

Decision of the European Ombudsman on complaint 275/2002/GG against the European Commission

Decision

Case 275/2002/GG - Opened on 26/02/2002 - Decision on 04/09/2002

Strasbourg, 4 September 2002

Dear Mr A.,

On 11 February 2002, you complained that the European Commission had failed to provide you with information that you had requested in your letters of 11 June, 3 October and 25 November 2001.

On 26 February 2002, I forwarded the complaint to the Commission for its comments.

The Commission sent its opinion on 13 May 2002, and I forwarded it to you on 16 May 2002 with an invitation to make observations. On 10 June 2002, I received your observations on the Commission's opinion.

On 17 June 2002, I forwarded your observations to the Commission and asked it to provide me with an opinion thereon.

The Commission sent its opinion on 30 July 2002, and I forwarded it to you on 31 July 2002 with an invitation to make observations. On 8 August 2002, I received your observations on the Commission's opinion.

I am now writing to let you know the results of the inquiries that have been made.

THE COMPLAINT

On 11 June 2001, the complainant wrote to President Prodi and to Commissioner Byrne to inform them of his concerns about the risks posed by a substance called oestradiol 17 β . It appears that this substance is a natural ingredient of some foodstuffs. However, it can also be used as a hormone to stimulate growth in animals.

In 1999, the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion concerning the assessment of potential adverse effects to human health of



hormone residues in bovine meat and meat products in which it concluded: " *There is a substantial body of evidence that the natural hormone oestradiol 17 β should be considered as a complete carcinogen exerting both tumour-initiating and tumour-promoting effects* " (1) . In the light of this opinion, the Commission considered that any deliberate addition of this hormone to the food supply should be prohibited. A proposal definitively to ban the use of this substance in farm animals for growth promotion was submitted on 24 May 2000. The measure has not yet been adopted by the Council and the EP.

The complainant is concerned about the presence of the substance in foodstuffs in general, that is to say, independently of whether it has been added artificially as a growth hormone. He points out that the SCVPH also noted that "*in consideration of the obvious differences in sensitivity of sex and age groups to hormones no threshold level can be established* ." The complainant takes the view that the above-mentioned proposal shows that the Commission considers public health to be placed in jeopardy by any amount of oestradiol 17 β and that the Commission should therefore take action, in accordance with Article 152 of the EC Treaty, to obviate the danger posed by the presence of the substance as a contaminant in foodstuffs. He notes that according to Article 1 of Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ 1993 L 307, page 1), a 'contaminant' is defined as "any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination". The complainant further points out that according to Regulation 315/93 food containing a contaminant in an amount that is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market. He considers that since the Commission states that oestradiol 17 β is a danger to public health, it has an absolute duty to act to obviate the danger posed to consumers by products containing the substance.

In his letter of 11 June 2001, the complainant asked President Prodi and Commissioner Byrne to take action, pointing out that Article 152 of the EC Treaty envisages Community action directed at obviating sources of danger to human health. He asked for information regarding the extent of contamination of foodstuffs from oestradiol 17 β , both in terms of the products affected and the quantity of oestradiol 17 β identified in these foodstuffs. He also asked for details regarding the action that the Commission proposed to take to remove this source of danger.

In its reply of 7 September 2001, the Commission explained that oestradiol 17 β was a naturally occurring hormone that was present at different levels in many foodstuffs of animal origin. The Commission considered, however, that in the light of the opinion of the SCVPH, the deliberate addition of this hormone to the food supply should be prohibited. It continued by explaining the legislative proposal it had submitted on 24 May 2000. On 3 October 2001, the complainant wrote again to demand an answer to his questions. In its reply of 5 November 2001, the Commission noted that "[s]ome foods naturally contain oestradiol-17- β " and stated: "It is neither politically acceptable nor practically feasible to remove these products from the market." The Commission further noted that the SCVPH had confirmed in its report that the balance of endocrinal hormones was a very delicate matter and "that in particular prepubertal children are



the group of greatest concern in this respect". In a further letter of 25 November 2001, the complainant concluded that the Commission did not intend to take any action whatsoever and asked whether this understanding was correct. He reiterated his other questions regarding the products affected and the level of contamination. The complainant pointed out that if the Commission should be unable to provide the information, he would appreciate being told whether this was due to a lack of scientific data or whether the Commission refused to provide the information.

The Commission's short reply of 20 December 2001 mentioned that some foods "such as meat, milk and milk products" naturally contain oestradiol 17 β . No further information was provided.

The complainant alleges that the Commission failed to provide the information he had requested. He indicates that if the Ombudsman found the Commission guilty of maladministration, he would seek that it immediately provided information to consumers and proposed the necessary legislative measures or at least submitted the matter to the appropriate bodies.

THE INQUIRY

The Commission's opinion

In its opinion, the Commission made the following comments:

Oestradiol 17 β is a naturally occurring endocrine hormone that regulated a variety of physiological functions in humans and animals. It is essential to maintain the body functions of female and male individuals.

The endogenous production of oestradiol 17 β in animals shows large variations depending on sex, age and physiological status. Consequently, foodstuffs of animal origin such as meat, milk and eggs may contain oestradiol 17 β at variable levels. No list of such foods as referred to by the complainant has been drawn up by the SCVPH, the competent Scientific Committee.

Oestradiol 17 β is not a contaminant according to Regulation 315/93. Endogenously produced hormones are natural constituents of foods. They are not the result of production, manufacturing, packing etc. and may rather be compared to other constituents such as fats or amino acids.

The SCVPH assessed the potential risks to human health from hormone residues in bovine meat and meat products and concluded that "*in case of oestradiol-17 β there is a substantial body of recent evidence suggesting that it has to be considered as a complete carcinogen*". In the light of the SCVPH's conclusions, the Commission reached the opinion that any deliberate addition of this hormone to the food supply should be prohibited to avoid a possible increase of risk to the consumer through additional artificial exposure of the population to this hormone. The Commission has therefore adopted a proposal definitively to ban the deliberate use of oestradiol 17 β in farm animals (COM(2000)320). Its measures would however not come into force before the European Parliament and the Council had agreed to them.



The complainant's observations

In his observations, the complainant maintained his complaint and made the following comments:

By stating that "foodstuffs of animal origin such as meat, milk and eggs may contain oestradiol 17 β at variable levels", the Commission was clearly aware of more scientific information than it is willing to provide. There was no reason why the Commission should not be able to provide the information it had available just because the SCVPH had not drawn up a list. In any event, the competent Scientific Committee to draw up such a list was not the SCVPH but the Scientific Committee on Food (SCF) that had been set up to advise the Commission on any problem relating to the protection of the health and safety of persons arising or likely to arise from the consumption of food.

The Commission had accepted the advice of the SCVPH that no level of oestradiol 17 β intake was acceptable. In view of the seriousness of the SCVPH' opinion on the substance, the Commission should mandate that a list of products containing oestradiol 17 β and at what levels be drawn up.

The Commission had once again reiterated the SCVPH opinion that oestradiol 17 β had to be considered a complete carcinogen. It made no difference whatsoever to this conclusion whether the oestradiol 17 β was considered as a veterinary residue or was entirely naturally present in food. To argue otherwise was illogical. Without producing the relevant information on which foodstuffs contain oestradiol 17 β and at what levels, the Commission was thus failing in its duty to protect the health of consumers.

According to the Ninth Report on Carcinogens of the International Agency for Research on Cancer (IARC), part of the World Health Organisation, the amount of oestradiol 17 β in beef from cattle treated with the hormone was 15.29 nanograms per kilogram, while the amount of oestradiol 17 β in milk from untreated cows was 31.67 nanograms per litre. The October 1999 report of the UK's Veterinary Products Committee had also stated that beef from pregnant cattle could contain substantially more (up to 1027 nanograms/kilogram in liver) oestradiol 17 β than beef from treated steers. According to the UK government, per capita beef consumption in the UK was currently around 17.2 kg per year. If this were all 'treated' beef this would be equivalent to 262.98 nanograms of oestradiol 17 β per year. In comparison, the average per capita consumption of milk in the UK is around 104 litres per year (equivalent to 3293.68 nanograms of the hormone).

The Commission appeared unwilling to address the question of why it was not prepared to move to protect public health from the presence of a complete carcinogen, of which consumption of any amount was dangerous. The fact that oestradiol 17 β may be a natural food constituent did not diminish the Commission's responsibilities to protect human health. Moreover, to state that some public health actions are politically unacceptable before requesting and analysing the necessary information and consulting outside the Commission could be said to be both an abuse of power and an abdication of responsibility.



When other issues of food safety became known, the Commission took immediate action to refer them to the SCF. Two of the most recent examples of this were dioxin and acrylamide.

The Commission appeared to have already made a determination that providing additional information on, or acting on the presence of oestradiol 17 β , was politically unacceptable. In other food safety areas, the Commission had made clear that other issues, such as socio-economic ones, 'cannot take precedence over human health protection'.

In any event, where issues of food safety were concerned it was in everyone's best interests for the Commission to provide information in a transparent manner, and where that information did indeed not exist, to act in a consistent and non-discriminatory way by requesting the appropriate Scientific Committee to investigate the matter without further obfuscation.

Further inquiries *Request for a second opinion*

In the light of the complainant's observations, the Ombudsman considered it appropriate to ask the Commission to comment on these observations.

The Commission's second opinion

In its second opinion, the Commission stressed that it had answered three letters from the complainant and provided an opinion on his complaint to the Ombudsman. The Commission underlined that it had provided the information it possessed and repeatedly explained the motives that had led it definitively to ban the deliberate use of oestradiol 17 β in farm animals. In its view, it had answered the complainant's inquiries to the fullest possible extent.

The Commission further stated that the complainant was a lobbyist representing the US meat industry.

The complainant's observations

The complainant thanked the Ombudsman for having sent him the Commission's comments. In the complainant's view, these comments were "highly extraneous" and he therefore had nothing further to add to his existing observations.

THE DECISION

1 Failure to provide information requested by the complainant

1.1 The complainant is concerned about the risks posed by the presence of a substance called oestradiol 17 β in foodstuffs, independently of whether it has been added artificially as a hormone. He therefore wrote to the Commission on 11 June 2001, 3 October and 25 November 2001 in order to ask for information regarding the extent of contamination of foodstuffs from oestradiol 17 β , both in terms of the products affected and the quantity of oestradiol 17 β identified in these foodstuffs. The complainant also asked for details regarding the action that the Commission proposed to take to remove this source of danger. In his complaint to the Ombudsman, the complainant alleges that the Commission failed to answer these questions.

1.2 The Commission notes that it replied to the complainant's letters on 7 September, 5 November and 20 December 2001 respectively. It points out that oestradiol 17 β is a naturally occurring endocrine and that foodstuffs of animal origin such as meat, milk and eggs may contain oestradiol 17 β at variable levels. It notes, however, that no list of such foods as referred



to by the complainant has been drawn up by the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH). The Commission stresses that oestradiol 17 β is not a contaminant according to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ 1993 L 307, page 1). It notes, however, that in the light of the conclusions of the SCVPH's report it reached the opinion that any deliberate addition of this hormone to the food supply should be prohibited to avoid a possible increase of risk to the consumer through additional artificial exposure of the population to this hormone. The Commission points to the proposal that it has submitted to this effect in May 2000.

1.3 It appears from the Commission's replies to the complainant's letters and its opinion on the complaint that the Commission argues that it does not dispose of details regarding the extent to which oestradiol 17 β is present in foodstuffs. The Ombudsman considers that it has not been established that this is incorrect and that the Commission would be withholding information it possesses.

1.4 It further appears from the Commission's replies to the complainant's letters and its opinion on the complaint that the Commission has submitted a proposal definitively to ban the deliberate use of oestradiol 17 β in farm animals but does not envisage taking any action with regard to the more general issue raised by the complainant. The Commission would thus appear to have provided the information the complainant was looking for in this respect.

1.5 The Ombudsman therefore concludes that the complainant has not proven his allegation according to which the Commission has failed to provide him with information in its possession.

1.6 If the complainant should consider that the Commission's failure to take further action as regards oestradiol 17 β constitutes maladministration, he could make a new complaint to the Ombudsman.

2 Conclusion

On the basis of the European Ombudsman's inquiries into this complaint, it appears that there is no maladministration on the part of the European Commission. The Ombudsman therefore closes the case.

The President of the European Commission will also be informed of this decision.

Yours sincerely,

Jacob SÖDERMAN

(1) The citation is from the Commission's letter to the complainant of 7 September 2001. In its opinion, the Commission quoted a slightly different text (see below).