Case T-70/99

Alpharma Inc.

v

Council of the European Union

(Transfer of resistance to antibiotics from animals to humans — Directive 70/524/EEC — Regulation withdrawing authorisation of an additive in feedingstuffs — Admissibility — Breach of essential procedural requirements — Manifest error of assessment — Precautionary principle — Risk assessment and risk management — Consultation of a scientific committee — Principle of proportionality — Legitimate expectations — Obligation to state reasons — Rights of the defence)

Summary of the Judgment

1. *Actions for annulment — Natural or legal persons — Measures of direct and individual concern to them — Regulation providing for the withdrawal of authorisation to market certain additives in feedingstuffs, including bacitracin zinc, within the Community — Admissibility*

   (EC Treaty, Art. 173, fourth para. (now, after amendment, Art. 230, fourth para., EC); Council Regulation No 2821/98)

2. *Acts of the institutions — Choice of legal basis — Criteria — Act of Accession*

3. *Community law — Principles — Legal certainty — Community rules — Requirements of clarity and foreseeability — Express indication of the legal basis — Limit*

4. *Agriculture — Common agricultural policy — Implementation — Requirements relating to protection of health to be taken into account — Application of the precautionary principle*
(EC Treaty, Art. 130r(1) and (2) (now, after amendment, Art. 174(1) and (2) EC) and Art. 129(1), third para. (now, after amendment, Art. 152 EC))

5. *Agriculture — Common agricultural policy — Discretion of the Community institutions — Possibility of adopting guidelines — Judicial review — Limits*

6. *Agriculture — Common agricultural policy — Use of bacitracin zinc as an additive in feedingstuffs — Scientific uncertainty as to the existence or extent of risks to human health — Application of the precautionary principle — Scope — Limits*
(EC Treaty, Art. 130r(1) and (2) (now, after amendment, Art. 174(1) and (2) EC))

7. *Agriculture — Common agricultural policy — Scientific risk assessment — Requirement for a high level of human health protection — Scope*
(EC Treaty, Art. 129(1), first para. (now, after amendment, Art. 152 EC))

8. *Agriculture — Common agricultural policy — Discretion of the Community institutions — Extent —Judicial review — Limits*

9. *Agriculture — Common agricultural policy — Application of the precautionary principle — Scope — Limits — Observance of guarantees afforded by the Community legal order in administrative proceedings*

10. *Agriculture — Common agricultural policy — Power of the Community institutions — Ability to withdraw authorisation from an additive in feedingstuffs without first having obtained a scientific opinion from the competent scientific committees — Exceptional nature*

11. Actions for annulment — Contested measure — Assessment of legality on the basis of the information available at the time when the measure was adopted
(EC Treaty, Art. 173 (now, after amendment, Art. 230 EC))

12. Agriculture — Common agricultural policy — Use of bacitracin zinc as a growth factor in feedingstuffs — Risk for human health — Discretion of the Community institutions — Manifest errors of assessment — None
(Council Regulation No 2821/98; Council Directive 70/524, Art. 3a(e))

13. Community law — Principles — Proportionality — Acts of the institutions — Proportional character — Criteria for assessment — Discretion of the Community legislature in relation to the common agricultural policy — Judicial review — Limits
(EC Treaty, Arts 40 and 43 (now, after amendment, Arts 34 EC and 37 EC))

14. Community law — Principles — Rights of the defence — Observance of the rights of the defence in legislative procedures — Limits

1. A regulation is of individual concern to a person where, in the light of the specific circumstances of the case concerned, it adversely affects a particular right on which that person could rely.

Furthermore, by terminating or, at the least, suspending the procedure which had been opened, at the request of an economic operator, for the purposes of obtaining a new authorisation of bacitracin zinc as an additive in feedingstuffs, and in the course of which it had the benefit of procedural guarantees, Regulation No 2821/98 providing for the withdrawal of the authorisation to market certain additives in feedingstuffs, including bacitracin zinc, within the Community affects that operator by reason of a legal and factual situation which differentiates it from all other persons. That fact is also such as to distinguish it for the purposes of the fourth paragraph of Article 173 of the Treaty (now, after amendment, the fourth paragraph of Article 230 EC).

(see paras 90-92, 96)

2. In the context of the organisation of the powers of the Community the choice of

a legal basis for a measure must rest on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure.

A provision of an Act of Accession may serve as the legal basis on which to adopt legislative measures.

(see paras 106-107)

3. The principle of legal certainty, which is a general principle of Community law, requires Community legislation to be clear and its application foreseeable for all interested parties. As a result of that requirement, the binding nature of any act intended to have legal effects must be derived from a provision of Community law which prescribes the legal form to be taken by that act and which must be expressly indicated therein as its legal basis. However, failure to refer to a precise provision of the Treaty need not necessarily constitute an infringement of essential procedural requirements when the legal basis for the measure may be determined from other parts of the measure. However, explicit reference is indispensable where, in its absence, the parties concerned and the Court are left uncertain as to the precise legal basis.

(see para. 112)

4. In accordance with Article 130r(2) of the Treaty (now, after amendment, Article 174(2) EC), the precautionary principle is one of the principles on which Community policy on the environment is based. The principle also applies where the Community institutions take, in the framework of the common agricultural policy, measures to protect human health. It is apparent from Article 130r(1) and (2) of the Treaty that Community policy on the environment is to pursue the objective *inter alia* of protecting human health, that the policy, which aims at a high level of protection, is based in particular on the precautionary principle and that the requirements of the policy must be integrated into the definition and implementation of other Community policies. Furthermore, as the third subparagraph of Article 129(1) of the Treaty (now, after amendment, Article 152 EC) provides, and in accordance with settled case-law, health protection requirements form a constituent part of the Community's other policies and must therefore be taken into account when the common

agricultural policy is implemented by the Community institutions.

(see para. 135)

5. The Community institutions may lay down for themselves guidelines for the exercise of their discretionary powers by way of measures not provided for in Article 189 of the Treaty (now Article 249 EC), in particular by communications, provided that they contain directions on the approach to be followed by the Community institutions and do not depart from the Treaty rules. In such circumstances, the Community judicature ascertains, applying the principle of equal treatment, whether the disputed measure is consistent with the guidelines that the institutions have laid down for themselves by adopting and publishing such communications.

(see para. 140)

6. Where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.

It follows, first, that as a result of the precautionary principle, as enshrined in Article 130r(2) of the Treaty (now, after amendment, Article 174(2) EC), the Community institutions were entitled to take a preventive measure regarding the use of bacitracin zinc as an additive in feedingstuffs, even though, owing to existing scientific uncertainty, the reality and the seriousness of the risks to human health associated with that use were not yet fully apparent. *A fortiori*, the Community institutions were not required, for the purpose of taking preventive action, to wait for the adverse effects of the use of the product as a growth promoter to materialise. Thus, in a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality.

However, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been

scientifically verified. Rather, it follows from the Community Courts' interpretation of the precautionary principle that 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 when the measure was taken.

The taking of measures, even preventive ones, on the basis of a purely hypothetical risk is particularly inappropriate in the matter of additives in feedingstuffs. In such matters a 'zero risk' does not exist, since it is not possible to prove scientifically that there is no current or future risk associated with the addition of antibiotics to feedingstuffs. Moreover, that approach is even less appropriate in a situation in which the legislation already makes provision, as one of the possible ways of giving effect to the precautionary principle, for a procedure for prior authorisation of the products concerned.

The precautionary principle can therefore apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated.

In such a situation, 'risk' thus constitutes a function of the probability that use of a product or a procedure will adversely affect the interests safeguarded by the legal order.

Consequently, the purpose of a risk assessment is to assess the degree of probability of a certain product or procedure having adverse effects for human health and the seriousness of any such adverse effects.

(see paras 152-161)

7. In the assessment of risk, it is for the Community institutions to determine the level of risk — i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects — which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty.

Although they may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero-risk', the Community institutions must nevertheless take account of their obligation under the first subparagraph of Article 129(1) of the Treaty (now, after amendment, Article 152 EC) to ensure a high level of human health protection, which, to be compatible with that provision, does not necessarily have to be the highest that is technically possible.

The level of risk deemed unacceptable will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, *inter alia*, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge.

In matters relating to additives in feedingstuffs the Community institutions are responsible for carrying out complex technical and scientific assessments. In such circumstances a scientific risk assessment must be carried out before any preventive measures are taken.

A scientific risk assessment is commonly defined, at both international level and at Community level, as a scientific process consisting in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk.

The competent public authority must, in compliance with the relevant provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice.

Scientific advice is of the utmost importance at all stages of the drawing up and implementation of new legislation and for the execution and management of existing legislation. The duty imposed on the Community institutions by the first subparagraph of Article 129(1) of the Treaty to ensure a high level of human health protection means that they must ensure that their decisions are taken in the light of the

best scientific information available and that they are based on the most recent results of international research.

Thus, in order to fulfil its function, scientific advice on matters relating to consumer health must, in the interests of consumers and industry, be based on the principles of excellence, independence and transparency.

When the precautionary principle is applied, it may prove impossible to carry out a full risk assessment, because of the inadequate nature of the available scientific data. A full risk assessment may require long and detailed scientific research. Unless the precautionary principle is to be rendered nugatory, the fact that it is impossible to carry out a full scientific risk assessment does not prevent the competent public authority from taking preventive measures, at very short notice if necessary, when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society.

The competent public authority must therefore weigh up its obligations and decide either to wait until the results of more detailed scientific research become available or to act on the basis of the scientific information available. Where measures for the protection of human health are concerned, the outcome of that balancing exercise will depend, account being taken of the particular circumstances of each individual case, on the level of risk which the authority deems unacceptable for society.

So, where experts carry out a scientific risk assessment, the competent public authority must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts. Consequently, if it is not to adopt arbitrary measures, which cannot in any circumstances be rendered legitimate by the precautionary principle, the competent public authority must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue. Notwithstanding the existing scientific uncertainty, the scientific risk assessment must enable the competent public authority to ascertain, on the basis of the best available scientific data and the most recent results of international research, whether matters have gone beyond the level of risk that it deems acceptable for society. That is the basis on which the authority must decide whether preventive measures are called for and, should

that be the case, which measures appear to it to be appropriate and necessary to prevent the risk from materialising.

(see paras 164-176)

8. In matters concerning the common agricultural policy the Community institutions enjoy a broad discretion regarding definition of the objectives to be pursued and choice of the appropriate means of action. In that regard, review by the Community judicature of the substance of the relevant act must be confined to examining whether the exercise of such discretion is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion.

The Community institutions enjoy a broad discretion, in particular when determining the level of risk deemed unacceptable for society.

Where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action.

It follows that judicial review of the Community institutions' performance of their duty must be limited. The Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the Community institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the Community institutions clearly exceeded the bounds of their discretion.

(see paras 177-180)

9. Under the precautionary principle the Community institutions are entitled, in the interests of human health to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally

protected positions, and they enjoy a broad discretion in that regard.

In such circumstances, the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case.

(see paras 209, 213)

It follows that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures.

(see paras 181-183)

10. Even if, under the relevant legislation, the Community institutions are able to withdraw authorisation of an additive in feedingstuffs, without first having obtained an opinion from the competent scientific committees, it must be held that it is only in exceptional circumstances and where there are adequate guarantees of scientific objectivity that the Community institutions may, when they are required to assess particularly complex facts of a technical or scientific nature, adopt a preventive measure withdrawing authorisation from an additive without obtaining an opinion from the scientific committee set up for that purpose at Community level on the relevant scientific matters.

(see paras 209, 213)

11. In an action for annulment under Article 173 of the Treaty (now, after amendment, Article 230 EC) the assessment made by the Community institutions can be challenged only if it appears incorrect in the light of the elements of fact and law which were or should have been available to them at the time when the contested measure was adopted.

(see para. 248)

12. The Community institutions did not make manifest errors of assessment in concluding, on the basis of the factual evidence available at the time of adop-

tion of Regulation No 2821/98 providing for the withdrawal of authorisation to market certain additives in feedingstuffs, including bacitracin zinc, within the Community that the use of that additive as a growth promoter constituted a risk for human health. It is clear, on the contrary, that they could reasonably take the view that there were serious reasons concerning human health, within the meaning of Article 3a(e) of Directive 70/524 concerning additives in feedingstuffs, why bacitracin zinc, as an antibiotic with a dual use as an additive in feedingstuffs and at the same time as a medicinal product for human use, should be confined to medical use.

(see para. 313)

13. The principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

However, in matters concerning the common agricultural policy, the Community legislature has a discretionary power which corresponds to the political responsibilities given to it by Articles 40 and 43 of the Treaty (now, after amendment, Articles 34 EC and 37 EC). Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate regard being had to the objective which the competent institution is seeking to pursue.

(see paras 324-325)

14. The right to be heard in an administrative procedure taken against a specific person, which must be observed, even in the absence of any rules governing the procedure, cannot be transposed to a legislative procedure leading to the adoption of a measure of general application. The fact that an economic operator is directly and individually concerned by the contested regulation does not alter that finding.

(see para. 388)