Case T-120/96

Lilly Industries Ltd
v
Commission of the European Communities

(Regulation (EEC) No 2377/90 — Request for inclusion of a recombinant bovine somatotrophin (BST) in the list of substances not subject to maximum residue limits — Rejection by the Commission — Application for annulment)

Summary of the Judgment

1. *Actions for annulment — Actionable measures — Acts intended to have binding legal effects — Rejection by the Commission of a request for the inclusion of a certain substance in one of the annexes to Regulation No 2377/90 — Decision addressed to the trader making the request — Standing of the trader to bring an action*

   (EC Treaty, Art. 173; Council Regulation No 2377/90)

2. *Agriculture — Uniform legislation — Maximum residue limits of veterinary medicinal products in foodstuffs of animal origin — Procedure for establishing such limits — Regulation No 2377/90 — Refusal by the Commission to include a certain substance in one of the annexes despite the favourable opinion issued by the Committee on Veterinary Medicinal Products — Illegality*

   (Council Regulations Nos 2377/90, Art. 6(1), and 2309/93; Council Directive 81/851)

1. Any measure which produces binding legal effects and is such as to affect the interests of an applicant by bringing about a distinct change in his legal position is an act or decision which may be the subject of an action under Article 173 of the Treaty for a declaration that it is void.

   This is so in the case of a Commission decision rejecting a request from a trader for inclusion of a certain pharmacologically active substance in one of the annexes to Regulation No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Such a decision constitutes the final stage in the procedure initiated by the trader on the basis of that regulation and, whilst it is true that, if the moratorium on BST introduced by the Council were to be lifted, the Commission might decide to reconsider its decision, the fact remains that, until then, the decision establishes the Commission's position definitively.

   Furthermore, if the decision is addressed to the trader making the request, he has standing to bring proceedings for annulment of the decision. The decision must also have been taken in a procedure which is clearly defined by a Community regulation, under which the Commission is required to rule on a request made by an individual pursuant to that regulation.

2. Where, under the Community procedure set up by Regulation No 2377/90 for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, the Committee on Veterinary Medicinal Products has given a favourable opinion on a request for the inclusion of a substance in Annex II, submitted under Article 6(1) of the regulation, the Commission is under an obligation to draw up a draft regulation including that substance in Annex II and to submit it to the Adaptation Committee for approval pursuant to Article 6(4) and (5). The Commission is in breach of the regulation if it rejects such a request on the ground that the marketing of the substance is banned because of a moratorium set up by the Council on its marketing and administration in the Community and that the conditions in Article 6(1) of the regulation are therefore not met.

   That provision does not make the inclusion of a substance subject to the condition that a product containing the substance should be capable of being used and marketed at once, as the procedure for the establishment of maximum residue limits under Regulation No 2377/90 is independent of and distinct from the procedures laid down in Directive 81/851 and Regulation No 2309/93 which govern respectively the issue of national and Community authorisations for the marketing of veterinary medicinal products.