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Press and Information

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Judgment of the Court of Justice in Case C-198/03 P

Commission of the European Communities v. CEVA Santé Animale SA and Pfizer Enterprises Sàrl

THE COURT SETS ASIDE THE JUDGMENT OF THE COURT OF FIRST INSTANCE FINDING THAT THE COMMISSION HAD UNLAWFULLY FAILED TO ACT IN REGARD TO THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR VETERINARY MEDICINAL PRODUCTS

The Commission did not breach Community law in such a clear and serious manner as to give rise to liability on the part of the Community

In 1990 the Council adopted a regulation for the establishment of maximum residue limits (MRLs) for veterinary medicinal products in foodstuffs of animal origin. [1] The Commission is required under that regulation to establish the MRLs which the Community may accept as being legally permitted or recognised as acceptable in or on foodstuffs.

In its original version, the regulation prohibited within the Community (with effect from 1 January 1997) the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances not mentioned in Annexes I, II or III to that regulation. [2] A later regulation [3] deferred that time-limit to 1 January 2000 in the case of a number of substances, including progesterone.

CEVA Santé Animale SA and Pfizer Enterprises Sàrl are pharmaceutical undertakings which market a veterinary medicinal product containing the active ingredient progesterone. In 1993 CEVA submitted an application to the Commission for the establishment of an MRL for

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[1] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1).

[2] Annex I comprises the list of substances for which MRLs have been fixed, Annex II comprises the list of substances that are not subject to MRLs, and Annex III comprises the list of substances for which provisional MRLs have been fixed.

[3] Council Regulation (EC) No 434/97 of 3 March 1997 amending Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1997 L 67, p. 1).

progesterone in cattle and horses. As it found itself faced with divergent and conflicting scientific information on the risks associated with progesterone, the Commission did not take a position on that application before 1 January 2000. On 25 July 2001 the Commission adopted a draft regulation amending the original regulation by classifying progesterone in Annex I to the latter.

In November 2000 CEVA and Pfizer brought proceedings before the Court of First Instance in which they sought, first, a declaration that, by failing to take the necessary measures for the inclusion of progesterone in Annex II to the regulation, the Commission had failed to comply with its obligations under Community law and, second, the payment of damages. Without examining the exact scope of the Commission's discretion in regard to the fixing of MRLs, the Court of First Instance ruled [4] that the Commission's inaction amounted to a clear and serious breach of the principle of sound administration capable of giving rise to liability on the Community's part, and it ordered the Commission to pay damages in that regard.

The Commission thereupon appealed to the Court of Justice of the European Communities against the judgment of the Court of First Instance.

The Court takes the view that the Court of First Instance **did not provide adequate reasoning for its judgment** with regard to the existence of a situation of scientific uncertainty. The Court of First Instance confined itself to referring to one single scientific opinion, without explaining whether and to what extent the Commission was obliged to follow that opinion and to disregard contrary opinions from other sources.

The Court of First Instance also **erred in law** in holding, without having established the scope of the discretion enjoyed by the Commission, that the latter's inaction constituted a clear and serious breach of Community law giving rise to liability on the part of the Community**.** According to the Court's case-law, the extent of such discretion is the determining factor in establishing whether a breach of that kind has occurred.

The Court accordingly sets aside the judgment under appeal in so far as it established that there had been inaction on the part of the Commission between 1 January 2000 and 25 July 2001 of such a kind as to give rise to liability on the part of the Community and has decided itself to rule on that issue in the dispute.

It states that that the Commission must be given **sufficient discretion** to allow it to determine, on a fully informed basis, which measures are necessary and appropriate for the protection of public health. Regard being had to the extent of the discretion available to the Commission and to all of the factual circumstances, in particular the scale of the divergences in the scientific data, it did not appear that, by taking a position on the matter only after 1 January 2000 (the date from which the administration of progesterone was banned), the Commission had disregarded in a clear and serious manner the limits on its discretion.

The Commission therefore did not breach Community law in a sufficiently serious way as to give rise to liability on the part of the Community.

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[4] In a judgment of 26 February 2003 in Joined Cases T-344/00 and T-345/00, reported at [2003] ECR II-229.

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