Case T-392/02 R

Solvay Pharmaceuticals BV

v

Council of the European Union

(Proceedings for interim relief — Directive 70/524/EEC — Withdrawal of marketing authorisation for an additive in feedingstuffs — Regulation (EC) No 1756/2002 — Application for suspension of operation — Admissibility — *Prima facie* case — Urgency — Balancing of interests)

Order of the President of the Court of First Instance, 11 April 2003 . . . II - 1831

Summary of the Order

1. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Regulation providing for withdrawal of marketing authorisation for the additive Nifursol in animal feedingstuffs — Admissibility*
(Art. 230, fourth para., EC; Council Regulation No 1756/2002)

2. *Agriculture — Common agricultural policy — Implementation — Taking account of the precautionary principle — No express reference — Not relevant — Application of the principle — Scope — Limits*

   (Arts 152 EC and 174 EC; Council Regulation No 1756/2002; Commission Regulation No 2430/1999; Council Directive 70/524, Art. 3a(b))

3. *Agriculture — Common agricultural policy — Re-evaluation of an additive in animal feedingstuffs expressly not subject to re-evaluation — Renewal of marketing authorisation — Withdrawal of authorisation — Obligation of the Commission to serve formal notice on the person responsible for bringing the additive into circulation — Limits*

   (Council Directives 70/524, Art. 9m, second and fifth indents, 3a(b) and 9h and 96/51)

4. *Applications for interim measures — Suspension of operation of a measure — Interim relief — Conditions for granting — Urgency — Assessment criteria — Decision to adjudicate on the substance of the action under an expedited procedure within the meaning of Article 76a of the Rules of Procedure of the Court of First Instance — Not relevant*

   (Rules of Procedure of the Court of First Instance, Art. 76a(1))

5. *Applications for interim measures — Suspension of operation of a measure — Suspension of operation of a regulation providing for withdrawal of marketing authorisation for an additive in animal feedingstuffs — Conditions for granting — Serious and irreparable damage — Damage of a financial nature — Scope — Limits*

6. *Applications for interim measures — Suspension of operation of a measure — Conditions for granting — Balancing of all the interests at stake — Priority to be given to protection of public health over economic considerations — Priority to be given to the protection of human health over that of animal health*

   (Art. 30 EC; Rules of Procedure of the Court of First Instance, Art. 108)

1. The fourth paragraph of Article 230 EC is designed in particular to prevent the Community institutions from being able, merely by choosing the form of a regulation, to preclude an individual from bringing an action against a decision which concerns him directly and individually and thus to make it clear that the nature of a measure cannot be changed by the form chosen.

   Given that the sole aim of Regulation No 1756/2002 amending Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999 was to withdraw marketing authorisation for the additive Nifursol, of which the trader is the sole holder, and given that the latter is

also — as is apparent from Annex I to Regulation No 2430/1999 — the 'person responsible for putting it into circulation', it seems prima facie, even if that regulation were to be regarded as a measure of general application, that that trader should be regarded as directly and individually concerned by it.

(see paras 56-57)

2. In accordance with Article 174 EC, the precautionary principle is one of the principles on which Community policy on the environment is based; this includes the policy relating to the protection of human health. The principle is also established in Article 152 EC as forming a constituent part of the Community's other policies, amongst them the common agricultural policy.

The absence of express reference to the precautionary principle in the recitals of Regulation No 1756/2002 amending Directive 70/524/EEC concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Commission Regulation (EC) No 2430/1999 is not enough to preclude the relevance of that principle to the interpretation, in the present case, of the term 'adversely affect' referred to in Article 3a(b) of Directive 70/524, as amended. It follows prima facie that the Community institutions may, in the course of applying Directive 70/524, as amended, adopt measures on the basis of Article 3a(b), which take account of that principle, but are not necessarily required, when they adopt them, to make express reference to it.

However, a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken. Even if the judgment in Case C-121/00 *Hahn* justified the legislature in adopting zero or near-zero tolerance, that presupposes that the risk in question is well-established. Although the fact that the scientific data concerning the extent of a risk are uncertain does not, in Community law, preclude the risk from being regarded as established, it seems that a minimum level of scientific knowledge is still required.

(see paras 71-72, 80-81)

3. The interpretation of the second and fifth indents of Article 9m, and of

Article 3a(b), on the one hand, and of Article 9h, on the other, of Directive 70/524 concerning additives in feedingstuffs, as amended by Directive 96/51, does not justify precluding, at first sight, that, when the Commission re-evaluates an additive which is expressly not made subject to re-evaluation by the Community legislature in Directive 96/51 and subsequently renews the authorisation for a period of 10 years pursuant to the amendments introduced by that directive, it should be required — except in urgent cases in which a new, clear and serious risk suddenly appears — by itself, or through the Member State which is the rapporteur of the file, to send formal notice to the person responsible for bringing the additive concerned into circulation. Such a notice should contain a short but specific indication of the scientific doubts justifying re-evaluation and be sent during the re-evaluation procedure or, at least, before the Commission proposes the withdrawal of the authorisation of the additive. Accordingly, in the absence of any communication in the nature of such formal notice, the President of the Court cannot exclude the possibility that the regulation withdrawing authorisation of an additive expressly not made subject to re-evaluation is unlawful owing to an infringement of the fifth indent of Article 9m of Directive 70/524, as amended, during the procedure which preceded its adoption.

(see paras 85-87)

4. The fact that the Court of First Instance decided to reject the applicant's request that the Court adjudicate on the substance of the action under an expedited procedure cannot influence either the assessment of urgency or, should it prove necessary, the balancing of the interests concerned by the Judge hearing the application for interim measures. The relevant criteria for the existence of a 'particular urgency' which, under Article 76(a)(1) of the Rules of Procedure of the Court of First Instance, are to be satisfied if the Court is to adjudicate under an expedited procedure and those which, according to the case-law, govern the assessment of the condition of urgency that must be satisfied before the Judge hearing an application for interim measures is able to adopt such measures are only partly the same. Furthermore, the grant of an application for a case to be decided under an expedited procedure lies within the discretion of the Court, as is apparent from the use of the word 'may' in the first subparagraph of Article 76a(1) of the Rules of Procedure and requires that account also be taken of other circumstances, including the impact which the grant will have on the length of the proceedings in other cases.

(see para. 104)

5. Damage of a purely pecuniary nature cannot, save in exceptional circumstances, be regarded as irreparable or even as being reparable only with difficulty, if it can ultimately be the subject of financial compensation.

Under that principle, suspension of a regulation withdrawing authorisation of an additive in animal feedingstuffs could be justified only if it appeared that, if the measure were not granted, the applicant would be placed in a situation which would endanger its very existence or irremediably affect its market share.

As regards the first of these hypotheses, assessment of an applicant's economic circumstances can be made by taking into account, for example, the characteristics of the group of which, by virtue of its shareholding structure, it forms part.

Concerning the second hypothesis, the risk of the introduction of a marketing prohibition, comparable to that introduced by the contested regulation, on certain markets in non-member European countries cannot validly be invoked to establish the urgency for suspending such a Community measure. If there are no obstacles of a structural or legal nature preventing the manufacturer of a product, who is required to have a marketing authorisation, from regaining a significant proportion of its market share with the help *inter alia* of appropriate publicity measures, it cannot be ruled out that the loss caused by a withdrawal of its authorisation is essentially of a financial nature. That would be so in the case of the loss arising from withdrawal of authorisation for Nifursol in animal feedstuffs. However, the President of the Court cannot wholly exclude the possibility that such arguments underestimate the difficulties which the applicant would have, probably at each level of the production chain and above all at the levels of the farmers and large retailers, in relaunching its product in two years at least. Furthermore, and more significantly, it is difficult to exclude the possibility that the structure of the Community market for the sale of turkey-meat might be permanently and significantly altered between now and the date on which judgment is given on the substance by an increase in imports from non-member countries.

In those circumstances, the risk of damage which is serious and partly irreparable or reparable only with difficulty following the withdrawal of Nifursol during the course of the main proceedings cannot be ruled out.

(see paras 106-108, 110, 113-120)

6. When balancing the interests, the Judge hearing the application for interim relief has to determine whether the annulment of the contested measure by the court hearing the main action would enable the situation brought about by its immediate implementation to be reversed and, conversely, whether suspension of the operation of that

measure would be such as to prevent its being fully effective in the event of the main application being dismissed.

In that respect, the requirements of the protection of public health must undoubtedly take precedence over economic considerations. It follows that, where a serious risk to human health is invoked by a defendant Community institution, the Judge hearing the application for interim relief, notwithstanding his formal discretion in balancing the interests, will almost inevitably lean in favour of protecting public health. That is the case even if the urgency justifying the grant of the interim measure requested is obvious.

Moreover, the protection of the interests of Community turkey-meat producers, although commendable, cannot outweigh the damage which might be caused by the suspension of Regulation No 1756/2002 amending Directive 70/524 concerning additives in feedingstuffs as regards withdrawal of the authorisation of an additive and amending Regulation No 2430/1999 if the reality of the risk on which the Council based the regulation is confirmed. The fact that the Council (or the Commission) may have recourse to Article 108 of the Rules of Procedure of the Court of First Instance, should the requested suspension be granted and/or more scientific data be available before the judgment on the substance, in order to justify the withdrawal ordered by the contested regulation does nothing to alter the situation, as it is not enough to eliminate the risks presented in the meantime by the transmission to consumers of potentially genotoxic residues.

As for the protection of animal health although it is true that an increase in morbidity and mortality in Community turkey-farming caused by more frequent and disastrous outbreaks of histomoniasis is foreseeable from now on, the protection of animal health — the importance of which is, admittedly, acknowledged in Community law, particularly in Article 30 EC — cannot outweigh the pre-eminent nature of the requirements related to human health.

(see paras 122-127)