Case T-392/02

Solvay Pharmaceuticals BV

v

Council of the European Union

(Directive 70/524/EEC — Community authorisation of an additive in animal feedingstuffs, linked to the person responsible for putting it into circulation — Transitional rules — Withdrawal of the authorisation — Action for annulment — Admissibility — Conditions for withdrawal — Precautionary principle — Principles of equal treatment, legal certainty, sound administration and good faith)

Summary of the Judgment

1. *Agriculture — Common agricultural policy — Additives in feedingstuffs — Directive 70/524 — Regulation providing for the withdrawal of authorisation to market certain additives in feedingstuffs — Replacement of a temporary authorisation for an additive with a definitive authorisation — Simultaneous implementation of a procedure for the withdrawal of the additive — Whether permissible*
(Council Directive 70/524, Arts 9h, 9m and 11)

2. *Agriculture — Common agricultural policy — Implementation — Requirements relating to protection of public health, safety and the environment to be taken into account — Application of the precautionary principle*

(Arts 3p EC, 6 EC, 152(1) EC, 153(1) and (2) EC and 174(1) and (2) EC)

3. *Agriculture — Common agricultural policy — Additives in feedingstuffs — Scientific uncertainty as to the safety of a substance — Application of the precautionary principle — Scope — Limits*

4. *Agriculture — Common agricultural policy — Additives in feedingstuffs — Directive 70/524 — Re-evaluation of an additive — Duty of the Commission to inform the person responsible for putting the additive into circulation of the principal gaps in its dossier*

(Council Directive 70/524, Art. 9m, fifth indent)

1. In the scheme of Directive 70/524 concerning additives in feedingstuffs the transitional provisions of Article 9h do not preclude the implementation, in parallel with the purely administrative procedure for replacing the provisional authorisation of an additive by a definitive authorisation, of a safeguard measure under Article 11 of that directive or of a procedure for withdrawing the additive based on Article 9m of that directive.

In particular, given the formal nature of the check carried out for the purposes of granting a new authorisation on the basis of Article 9h of Directive 70/524, the grant of an authorisation on the basis of that provision is not such as to give rise to a presumption that the substance in question is safe or, therefore, to have any bearing on the totally autonomous assessment of that substance carried out under the re-evaluation procedure.

(see paras 112-113)

2. The precautionary principle constitutes a general principle of Community law requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Since the Community institutions are responsible, in all their

spheres of activity, for the protection of public health, safety and the environment, the precautionary principle can be regarded as an autonomous principle stemming from the Treaty provisions, in particular Articles 3(p) EC, 6 EC, 152(1) EC, 153(1) and (2) EC and 174(1) and (2) EC.

to take precedence over economic interests, as well as with the principles of proportionality and non-discrimination.

(see paras 121-122, 125)

In the field of public health, the precautionary principle implies that, where there is uncertainty as to the existence or extent of risks to human health, the institutions may take precautionary measures without having to wait until the reality and seriousness of those risks become fully apparent.

3. In the domain of additives for feedingstuffs, 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 withdrawal of the authorisation for that substance. 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.

Where scientific evaluation does not make it possible to determine the existence of a risk with sufficient certainty, whether to have recourse to the precautionary principle depends on the level of protection chosen by the competent authority in the exercise of its discretion, taking account of the priorities that it defines in the light of the objectives it pursues in accordance with the relevant rules of the Treaty and of secondary law. That choice must, however, comply with the principle that the protection of public health, safety and the environment is

To make the maintenance of the authorisation of a substance subject to proof of the lack of any risk, even a purely hypothetical one, would be both unrealistic — in so far as such proof is generally impossible to give in scientific terms since 'zero risk' does not exist in practice — and contrary to the principle of proportionality.

Furthermore, the adoption of a precautionary measure in order to prevent

a risk which cannot be demonstrated in the state of scientific knowledge at the date of that adoption, but which is supported by sufficiently serious evidence, may in certain cases be deferred on the basis of the nature, the seriousness and the scope of that risk on the basis of a balancing of the various interests involved. During that balancing exercise the competent authority enjoys a wide discretion.

(see paras 129-130, 135)

4. In so far as the fifth indent of Article 9m of Directive 70/524 concerning additives in feedingstuffs refers to requests for information addressed to the person responsible for putting an additive into circulation for the purposes of re-evaluating that substance, it must be interpreted, in relation to the principles of legal certainty and sound administration, as meaning that it constitutes the legal basis of a right on the part of the person responsible for putting an additive into circulation to be informed of the main gaps in its authorisation dossier. Apart from urgent cases, the Commission cannot withdraw the authorisation for an additive without allowing its holder to provide the information which the Commission considers appropriate in order to fill those gaps.

It follows that, whilst there can be no requirement for the Commission to give formal notice to the person responsible for putting an additive into circulation, in the absence of any express procedural provision to that effect, that person must however be closely associated with the procedure for the re-evaluation of that additive and may invoke the right to be informed of the main gaps in its dossier which stand in the way of the authorisation being maintained.

Compliance with those procedural safeguards is subject to judicial review by means of an action against the contested regulation which brings the re-evaluation procedure to an end.

(see paras 186-188)