Summary report of the meeting held on 30 November in Brussels (approved at the meeting on 21 December 1998)

List of Participants

MEMBERS

Prof. A. Osterhaus (chairperson), Prof. R. Gilbert (first vice-chairperson), Prof. J. Fink-Gremmels, Prof. A. Johnston, Prof. O. Kaaden, Prof. A. Macri, Prof. A. Mantis, Prof. E. Nurmi , Prof. E. Quinto Fernandez, Dr. J. Schlundt, Dr. I. Vagsholm, Prof. F. Van Knapen, Prof. P. Willeberg

APOLOGIES

Prof. D. Vuitton (second vice-chairperson)

ABSENT

Prof. V. Caporale

COMMISSION

Mr. P. Wagstaffe, Mr. T. Christoforou (LS), Mr. R. Vanhoorde (DG XXIV), Mr. B. Verleysen (DG XXIV) , Mr. H. Winter (DG VI), Mr. Veli-Mikko Niemi (DG VI), Mme A. Fabre (DG XII), Mrs. N. Huyghe (DG XXIV), Mr. H. Belvèze (point 13) (DG XXIV), Mr. K. Madsen (point 13) (DG XXIV)

1. Declarations of interest

See point 7 of the agenda.

2. Adoption of the Agenda

The agenda was adopted.

3. Adoption of the minutes of the meeting of 30 October 1998

The minutes were adopted.

4. Discussion and possible adoption of a scientific opinion concerning cooling of carcasses during transport

The Committee examined the draft report and the additional comments that were received from two members of the working group. The secretariat was asked to amend the draft report for the next plenary in the light of the outcome of this exercise.

Some members considered that the report needs to be clarified in several places on whether the temperature is referring to deep muscle or to surface temperature. Others insisted that statements on acceptability of temperature limits should be underpinned by hard scientific data.

Considering the advanced stage of the draft report, the Committee decided to finalise the opinion on this long outstanding question within the plenary. Certain members were asked to provide specific input for the next meeting on the following aspects: the impact of possible differences in carcass size, the acceptability of a maximum deep muscle temperature of 16°C, modelling of microbial growth, the impact of stress and the capacity of mobile refrigeration units.

5. Information concerning the mandate for a Working Group on the complementary risk assessment on the use of hormones and the establishment of a Working Group

Commission representatives presented the mandate (copy attached) which had been circulated to the members before the meeting. They explained the background, the recent factual, legal, international and scientific developments. The importance attached by the Commission to this issue and the need to have an opinion of the highest possible scientific quality were highlighted. Reference was also made to the recently initiated and to ongoing research projects that are financed by the Commission. Several members requested clarifications and some questioned the tightness of the timetable. It was clarified that the Committee is requested to report if possible before the end of April 1999. But if the opinion is not possible or not conclusive before then, work should continue and be finalised as soon as possible in the light of the studies initiated by the Commission.

The Committee in general and the chairperson of the Working Group in particular will reflect on highly qualified external experts for the working group and to communicate their details to the Secretariat before the next plenary. Having considered the issues raised by the mandate, the following fields of expertise will have to be included: endocrinology (human / veterinary), carcinogenicity/genotoxity, toxicology / pathology, (cancer) epidemiology, biochemistry / analytical chemistry, cellular biology / metabolism, chemical risk assessment, etc.

6. Establishment of a joint Working Group with the Scientific Committee for Food (SCF) on microbiological standards for listeria

The Secretariat informed the Committee on the draft mandate. It was explained that, as its final wording is still being discussed in the Commission services, it might be subject of some minor amendments.

Three members of the Committee will participate in the Working Group that will be extended by experts to be appointed by the SCF.

7. Progress report on the request for a scientific opinion concerning the revision of ante- and post- mortem inspection procedures for an alternative inspection system for the slaughter of pigs

As it was agreed at the last plenary, the rapporteur provided a written description of possible interests and a declaration expressing his ability to act independently. After a thorough evaluation of the situation, the Committee confirmed unanimously its confidence in his independence.

The Secretariat was asked to explore the possibilities of organising an additional Working Group meeting on one of the following dates: 21 or 22 January or 1, 2 or 3 February.

8. Progress report on the request for a scientific opinion concerning the use of Bovine Somatotropin

The draft reports from the groups addressing respectively the pubic health aspects and the animal health and animal welfare aspects are being finalised and will be integrated in a global draft report.

It is expected to have a first global draft report available for the next plenary session.

9. Progress report on the request for a scientific opinion on the evaluation of microbiological criteria and temperatures for storage and transport of products of animal origin intended for human consumption:
- partim microbiological criteria;

- partim temperatures for storage and transport;

The rapporteur announced that a working document will be circulated in view of the working group meeting that is scheduled for 17 December. The Secretariat informed the Committee that the mandate had been slightly amended to take into account the difficulties that were expressed at the last working group meeting.

10. Progress report on the request for a scientific opinion concerning the prevalence and methods of control of cysticercosis

The first Working Group meeting is scheduled for 29 January.

11. Progress report on the state of progress on the multidisciplinary working group on antimicrobial resistance

Feedback was given on the ongoing work. A working group meeting is planned for 03 December.

12. Feed-back by the chairman on subjects discussed in the SSC which are of interest to the Committee

Item postponed until the next plenary. In future agendas and minutes of the SSC will be made available to the Committee for information.

13. Feed-back by members of the Committee having attended working group meetings of other Scientific Committees

Reference was made to the work carried out in the SCF on Spanish soups.

14. Miscellaneous

Next meetings are scheduled for:

21 December 1998,

05 February 1999,

15 March 1999,

30 April 1999,

11 June 1999.

ANNEX

HORMONES USED FOR GROWTH PROMOTION PURPOSES IN CATTLE

TERMS OF REFERENCE

In the context of the WTO case on *Hormones*, the European Commission intends to evaluate the potential for adverse effects to human health from residues in bovine meat and meat products resulting from the use of the six hormones for growth promotion purposes in cattle and whether the currently available scientific information necessitates the revision of previous risk assessments.

The Commission consequently requests the SCVPH to deliver an opinion on the potential for adverse effects to human health arising from the administration of the six hormones oestradiol-17 b , progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate used individually or in combinations for animal growth promotion.

The deadline set by the WTO Arbitrator for the EC to bring its measure into conformity with the SPS agreement is 13 May 1999. The SCVPH is, therefore, requested to deliver an opinion before the end of April 1999, responding as far as possible to the questions stated below. If this opinion is not conclusive, the Commission will request the SCVPH to subsequently complete its opinion as soon as possible in the light of the studies initiated by the Commission.

QUESTIONS

In light of the preceding and taking into account:

- the use of the six hormones, individually or in combinations, for growth promotion purposes in cattle,

- the current scientific information with respect to health-related biological actions such as genotoxicity, carcinogenicity, embryotoxicity (including teratogenicity), endocrine and reproductive effects of the hormones in question and their metabolites,

- possible long-term exposure and potential synergistic effects,

- the current techniques and standards for the evaluation of the safety of substances leaving residues in food,

- possible effects on the most vulnerable parts of the population, in particular young children.

Question 1:

a) What are the potential adverse effects on human health from residues in bovine meat and meat products resulting from the use of the six hormones in question for growth promotion in cattle?

In answering this question, the SCVPH is asked to include an assessment in terms of carcinogenicity, genotoxicity, embryotoxicity (including teratogenicity) and endocrine, reproductive or other effects, taking into account long-term and synergistic effects from exposure to residues of these hormones and their metabolites in meat and meat products.

b) To what extent is the currently available information (clinical and epidemiological evidence included) sufficient to allow the SCVPH to complete its assessment, in particular for MGA?

Question 2:

The main criticism of the WTO Panel and Appellate Body reports of the scientific evidence presented by the EC was that this evidence "constitute general studies which do indeed show the existence of a general risk of cancer, but they do not focus on and do not address the particular kind of risk here at stake - carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes".

In relation to the reply to question 1, please specify:

a) which are the appropriate systems (in vivo and/or in vitro) to test for potential carcinogenic or genotoxic effects?

b) if it has been scientifically established that these hormones or their metabolites are carcinogenic or genotoxic in general in vivo and/or in vitro studies, is it still necessary to establish whether the residues in bovine meat are carcinogenic or genotoxic?

c) whether the risk assessments of the five hormones by JECFA in 1987/1989 and of MGA by the US and Canadian authorities were based on evidence focusing specifically on the lack of carcinogenic, genotoxic, or endocrine effects of the residues of these hormones in bovine meat and meat products?

Question 3:

The basis for the risk assessments of the five hormones by JECFA in 1987/1989 and of MGA by the competent US and Canadian authorities was the assumption that their carcinogenic potential is exclusively related to their hormonal activity. Is this assumption still valid in light of the currently available scientific information, e.g. on carcinogenicity, genotoxicity, endocrine and synergistic effects from long-term exposure to residues of one or more of these hormones?

Question 4:

a) What are the potential adverse effects if the approved conditions of use stated in the label instruction are not respected, for instance due to other routes of administration, higher and more frequent doses, different or un-authorised combinations or non-respect of prescribed withdrawal periods?

b) Are there particular risks associated with the practical administration of these substances?

c) Are adequate analytical methods available to control that the approved conditions of use for the six hormones and, in particular, the three natural ones have been adhered to?