquat show that such use is a source of risks.
- 70 First of all, with regard to the modelizations, the Commission maintains that they unequivocally indicate that users' exposure to paraquat exceeds the NAEO. On this point, it makes it clear that according to the two modelizations used to calculate professional users' exposure to paraquat, taking into account the existence or absence of protective equipment to be used by staff as well as the various methods used while handling the substance (using knapsack type sprayers or using a tractor) the exposure suffered by these users exceeds the set threshold by 4 to 100 times. The values calculated are 20 to 100 times greater than the NAEO when workers not wearing protective clothing used knapsack type sprayers whereas when gloves were used while manipulating and spraying the substance, the values are approximately 60 times higher than the NAEO. Finally, even when using gloves, respiratory protection, protective clothing, wide brim hats and sturdy shoes, the level of exposure still remains higher than the NAEO.

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- 71 Secondly, with regard to field studies, the Kingdom of Sweden wishes to argue that these indicate the existence of exposure levels higher than the NAEO.
- 72 Also, a study carried in Sri Lanka , in which users were not wearing protective equipment, shows, according to the rudimentary analysis methods, that the quantities absorbed through the skin were 8 to 18 times greater than the NAEO. The corresponding assessment based on a urine test showed exposure levels 2 to 8 times greater than the NAEO.
- 73 A study carried out in 1996 in Guatemala on 20 persons that had used protective equipment indicates that one of the users had been subjected to an exposure level equivalent to 118% that of the NAEO in spite of wearing his protective equipment (hereinafter referred to as the “ Guatemalan study ”). Moreover, there is a mention of the fact that another user also wearing his protective clothing had been subjected to a level of exposure equivalent to 92.8% of the threshold whereas, according to the terms of study, the user in question had used utmost caution to apply the product.
- 74 The Guatemalan study is relevant in the sense that the spraying method is applicable to Europe. In this respect, the Kingdom of Sweden wishes to argue that even if the high level of exposure revealed in this study stems from the fact that the user in question had sprayed the product in question on a hilly site, a similar scenario could very well arise in Europe as paraquat is used particularly in vineyards and olive groves, 2.5 million hectares of which are located on hilly sites.
- 75 A study carried out in 1997 in a citrus fruit plantation in Spain and which concerned 20 users benefiting from protective equipment shows that the average exposure reached 15% of the threshold, that 75% of that corresponded to 48% of the threshold, that the highest dose whose absorption was measured corresponded to 81% of the threshold and that 4 users presented an exposure level greater than 50% of the threshold (hereinafter referred to as “ the Spanish study ”).
- 76 A French study invoked by the Commission within the framework of the procedure before the Court shows an unacceptable exposure level. Therefore, following a report of the standing committee’s workgroup in December 2002, this study reached the conclusion that the use of hand held d devices can make the level of exposure for operators unacceptable. It also appears from the report in question that the French study recommends that paraquat should be banned in private gardens and also that check-ups should be routinely carried out on users.
- 77 Finally, with regard to the data submitted by the Republic of Italy and the Republic of Portugal, invoked by the Commission in its written documentation before the Court, and according to which the risks associated with paraquat had been correctly managed in the Member States, the Kingdom of Sweden wishes to argue that

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this data is not backed by any kind of scientific evidence and it is based entirely on the personal and respective experience of the Member States in question.

- 78 First of all, the Commission sustains that the mathematical modelizations in respect of exposure must be followed by field studies whenever, as in this case, they indicate the existence of problems. The Commission also wishes to add that, as noted in the scientific committee's opinion report, field studies have shown that theoretical models have overestimated the real exposure in a working environment.
- 79 With regard to the studies in Sri Lanka, Spain and Guatemala, the Commission sustains that they were commented by RMS in the addendum to the preliminary report and it results from this comment that the NAE0 was not exceeded provided that the proposed conditions of use in the case of paraquat were adhered to.
- 80 It adds that the French study reaches the conclusion that the level of exposure can be made acceptable by using special equipment in the case of spraying with tractors, while the use of hand held equipment can make it unacceptable and that the said study recommends banning the use [of paraquat] in private gardens as well as ensuring that users of paraquat are routinely checked up. It also argues that the data released by the Republic of Italy and the Republic of Portugal indicates that it has been possible to adequately manage the risks connected to the use of paraquat.

D – Regarding the effects of paraquat on animal health

- 81 Both parties agree that field studies indicate that paraquat can be considered harmful to and lethal for hares. Both parties also agree that exposure of eggs to paraquat can constitute a danger for bird embryos.

II - Regarding the group of means arising from the dossier in violation of article 7 of regulation No 3600 / 92, of article 5 of directive 91 / 414 and article 174, paragraph 3, EC

A – Arguments of the parties

- 82 The Kingdom of Sweden sustains that the treatment of the application for registration of paraquat is tainted by several serious failures in violation of the procedures contained in regulation No 3600 / 92, in directive 91 / 414 and in article 174, paragraph 3, EC.
- 83 In the first instance, the treatment of the application for the registration of paraquat violates the procedures contained in these provisions with regard to examining the question of a link between paraquat and Parkinson's disease.
- 84 In support of this argument, the Kingdom of Sweden wishes to allege, first of all, that the question of a link between paraquat and Parkinson's disease was never addressed, either by the author of the notification, RMS or the Commission in

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the light of risk assessment, whereas in scientific literature, and, in particular, in the Hertzman and McCormack studies, there are signs which point to the fact that paraquat affects the nervous system.

- 85 With regard to the McCormack study, the Kingdom of Sweden sustains, in particular, that it contains essential data regarding paraquat's capacity to damage, and even destroy the nerve cells of the brain (more particularly the dopaminergic neurones located in the pars compacta of the “ black substance ”) and that the lesions involving these nerve cells are generally acknowledged to be the primary cause of Parkinson's disease in humans.
- 86 Secondly, the Kingdom of Sweden wishes to argue that in order to be able to consider that the documentation concerning the connection between the use of paraquat and Parkinson's disease has been taken into account and examined, this would have required, first of all, the official report of the meeting of the standing committee should have made a reference regarding this matter. However, although some of the data, and in particular the Hertzman and McCormack studies, was disseminated and discussed during a meeting of the workgroup of the standing committee on 20 July 2003, the talks regarding this matter were not included in the official report of that meeting. Then, the documentation concerning the connection between the use of paraquat and Parkinson's disease should have been the object of a written comment on the part of RMS - which was not the case. Finally, RMS should have given the other Member States the opportunity to comment on the matter - which is clearly lacking in this case.
- 87 Thirdly, the Kingdom of Sweden sustains that the articles relating to the absence of any connection between paraquat and Parkinson's disease, to which the Commission refers in its written documentation before the Court, were not available during the procedure that led to the adoption of the directive under attack whereas, contrary to other documents that have been taken into account in order to assess the active substance in question, these articles were not accessible on the internal website of the Commission (Communication & Information resource Center Administrator – CIRCA). In particular, the contents of these articles were neither raised nor discussed during the treatment of the application for the registration of paraquat. In respect of this, the written documentation of the Commission before the Court makes it impossible to clearly grasp the context in which this institution has carried out the analysis and assessment of the documents to which it is referring.
- 88 Fourthly, the Kingdom of Sweden sustains that the question of a link between the use of paraquat and Parkinson's disease was of a complex nature. [Yet] , an adequate examination of the question of registration in appendix 1 of directive 91 / 414 would have also required consulting beforehand the scientific committee. By negligently omitting to consult this committee, the Commission made an obvious mistake when dealing with this dossier, contrary to article 174, paragraph 3, EC, article 5, paragraph 1 of

directive 91 / 414, A2, a), of appendix VI, and article 7, paragraph 1, of regulation No 3600 / 92.

- 89 Additionally, the Kingdom of Sweden sustains that the Commission has ignored the procedures contained in regulation No 3600 / 92 , concerning the examination of the French study as well as the data released by the Republic of Italy and the Republic of Portugal.
- 90 In this respect, the Kingdom of Sweden suggests, first of all, that it was only after reading the testimony in defence that it became aware of the importance these studies and data in the Commission's assessment.
- 91 The Kingdom of Sweden then wishes to argue that the data according to which the risks associated to the use of paraquat had been correctly managed in Portugal and Italy was orally transmitted during two meetings of the workgroup of the standing committee, without any reference being made to any scientific study or report whatsoever. However, in order for this data to be taken into consideration in a risk assessment exercise, it needs to be the object of a written scientific dossier likely to be discussed.
- 92 Moreover, the Kingdom of Sweden wishes to highlight the fact that the French study was presented orally and summarily during a meeting of the working group of the standing committee in December 2002 and it has not been made available to the Member States. Moreover, RMS has not indicated whether or not this study had been the object of any form of examination. Should the study have been taken into consideration, RMS would have had to ensure, in accordance with the provisions contained in regulation No 3600 / 92 , that the other Member States were in a position to have knowledge of it before taking any decision.
- 93 Finally, the Kingdom of Sweden sustains that the French study should have been made available in a written form and, in accordance with the provisions laid down in regulation No 3600 / 92, they should have given rise to a debate and a common assessment before reaching the conclusion that the risks were acceptable within the framework of a particular usage. Moreover, since the French study stated that there were unacceptable risks within the framework of some uses of paraquat, it should have been sent to the scientific committee for an opinion report.
- 94 The Republic of Finland wishes to add, in substance, that neither the scientific committee nor the standing committee had at their disposal any studies concerning the effects of paraquat on aquatic organisms.
- 95 The Commission sustains, first of all, that, in accordance with article 7, paragraph 1, of regulation No 3600 / 92, it is up to RMS to examine all available data. Obviously, it is the Commission's responsibility to coordinate the processing of the dossier, the final assessment and the final adoption of the decision at a Community level. However, the Member States do exert a significant influence on the management of the dossier.

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- 96 On the subject of any possible and potential connection between paraquat and Parkinson's disease, the Commission maintains that all the data to which the Kingdom of Sweden refers, was taken into consideration by both the Commission itself and RMS. In connection with this, the Commission wishes to argue, in particular, that the United Kingdom itself admits that some data regarding the link between paraquat and Parkinson's disease was disseminated and discussed during the meeting of the standing committee in July 2003. Thus, the Hertzman and McCormack studies were referred to in the bulletin of the Pestizid Aktions – Netwerk eV (PAN) organisation which was available during the meeting of the standing committee in July 2003.
- 97 The Commission also wishes to argue that since this stems from some correspondence dated 23 May 2003 on the part of a competent authority within RMS and addressed to the Commission, EMR has assessed the relevance of the documents which named paraquat in relation to Parkinson's disease, and it has reached the conclusion that there are not sufficient reasons to take them into account during the examination of the question of whether or not paraquat could be registered in appendix I of directive 91 / 414. Moreover, the Commission puts it to the audience that the assessment which RMS proceeded to carry out was based on the Dewhurst examination.
- 98 The Commission wishes to add that there is no obligation whatsoever according to which an examination report by the Commission has to contain all the data or all the documents that have been the object of a discussion during the assessment, as the Commission is not obliged to discuss all the points of fact and law that have been raised by each interested party during the course of the administrative procedure.
- 99 With regard to the French study and the data released by the Republic of Italy and the Republic of Portugal, the Commission wishes to argue, as a main point, that the criticisms arising from the irregularity of the procedure in respect of the examination of this study and the data have been expressed too late in accordance with article 48, paragraph 2 of the rules of procedure, given that they were only raised at the reply stage. However, the circumstances being invoked in the reply were known to the Kingdom of Sweden during the examination stage of the dossier and they could have therefore been invoked in the request.
- 100 As a subsidiary argument, the Commission contests the accusation according to which it has violated the substantial formalities with regard to the treatment of the French study and the data released by the Republic of Italy and the Republic of Portugal. In this respect, it wishes to reiterate, first of all, the argument according to which article 7, paragraph 1 of regulation No 3600 / 92 is addressed to RMS and not the Commission. It also wishes to sustain that this same provision does not contain any requirement according to which all dossiers for assessment must be in the form of written scientific dossiers and based on written documentation. Then, the Commission would not be subjected to the general obligation to consult with the scientific committee, and even less so since, in this case, the information transmitted by the Member States was not so technically complex that it entailed a particular reason for consulting the scientific committee. Finally, the data released by the Republic of Italy and the Republic

of Portugal, as was the case for the French study, would have confirmed the conclusions of RMS, of the standing committee and the scientific committee, so that the Commission would have had no particular reason to consult again with the scientific committee.

101 Finally, with regard to the argument put forward by the Republic of Finland according to which neither the scientific committee nor the standing committee had at their disposal studies concerning the effects of paraquat on aquatic organisms, the Commission sustains, in this case, that the studies required by directive 91 / 914 should be taken into account and analysed, and in the event of a Member State estimating that some data should have been included in the evaluation dossier, this Member State should have reported it within the framework of the evaluation procedure, which the Republic of Finland failed to do.

B - The Court's assessment

- 102 The complaint drawn from the alleged failure in the handling of the case regarding the issue of an eventual connection between paraquat and Parkinson's disease should be examined first and foremost.
- 103 In this regard, there is first of all a need to point out that the examination report of the Commission shows that there is no indication of neurotoxicity of paraquat.
- 104 As part of the examination of the present legal means, it is sufficient to analyze whether the procedure that led the Commission to such a statement is compliant with the procedural requirements set by the provisions the violation of which is alleged by the Kingdom of Sweden.
- 105 In this regard, it should be reiterated that Article 7, para. 1, sub a) and c) of Regulation No. 3600/92 shows that the RMS must examine the case referred to in Article 6, para. 2, of this same regulation and remit a report on said case to the Commission. Article 6 of Regulation No. 3600/92 specifies that the author of the notification is obligated to remit to the competent authority of the RMS a summary file that includes, for each point of Annex II of Directive 91/414, the summaries and results of available tests, or for lack of this, a statement of the reasons for which this information is not necessary to evaluate a substance according to the criteria of Article 5 of Directive 91/414, or a commitment to forward the missing information later. Annex II of Directive 91/414 includes a point 5.7 specifying that delayed neurotoxicity analyses must be conducted for substances of a structure similar or related to the structure of those substances apt to cause a delayed neurotoxicity like organophosphates.
- 106 In the case at hand, it should be noted that with the Kingdom of Sweden, the issue of the relationship between paraquat and Parkinson's was never mentioned by the author of the notification. In addition, the preliminary report shows that the author of the notification did not provide the RMS with any data concerning

the neurotoxicity of paraquat nor any reason why there was no need to provide information on this point. Moreover, whereas, by virtue of Article 7 para. 2 of Regulation No. 3600/92, the RMS could have invited the author of the notification to provide improvements or additions to his file, this possibility was not made use of. In effect, in its preliminary report, the RMS explicitly states that the information provided by the author of the notification concerning the toxicological aspects of paraquat are sufficient to enter this substance in Annex I of Directive 91/414.

- 107 The Commission indeed maintains, within the framework of the present proceeding, that the RMS actually evaluated the relevance of the documents based on the Dewhurst examination, citing paraquat in connection with Parkinson's and that it concluded that there were no sufficient grounds to take these documents into account when examining the issue of whether paraquat could be entered in Annex I of Directive 91/414 (see Point 97 above).
- 108 However, even admitting that this evaluation took place, as the email dated May 23, 2003 - referred to by the Commission and the Dewhurst examination appearing in the file of the present proceeding - tends to indicate, it should be noted that this evaluation does not meet the requirements specified by Article 7 of Regulation No. 3600/92. In effect, as the Kingdom of Sweden is asserting (see point 65 above) without being contradicted on this point by the Commission, the indications of a connection between the use of paraquat and the occurrence of Parkinson's appear in the literature concerning the neurotoxicity of paraquat. Consequently, If the RMS evaluated the literature regarding the eventual connection between Parkinson's and paraquat, this evaluation was part of the examination of the neurotoxicity of paraquat. Article 7, para. 1, sub c) of Regulation No. 3600/92 orders that the evaluation of an active substance that the RMS conducts must result in a report to the Commission which, by virtue of Article 7, para. 3 of the same regulation, must be forwarded to the standing committee and to the other Member States for their information.
- 109 But in the case at hand, as the Kingdom of Sweden is asserting in substance (see point 86 above), without being contradicted on this point by the Commission, the reports of the RMS did not contain any evaluation of the literature concerning the eventual connections between paraquat and Parkinson's. In addition, the Commission does not establish nor even allege that such an evaluation was forwarded to the standing committee.
- 110 In light of the preceding, it should be considered that the statement contained in the Commission's examination report proceeds from a handling of the case that does not meet the procedural requirements posed by Article 7 of Regulation No. 3600/92. One should thus receive the complaint drawn from the irregularity of the proceeding concerning the examination of an eventual connection between paraquat and Parkinson's, with

no need to comment on the other arguments put forward as part of this complaint.

- 111 Secondly, the complaints drawn from the irregularity of the procedure concerning the examination of the French analysis of the data forwarded by the Republic of Italy and the Republic of Portugal.
- 112 In this regard, the demurrer raised by the Commission concerning these complaints should be examined first and foremost.
- 113 Under the terms of Article 48, para. 2 of the procedural regulation, the presentation of new legal means during trial is prohibited unless these means are based on elements of law and fact that were revealed during the proceeding.
- 114 As the Commission notes (see point 99 above), by maintaining in its reply that the data submitted by the Republic of Italy and by the Republic of Portugal as well as the French analysis should have been available in written form and should have been forwarded to the scientific committee, the Kingdom of Sweden is asserting legal means that do not appear in the petition and that are consequently new in the meaning of Article 48, para. 2 of the procedural regulation.
- 115 In addition, it is consistent that the information provided by the Republic of Italy and by the Republic of Portugal was forwarded orally during the meetings of the work group of the standing committee and that the French study was mentioned in the reports of this same work group's meetings of December 2002 and February 2003. The existence of this information and this study is thus not an essential element that was revealed during the proceeding before the Court.
- 116 However, it should be emphasized that the Kingdom of Sweden is asserting the new legal means mentioned in Point 114 above only insofar as the Commission alleges in its defense statements that the information provided by the Republic of Italy and by the Republic of Portugal as well as the French study had a certain importance for admitting the entering of paraquat in Annex I of Directive 91/414.
- 117 But it should be considered that the circumstances under which the information and the study in question was taken into account did not in any way indicate the importance that these elements had for the Commission for purposes of entering paraquat in Annex I of Directive 91/414. In effect, as the Kingdom of Sweden notes (see point 77 above), without being contradicted by the Commission on this point, the information provided by the Republic of Italy and by the Republic of Portugal consisted of the simple statement that, in the experience of each of these two Member States, the risks associated with paraquat could be properly managed without presenting any study or written document apt to support these statements. In addition, it is consistent that

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the French study was only presented orally and summarily to the standing committee and that it was not made available to the representatives of the Member States in the standing committee. In light of these circumstances, it should be considered that the alleged importance of the information and of the study in question for admitting the entering of paraquat in Annex I of Directive 91/414 constitutes an element of fact that was only revealed during the proceeding before the Court. Consequently, the complaints put forward against the handling of the French study and the information provided by the Republic of Italy and by the Republic of Portugal must be considered admissible by virtue of Article 48, para. 2 of the procedural regulation.

- 118 Concerning the validity of these complaints, the complaints put forward against the handling of the French study should be examined first of all.
- 119 In this regard, it should be reiterated first of all that the Commission cites the French study as an important element of the evaluation of paraquat and accentuates that this study reaches the conclusion that the operators' level of exposure to paraquat can be made acceptable by using tools for tractors, while the use of hand tools may make it unacceptable, and that this study recommends banning its use in individuals' gardens and ensuring a monitoring of the users.
- 120 It should then be noted that the parties agree on the fact that there is no written evaluation file concerning the French study and this study was not forwarded to the scientific committee for an opinion. In addition, as the Kingdom of Sweden notes, nothing in the case makes it possible to establish that the RMS was able to take cognizance of the French study and that it examined this study before a decision on entering paraquat in Annex I of Directive 91/414 has been adopted.
- 121 Since it is not established that a report of the RMS on the French study was forwarded to the standing committee, it should be noted that the handling of this study, concerning which the Commission maintains that it was important in its evaluation of paraquat, is not compliant with the procedural requirements specified by Article 7 of Regulation No. 3600/92. More specifically, as was already noted in point 108 above, Article 7, para. 1, sub c) of Regulation No. 3600/92 requires that the evaluation the RMS conducts results in a report to the Commission, which, by virtue of Article 7, para. 3 of the same regulation must be forwarded to the standing committee and to the other Member States for their information.
- 122 In addition, the handling of the French study differs significantly from the handling of the studies concerning the operator's level of exposure to paraquat as conducted in Sri Lanka, in Guatemala and in Spain. In effect, these studies, the first two of which attest to cases in which the operators' level of exposure to paraquat was greater than the AOEL [Acceptable Operator Exposure Level], were all examined by the RMS. The examination of these studies by the RMS was the subject of a written summary appearing either in the

preliminary report or in the addendum to this report. In addition, these reports were submitted to the standing committee as well as to the scientific committee.

- 123 Since, according to the Commission, the French study had a certain importance for evaluating paraquat, it should have been subjected to an examination procedure similar to the one used to evaluate the Sri-Lankan, Guatemalan and Spanish studies, including the examination thereof by the scientific committee.
- 124 Secondly, concerning the handling of the information provided by the Republic of Italy and by the Republic of Portugal, it should be noted that the file does not contain any indication according to which this information considered important by the Commission was the subject of a report from the RMS. For the reasons already mentioned in points 108 and 121 above, the absence of such a report constitutes a lack of knowledge of the provisions of Article 7 of Regulation No. 3600/92.
- 125 Consequently, the complaints drawn from the irregularities of the irregularities of the procedure in the handling of the French study and of the information provided by the Republic of Italy and by the Republic of Portugal must be admitted.
- 126 Considering all of the preceding, there is a need to allow the legal means drawn from a handling of the case in violation of Article 7 of Regulation No. 3600/92, with no need to examine the other means, complaints and arguments of a procedural nature put forward by the parties.

III – Regarding the group of legal means drawn from the violation of Article 5 of Directive 91/414, the requirement of integration, the principle of high level of protection and the principle of cautiousness

- 127 The present group of legal means is organized into two branches the first of which deals with the protection of human health and the second of which concerns the protection of animal health.
- 128 In addition, the parties asserted a number of considerations regarding the scope of the principles of integration, cautiousness and high level of protection concerning which the Kingdom of Sweden, without being contradicted on this point by the Commission, told the hearing that they are only used to support the legal means and arguments explicitly raised elsewhere.

A – As to the first branch concerning the protection of human health

1. Arguments of the parties

- 129 The Kingdom of Sweden, supported by the intervening parties, asserts that within the framework of the examination of risks for human health caused by the use of paraquat, the Commission failed to recognize the principle of cautiousness, the principle of high level of protection, the requirement of integration as well as Article 5

of Directive 91/414 and the specific requirements of Annex VI. To this extent, it allegedly clearly exceeded the limits of its power of assessment. In this regard, the Kingdom of Sweden, supported by the intervening parties, asserts in substance three complaints that the Commission contests.

a) Regarding the complaint drawn from an operator exposure greater than the AOEL [Acceptable Operator Exposure Level]

- 130 The Kingdom of Sweden, supported by the Kingdom of Denmark, first of all sets forth that within the framework of the examination of an active substance under Article 5 of Directive 91/414, the uniform principles specified in Annex VI, to which the Member States refer as part of the national authorization procedures for phytopharmaceutical products are applicable.
- 131 In this regard, Article 5 of Directive 91/414 in fact referred, at least indirectly, back to the criteria of Annex VI. By virtue of Article 5, paragraph 1, sub b) of Directive 91/414, the fundamental requirements posed by Article 4, paragraph 1, sub b), iv) and v), of Directive 91/414 would thus be applicable during the evaluation of an active substance. But it would not be possible to evaluate compliance with these fundamental requirements without applying the principles of Annex VI, which determine the content of these provisions.
- 132 The applicability of the uniform principles of Annex VI would also result in a practice of the Commission which, in the absence of the specific guidelines on compliance with the requirements set in Article 5 of Directive 91/414, would still apply the criteria of Annex VI.
- 133 The Kingdom of Sweden secondly asserts that the modelling and studies ground clearly show that in the case at hand, the level of protection does not meet the requirements expressed in point C 2.4.1.1 of Annex VI which specifies that the operator's level of exposure while handling and applying the phytopharmaceutical product under the proposed conditions of use (and in particular the dosage and the method of application) cannot exceed the AOEL. Due to the exceeding of the AOEL, the Commission thus failed to recognize Annex VI during the examination of paraquat, Article 5 of Directive 91/414 and the principle of high level of protection.
- 134 The Republic of Finland also adds that the neurological effects of paraquat as they result from science studies should have been taken into account to set the AOEL and the daily dose acceptable for operators. According to it, for lack of having taken into consideration the studies regarding the neurological effects of paraquat, the AOEL and the acceptable daily dose considered to assess the risk for operators are allegedly too high.
- 135 The Commission contests the statement according to which it should have applied the uniform principles of Annex VI when it evaluated paraquat.

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- 136 First of all, Article 5, paragraph 1, sub b) of Directive 91/414 referred back to Article 4, paragraph 1, sub b), iv) and v) of this same directive, which does not mention Annex VI. Consequently, the Commission is allegedly not formally obligated to apply the uniform principles of this annex when it evaluates an active substance. It then sets forth in substance that though it is not obligated by these principles, it can nevertheless take them into consideration when evaluating an active substance.
- 137 It maintains that the arbitrary risk which, according to the Kingdom of Sweden, would result from not applying the principles of Annex VI, does not appear particularly probable considering the magnitude of the evaluation measures that an active substance is subjected to in accordance with the laws on pharmaceutical products.
- 138 Concerning the argument of the Republic of Finland according to which the safety factors that the AOEL and the acceptable daily dose represent were allegedly set at excessively high levels due to the failure to take paraquat's neurological effects into account, the Commission maintains that it deemed that there was no need to evaluate the effects of paraquat on Parkinson's and that no Member State had made this request.
- b) Regarding the complaint drawn from the insufficiently probative nature of the scientific dossier to conclude the absence of significant risk of paraquat for human health.
- 139 The Kingdom of Sweden contests the Commission's point of view according to which the scientific dossier allegedly indicates that paraquat does not present significant risk for human health.
- 140 In this regard, the Kingdom of Sweden, supported by the Kingdom of Denmark, asserts first of all that Article 5, paragraph 1 of Directive 91/414 that a substance can only be entered in Annex I if it is proven beyond a reasonable doubt that a product containing the active substance can be used in total safety in at least one representative sphere of use. Such a proof should be based on a risk assessment supported by a scientific dossier.
- 141 The Kingdom of Denmark contests that the wording of Article 5, paragraph 1 of Directive 91/414 indicates that the Commission is subject to an obligation of proof attenuated to such an extent that the simple possibility, uncertain or theoretical, that a product containing the active substance could be acceptable would be sufficient to admit the entering of this substance in Annex I of Directive 91/414. If there are indicators that a certain active substance may present a particular type of risk for human health or for the environment, before deciding to enter the substance in Annex I, sufficient information should be gathered together to be able to assess this risk

scientifically and the effectiveness of eventual restrictions on use should be assessed with the same scientific rigorouslyness.

- 142 But in the case at hand, according to the petitioner, the scientific dossier allegedly does not allow one to conclude that paraquat meets the requirements set by Article 5 of Directive 91/414.
- 143 First of all, the mathematical modelling allegedly short unambiguously that users' exposure to paraquat is greater than the limit set. The Guatemalan study and the French study allegedly show an exposure level unacceptable for users and only the Spanish study allegedly concludes an acceptable exposure level.
- 144 Subsequently, allegedly neither the Guatemalan study nor the French study were adequately taken into account. Thus, although the Guatemalan study indicates that a person having used the recommended protection equipment sustained an exposure greater than the AOEL, in its opinion the scientific committee allegedly concluded that only individuals who did not follow the recommended work procedure showed exposure levels near the threshold. In addition, although the French study indicates that there was a need to prohibit the use of a sprayer carried on the back and that using paraquat in individuals' gardens was advised against, the directive contested allegedly limits itself to prohibiting the use of sprayers carried on the back or handheld only in "amateur gardens".
- 145 The Commission maintains that the scientific dossier was sufficiently probative to justify entering paraquat in Annex I of the directive.
- 146 In this regard, it asserts first and foremost considerations on the scope of Article 5 of Directive 91/414. Thus, it first of all contests the interpretation of Article 5 of Directive 91/414 according to which this provision would require that, before entering an active substance in Annex I, it has been proven that a product containing the active substance was used in total safety, with no reasonable doubt, in at least one representative sphere of use, taking all potential risks into account.
- 147 On the one hand, such a requirement would be close to zero tolerance. But jurisprudence allegedly shows that a preventive measure could not be validly justified by a purely hypothetical risk approach based on simple suppositions not yet verified scientifically. More specifically, the court allegedly deemed that the European Community institutions cannot orient their decisions toward a zero risk level (Court decision of September 11, 2002, Pfizer Animal Health/Conseil, The-13/99, Rec. p. II-3305, point 152).
- 148 On the other hand, such a requirement would contradict the wording of Directive 91/414 and the elements of proof that the latter requires for the entering of an active substance. Thus, by using the expression "if one is allowed to expect" instead of, for example, the terms "if it can be demonstrated",

the legislator would have admitted that it imposes to foresee all possible and imaginable situations in which a phytopharmaceutical product containing the active substance could be used and that the environmental conditions to be taken into account for the use of phytopharmaceutical products containing the active substance could vary considerably from one Member State to another, reasons for which the laws concerning phytopharmaceutical products also attribute an active role to the Member States.

- 149 Concerning the restrictions on use specified in Article 5, paragraph 4 of Directive 91/414, the Commission denies that it must be scientifically verified that these restrictions actually have the effect of reducing risks. In this regard, it asserts that Article 5, paragraph 1 of Directive 91/414 provides that by taking into account the "state" of scientific and technical knowledge, there is a need to determine whether it "one is allowed to expect" that the conditions will be met for entering a substance in Annex I of this directive.
- 150 Secondly, the Commission contests the insufficiency of the scientific dossier to support an entering of paraquat in Annex I of Directive 91/414.
- 151 Thus, there allegedly exists scientific documentation sufficient to deem that, independently of the risks that using paraquat could present, the risks evaluated were acceptable in light of the introduction of measures intended to reduce them, such as prohibiting individuals from using phytopharmaceutical products containing paraquat and imposing professional conditions of use of this substance.
- 152 In addition, the mathematical modelling indicating an exceeding of the AOEL [Acceptable Operator Exposure Level] are allegedly not relevant. In this regard, the Commission maintains that when the modelling do not reveal the existence of problems, they must be followed by ground studies. But in the case at hand, the RMS allegedly deemed in its addendum that the AOEL would not be exceeded if the conditions of use envisaged for paraquat were complied with. Moreover, the scientific committee allegedly came to the same result as the RMS in noting that even if the exposure models indicated that the AOEL could eventually be exceeded, the ground studies of various countries showed that models had overestimated actual exposure in work situations.
- 153 In addition, the Commission denies that it only considered the Spanish study to form an opinion. In this regard, it reiterates that the RMS and the scientific committee as well as the experts of the ECCO deemed that the studies that had been presented were sufficient and that one could universally agree that, if used in accordance with the proposed conditions, paraquat did not present significant risks for health.

- 154 Concerning the alleged failure to take into account the Guatemalan study in the procedure leading to the adoption of the contested directive, the Commission maintains that the opinion of the scientific committee shows that it had in its possession the addendum to the preliminary report in which the Guatemalan study appeared. In addition, in its second report, the RMS allegedly indicates that the scientific committee based its opinion ground studies. Thus, nothing would allow one to establish that the scientific committee did not take into account the Guatemalan study.
- 155 The Commission also contests that the conditions of use of paraquat specified by the contested directive do not reflect the conclusions of the French study. In this regard, it asserts on the one hand that the contested directive does not generally authorize hand tools and, on the other hand, that obtaining an authorization to use a phytopharmaceutical product will be contingent upon adherence to good practice.
- c) Regarding the complaint drawn from a reduction of the level of protection
- 156 The Kingdom of Sweden, supported by the Republic of Austria, asserts in substance that by admitting the entering of paraquat in Annex I, the Commission failed to recognize the principle of high level of protection for human health.
- 157 Thus, the fact that the contested directive imposes on the one hand implementing operator safety management programs and, on the other hand, forwarding an annual report to the Commission concerning the impact of the use of paraquat on operators' health, would indicate that the Commission is hesitant regarding the risks presented by paraquat. No other active substance entered in Annex I would result in the providing of such annual reports. It follows from this that in the case at hand, the Commission tried a kind of experiment, contrary to Directive 91/414, the principle of cautiousness and the principle of high level of protection.
- 158 By authorizing paraquat, the most toxic substance there is, the Commission thus allegedly seriously reduced the level of protection governing the choice of substances able to be entered in Annex I. In so doing, it allegedly clearly failed to recognize the objective of the provisions in question aiming to guarantee a high level of protection, as well as the terms of the preamble of Directive 91/414, according to which the objective of improving vegetal production should not harm the protection of human and animal health and that of the environment.
- 159 The Commission replies that it is inexplicable that the Kingdom of Sweden is criticizing it for requiring that the holders of an authorization for a phytopharmaceutical product containing paraquat establish a user protection program and annually report any occurrence of health or pollution problems related to the use of the product.

2. The Court's assessment

a) Regarding the framework for assessment

- 160 Annex 5, para. I of Directive 91/414 specifies that in order for a substance to be entered in Annex I of this same directive, one must be allowed to suppose, considering the state of scientific and technical knowledge, that the use of phytopharmaceutical products containing the active substance in question, following an application compliant with good phytosanitary practices, has no harmful effect on human health, in accordance with Article 4, para. 1, sub b), iv) of Directive 91/414.
- 161 This provision, interpreted in connection with the principle of cautiousness, implies that concerning human health, the existence of serious indicators which, without eliminating scientific uncertainty, reasonably allow one to doubt the innocuousness of a substance, opposes in principle the entering of this substance in Annex I of Directive 91/414. In effect, the principle of cautiousness tends to prevent potential risks. On the other hand, purely hypothetical risks based on unsupported scientific hypotheses cannot be considered (Court decision of October 21, 2003, Solvay Pharmaceuticals/Conseil, T-392/02, Rec. p. II-4555, point 129).
- 162 To assess whether the requirements of Article 5, para. 1 of Directive 91/414 are met as regards human health, this same provision refers back to Article 4, para. 1, sub b), iv) of Directive 91/414, which cites in substance that it must be established that a phytopharmaceutical product has no direct or indirect harmful effect on human health or on groundwater.
163. It should still be noted that Article 4, para. 1, sub a), of Directive 91/414 shows that in order to establish whether the requirements specified by Article 4, para. 1, sub b), iv) of this same directive are met, the uniform principles cited in Annex VI should be applied. In addition, the second consideration of Directive 97/57, establishing the content of Annex VI, indicates that this annex must establish uniform principles to ensure a uniform application with the desired rigorousness of the requirements cited in Article 4, para. 1, sub b) to e), of Directive 91/414.
164. It follows from this that Article 4, para. 1, sub b), iv) of Directive 91/414, to which Article 5, para. 1, sub b) of the same directive explicitly refers, demands compliance with the uniform principles of Annex VI.
165. In addition, if the reference made by Article 5, para. 1, sub b) of Directive 91/414 did not imply the applicability of the uniform principles cited in Annex VI, this reference would be deprived of any real usefulness. In effect, in such an eventuality, in order to assess the absence of harmful effects on human health in accordance with Article 5, para. 1, sub b) of Directive 91/414, the reference

made by this provision would be limited to the application of a nearly identical criterion stemming from the absence "of direct or indirect harmful effects on human health [...] (for example, through potable water or foodstuffs intended for human consumption [...]) or on the groundwater."

- 166 Finally, it should be noted that the Commission admitted at the hearing that it had already had recourse to the criteria of Annex VI within the framework of the examination of certain active substances by virtue of Article 5, para. 1 of Directive 91/414.
- 167 In light of the preceding, it should be considered that when the Commission examines an active substance in order to enter it in Annex I of Directive 91/414, it follows from Article 5, para. 1, sub b) of this directive that the criteria of Annex VI are to be applied.
- 168 More specifically, point C 2.4.1.1 of Annex VI cites that an authorization is not granted if the operator's level of exposure during the handling and application of the phytopharmaceutical product under the proposed conditions of use, and in particular the dosage and method of application, exceeds the AOEL [Acceptable Operator Exposure Level].
- 169 Article 5, para. 4 of Directive 91/414, according to which the entering of an active substance in Annex I can be subordinated to certain restrictions of use, has the effect of allowing the entering of substances that do not meet the requirements of Article 5, para. 1 of this same directive by imposing certain restrictions that rule out problematic uses of the substance in question.
- 170 Since this provision appears as a tempering of Article 5, para. 1 of Directive 91/414, it should be interpreted in light of the principle of cautiousness. Consequently, before entering a substance in Annex I of Directive 91/414, it must be established beyond any reasonable doubt that the restrictions on the use of the substance in question allow one to ensure a use of this substance that is compliant with the requirements of Article 5, para. 1 of Directive 91/414.
- 171 The various complaints of the present branch\ should be examined in consideration of the rules that were just set forth.
- b) Regarding the complaints put forward
- 172 One should first of all examine jointly the first two complaints drawn, respectively, from an exceeding of the AOEL and from the insufficiently probative nature of the case to admit the entering of paraquat in Annex I of Directive 91/414.

- 173 Within the framework of these two complaints, it is consistent between the parties that the standing committee has set a AOEL [Acceptable Operator Exposure Level] equal to 0.005 milligrams per kilogram of body weight as regards short-term exposures to paraquat.
- 174 It is also admitted between the parties that the mathematical modelings indicate an exposure of the operators of 4 to 100 times greater than the AOEL . However, as the Commission rightly asserts, in its opinion the scientific committee stated that the on the ground studies conducted in various countries have shown that the mathematical modelings largely overestimated the operators' actual exposure in work situations. Consequently, it should be considered that under the circumstances of the case at hand, the mathematical modelings do not by themselves constitute serious indicators that reasonably allow one to doubt the innocuousness of paraquat.
- 175 In addition, it follows from the observations of the author of the notification regarding the Guatemalan study, as the observations were reported in the addendum to the preliminary report, that the operators subjected to the highest potential and systemic exposures do not seem to have mixed, filled the tanks of the pulverizers and applied the product differently than the other participants in the study. The addendum to the preliminary report also indicates that all operators having participated in the study generally followed the recommendations of the instructions for mixing the product and filling the pulverizers and that they seem to have demonstrated a generally good compliance with hygiene standards during the mixing of the product in question.
177. The addendum to the preliminary report also states that pulverization at chest or head height in the irrigation canals caused a significant contamination of the operators' clothes and that the operator for whom an exposure level of 118% of the AOEL was observed applied the product in an irrigation canal zone, which led him to hold the lance of the pulverizer at head height.
- 178 The addendum to the preliminary report indeed indicates that the circumstances under which the operator sustained an exposure greater than the AOEL within the framework of the Guatemalan study must be considered as not representative of applications practiced in Europe. However, one cannot help but note that the addendum to the preliminary report provides no reason why the application of paraquat in an irrigation canal zone causing the operator to hold the lance of the pulverizer at head height is not representative of conditions of use in Europe. On the other hand, the Kingdom of Sweden, without being contradicted by the Commission on this point, maintains that

the use of paraquat on sloping land is one of the uses envisaged for paraquat in Europe (see point 75 above).

- 179 In addition, it should be noted that no restriction adopted under Article 5, para. 4 of Directive 91/414 prohibits the use of paraquat under the circumstances that led to an exposure of the operator greater than the AOEL [Acceptable Operator Exposure Level] as part of the Guatemalan study. In effect, it follows from the criticized directive that the only explicit restriction affecting the use of portable pulverizers to apply products containing paraquat concerns "amateur gardens" in which such a use is prohibited. In addition, the fact that the specific provisions of the criticized directive specify that the Member States must give special attention to protecting the operators, in particular for applications with pulverizers carried on the back and handheld apparatuses, does not imply the prohibition of a use such as the one that led to the exceeding of the AOEL within the framework of the Guatemalan study. Lastly, Annexes I and II of the Commission's examination report, to which the specific provisions of the criticized directive refer, do not mention a prohibition of the problematic use. It should thus be considered that the Guatemalan study reports on a problematic use of paraquat concerning which nothing indicates that it could occur in Europe.
- 180 Concerning the scientific committee's statement according to which only individuals who did not follow the recommended work procedure showed exposure values close to the threshold, it should be noted that concerning the Guatemalan study, this statement is not corroborated by any element of the file. On the other hand, as was noted in point 176 above, the addendum to the preliminary report indicates that hygiene recommendations and standards were generally complied with by the operators in the Guatemalan study. It should thus be considered that this study reports on a case of problematic exposure to paraquat whereas the recommended work procedures had been followed.
- 181 In light of the preceding, the Guatemalan study appears to be a serious indicator allowing one to reasonably doubt the innocuousness of paraquat for the operator in charge of applying it.
- 182 Since the Guatemalan study attests to an exposure level greater than the AOEL based on a use of paraquat under the proposed conditions, the requirement posed in point C 2.4.1.1 of Annex VI, which prohibits any exceeding of the AOEL, is not fulfilled. But, for the reasons set forth in points 162 to 168 above, the criteria of Annex VI are to be applied within the framework of the evaluation of an active substance by virtue of Article 5, para. 1, sub b) of the same directive. Consequently, the criticized directive fails to comply with the requirement to protect human health as it appears in Article 5, para. 1, sub b) of Directive 91/414. The complaint drawn from an exposure of the operator greater than the AOEL must therefore be admitted.

- 183 Secondary, concerning the French study, it should be noted first of all that after it was presented by the Commission as part of the measures organizing the proceeding, it appeared that this document is not an on the ground study but rather an evaluation by the French toxicity study commission (hereinafter the "CET") of the operators' exposure to paraquat as this exposure follows from various studies. Thus, the CET evaluated the operators' exposure in the case of a paraquat treatment carried out with a tractor. This evaluation took into account the exposure calculations carried out based on a mathematical model as well as an on the ground study conducted in the United States. The CET also evaluated the operators' exposure in the case of paraquat treatment carried out with a pulverizing apparatus carried on the back. This evaluation took into account the exposure calculations carried out based on a mathematical model as well as the Sri-Lankan, Guatemalan and Spanish studies. As a conclusion of the French study, the CET gave an opinion in which it states that it "maintains an unfavorable opinion toward authorizing paraquat-based preparations for all uses requiring the use of a treatment with a pulverizer carried on the back ." It adds that it "offers a favorable opinion toward authorizing paraquat-based preparations for uses requiring exclusively crop treatment using a tractor."
- 184 But it should be noted that the criticized directive prohibits applications with pulverizers carried on the back and handheld apparatuses only in "amateur gardens", such that applications using pulverizers carried on the back, outside of "amateur gardens", are authorized whereas they received an unfavorable opinion from the CET in the French study.
- 185 Since the Commission stated that the French study had played a major role in its decision to enter paraquat in Annex I of Directive 91/414, for the purposes of the present proceeding it should be considered that this study's conclusion, according to which uses requiring the use of a treatment with a pulverizer carried on the back receive an unfavorable opinion, constitutes a serious indicator that reasonably allows one to doubt the innocuousness of paraquat during such a use.
- 186 In light of the preceding, one should admit the complaints drawn, respectively, from an exposure greater than the AOEL [Acceptable Operator Exposure Level] and from the insufficiently probative nature of the case to admit the entering of paraquat in Annex I of Directive 91/414.
- 187 Then, concerning the complaint drawn from a reduction of the level of protection of human health, it should be reiterated that Article 5, para. 4 of Directive 91/414 specifies the possibility for the Commission to subordinate to certain restrictions the entering of a substance in Annex I of the directive. Consequently, the sole fact that the criticized directive provides for specific requirements

cannot be considered to be contrary to Article 5 of Directive 91/414.

- 188 In addition, the fact that the specific requirements specified by the criticized directive consist in particular of the obligation imposed on the Member States to make sure that the holder of authorizations forward, not later than March 31 of each year until 2008, the indicators regarding the operators' health and that this information be completed by data on sales and an inquiry regarding the types of uses, in order to have a realistic picture of the toxicological impact of paraquat, does not indicate by itself that the Commission is violating the principle of the high level of protection of human health.
- 189 Thus, contrary to what the Kingdom of Sweden is stating, supported by the intervening parties, these specific requirements for paraquat do not by themselves indicate that the Commission had hesitations regarding the risks presented by this substance, nor that it decided to replace an a priori assessment of paraquat with the observation of the consequences, after the fact, of using this substance.
- 190 The third complaint must consequently be rejected.
- 191 It follows from all of the preceding that the first branch regarding the protection of human health must be admitted, with the exception of the third complaint.

B – Regarding the second branch relating to animal health protection

1. Arguments of the parties

a) Regarding the complaint drawn from the insufficiently probative nature of the scientific dossier

- 192 The Kingdom of Sweden maintains in substance that the Commission admitted the entering of paraquat in Annex I of Directive 91/414 based on a lacking dossier concerning the harmful effects of paraquat on the health of hares and bird embryos and the effectiveness of the measures envisaged to attenuate these effects, something which, on the one hand, is allegedly contrary to Article 5 of Directive 91/414 read in connection with the principles of cautiousness and high level of environmental protection and, on the other hand, attests to the arbitrary nature of the Commission's assessment according to which paraquat could be entered in Annex I of Directive 91/414.
- 193 Concerning hares, the Kingdom of Sweden maintains first of all that the motives for the contested directive and the dossier on which it is based show that paraquat has a lethal or sublethal effect on these mammals.
- 194 It then states that the motives for the contested directive, the scientific committee's opinion and the Commission's examination report indicate that the

information available did not allow one to establish the proportion of hares that could be affected by paraquat.

- 195 It also asserts that in the RMS's second report, it envisaged a scenario concerning the use of paraquat in stubble fields in the United Kingdom, which shows that approx. 2% of the total population of hares could be exposed in the most unfavourable hypothesis, which, according to the Kingdom of Sweden, represents 16,000 hares per year for the territory of the United Kingdom. This estimate is allegedly based on a hypothesis of 0.4% spraying of the total grain-growing surface, whereas no country has yet found it advisable to limit in practical reality the surfaces able to be treated with pesticides.
- 196 In addition, supported by the intervening parties, the Kingdom of Sweden states that other animals such as rabbits, moles, voles and shrews are exposed to the same risks as the hares and that these mammals were not taken into account when defining the measures aiming to attenuate the risks. The fact that so many animals are at risk of dying or sustaining serious lesions and suffering from this would be unacceptable.
- 197 It adds that the RMS's assessment clearly shows that it was not possible to find a safe use of paraquat as regards hares. On the one hand, instead of examining the spheres of use proposed by the author of the notification, the RMS concluded that the risk for hares had to be evaluated at the level of the Member States. On the other hand, assuming the RMS recommends a specific use of paraquat, this would only be valid for uses of paraquat in stubble fields, considering the fact that it based itself on a scenario concerning only this sphere of use. But the author of the notification allegedly envisages several spheres of use such that, for paraquat to be able to be entered in Annex I of Directive 91/414, it would have been necessary to evaluate the risks in each of these spheres of use.
- 198 It also states that in its opinion, the scientific committee mentioned measures that were eventually apt to reduce the risk for hares, but that in the absence of scientific data able to demonstrate the presume effects of the measures identified, the committee had no choice but to conclude that considering the data presented, paraquat could cause lesions or even the death of some individuals. According to it, the data gathered in the studies conducted on the ground, in which hares were exposed to the substance, show that the risks are real, but that it is not possible to estimate the proportion of animals affected. On the other hand, no new scientific data was presented in support of the statement of the author of the notification, according to which the measures apt to reduce the risk for hares were effective. The information concerning the eventual effects of the measures proposed should have – in accordance with the usual practice in matters of registering active substances - been

handled\processed in writing and scientifically evaluated in order to serve as a basis for the assessment conducted in the case at hand.

- 199 Concerning the bird embryos, the Kingdom of Sweden asserts first of all that the motives for the contested directive and the Commission's examination report indicate that paraquat has harmful effects on birds' reproduction. It maintains more specifically that the scientific committee deemed that the study on exposures carried out shows that paraquat may constitute a danger for bird embryos but that, to evaluate the risks, it was necessary to obtain additional information from realistic studies.
- 200 According to the Kingdom of Sweden, the author of the notification provided additional information that consisted, on the one hand, of three estimates of doses at which paraquat would damage bird eggs, carried out based on lab tests and, on the other hand, of various allegations regarding the places and times of nest building of birds nesting on the ground including in particular the alleged according to which it was unlikely that birds reproducing on the ground nest in orchards, olive groves and vineyards. This new information allegedly did not include any realistic study conducted on the ground and were allegedly not supported by proof. They were thus allegedly misleading and incomplete and allegedly did not make it possible to answer the scientific committee's questions. The Kingdom of Sweden also adds that the fact that the Commission contented itself with this lacking dossier to authorize the registration of paraquat shows that its assessment was contrary to the principle of cautiousness.
- 201 The Kingdom of Sweden also states that the RMS indicates in its second report that the risk of exposure for birds nesting on the ground is low in alfalfa fields in autumn and winter. The Kingdom of Sweden maintains that considering the data available, that is the only use that was considered acceptable from the perspective of birds, such that only this use should be authorized. Consequently, it asserts that the Commission did not at all demonstrate more generally that there was a use of paraquat for which the risk of exposure for birds nesting on the ground would be acceptable.
- 202 The Commission contests the absence of sufficiently probative nature of the dossier concerning animal health to allow paraquat to be entered in Annex I of Directive 91/414.
- 203 With regard to hares, the Commission maintains first of all that the experts of the ECCO indicated that additional information was necessary to be able to evaluate the product on hares, after which the author of the notification completed the dossier.
- 204 It then notes that the scientific committee declared that the available information did not make it possible to evaluate the number of hares able to be affected,

but that there were measures making it possible to reduce the risks vis-à-vis these animals.

- 205 In this regard, it states that in its second report, the RMS indicated that the scientific committee and the author of the notification proposed measures aiming to reduce the risks for hares (spray early in the morning, since hares are nocturnal animals; add a dissuasive substance to the product; spray starting from the middle of the field; avoid spraying on the entire field the same day) and that according to the situation in the various Member States, these States should be authorized to stipulate adapted conditions of use when granting authorizations of phytopharmaceutical products.
- 206 The Commission adds that before the uncertainty regarding the number of hares concerned, the RMS evaluated a scenario regarding the use of paraquat in stubble fields in the United Kingdom. According to it, the choice of this scenario was justified by the fact that such a use had caused incidents in the 1960s, that data were available for the United Kingdom and that such a use of paraquat was envisaged by the author of the notification.
- 207 It also asserts that the evaluation table shows that the author of the notification stated that the restrictive measures proposed by the scientific committee had been effective. It also maintained that the evaluation table indicates that the RMS and the standing committee deemed that the information available was sufficient.
- 208 Finally, it states that a specific condition concerning hares was introduced in the contested directive.
- 209 Concerning birds, the Commission first of all asserts that the scientific committee limited itself to stating that the method consisting in dipping an egg in paraquat for 30 seconds clearly went beyond the most unfavourable realistic scenario and that, consequently, to be able to comment on the risks, more realistic studies - based, for example, on a spraying - were necessary.
- 210 It then notes that the author of the notification forwarded additional data. It contests that this information was allegedly fallacious and insufficient and that it did not answer the scientific committee's questions. In this last regard, it asserts firstly that the Kingdom of Sweden does not specify what questions of the scientific committee allegedly remained unanswered. Secondly, it maintains that in its second report, the RMS took into account the effects of spraying eggs and deemed that in numerous situations, the exposure of birds nesting on the ground was negligible and, consequently, the risk was acceptable, but that in cases where exposure was possible, the risk had to be assessed, if possible at the level of the Member State.

- 211 The Commission also asserts that in the addendum to the preliminary report, the RMS emphasized that the initial evaluation of the risk remained acceptable, that the information provided by the author of the notification had been critically examined, that this information was reliable and could be used for an evaluation of the risk at European level and that, under the proposed conditions of use, paraquat did not expose birds nesting on the ground to an unacceptable incidence.
- 212 It adds that the evaluation table shows that the experts of the ECCO deemed that the risk for birds could be reduced thanks to the conditions of use. This table also allegedly showed that the RMS, which had evaluated the additional information provided by the author of the notification, deemed that the data forwarded were reliable and relevant, because they form the basis for a better evaluation of the risks for birds nesting on the ground. Lastly, this table allegedly indicates that paraquat did not present any unacceptable incidence if the specified conditions of use were complied with.
- 213 In addition, it also emphasizes that the contested directive explicitly specifies, as regards birds nesting on the ground, that when the scenarios of use indicate a potential exposure of the eggs, an evaluation of the risks must be carried out and, should the occasion arise, measures aiming to attenuate the risks must be implemented.
- 214 Lastly,, the Commission asserts that though it is true that the contested directive does not specify any specific measure for mammals other than hares, that is because it is impossible to take into account the eventual risks for each mammal, which is why, during the evaluation, a pragmatic and realistic approach would lead one to concentrate this evaluation on the most exposed to animals. However, the dossier allegedly attests that information concerning other mammals, such as voles and rats, was also examined. In addition, it maintains that when a Member State must decide on the eventual authorization of a phytopharmaceutical product containing an active substance entered in Annex I, it is obligated to comply with the provisions of Annex VI, point B 2.5.2.1 of which demands that it assess the possible of exposure of birds and other land vertebrates to the phytopharmaceutical product and, if this possibility is real, to evaluate the magnitude of the risk in the short-term and the long term, and in particular for reproduction, to which these organisms could be exposed to after application of the product according to the proposed conditions of use. This provision would thus be adapted to the specific conditions that may prevail in a specific Member State and for a precise method of use. In addition, the Member State could combination the authorization with specific conditions, such as the adding of a dissuasive substance.

b) Regarding the complaint drawn from the inadequacy of the ratio of long-term toxicity to exposure in light of point C 2.5.2.1 of Annex VI.

215 The Kingdom of Sweden asserts in substance that point C 2.5.2.1 of Annex VI indicates that in case of potential exposure of birds and other land vertebrates not referred to, one should apply a special limit value and a safety margin according to which the ratio of long-term toxicity to exposure must be equal to or greater than 5. But the studies on which the Commission allegedly based its assessment within the framework of the evaluation of paraquat allegedly indicate that the ratio concerned was only 2. It adds that the Commission has not demonstrated that there was a use of paraquat for which the risk of exposure for birds nesting on the ground would be acceptable. It allegedly follows from this that the Commission, basing itself on the existing dossier, could not conclude that there was no unacceptable risk.

216 The Commission maintains in substance that it falls to the Member States and not to it to apply Annex VI when authorizing a phytopharmaceutical product.

c) Regarding the complaint drawn from leaving the evaluation and eventual management of risks to the Member States

217 The Kingdom of Sweden, supported by the Republic of Austria and the Kingdom of Denmark, asserts that the conditions specified by the contested directive attest that the Commission chose to leave to the Member States the evaluation of the risks, as well as the fundamental assessment of the question whether it is possible to attain an acceptable level of risk. Such a leaving is allegedly contrary to Directive 91/414.

218 The Commission contests having chosen to transfer the evaluation of the risk to the Member States and leaving to them the task of fundamentally assessing whether or not it is possible to attain an acceptable level of risk. In this regard, it asserts in substance that a community evaluation was carried out. Thus, concerning hares it states that the RMS and the evaluation group of the standing committee both deemed that the available information was sufficient to assess the risks and that the contested directive specifies that, when the scenarios of use indicate a potential exposure of hares, an evaluation of risks must be carried out and, should the occasion arise, measures aiming to attenuate the risks must be implemented.

219 Concerning birds, it states that in the RMS's second report, it deemed that in numerous situations, the exposure of birds nesting on the ground 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 cites the addendum's conclusion according to which, in the proposed conditions of use, paraquat does not expose

birds nesting on the ground to an unacceptable incidence. Lastly, it mentions the evaluation table that allegedly shows that according to the examination report of the ECCO, the risk for birds could be reduced thanks to the conditions of use.

d) Regarding the complaint drawn from the existence of unacceptable pains for exposed animals

- 220 The Kingdom of Sweden asserts first of all that Article 5, paragraph 1, sub b), of Directive 91/414 specifies that in order to be entered in Annex I of this directive, an active substance must meet the requirements of Article 4, paragraph 1, sub b), iv) and v) of this directive and that, by virtue of Article 4, paragraph 1, sub b), v), second dash, of this directive, using the phytopharmaceutical product in question cannot have an unacceptable influence on the environment, considering its effect on the species that are not referred to. This last provision should be interpreted in the sense that using the phytopharmaceutical product concerned cannot cause unacceptable suffering and pains in the species not referred to since, concerning vertebrates to be combated, Article 4, paragraph 1, sub b), iii) of this directive allegedly contests that the product concerned causes such suffering or such pains.
- 221 It then asserts that it is known that persons exposed to paraquat undergo strong pains and severe suffering and that the scientific dossier shows that this is also the case in the other mammals. Consequently, the contested directive is allegedly contrary to the requirements of Article 5, paragraph 1, sub b) of Directive 91/414.
- 222 The Commission has not taken a position on this complaint in its briefs. However, it did contest at the hearing the relevance of Article 4, paragraph 1, sub b), v), second dash, of Directive 91/414 for the evaluation of an active substance.

2. Assessment by the Court

a) Concerning the assessment framework

- 223 With respect to protecting animal health, Article 5, Paragraph 1 of Directive 91/414 provides that, in order for a substance to be registered in Annex I to this Directive, one must be able to rest assured that, given the existing scientific and technical know-how, when administered in accordance with phytosanitary best practices, the use of the phytopharmaceutical products containing the active substance in question will not produce any harmful effects on animal health, in accordance with Article 4, Paragraph 1, subsection b), iv), of Directive 91/414.
- 224 For reasons similar to those expressed in the context of the first prong of this argument relating to the protection of human health (see Point 161 above), this provision, read in conjunction with the Precautionary Principle

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implies that, with respect to animal health, the existence of serious signs that, without ruling out scientific uncertainty, would give rise to reasonable doubts as to the harmlessness of a substance, in principle would argue against registering such a substance in Annex I to Directive 91/414.

- 225 In order to assess whether the requirements concerning the protection of animal health stipulated in Article 5, Paragraph 1 of Directive 91/414 have been satisfied, it is advisable to apply the uniform principles set forth in Annex VI, for the reasons expressed in Points 162 through 167 above.
- 226 More specifically, Point C 2.5.2.1 of Annex VI provides, in essence, that no authorisation shall be granted in the event of potential exposure of non-target birds and other terrestrial vertebrates if the long-term toxicity/exposure ratio is below 5, unless a suitable risk assessment specifically determines that there is no negative impact following use of the phytopharmaceutical product under the proposed conditions.
- 227 Finally, for the reasons expressed in Points 169 and 170 above, before making any entry to Annex I to Directive 91/414, it must be established beyond any and all reasonable doubt that the restrictions on use of the substance in question under the conditions stipulated in Article 5, Paragraph 4 of Directive 91/414 will make it possible to guarantee that this substance can be used in a way that complies with the requirements of Article 5, Paragraph 1 of Directive 91/414.
- 228 In view of the rules just described, it is advisable to review the various grievances put forward as part of this prong (of the argument).

b) Concerning the grievances put forward

Concerning the first grievance, based on the failure of the case records to convincingly demonstrate that the *paraquat* (Translator's Note: toxic herbicide) does not produce harmful effects on animal health

- 229 To begin with, it is advisable to investigate whether, when the Commission examines an active substance pursuant to Article 5, Paragraph 1, subsection b) of Directive 91/414, this institution is obliged to assess all the typical uses of the substance in question, such as those indicated by the Notifying Party.
- 230 In this respect, one should note that, according to Preamble 2 of the Directive being contested, the effects of the *paraquat* (toxic herbicide) were analysed in accordance with the provisions of Regulation No. 3600/92 for a series of applications suggested by the Notifying Party.
- 231 Moreover, in response to a question posed by the Court, the Commission made it clear, during the hearing, that it was required to investigate the use of the *paraquat* as a herbicide for the fourteen uses mentioned in Annex IV to the Commission's Assessment Report, namely, the use of the *paraquat* in the farming of lemons,

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walnuts, treenuts (hazelnuts), apples, grapes, strawberries, olives, fruiting vegetables (tomatoes/cucumbers), vegetable crops/beans, potatoes, and lucerne/alfalfa, as well as using this substance on stubble fields (autumn stubbles), during spring land preparation, in forestry and on ornamental plants, and for non-crop land.

- 232 In this instance, therefore, one should take into account the fact that the Commission's assessment, which concluded that the *paraquat* is not harmful to animal health, is based on an analysis of the fourteen uses considered by the Notifying Party.
- 233 Now, to investigate the *paraquat*'s effects on the health of hares and on bird embryos, only two types of use were examined, namely, with respect to the hares, the use of the *paraquat* in the autumn stubble fields, and, with respect to birds, the use of the *paraquat* in the lucerne/alfalfa fields in fall and winter.
- 234 Moreover, the Commission does not put forward any reason why it was not necessary to investigate the twelve other typical uses of the *paraquat* in order to evaluate this substance's impact on the health of the hares and the bird embryos.
- 235 Under these conditions, it is advisable to uphold the grievance, based on the failure of the case records to convincingly demonstrate that the *paraquat* does not produce harmful effects on the health of the hares and the bird embryos.
- 236 Secondly, it is advisable to investigate whether, as disputed by the Kingdom of Sweden, it has been adequately established that the measures put forward by the Commission have actually made it possible to reduce the risk to the hares' health posed by the *paraquat*.
- 237 In this respect, the Commission alleges that the Scientific Advisory Board and the Notifying Party have identified steps that might be able to reduce the risk to the hares, that the Notifying Party has confirmed that these steps were effective and that the RMS ("Rapporteur Member State") and the Permanent Committee felt that the information available was adequate to evaluate the *paraquat*'s impact on the hares' health.
- 238 These factors alone do not enable one to conclude that the effectiveness of the alleged steps has been adequately established for legal purposes.
- 239 Indeed, it must be noted that the conclusion contained in the Scientific Advisory Board's opinion indicates that one could expect the *paraquat* to have lethal or sublethal effects on the hares and that this was confirmed by the field studies.

Further, it must be emphasised that the Scientific Advisory Board came to this conclusion after considering the steps which the Commission maintains will make it possible to reduce the identified risk. Therefore, the effectiveness of the measures put forward might be considered adequately established only on the basis of the new scientific data, as opposed to the data considered by the Scientific Advisory Board. Now, there is no denying that the Commission does not put forward the slightest piece of data of this kind. Thus, one must conclude that the Commission has failed to establish the effectiveness of the measures that it puts forward.

- 240 Moreover, it must be noted that the measures which the Commission claims would be capable of reducing the risks to the hares, such as spraying the *paraquat* early in the morning, adding a deterrent substance to the product, spraying it from the middle of the field toward the borders of the field or spraying only one part of the field, are mentioned neither directly nor indirectly in the disputed Directive as specific provisions under Article 5, Paragraph 4 of Directive 91/414.
- 241 More specifically, the fact that the Annex to the disputed Directive requires that the Member States pay particular attention to protecting hares and, where needed, perform a risk assessment and manage such risks, can in no way be deemed to be a restriction on the use of the *paraquat*, under the terms of Article 5, Paragraph 4 of Directive 91/414, which establishes, beyond any reasonable doubt, that the Directive allows a guarantee that this substance may be used, in compliance with the requirements of Article 5, Paragraph 1 of Directive 91/414.
- 242 Consequently, the grievance's reproach of the Commission – for relying on a case that does not enable it to adequately establish for legal purposes that the alleged steps are capable of reducing the identified risk to the hares – should likewise be upheld.
- 243 Thirdly, concerning the grievance, based on the failure of the case records to convincingly demonstrate that the steps prescribed for reducing the risks to the birds' health, this grievance shall be investigated jointly with Grievances Two and Three put forward in this prong of the argument (see Point 252 below).

Concerning Grievances Two and Three, relating, respectively, to the insufficiency of the long-term toxicity/exposure ratio regarding Point C 2.5.2.1, and to the fact that it has relegated to the Member States the responsibility for assessing and managing the risks relevant to the protection of the health of bird embryos

- 244 Regarding the long-term toxicity/exposure ratio, to start with, it can be concluded from the Kingdom of Sweden's response to a written question submitted by the Court, which was not disputed by the Commission, that the terms "long-term toxicity/exposure ratio" and "safety margin" are synonymous. Likewise, it can be concluded from this response that, in order to assess the risks to ground-nesting birds, the Commission

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is relying on the studies indicating that the negative impact on the hatching of eggs were observed when these eggs were exposed to a dose of *paraquat* equivalent to spraying 2.24 kilograms of the substance per hectare of surface area sprayed, whilst the maximum dose recommended by the Notifying Party was 1.1 kilograms of the substance per hectare. The Kingdom of Sweden concludes, and the Commission does not contradict it on this point, that this body is relying on a safety margin of 2, and not a safety level of 5, as recommended by Point C 2.5.2.1 of Annex VI.

- 245 However, selecting a safety margin lower than 5 does not violate Point C 2.5.2.1 of Annex VI, except to the extent that it appears that no suitable assessment of the risk was performed that specifically establishes that there is no unacceptable impact when a phytopharmaceutical product containing the *paraquat* is used under the suggested conditions.
- 246 Therefore, it is advisable to investigate whether the Commission has proven that in fact there was a way of using the *paraquat* that would yield an acceptable risk of exposure for ground-nesting birds, a fact which is disputed by the Kingdom of Sweden, both within the context of the grievance relating to the disregard of Point C 2.5.2.1 and within the framework of the first grievance, based on the unconvincing case records.
- 247 In its opinion, the Scientific Advisory Board indicated that the *paraquat* could represent a risk to bird embryos but that, in order to assess the risks, it would require additional information from realistic tests.
- 248 The second RMS report notes that additional information was provided by the Notifying Party, in the form of three studies dealing with the results of spraying the *paraquat* on Japanese quail (*Coturnix coturnix japonica*) eggs, mallard duck eggs and pheasant (*Phasianus colchicus*) eggs.
- 249 In its second report, the RMS indicates that the conclusion of the studies referred to in the preceding point is that spraying the mallard duck eggs and the pheasant eggs with twice the recommended dose of *paraquat* results in an overall reduction in the number of such eggs that hatch. Further, the RMS asserts that some of the uses suggested by the Notifying Party pose little risk to bird embryos, due to the time of use or because of the unlikelihood of any nest-building in the farming areas affected by a dose of *paraquat*, but that certain farming areas where the use of the *paraquat* is planned may be a suitable habitat for the ground-nesting birds. However, the RMS makes it clear that it does not have information that would allow it to determine whether birds are actually nesting in such farming areas, and if so, in what numbers. The RMS adds that these data are specific to each Member State and that, as a consequence, the risk must be determined at the level of the Member States.

- 250 The disputed Directive explicitly states that the assessment performed by the standing committee concluded that the risk to birds would be acceptable, provided that the appropriate measures designed to mitigate the risks were taken.
- 251 In view of the above, there is no denying that the Commission has not put forward any specific measure for which it has been established beyond a reasonable doubt that such measure would indicate that the *paraquat* should be entered in Annex I to Directive 91/414, in compliance with the requirements stipulated by Article 5, Paragraph 1, subsection b) of Directive 91/414 relating to the health of birds.
- 252 As a result, when the *paraquat* was registered in Annex I to Directive 91/414, it had not yet been specifically established that the *paraquat* did not have any unacceptable impact on the health of bird embryos, because only future steps to be taken by Member States were likely to make this risk acceptable. Therefore, the grievance resulting from the Commission's disregard of Point C 2.5.2.1 of Annex VI must be upheld. The same applies to the grievance based on the failure of the case records to convincingly provide grounds for registering the *paraquat* in Annex I to Directive 91/414 under the terms of the requirements stipulated by Article 5, Paragraph 1, subsection b) of the same Directive relating to the health of birds. Finally, in view of the above, the grievance resulting from the fact that the responsibility for assessing and managing the risks relevant to the protection of the health of bird embryos has been relegated to the Member States, in violation of Article 5 of Directive 91/414, must likewise be upheld.

Concerning Grievance Four, resulting from the unacceptable suffering of these animals caused by exposure to the *paraquat*

- 253 In this regard, one must note that the Kingdom of Sweden is starting from the assumption that Article 4, Paragraph 1, subsection b), v), Item 2 of Directive 91/414 – which stipulates the absence of any unacceptable environmental impact, specifically taking into account the effect on non-target species of the product containing the active substance – is relevant for the purposes of assessing whether the requirements stipulated by Article 5, Paragraph 1, subsection b) of Directive 91/414 concerning animal health have been met.
- 254 However, this is not the case. Indeed, Article 5, Paragraph 1 of Directive 91/414 draws a distinction, on the one hand, between human or animal health, for which no harmful effects are tolerated, and, on the other hand, the environment, for which only unacceptable effects are regarded as inadmissible. Similarly, Article 4, Paragraph 1, subsection b) of Directive 91/414 deals separately with the issue of harmful effects on human or animal health [Article 4, Paragraph 1, subsection b), iv), of Directive 91/414] and the issue of unacceptable environmental impact [Article 4, Paragraph 1, subsection b), v), of Directive 91/414]. It follows from the structure of Articles 4 and 5 of Directive 91/414 that, with respect to assessing an active substance from the standpoint of

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protecting animal health pursuant to Article 5, Paragraph 1, subsection b) of Directive 91/414, the cross-reference that this provision makes to Article 4, Paragraph 1, subsection b) of the same Directive concerns only that provision of the latter article dealing specifically with animal health, namely Article 4, Paragraph 1, subsection b), iv) of the Directive in question.

- 255 Consequently, due to the fact that Article 4, Paragraph 1, subsection b), iv) of Directive 91/414 already deals specifically with the issue of the impact on animal health of the product containing the active substance, Article 4, Paragraph 1, subsection b), v), Item 2 of the same Directive relating to the absence of any unacceptable environmental impact, taking into account its effect on non-target species, is not relevant in assessing whether a substance meets the requirements stipulated by Article 5, Paragraph 1, subsection b) of the Directive concerning the impact on non-target species.
- 256 Moreover, it is advisable to add, in any case, that even if it happens that Article 4, Paragraph 1, subsection b), v), Item 2 of Directive 91/414 does in fact apply, in order to assess whether the requirements stipulated in Article 5, Paragraph 1, subsection b) of Directive 91/414 concerning animal health have been met, the Kingdom of Sweden's grievance should not be upheld.
- 257 True, if it happens that Article 4, Paragraph 1, subsection b), v), Item 2 of Directive 91/414 does in fact apply, there is every reason to believe that this provision requires the absence of unacceptable suffering or pain by non-target animals on account of the product containing the active substance in question. Indeed, as Article 4, Paragraph 1, subsection b), iii) of Directive 91/414 opposes unacceptable suffering or pain by the vertebrates which the product in question is designed to combat, as asserted by the Kingdom of Sweden, *a fortiori*, the animals which the product in question is not designed to combat should enjoy at least equal protection.
- 258 However, the Kingdom of Sweden has failed to put forward even the slightest argument that would allow one to conclude that the *paraquat* causes the hares unacceptable suffering or pain and restricts itself to noting that, since the *paraquat* causes such pain and suffering in humans, it should be assumed that it has identical effects on mammals such as the hare, on which the *paraquat* certainly has lethal or sublethal effects.
- 259 Now, although it is probable that those animals which are exposed to deadly doses of the *paraquat* experience severe pain and suffering, it does not necessarily follow that such pain and suffering constitute a violation of those provisions of Article 4 that were explicitly put forward by the Kingdom of Sweden as part of this grievance. Indeed, in contrast to Article 4, Paragraph 1, subsection b), iv) of Directive 91/414, which does not tolerate any direct or indirect harmful effects on animal health by the product containing the active substance, Article 4, Paragraph 1, subsection b), iii) and v) of Directive 91/414 limit themselves to prohibiting suffering and

pain of an unacceptable nature. Consequently, these provisions are deemed to have been disregarded only if it has been established that the threshold of acceptability has been exceeded, which in this case the Kingdom of Sweden has failed to establish. Thus, the Kingdom of Sweden does not endeavour either to specify beyond which threshold such pain and suffering would be considered unacceptable or to define when such threshold was exceeded in this particular case.

- 260 Thus, in the absence of any facts to bolster its assertion that exposure to the *paraquat* causes unacceptable suffering or pain to the hares, Grievance Four cannot be upheld.
- 261 It follows that, with the exception of Grievance Four, the second prong of the argument concerning animal health should be upheld.
- 262 In view of the above and the conclusion reached in Point 191 above, there is every reason to uphold, in essence, each of the two prongs of the group of arguments resulting from the violation of Article 5 of Directive 91/414, the principles of integration, the Precautionary Principle and the principle of a high level of protection.
- 263 As both of the two groups of arguments raised have been upheld, at least partially, it is advisable that the disputed Directive be declared void.

Concerning costs

- 264 Under Article 87, Paragraph 2 of the Rules of Procedure, each unsuccessful Party is to be ordered to pay the costs, if they have been applied for in the successful Party's rulings. Otherwise, under Article 87, Paragraph 4 of the Rules of Procedure, the Member States joining in the action shall bear their own expenses.
- 265 As the Commission has been unsuccessful, it must be ordered to pay the costs incurred by the Kingdom of Sweden, as applied for by the latter Party.

On these grounds,

THE COURT (Second Chamber, Extended Composition)

hereby declares and rules that:

- 1) The Commission's Directive 2003/112/CE dated 1 December 2003 amending the Council's Directive 91/414/CEE in order to register the active substance *paraquat* therein, is null and void.**
- 2) The Commission must pay the expenses incurred by the Kingdom of Sweden, as well as its own expenses.**

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3) The Kingdom of Denmark, the Republic of Austria and the Republic of Finland shall bear their own expenses.

Pirrung

Meij

Forwood

Pelikánová

Papasavvas

Delivered in open court in Luxembourg, 11 July 2007.

The Registrar

The Presiding Judge

E. Coulon

J. Pirrung

Case ID: 220300429