Decision of the European Ombudsman on complaint 8/2000/OV against the European Commission

Decision
Case 8/2000/OV - **Opened on** 01/02/2000 - **Decision on** 12/07/2001

Strasbourg, 12 July 2001
Dear Mr B.,

On 23 December 1999 you made a complaint to the European Ombudsman on behalf of Kemin Europa concerning the fact that the Commission had still not decided on the application for registration of Kemzyme, which was submitted in December 1995.

On 1 February 2000, I forwarded the complaint to the President of the European Commission. On 10 March 2000 I wrote an additional letter to the Commission informing it of a new element in your complaint which you had brought to my attention in your letter of 7 March 2000. The Commission sent its opinion on 31 May 2000 and I forwarded it to you with an invitation to make observations, if you so wished. On 22 August 2000, I received your observations on the Commission's opinion. On 16 May 2001, you sent an e-mail with the latest information concerning your file.

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

I apologise for the length of time it has take to deal with your complaint.

THE COMPLAINT

According to the complainant, the relevant facts were as follows:

The company on behalf of which the complaint was made (hereafter "the complainant") is specialised in animal nutrition and more specifically in enzyme-products. The registration of those products is obligatory under Directives 93/113/EC (1) and 87/153/EEC (2) . The assessment of new products is done by the Permanent Committee Animal Nutrition, working group "enzymes and micro-organisms".

In December 1995, the complainant sent in an application for the registration of the product "Kemzyme" according to the above Directives. Later the complainant also sent additional

information. However, in December 1999 the Permanent Committee Animal Nutrition had still not taken a decision on the registration of the product. The complainant alleges that the decision was always postponed to a later date, because the Commission was asking additional studies and elements which were not required by the Directives 93/113/EC and 87/153/EEC applicable at the time of the submission of the application. The initial time-limit for the assessment of the application (1 July 1997) was postponed until 1 July 1998 and later 1 July 1999. Given that there was still no decision on the registration, the complainant had to remove its products from the market.

On 29 April 1999, the complainant sent a letter to the Commission, but received no reply. The complainant also tried to have a meeting with the president of the Permanent Committee Animal Nutrition, but without success. The complainant therefore wrote to the Ombudsman, making the following allegations:
- The Commission had still not decided on the registration of the product Kemzyme which was submitted in December 1995, and has not respected the time table which it put forward (1 July 1997, later 1 July 1998, and 1 July 1999).
- The Commission is requiring additional tests and asking for additional studies which were not required by the Directives 93/113/EC and 87/153/EC applicable at the time of submitting the registration application.
- The European Commission has not replied to the complainant's letter of 29 April 1999.

In an annex, the complainant explains more in detail the problems raised by the additional tests and studies required by the Permanent Committee Animal Nutrition, namely 1) the additional stability test after granulation, 2) the animal experimentation without the use of growth accelerators AGP, 3) toxicological tests on Dafazyme, and 4) the timing of the instruction. On 7 March 2000, the complainant wrote an additional letter to the Ombudsman informing him that the Commission had finally decided to prohibit the sale of Kemzyme, because it did not figure on the European list of approved products. The complainant referred to the urgency of the matter, because this prohibition would lead to a 20 % reduction in the company's turnover and to a reduction of 40 employees.

THE INQUIRY

The Commission's opinion

As an introductory remark, the Commission observed that only 66 of the 203 applications led to commercialisation authorisations, because numerous files were considered inadmissible or presented failures with regard to the Directive 87/153/EEC. This resulted in a delay in the instruction of the files and in the delivery of the authorisations.

The Commission then recalled the chronology of the "Kemzyme" file: On 18 December 1995 Belgium, acting as rapporteur, transmitted the files to the Commission in application of Article 3 (b) of the Directive 93/113/EC. A small group of national experts, which made a first assessment of the Kemzyme files in April 1996, noticed failures which were communicated to the rapporteur. In December 1996 and April 1997, the Committee of Experts Enzymes and Micro-organisms (EMO) which evaluated the files for the first time, considered that they were not presented in

accordance with Council Directive 87/153/EEC. The new files were sent to the Commission and the Member States only in May 1998, this is more than one year after the failures were noticed. Consequently, the effective evaluation did start in the second semester of 1998. This was complicated by the fact that the complainant does not produce the enzymes which enter in the preparations that it commercialises. Therefore the firms producing the various enzymes entering in the composition of the preparations provided files on the basic enzymes directly to the Commission and the Member States, whereas the complainant prepared the files corresponding to the commercialised preparations. In some cases where the specifications provided by the former firms did not correspond to those indicated in the complainant's application, clarifications had to be asked. The complainant, which did not have knowledge of the basic files, had to contact its suppliers to reply to certain question asked.

As regards the supplementary questions which were raised later on, the Commission observed that this is a current practice all along the instruction period. At this stage, no particular provision is foreseen in Council Directive 70/524/EEC concerning additives in feeding-stuffs which would oblige Member States to ask questions within a certain deadline. This is justified by the fact that a safety problem can be detected at the latest stage of the instruction of the file. Whatever the stage of the instruction, the company applying has to reply to the questions when these are justified in view of the Directive 87/153/EEC. In the present case, the complainant did or not reply to certain questions or provided answers which were unsatisfactory.

As regards the unreasonable conditions imposed for the additional elements, the Commission observed that the questions which remained unanswered and were asked by the Member States and the Scientific Committee of Animal Nutrition (SCAN) were in line with the Directive 87/153/EEC. It is indispensable for the Commission to dispose of these elements in order to evaluate the impact of the products on the consumer's health, on the operator who manipulates the products and on the animal which consumes the product containing enzymes. This information was also requested during the instruction of files concerning other "multi-enzymes".

As regards the first allegation concerning the delay in the instruction of the file, the Commission observed that the Council Directive 93/113/EC foresaw that the Commission had to decide on the applications before 1 January 1997. Upon a proposal of the Commission, the Council decided to postpone the time-limit until 1 July 1998 (18 supplementary months). The Commission cannot be held responsible for the non-authorisation of products for which the instruction was not terminated. It is up to the applying company to furnish the elements which the EMO Committee of Experts and the SCAN consider to be missing. In the present case, the instruction could only start in the second semester of 1998. Every time when complementary information was provided, it was assessed by the competent Committee of Experts without delay. Since 14 May 1998, the Kemzyme products were 6 times handled by the EMO Committee of Experts. It is not possible to grant a provisional authorisation, as long as the answers to the questions are not considered satisfactory by the two Committees.

As regards the allegation concerning the failure to reply, the Commission observed that, considering the number of letters addressed to the Commission services further to the 203 applications for authorisations, it had not been possible to reply to every letter individually. The

Commission services regretted that this attitude was considered as non-collaboration, because the Commission's wish was to deal with those problems rapidly and in a non bureaucratic way.

The Commission also submitted a detailed 6 pages opinion on the 4 points raised in the annex 1 of the complaint.

The complainant's observations

The complainant rejected the Commission's allegation that the responsibility for the delayed handling of the Kemzyme file lies with the complainant. The guidelines for assessing an additive in animal nutrition do not indicate clearly which elements are required for a file. This led to a prolongation and a delay in the approval of the application of the complainant.

The complainant observed that the Commission did not respect the Directive 93/113/EEC modified by Directive 97/40/EC which stipulates that a decision on the files had to be taken before 1 July 1998. Because no decision on the files was taken, the complainant can not commercialise its enzyme products. The European Commission should distribute a communication according to which the products are authorised for sale on basis of the lists of national authorisations.

The complainant observed that no fundamental failures were detected for the 7 Kemzyme products where the file mentioned "yes" in all rubrics. The complainant stated that the observations in annex III of the Commission's opinion do not mention that the files were not introduced in accordance with the requirements of Directive 87/153/EEC. The complainant was not informed of this element. Neither the letters from the Belgian Ministry of Agriculture of 12 December 1996 and 30 April 1997 mention that there were shortcomings in the files. On the request of the rapporteur, new files with additional information were presented, not in May 1998, but in December 1995.

As regards the Commission's statement that the effective assessment only started in the second semester of 1998, the complainant observed that the assessment really started in 1996 and that the files were under consideration since 1996. This is proved by the letters with comments on the files (annex III of the Commission's opinion).

As regards the additional question from a Member State concerning an additive, the complainant observed that the procedures were not followed, because according to the information from the Belgian rapporteur, a product can only be put to the vote when there is a formal agreement from the Permanent Committee and the SCAN. This appeared not to be the case for a product which was figuring in the draft Regulation in April 2000. Therefore the approval of Kemzyme liquid was postponed with one month. To avoid that the decision on a file is regularly postponed, the Commission should put a deadline for asking questions.

The Commission never sent a complete analysis of the files mentioning the lacking studies or reports. Until 1999 new questions were raised to proceed to additional tests (stability test after granulation, toxicological tests on an enzyme-ingredient)

With regard to the Commission's failure to reply, the complainant observed that it had still not

received a reply with the results of the discussions. The complainant wished to receive some feed-back on this. The complainant criticises the practice that no discussion is allowed between the Permanent Committee and the applying firms and that all communication has to pass through the rapporteur from the Member State. The complainant also observed that, if 203 files are too many to deal with for the Commission, the system should change or the Commission should recruit more personnel.

The complainant made 4 conclusions: 1) the Commission should allow a direct communication between the applicant and the body which assesses the file, 2) the files should be assessed in accordance with the requisites and guidelines which apply on the moment of the introduction of the file, 3) The European Commission should allow that the position of the Committee of experts and the SCAN can be refuted on the basis of a scientific justified argumentation, and 4) as long as no decision is taken on the files, the Commission should allow that the enzyme products concerned are commercialised on the basis of the national registrations.

On 16 May 2001, the complainant informed the Ombudsman's office by e-mail that the Permanent Committee Animal Nutrition had finally taken a decision in September 2000: Seven Kemzyme applications were approved, whereas three others were not approved (Commission Regulation (EC) N° 2437/2000 of 3 November 2000 concerning the permanent authorisation of an additive and the provisional authorisation of new additives in feedingstuffs (3)).

THE DECISION

1 The alleged delay in the decision on the registration

1.1 The complainant alleged that the Commission had still not decided on the registration of the product Kemzyme which was submitted in December 1995, and had not respected the time table which it put forward (1 July 1997, later 1 July 1998 and 1 July 1999). The Commission observed that the Council Directive 93/113/EC initially foresaw that the Commission had to decide on the applications before 1 January 1997. However, upon a proposal of the Commission, the Council decided to postpone the time-limit until 1 July 1998. The Commission alleged that it could not be held responsible for the non-authorisation of products for which the instruction was not terminated, as it is up to the applying company to furnish the elements which the EMO Committee of Experts and the SCAN considered to be missing. In the present case, the instruction could only start in the second semester of 1998.

1.2 According to Article 3 (b) of Directive 93/113/EC, the files had to be submitted to the Commission before 1 January 1996, In the present case, it appears that Belgium transmitted the Kemzyme files to the Commission on 18 December 1995. The final decisions on the authorisations were taken in September 2000.

1.3 The Ombudsman notes that Article 5 of Directive 93/113/EC provided that *"before 1 January 1997, a ruling will be given* in accordance with the procedure laid down in Article 24 of Directive 70/524/EEC on the dossiers referred to in Article 3 (b) concerning the authorisation of additives in animal nutrition". Article 24.3 of Directive 70/524/EEC provides that *"the Commission shall adopt the measures and implement them forthwith where they are in accordance with the*

opinion of the Committee. Where they are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted". Upon the Commission's proposal, based on the fact that the large number of files submitted by the Member States has made it impossible to decide on all the authorisation applications by 31 December 1996, this deadline was postponed with 18 months in Directive 97/40/EC, Article 1 of which provides that *"The date of 1 January 1997 in Article 5 of Directive 93/113/EC shall be replaced by 1 July 1998".*

1.4 The Ombudsman notes that on basis of Article 5 of Directive 93/113/EC, as amended by Article 1 of Directive 97/40/EC, the Commission had a legal obligation to adopt the relevant measures by 1 July 1998. In the present case, the decisions on the authorisation of Kemzyme were taken in September 2000, i.e. with a delay of more than two years. The Commission has therefore failed to act in accordance with a rule which is binding upon it. This constitutes an instance of maladministration and the Ombudsman makes the critical remark below.

2 The requirement of additional tests and studies

2.1 The complainant alleged that the Commission required additional tests and asked for additional studies which were not required by the Directives 93/113/EC and 87/153/EC applicable at the time of submitting the registration application. The Commission observed that asking additional questions is a current practice all along the instruction period, and that no particular provision is foreseen in Council Directive 70/524/EEC concerning additives in feeding-stuffs which would oblige Member States to ask questions within a certain deadline. This is justified by the fact that a security problem can be detected at the latest stage of the instruction of the file. Whatever the stage of the instruction, the company applying has to reply to the questions when these are justified in view of the Directive 87/153/EEC. All the complementary questions asked were in conformity with the guidelines of the Directive 87/153/EEC.

2.2 The Ombudsman notes that the Directive 87/153/EEC does not indicate precisely which tests are required for the assessment of additives in animal nutrition. The Directive contains an annex entitled "Guidelines for the assessment of additives in feedingstuffs". This annex which is a descriptive document can be subject of different interpretations. The annex states that "these guidelines are intended as a guide for establishing dossiers on substances and preparations being submitted for authorisation as additives in feedingstuffs. (.) All the studies outlined in these guidelines may be required and, if necessary, additional information will be requested. As a general rule, studies to establish the identity, conditions of use, physico-chemical properties, methods of determination and efficacy of the additive, and also its metabolism, biological and toxicological effect on target species must be provided. The studies necessary for the evaluation of risks to human health or the environment will depend essentially on the nature of the additive and the circumstances of its use. In this respect, no strict rule is applicable".

2.3 The Ombudsman notes that a careful reading of these guidelines seems to suggest that there exists a certain margin of appreciation on which tests are required for the assessment of the additives. This appears for instance from the descriptive way in which the lists of tests required are presented and from the fact that the guideline several times mentions "etc." which presupposes that the lists are not exhaustive.

2.4 From the information available to the Ombudsman, it appears that by having requested additional studies and tests with regard to the product Kemzyme, the Commission stayed within the limits of its legal authority. No instance of maladministration was therefore found with regard to this aspect of the case. The Ombudsman must however recall that the Court of Justice is the highest authority on questions of interpretation and application of Community law.

3 The alleged failure to reply

3.1 The complainant alleged that the Commission had not replied to his letter of 29 April 1999. The Commission observed that, considering the number of letters addressed to the Commission services further to the 203 applications for authorisations, it had not been possible to reply to every letter individually. The Commission services regretted that this attitude was considered as non-collaboration, because the Commission's wish was to deal with those problems rapidly and in a non bureaucratic way.

3.2 Principles of good administration require that the Community institutions and bodies reply within a reasonable time-limit to letters and requests from citizens (4) . In the present case, the Commission failed to reply to the complainant's letter of 29 April 1999. The Commission however regretted that it had not replied to the complainant's correspondence and that this attitude had been considered as non-collaboration. The Ombudsman therefore considers that no further inquiries are necessary into this aspect of the case.

4 Conclusion

On the basis of the European Ombudsman's inquiries into part 1 of this complaint, it appears necessary to make the following critical remark:

On basis of Article 5 of Directive 93/113/EC, as amended by Article 1 of Directive 97/40/EC, the Commission had a legal obligation to adopt the relevant measures by 1 July 1998. In the present case, the decisions on the authorisation of Kemzyme were taken in September 2000, i.e. with a delay of more than two years. The Commission has therefore failed to act in accordance with a rule which is binding upon it. This constitutes an instance of maladministration.

Given that this aspect of the case concerns procedures relating to specific events in the past, it is not appropriate to pursue a friendly settlement of the matter. The Ombudsman has therefore decided to close the case.

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

Yours sincerely,

Jacob SÖDERMAN

(1) Council Directive 93/113/EC of 14 December 1993 concerning the use and marketing of enzymes, micro- organisms and their preparations in animal nutrition, OJ 1993 L 334/17.

(2) Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition, OJ 1987 L 64/19.

(3) OJ 2000 L 280/28.

(4) Article 17.1 of the Ombudsman's Code of Good Administrative Behaviour.