Case T-229/04

Kingdom of Sweden

v

Commission of the European Communities

(Directive 91/414/EEC — Plant-protection products — Paraquat as an active substance — Marketing authorisation — Authorisation procedure — Protection of human and animal health)

Summary of the Judgment

1. *Agriculture — Approximation of laws — Placing of plant protection products on the market — Directive 91/414*

   (Commission Regulation No 3600/92, Art. 7(1)(c) and (3); Council Directive 91/414; Commission Directive 2003/112)

2. *Agriculture — Approximation of laws — Placing of plant protection products on the market — Directive 91/414*

(Council Directive 91/414, Arts 4(1)(b)(iv) and 5(1) and (4), Annex I)

3. *Agriculture — Approximation of laws — Placing of plant protection products on the market — Directive 91/414*

(Council Directive 91/414, Arts 4(1)(b)(iv) and (v), second indent, and 5(1)(b))

1. In adopting Directive 2003/112 amending Directive 91/414 concerning the placing of plant protection products on the market, in order to include paraquat as an active substance in Annex I thereto, the Commission, by stating in its assessment report that there was no indication that paraquat was neurotoxic, failed to fulfil the procedural requirements laid down in Article 7 of Regulation No 3600/92 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414, concerning the examination of a possible link between paraquat and Parkinson's disease.

There are, in the literature concerning the neurotoxicity of paraquat, indications of a link between use of that substance and the appearance of Parkinson's disease. Consequently, if the rapporteur Member State had assessed the literature concerning the possibility of a link between use of paraquat and Parkinson's disease, that assessment would have been carried out in the context of an assessment of paraquat's neurotoxicity. Article 7(1)(c) of Regulation No 3600/92 requires that the examination of an active substance by the rapporteur Member State be followed by a report to the Commission, which, by virtue of Article 7(3) of the regulation, must be referred to the Standing Committee on the Food Chain and Animal Health and to the other Member States for information.

In this case, however, the reports of the rapporteur Member State contain no assessment of the literature concerning possible links between paraquat and Parkinson's disease. Nor has the Commission established, or even claimed, that such an assessment was sent to the Standing Committee.

(see paras 108-110)

2. For a substance to be capable of inclusion in Annex I to Directive 91/414 concerning the placing of plant protection products on the market, Article 5(1) of that directive provides that it must be possible to expect that, in the light of current scientific and technical knowledge, the use of plant protection products containing the active substance, consequent on an application consistent with good plant protection practice, will not have any harmful effects on human and animal health, in accordance with Article 4(1)(b)(iv) of Directive 91/414.

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

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

Article 5(1) of that directive, interpreted in combination with the precautionary principle, that, in the domain of human and animal health, the existence of solid evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies the refusal to include that substance in Annex I to Directive 91/414. The precautionary principle is designed to prevent potential risks. By contrast, purely hypothetical risks, based on mere hypotheses that have not been scientifically confirmed, cannot be accepted.

(see paras 160, 161, 169, 170, 223, 224, 227)

3. Article 5(1) of Directive 91/414 concerning the placing of plant protection products on the market draws a distinction between, on the one hand, human or animal health, in respect of which the existence of harmful effects is not

tolerated, and, on the other, the environment, in respect of which only unacceptable influences are excluded. Similarly, Article 4(1)(b) of Directive 91/414 deals separately with the question of harmful effects on human or animal health (Article 4(1)(b)(iv) of the directive) and the question of unacceptable influence on the environment (Article 4(1)(b)(v) of the directive). It follows from the structure of Articles 4 and 5 of Directive 91/414 that when an active substance is to be assessed from the point of view of the protection of animal health under Article 5(1)(b) of that directive, the reference which that provision makes to Article 4(1)(b) applies only to the provisions of the latter article which deal specifically with animal health, namely Article 4(1)(b)(iv). Consequently, by reason of the fact that Article 4(1)(b)(iv) of Directive 91/414 already deals specifically with the question of the effects of a product containing the active substance on animal health, the second indent of Article 4(1)(b)(v) thereof, concerning the absence of an unacceptable influence on the environment having regard to the impact on non-target species, is not relevant when assessing whether a substance fulfils the requirements of Article 5(1)(b) of the directive in regard to the impact on non-target species.

(see paras 254, 255)