



Summary Record of the 111th SCAN Plenary Meeting (Brussels, 11 November 1997)

(approved at the 113th meeting on 5-6 February 1998)

Opening

Mr. Carsin congratulated new members and thanked them for their availability to attend this meeting in such a short notice and made short reference to the background of the Commission decision to modify the legal basis of the Scientific Committees (Note by the Secretary: For information about the decision to transfer the Committees to DGXXIV See summary records of the 107, 108 and 109 Plenaries). The European Parliament will meet the Commission to comment about the changes in about a week time and conclusions will be drawn. He reminded that SCAN members are independent experts (independent from the Member States and/or firms) and that the maximum number (19 per Committee) was not covered to leave room for new members should this be necessary. The Committee will be consulted when required by Directives establishing compulsory consultation (Note by the Secretary: Only Council Directive 82/471/EEC on certain products used in animal nutrition - OJ No L213, 21.7.82, p.8.) Establishes compulsory consultation to SCAN for the use of yeasts and bacterias as feedingstuffs), or at the Commission's request although the SCAN may also draw the attention of the Commission on whatever matter it considers necessary. He reminded members that the consumer's interest constitutes as from now an essential element in the preparation of the reports. He explained that the Steering Committee may cover areas not covered by the mandates of other Committees (Commission Decision 97/579 of 23 July 1997 setting up Scientific Committees in the Field of Consumer and Food safety - O.J. N° 237, 28.8.97, p.18.) or particular matters of a multi-disciplinary nature. The Steering Committee may also have a role in examining very complex questions and identify the best way of dealing with subjects and scientific opinions issued by other Committees which may raise contradictions. He exhorted members to attend all meetings.

1. APPROVAL OF THE AGENDA

The agenda was approved

2. RULES OF PROCEDURES

Mr. J. Kreysa informed the Committee on the new rules: The Committee will be free to establish its own rules to deal with questions in so far they respect the principles of excellency, independence and transparency. The Committee should be sure that it can count within the Committee on the necessary expertise to undertake the requested tasks.

The rules will also foresee the possibility to consult other committees. If external experts are to be invited they will also be bound by the confidentiality and independence (declaration of interest). Independence does not necessarily mean not to be able to count on the member's expertise or scientific knowledge if they are engaged with a company, but instead the expert should declare this before passing opinions on the matters under study. Timing is important and may be used by the Commission in establishing the questions, therefore the possibility exists to have "written procedures" to proceed without the need to have more than one plenary to establish an opinion, if this is required.

Next to the constitution of the new committees and the meeting of the Steering Committee, the rules will be definitively adopted and circulated. It was proposed to delay discussion of these rules until they are finalised. The proposal was accepted.

3. ELECTION OF A CHAIRMAN AND TWO VICE-CHAIRMEN

Chairman : Dr. Bories was elected as Chairman.

Vice Chairmen : Dr. Anadón and Dr. Pugh were elected as Vice Chairman

4. REPARTITION OF SCIENTIFIC SKILLS BY SPECIALISM:

4.1. Animal Nutrition and food (of animal origin) quality:

Drs. Aumaitre, Brufau, Fernandes, Flachowsky, Gropp, Leibetseder, Piva

4.2. Microbiology and genetic engineering

Drs. Aumaitre (GM feed crops), Chesson, Franklin, Guillot, Von Wright (also GM feed crops)

4.3. Metabolism and residues of additives, in special of antibiotics and coccidiostats

Dr. Anadón, Beretta, Bories, Pugh, Agergaard

4.4. Toxicology of feed additives & residues

Drs. Anadón, Wester, Kovatsis, Pugh, Leibetseder

4.5. Pharmacology

Drs. Anadón, Beretta, Pugh

4.6. Environment

Drs. Flachowsky, Gropp, Guillot (area of microbial impact), Piva, Wester.

The Chairman proposed to establish a procedure for fast communication between members when urgent questions arise. This will be discussed at a next meeting.

Prof. Pugh made it clear that there is a necessary link between the SCAN and the existing Community legislation in animal nutrition: in his view this cannot be neglected in favour of new matters. Co-operation with the legislative service (DGVI/BII/1) is required. The Chairman agreed to this.

5. APPROVAL OF THE SUMMARY RECORD OF THE 110TH PLENARY

The summary record was approved by mail.

6. ACTIONS UNFINISHED BY THE 6TH SCAN

Update and eventual renewal of the mandate of the existing working groups for evaluation of the report on the following questions:

6.1. Question 53 on the use of by-products from fermentation by *Corynebacterium melassecola* as feedingstuffs

Because of lack of time this point was postponed to another meeting

6.2. Question 54 on the use of by-products from fermentation by *Brevybacterium lactofermentum* as feedingstuffs

Because of lack of time this point was postponed to another meeting

6.3. Question 70 on the use of formaldehyde as preservative-agent for feed

Because of lack of time this point was postponed to another meeting

6.4. Question 76 on the use of flavophospholipol as feed additive for chickens reared for laying (withdrawal of question)

Because of lack of time this point was postponed to another meeting

6.5. Question 79 on the use of Semduramycin as feed additive for chickens for laying

Because of lack of time this point was postponed to another meeting

6.6. Question 85 on the safety of use the micro-organism additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17)

Because of lack of time this point was postponed to another meeting

6.7. Question 86 on the safety of use enzyme additives listed in notice 96/263 (O.J. N° C263, 11.9.96, p.3) following Article 5 of Council Directive 93/113/EC (O.J. N° L334, 31.12.93, p.17).

Because of lack of time this point was postponed to another meeting

6.8. Question 87 on the re-evaluation of the safety of use of nitroimidazoles as feed additives (ronidazole, ipronidazole & dimetridazole). Fixation of a working schedule for the examination of the new data (clause of safeguard by DE) and preparation of a draft report to be submitted at the 112 Plenary

The Chairman suggested that Drs. Anadón, Beretta, Wester and himself could undertake this. Dr. Beretta announced that he has new data supporting the possibility of an ADI for Dimetridazole based on the carcinogenicity studies. It was reminded that an ADI could not be obtained for Ronidazole. The Chairman asked for this new data to be circulated.

Dr. Anadón asserted that a full assessment report of dimetridazole is necessary before producing an opinion.

The Chairman proposed to answer first the clause of safeguard from Germany and to leave the full assessment-report for later. The proposal was accepted and a Working Group is agreed for 11 December 1997.

6.9. Question 90 on *Candida guilliermondii* yeast

Because of lack of time this point was postponed to another meeting

6.10. Question 91 on the re-evaluation of the safety of use of quinoxaline-n-dioxides (carbadox, olaquinox): Fixation of a working schedule for the examination of the new data submitted by Pfizer (FR), Nordfeed (UK) and Doxal-Italy (IT) and preparation of a draft report to be submitted at the 112th plenary.

(Note: for other data see the question as modified at the 109th and 110th meeting)

Drs Anadón, Beretta, Kovatsis and Pugh will undertake the evaluation. A Working Group can be created. Dr. Pugh commented on a paper he distributed earlier (Note by the Secretary: Dr. Pugh referred to SCAN/97/102 and SCAN/97/103). At the request of Prof Anadón, the Secretary will send the question again (See under annex III).

7. NEW QUESTIONS TO BE ANSWERED BY THE 7TH SCAN

(Note: Other questions will be agreed on by the new procedure)

7.1. Question 89 on the use of Diclazuril as feed additive for to rabbits: Fixation of a working group and of a working schedule to prepare a draft report to be submitted to the plenary

Because of lack of time this point was postponed to another meeting

7.2. Question 92 on the evaluation of the reasons provided by FI to justify an extension of the derogation to reserve the use of tylosin & spiramycin for exclusive therapeutic use, and banning their use as feed additives: Fixation of a working group and of a working schedule to prepare a draft report to be submitted to the 112th plenary

Mr. Florez (DGVI/BII/1) raised the urgency of this question as the derogation period expires on 31 December. The Chairman acknowledged the urgency of the matter but considered it unfeasible to give an answer in such a short notice (data arrived only in July).

Dr. Pugh asserted that because of the precaution principle applied in the avoparcin case, it is difficult to reach different conclusions now (in both cases spread of resistance factors in the food chain is mentioned). Therefore, he suggested that this matter should be dealt with by DGVI on an administrative approach, applying the same solution as for avoparcin.

The Chairman did not accept; new elements should be examined and an opinion delivered. He suggested to launch a Working Group by the microbiologists: Drs. Chesson, Franklin (rapporteur), Guillot and Pugh. The suggestion was accepted. The secretary explained that the final text of the specific question was not received from DGVI and although the case is clear it will be advisable to have the draft discussed to be sure that the matter is well understood and the key points well identified. Dr. Franklin will try to find a suitable date for the Working Group meeting and communicate this to the secretary.

8. WORK PROGRAMME AND SCHEDULE OF MEETINGS FOR 1998

The need to have a year-round planning was raised but it was explained that this is only possible after 21 November (first meeting of the Steering Committee). This point was reported to the next meeting scheduled for the 10-11 December.

9. OTHER POINTS

The issue of organisation of work was raised by Drs. Gropp, Leibetseder and other members and the Chairman commented on the difficulties encountered not only today, but also in the past and on the need to find the best compromise. He commented also on the necessary equilibrium between the expert-report on the matter under study and the role as a SCAN member. At the request of the Chairman, a calendar will be faxed to all members.

And without further points the meeting came to an end.

Annex I: Attendance

Members:

Prof. Arturo ANADÓN, Dr. Louis Aimé AUMAITRE, Prof. Dr. Carlo BERETTA, Dr. Georges BORIES, Dr. Joaquim BRUFAU, Dr. Andrew CHESSON, Prof. Tito H. FERNANDES, Prof. Gerhard FLACHOWSKY, Dr. Anders FRANKLIN, Prof. Dr. Jürgen GROPP, Prof. Jean-François GUILLOT, Prof. A. V. KOVATSIK, Prof. Dr. Josef LEIBETSEDER, Prof. Gianfranco PIVA, Dr. David Michael PUGH, Dr. ATTE VON WRIGHT, Dr. Pieter WESTER.

For the Commission:

DGXXIV:

Mr. Bertrand CARSIN (Director), Dr. Juan Pérez-Lanzac (Principal Administrator, Secretary), Mr. Joachim Krysa (Principal administrator), Mr. Paul Vossens (Administrator), Mrs. Marion Duboile-Schokker (Secretary)

DGVI/BII/1:

Mr. Jean Thibaux, Mr. M. Florez (DGVI/BII.1)

Annex II Documents

SCAN/97/132 Question 91: Data by Pfizer on safety

SCAN/97/133 Summary Record of the 110th plenary meeting of 25-26 September 1997

SCAN/97/134 Question 85: List of micro-organisms and their preparations in animal nutrition permitted for use in individual member states

SCAN/97/135 Question 86: List of enzymes and their preparations in animal nutrition permitted for use in individual member states

SCAN/97/136 Question 85/86: Situation on the examination of products

SCAN/97/137 Question 87: Opinion of the CVMP on MRL for metronidazole in pigs" (Distributed at the request of DG VI.BII.1)

SCAN-info97-51 Article in Biofutur 170: "Comment la résistance vient aux bactéries"

SCAN-info97-52 Press Release WHO/73: "Antibiotic use in food-producing animals must be curtailed to prevent increased resistance in humans"

SCAN/97/138 Question 86: Draft report of the SCAN on enzymes

SCAN/97/139 Question 86: Comments by Dr. Viikari

SAN/97/140 Question 86: Comments by Dr. Brufau

Annex III

QUESTION 91 TO THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON POSSIBLE RISKS FOR THE CONSUMER, THE ANIMAL AND THE USERS (OPERATORS) OF THE USE OF CARBADOX AND OLAQUINDOX AS FEED ADDITIVES

TERMS OR REFERENCE (June 1997) (reviewed August 1997 and September 1997)

The Scientific Committee for animal nutrition is requested to re-evaluate the authorizations of carbadox and olaquinox, and to answer the following question:

In view of the information provided to the Commission (See under references) should the withdrawal of the quinoxaline-N-dioxides Carbadox and olaquinox be considered?

BACKGROUND

Carbadox [methyl-3-(2-quinoxalinylyl methylen) carbazate-N1, N4 -dioxide] was first admitted to Part E (other additives) of the Annexes to Council Directive 70/524/EEC concerning additives in animal feedingstuffs (OJ No L270, 14/12/70, p.1, as last amended by as last amended by Council Directive 96/51/EC of 23 July 1996 amending Directive 70/524/EEC concerning additives in feedingstuffs - O.J. No. L235, 17/9/96 p.39) by the Eighth Commission Directive 74/378/EEC (of 1 July 1974 amending the Annexes of the Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs. - O.J. No. L199, 22/7/1974 p.13). The Community authorization (Annex I) was granted by Council Directive 87/316/EEC (Of 16 June 1987 amending Directive 70/524/EEC concerning additives in feedingstuffs in respect of Carbadox. - O.J. No. L160, 20/6/1987 p.32). A new definition of carbadox was adopted by Commission Directive 90/110/EEC (Of 19 February 1990 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. - O.J. No. L67, 15/3/90 p.44). The approved conditions for use appears under Table 1.

Olaquinox [2-(N-2' (hydroxymethyl) carboamoyl)-3-methylquinoxaline N1, N4 -dioxide] was first listed under part F of the Annex II (national authorizations), by the Sixteenth Commission Directive 76/933/EEC (Of 1 December 1976 amending the Annexes to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs. - O.J. No. L364, 31/12/1976 p.18).

I. The Community authorization was granted by Council Directive 87/317/EEC. The conditions of use of carbadox were modified in February 1996 by Commission Directive 96/7/EC (Of 21 February 1996 amending Council Directive 70/524/EEC concerning additives in feedingstuffs - O.J. No. L51, 01/3/1996 p.45). The approved conditions for use of Olaquinox appears under table 2

II. The SCAN expressed its favorable opinion of the use of Carbadox and Olaquinox in the following reports:

A. Report of 6 July 1978, on the use of Carbadox in feedingstuffs for pigs (Reports of the scientific Committee for Animal Nutrition, Second Series (1980) Report 6918 EN. Catalogue N° CDE-NK-80-002-EN-C (p.7).

B. Report of 8 July 1981 on the use of Olaquinox in the feedingstuffs for pigs.

C. Report of 7 July 1982 on the use of Carbadox in feedingstuffs for pigs (Second report) (Reports of the Scientific Committee for Animal Nutrition, Fourth Series (1984) Report EUR 8769. Catalogue N° CD-NK-83-010-EN-C) (p.82).

D. Report of 3 May 1984 the use of Olaquinox in feedingstuffs for pigs (Second report) (Reports of the Scientific Committee for Animal Nutrition, Fifth Series (1986) Report EUR 1041 EN. Catalogue N° CD-NK-83-003-EN-C) (p.11)

E. Report of 18 November 1992 on the possible implication of olaquinox in cases of photoallergic contact-dermatitis developed in pig-farmers

III. The CEAS study on "*The impact on animal husbandry in the European Community of the use of growth promoters in animal Feed*" (See under references) raised concerns on the use of carbadox and olaquinox. These concerns address

A. the genotoxicity and carcinogenicity potential for the users of these molecules;

B. the weak adverse effects on target animals;

C. the impossibility to set an ADI because of lack of a marker residue;

D. the phototoxicity for users;

E. the fact that, as these molecules are "generics" the formulation is less suitable.

IV. The Scientific Conference on the use of growth promoters in meat production (See under reference) concluded also that a re-evaluation of the Quinoxaline-n-dioxides should be considered, because

A. carbadox and olaquinox possess genotoxic and/or carcinogenic properties;

B. appreciable amounts of residues are found in treated animals;

C. ADI values cannot yet be established although their restricted use in pigs only during the first four months coupled with the specified 28-day withdrawal period should lead to negligible residues at the time of slaughter and minimize the risk of exposure for consumers;

D. it is questionable whether the use of genotoxic and carcinogenic feed additives is acceptable.

V. The Federal Republic of Germany, in its communication of 14. February 1997 has invited the services of the Commission to re-evaluate the authorizations of carbadox and olaquinox, and in discussing this, during the meeting of the Standing Committee for Feedingstuffs (Council Decision 70/372/EEC of 20 July 1970 - O.J. L170, 3/8/70 p.1) on 24-25 February 1997, several Member States gave their full support to the German request, and the Standing Committee decided to proceed to a re-evaluation of the quinoxaline-n-dioxides by examining the new elements arising since the first authorization (Sixteenth Commission Directive 76/933/EEC of 1 December 1976 amending the Annexes to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs. - O.J. No. L364, 31/12/1976 p.18) concerning the possible risks for consumers operators and animals due to the use. of carbadox and olaquinox

VI. Sweden provided on 19 March 1997 (SCAN/97/49) a list of references on Quinoxaline-n-dioxides followed on the 10 April 1997 by an extended list including photocopies of scientific literature (SCAN/9763).

VII. The firm CRAFT, on behalf of the firms manufacturing Olaquinox as a generic feed additive has submitted, for its examination by SCAN the results of further studies on the safety for users of Olaquinox.

VIII. On 18 July 1997, The Dutch Ministry of Agriculture, Environment and Fisheries announced to the Commission the prohibition of carbadox in application of Article 11 of Directive 70/524/EEC on grounds that :

- carbadox has been found to be genotoxic and carcinogenic;
- there is a serious risk for workers in the feed industry;
- there is no reason for the use of carbadox under Good Agricultural Practice in animal husbandry.
- and that preventive measures at community level are necessary in the short term in order to safeguard users and workers in the feed industry from any harmful substances.

IX. A report drawn up by the Rijks-Kwaliteitsinstituut voor land-en tuinbouwprodukten - Dienst Landbouwkundig Onderzoek entitled "Carbadox - an evaluation" was presented to the Commission and joined to the Dutch request. This document is claimed to contain detailed grounds for establishing that carbadox should no longer be approved as a feed additive.

X. The firm Pfizer, on 12 September 1997 provided the SCAN members with a file with a review of the Safety of Mecadox (Carbadox) feed additive.

REFERENCES I:

STUDIES AND DOCUMENTS SUBMITTED TO THE COMMISSION)

1. CEAS Consultants (WYE) LTD, 1991. *The impact on animal husbandry in the European Community of the use of growth promoters in animal Feed* A report prepared for the Commission by CEAS Consultants (WYE) LTD. (Wye College University of London,) Agricultural Economics department (Wye College Univ. of London), Institut für physiologie Chemie un Ernährungsphysiologie (Ludwig Maximilians Universiät, Munchen), Department of Applied Biochemistry and Food Science (University of Nottingham School of Agriculture) Institut für Medizinische Mikrobiologie Infections und Seuchenlehre,(Ludwig-Maximilian-Universität München).
2. Commission of the EU: Scientific Conference on the use of growth promoters in meat production. Conclusions of Session I. (Brussels December 1995).
3. Communication of Federal Republic of Germany, of 14. February 1997.
4. List of references on Quinoxaline-n-dioxides provided by Sweden on 19 March 1997 (SCAN/97/49) Followed on the 10 April 1997 by an extended list including photocopies of scientific literature (SCAN/9763).
5. CRAFT GEIE, 1997: Carbadox and Olaquinox: Their dust emission in premixes, supplements and feeds, in seven countries in the European Union [Center for the Research & Development of Advanced Technology, CRAFT, -An European economic interest group constituted in accordance with Council regulation (EEC) No. 2137/85. Studies on behalf of Nord-feed (UK) Ltd and Doxal Italia SpA.).
6. CRAFT GEIE, 1997: The toxicological risk to non target species of the use of olaquinox (From CRAFT Olaquinox 10%) as feed additive in pig rations. [Centre for the Research & Development of Advanced Technology, CRAFT, -An European economic interest group constituted in accordance with Council regulation (EEC) No. 2137/85. Studies on behalf of Nord-feed (UK) Ltd and Doxal Italia SpA.).
7. Communication by the Kingdom of Netherlands of 18 July in order to forbid the use of the additive carbadox in the feed of piglets (Article 11 of Directive 70/524/EEC)
8. PFIZER ANIMAL HEALTH (August 1977). Mecadox Feed Additive: Review of Safety (264 pp) .

REFERENCES (II)

COMMUNITY LEGISLATION AND SCAN OPINIONS

1. Eighth Commission Directive 74/378/EEC of 1 July 1974 amending the Annexes of the Council Directive of 23 November 1970 concerning additives in feedingstuffs. (O.J. No. L199, 22/7/1974 p.13) Action: *Carbadox enters under "Other Additives" Part "E" of the Annexes.*
2. Fifteenth Commission Directive 76/603/EEC of 21 June 1976 amending the Annexes to the Council Directive of 23 November 1970 concerning additives in feedingstuffs (O.J. No. L 198, 23/7/76 p. 10) Action: *Extension of Annex II for further studies. Under part F*
3. Sixteenth Commission Directive 76/933/EEC of 1 December 1976 amending the Annexes to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs. (O.J. No. L364, 31/12/1976 p.18) Action: *Olaquinox enters under part F of the Annex II*
4. 20th Commission Directive 78/58/EEC: of 7 December 1977 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (O.J. No. L 018, 24/1/78 p. 072) Action : *Extension Carbadox until 31/12/78*
5. Report of the Scientific Committee for Animal Nutrition on the use of Carbadox in feedingstuffs for pigs. Opinion expressed: 6 July 1978. p.7. Second Series (1980) Report 6918 EN. Catalogue N° CDE-NK-80-002-EN-C:
6. Twenty-fifth Commission Directive 78/974/EEC of 16 November 1978 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L330, 25/11/1978 p.30) Action *Extension carbadox olaquinox 31/12/79*
7. Twenty-ninth Commission Directive 79/1011/EEC of 15 November 1979 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L310, 06/12/1979 p.24) Action: *Extension Carbadox & Olaquinox until 31/12/1980*
8. Thirty-sixth Commission Directive 80/1156/EEC of 28 November 1980 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L343, 18/12/1980 p.35) Action: *Extension of Carbadox until 30 June 1981. (different for olaquinox). Extension of Olaquinox until 30 November 1981.*
9. Report of the Scientific Committee for Animal Nutrition on the use of Olaquinox in the feedingstuffs for Pigs. Opinion expressed: 8 July 1981. p. 1.(Fourth Series (1984) Report EUR 8769. Catalogue N° CD-NK-83-010-EN-C)
10. Thirty-eighth Commission Directive 81/632/EEC of 16 July 1981 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L231, 15/8/1981 p.30) Action *Extension of Carbadox to 30 November 1981 (See above)*
11. Thirty-ninth Commission Directive 82/91/EEC of 15 January 1982 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L42, 13/2/1982 p.16) Action *Extension of Carbadox until 30 June 1982. (different for olaquinox). Extension of Olaquinox until 30 November 1982*
12. Fortieth Commission Directive 82/474/EEC of 23 June 1982 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (O.J. No. L 213, 21/7/82 p. 22) Action: *Extension of Carbadox to 30 November 1981 (See above)*
13. Second report of the Scientific Committee for Animal Nutrition on the use of Carbadox in feedingstuffs for Pigs. Opinion expressed: 7 July & 1982. p. 82. (Fourth Series, 1984. Report EUR 8769. Catalogue N° CD-NK-83-010-EN-C) Note *This report on carcinogenic potential of carbadox and its metabolites. First report on 2nd Series, p.7.*
14. Forty-first Commission Directive 82/822/EEC of 19 November 1982 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L347, 07/12/1982 p.16) Action *Extension of Carbadox and Olaquinox until 30 November 1984.*
15. Second report of the Scientific Committee for Animal Nutrition on the use of Olaquinox in feedingstuffs for Pigs. Opinion expressed 3/May/84 (Fifth Series (1986) Report EUR 1041EN. Catalogue N° CD-NK-86-003-EN-C, p. 11. (First

report in 4th Series, p.:11)

16. Council Directive 84/587/EEC of 29 November 1984 amending Directive 70/524/EEC concerning additives in feedingstuffs (O.J. No. L319, 8/12/84 p. 13) Action 3rd/Amendment. *Consolidation of the annexes.*
17. Forty-eighth Commission Directive 85/157/EEC of 6 February 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L59, 27/2/1985 p.27) Action: *Extension Carbadox and Olaquinox until 31/5/85*
18. forty-ninth Commission Directive 85/312/EEC of 31 May 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L165, 25/6/1985 p.21) Action: *Extension of carbadox and Olaquinox unto 31 October 1985.*
19. Commission Directive 85/520/EEC of 11 November 1985 amending Commission Directive 85/429/EEC, amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L323, 4/12/85 p.12) Action: *Extension of Carbadox, Olaquinox and Nitrovin until 31/12/86*
20. Commission Directive 86/525/EEC of 27 October 1986 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (O.J. No. L 310, 5/11/86 p. 19) Action: *Last directive for 1986 concerning 70/524/EEC, therefore the date of 31/12/86 arrived without extension for Carbadox and Olaquinox under the Annex II. In practice this is a banning (principle of a "positive list").*
21. Commission Directive 86/530/EEC of 28 October 1986 amending the Annex to Council Directive 82/471/EEC concerning certain products used in animal nutrition (O.J. No. L 312, 7/11/86 p. 39). Action: *Last directive for 1986. It does not concerns 70/524.*
22. Proposal for a Council Directive amending directive 70/524/EEC Concerning additives in feedingstuffs in respect of Carbadox /*COM/87/113FINAL */ (16/3/1987; Transmission 18/3/1987; Forwarded to the Council Adopted-by Dir. 87/316
23. Proposal for a Council Directive amending Directive 70/524/EEC concerning additives in feedingstuffs in respect of Olaquinox /* COM/87/113FINAL */ (16/3/1987) Forwarded to the Council: 18/3/1987adopted by 87/317
24. Commission Directive 87/243/EEC of 23 April 1987 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs in respect of Carbadox. (O.J. No. L110, 25/4/1987 p.34) Action: *Extension to 30/11/87 ["Whereas, in accordance with the Order of the President of the Court of Justice of the European Communities of 8 April 1987 in Case 65/87 R, measures should be taken to ensure that Carbadox has the status of an additive listed in Annex II to Directive 70/524/EEC pending the completion of the procedure of including it in Annex I to the said Directive or pending the judgement of the Court of Justice in that case; " The same measures applies to Olaquinox"*
25. Commission Directive 87/244/EEC of 23 April 1987 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs in respect of Olaquinox. (O.J. No. L110, 25/4/1987 p.35) Action: *Extension to 30/11/87 ["Whereas in accordance with the Order of the President of the Court of Justice of the European Communities of 8 April 1987, Case 65/87R, measures should be taken to ensure Carbadox in the Annex II to Directive 70/524/EEC pending the completion of the procedure if including it in annex I to the said directive or pending the judgement of the Court of justice. The same measures applies to Carbadox"]*
26. Council Directive 87/316/EEC of 16 June 1987 amending Directive 70/524/EEC concerning additives in feedingstuffs in respect of Carbadox. (O.J. No. L160, 20/6/1987 p.32) Action: Carbadox in Annex I
27. Council Directive 87/317/EEC of 16 June 1987 amending Directive 70/524/EEC concerning additives in feedingstuffs in respect of Olaquinox. (O.J. No. L160, 20/6/1987 p.34) Action: Olaquinox in Annex I
28. Commission Decision 90/38/EEC of 13 December 1989 relating to a proceeding under Article 85 of the EEC Treaty (IV/32.026 - Bayo-n-ox) (Only the German text is authentic). (O.J. No. L021, 26/1/1990 p.71 Action: (A1): *The agreements which were in force from 10 July 1986 to 13 November 1989 between Bayer AG and its customers, under*

which such customers were required to use 'Bayo-n-ox Premix 10 %' solely to cover their own requirements in their own works, constitute infringements of Article 85 of the EEC Treaty.(A2): A fine of ECU 500 000 is imposed on Bayer AG in respect of the infringement referred to in Article 1.

29. Commission Directive 90/110/EEC of 19 February 1990 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. (O.J. No. L67, 15/3/90 p.44) Action: *New definition of Carbadox.*

30. Report of the Scientific Committee for Animal Nutrition on the possible implication of olaquinox in cases of photoallergic contact-dermatitis developed in pig-farmers. Opinion expressed 18 November 1992. (9th Series, In press).

31. Commission Decision 96/516/EC of 29 July 1996 on financial aid from the Community for the work of the Laboratoire des médicaments vétérinaires, Fougères, France, a Community reference laboratory for residue testing. (O.J. No. L217, 28/8/1996 p.4) Action: *Analysis of residues of carbadox Olaquinox*

32. Commission Directive 96/7/EC of 21 February 1996 amending Council Directive 70/524/EEC concerning additives in feedingstuffs). (O.J. No. L51, 01/3/1996 p.45) Action: *New conditions for users (labelling). Follows the advice by SCAN*

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC. (O.J. No. L125, 23/5/1996 p.10. Action: *Residues in meat of carbadox and Olaquinox: (Annex V): Laboratoire de médicaments vétérinaires (CNVEVADO-LMV). La Haute Marche, Javene. F-35135 Fougères*

Table 1. Annex I, Section J "Growth Promoters"

| EEC No | Additive | Chemical formula, description | Species or category of animal | Maximum age | Minimum Content Maximum Content | Other provisions |
|--------|----------|--|-------------------------------|-------------|--|--|
| E 850 | Carbadox | methyll-3-(2-quinoxaliny methyl) carbazate-n 1 , n 4 - dioxide. Minimum purity 96%. particular features of the authorised preparations - max. carbadox content 5 or 10% - Minimum stability: 24 month - Propionic acid: 0.5% - Soybean oil: 7% - Soybran meal: up to 100% | Piglets | 4 month | 20 50 mg/kg of Complete feedingstuffs | Used prohibited at least 4 weeks before slaughter Maximum amount of dust emitted during handling as determined by the Stauber Heibach method (Literature reference: Fresenius Z, Anal. Chem. (1984) 318: 522-524, Springer Verlag 1984) : 0,1 µg Carbadox Indication on the label of the additives, premixtures and feedingstuffs of safety instructions and warning designed to protect the health of operators and in particular to avoid any exposure to the additive, specially by touch or inhalation |

Table 2: Annex I, under part J "Growth Promoters"

| EEC | Additive | Chemical formula, | Species | Maximum | Minimum Maximum | Other provisions |
|-----|----------|-------------------|---------|---------|-----------------|------------------|
|-----|----------|-------------------|---------|---------|-----------------|------------------|

| No | | description | or category of animal | age | Content Content mg/kg of Complete feedingstuffs | |
|-------|-----------|---|-----------------------|---------|--|--|
| E 851 | Olaquinox | <p>2-(N-2' (hydroxymethyl) carboamoyl)-3-methylquinoxaline N 1 , N 4 - dioxide.</p> <p>Minimum purity 98%. Particular features of the authorised preparations</p> <ul style="list-style-type: none"> - maximum olaquinox content 10% - Minimum stability: 24 month - Medium: calcium carbonate containing 1,5 of Glyceyl poliethylenglycol ricinoleate | Piglets | 4 month | <p>15 - 50</p> <p>50 - 100</p> <p>(Milk- (Milk replacers - replacers only) - only)</p> | <p>Used prohibited at least 4 weeks before slaughter</p> <p>Maximum amount of dust emitted during handling as determined by the Stauber Heibach method (Literature reference: Fresenius Z, Anal. Chem. (1984) 318: 522-524, Springer Verlag 1984) : 0,1 µg Olaquinox</p> <p>Indication on the label of the additives, premixtures and feedingstuffs of safety instructions and warning designed to protect the health of operators and in particular to avoid any exposure to the additive, specially by touch or inhalation with the mention "Warning: Risk of photoallergy for people so predisposed"</p> |