STANDING COMMITTEE

1. Discussion and possible request for an opinion on a Draft Commission Regulation concerning the authorisation of a new use of an additive in feedingstuffs (SANCO/3128/2003 rev.1).

The vote was taken and the Committee adopted an opinion in favour of the Regulation concerning a new use of a coccidiostat (salinomycin for chicken reared for laying), for ten years, by qualified majority. One delegation abstained.

2. Discussion and possible request for an opinion on a Draft Commission Regulation concerning the provisional authorisation of new additives in feedingstuffs (SANCO/2097/2003 rev.3)

The vote was taken and the Committee adopted an opinion in favour of the Regulation concerning a new use of a microorganism (Enterococcus faecium), for four years, by unanimity.

3. Discussion and possible request for an opinion on a Draft Commission Regulation concerning the provisional authorisation of a new use of an additive and the permanent authorisation of an additive already authorised in feedingstuffs.

The draft Commission Regulation was presented and discussed. It concerns a 4-year authorisation for an enzyme (xylanase) and the conversion of a provisional authorisation for a microorganism into a permanent authorisation (Saccharomyces cerevisiae).

The proposed Regulation was adopted by unanimity.

4. Discussion and possible request for an opinion on a Draft Commission Directive authorising isopropyl ester of 2-hydroxy-4-methylthiobutanoic acid (HMBi).

After a short discussion where some small changes were introduced, the proposed Directive was adopted by unanimity.

5. Discussion on a Draft Commission Regulation amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the trace elements group.

A representative of the Commission explained that it was necessary to amend Regulation 1334/2003 in order to introduce some changes in the provisions for copper and iron.

The proposal would be put to the vote in the next Standing Committee.

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed will apply from 1 August 2003 onwards. One of the main provisions of this Directive is the total prohibition of the dilution of non-complying products intended for animal feed.

When the above-mentioned Directive was adopted, the Commission made a commitment to undertake a review of the provisions laid down in the Annex of the Directive on the basis of updated scientific risk assessments and taking into account the prohibition of any dilution of contaminated non-complying products intended for animal feed.

The Commission has therefore requested the Scientific Committee for Animal Nutrition (SCAN) to provide these updated scientific risk assessments without delay. The opinion adopted by SCAN in April 2003 provides a comprehensive overview of the possible risks for animal and public health due to the presence of the various undesirable substances in animal feed. It is nevertheless acknowledged that detailed risk assessments are necessary to permit a complete review of the provisions in the Annex.

Information was brought to the attention of the Committee to the effect that, as from 1 August 2003, the supply of some valuable feed materials might be jeopardised as a result of the level of undesirable substances in some feed materials — owing to background contamination — being near to or in excess of the maximum permitted level laid down in the Annex.

In the light of this fact and after extensive discussion in the Committee, the following amendments to the Annex of Directive 2002/32/EC were submitted to the Committee for an opinion:

- arsenic in calcium carbonate (15 ppm), palm kernel expeller (4 ppm), calcareous marine algae (10 ppm), magnesium oxide (20 ppm), feedingstuffs obtained from the processing of fish or other marine animals (15 ppm), seaweed meal and feed materials derived from seaweed (40 ppm) and fish feed and feed for fur animals (6 ppm);
- lead in phosphates, calcareous marine algae and mineral feedingstuffs (all 15 ppm) and in calcium carbonate (20 ppm);
- fluorine in marine crustaceans such as marine krill (2000 ppm), magnesium oxide (600 ppm), calcium carbonate (350 ppm) and calcareous marine algae (1000 ppm);
- aflatoxin B1 in all feed materials (0.02 ppm) and in compound feedingstuffs with a maximum level above 0.02 ppm (0.02 ppm);
- free gossypol in cotton seed (5000 ppm) and feed materials derived from cotton seed (1200 ppm);
- endosulfan: the maximum level for maize (0.2 ppm) and oilseeds (0.5 ppm) is also applicable to the products derived from their processing.
It was stressed that these amendments are provisional, subject to a review on the basis of a detailed risk assessment. The Commission has already submitted a request for these risk assessments to the European Food Safety Authority (EFSA) as a matter of priority.

Attention was drawn to a specific recital indicating that in cases where feed materials are directly fed to animals or in cases where complementary feedingstuffs are used, their use in a daily ration should not lead the animal being exposed to a higher level of an undesirable substance than the corresponding maximum level of exposure where only complete feedingstuffs are used in a daily ration.

With regard to the analysis of arsenic and in the absence of a Community method of analysis for the determination of total arsenic, it is necessary to prove the satisfactory performance of the sample treatment procedure and method of analysis employed by making use of certified reference materials containing a significant part of the arsenic in its organic form.

Member States have to transpose this Directive at the latest within twelve months after its entry into force

One delegation indicated that, according to information they have recently obtained, free gossypol could endanger animal health and could be transferred into tissues of animal origin. Consequently, they are against the proposed modifications concerning free gossypol. The Commission referred to the opinion of SCAN (see above), but agreed to submit this new information as a matter of priority to EFSA for a detailed risk assessment.

A request for a risk assessment for the presence of Camelina sativa in animal feed was also made in order to allow the Commission to take a decision on the appropriateness of maintaining Camelina sativa on the list of undesirable substances.

The issue of the presence of mercury in calcium carbonate was raised again.

The vote was taken and the Committee expressed a favourable opinion by qualified majority (one Member State against) on the proposed draft Directive.

7. Feed additives. Products requiring conversion from provisional to full authorisation

The situation with a large number of dossiers being submitted already at present and in the near future with additional scientific data supporting requests to make existing provisional authorisations permanent was discussed.

After discussion, a consensus was reached along the following lines regarding such dossiers:

- The Commission will continue consulting EFSA in all matters in these dossiers relating to the safety of consumers, operators, animals, and the environment. However, it is not considered necessary to ask the EFSA to evaluate dossiers containing exclusively data on efficacy where no safety issue is involved. The only exception is in cases where SCAN has previously delivered an opinion on efficacy.
and requests additional information on this aspect, so that scientific advice is needed to review the situation when new information is submitted.

- Member States agree to prepare a more comprehensive expert report when acting as Rapporteurs and to circulate it simultaneously with the dossier to facilitate examination by all other Member States. Where the dossier for full authorisation has already been submitted, the rapporteur will also produce a more comprehensive report to aid assessment? It was generally agreed that the assessment of efficacy should be made on the rapporteur’s report, thus avoiding the need for all Member States to undertake a detailed assessment of the efficacy data.

- Member States agree to adopt informally a three-month period for submitting comments on a dossier starting from the receipt of the rapporteur’s report.

8. Procedure laid down in Article 9g of Directive 70/524/EEC.

Generic copies of “Article 9g” additives, the provisional authorisation of which was not withdrawn and for which the re-evaluation procedure is still ongoing, may continue to be put into circulation until the regulation referred to in Article 9g (5) of Directive 70/524/EEC takes effect for these additives.

Where, for reasons beyond the control of the applicant for authorisation, no regulation may be adopted on the ten-year authorisation by 1 October 2003, the period of provisional authorisation of the additives concerned shall be automatically extended until the Commission takes a decision in accordance with Article 9g (6). However, as the extended provisional authorisation would not yet be linked to a person responsible for putting them into circulation, generic copies would still be allowed on the market during this period.

There is no intention to take any other action than to continue implementing Article 9g of the Directive, i.e. taking all necessary measures to ensure that re-evaluation of the additive dossiers concerned is completed within the required time limit before adopting a withdrawal or authorisation measure, as the case may be, in accordance with Article 9g (5) of the Directive.

Article 9g can still be used for the ongoing re-evaluation process and withdrawals and/or the linkage of the molecules to a person responsible for putting them into circulation can still be based on this Article after the date of entry into force of the new Regulation (October 2003).

In addition, authorisations could be extended until the Commission has taken a decision following the final risk evaluation of the EFSA. Should the EFSA require further scientific data, the Commission services would set a clear time limit for completing the Article 9g procedure before the application date of the new Regulation (October 2004).

If there are still substances for which re-evaluation is not finished after the date of application of the Regulation they would be considered to be existing

A draft Commission Directive on analytical methods for the evaluation and estimation of constituents of animal origin for the official control of feedingstuffs and repealing Commission Directive 98/88/EC was considered. Reservations were expressed regarding the mandatory character of the proposed provisions by delegates from several member States. No delegates objected to the provision imposing the microscopic test as the only official control method for the time being. Comments were made on the Annex (procedure for the microscopic method). It was decided to discuss the technical amendments to the Annex in a separate meeting with experts on microscopy.


A representative of the Commission presented a proposal for a recommendation for the co-ordinated inspection programme in animal nutrition in 2004. The delegations were invited to send comments by e-mail within two weeks. The number of control tasks proposed might be reduced at the next meeting. However, the Commission services consider that at least controls on mycotoxins and feed materials of animal origin are a priority.

11. SETTING THE TIMETABLE FOR ADDITIVES

11.1. "KDF PRESERVATIVE" 50±5% potassium diformate and water 50±5%.

The Committee gave a favourable opinion on this dossier according to Dir. 87/153/EEC (Art. 4 Dir. 70/524/ECC).


categories: chickens for fattening, laying hens, turkeys for fattening, piglets and pigs for fattening, sows. Request for permanent authorisation. **Expiration of temporary authorisations:** a) for animal categories: chickens for fattening, laying hens, turkeys for fattening, piglets and pigs for fattening **30.06.2004**, b) for animal category: sows **1.2.2007**

11.5 “Yea Sacc” – *Saccharomyces cerevisiae* CBS 493.94 – **Application for permanent authorisation.** Animal category: calves. The provisional authorisation will expire on 30.06.2004. Rapp: B

11.6 “Yea Sacc” – *Saccharomyces cerevisiae* CBS 493.94 – **Application for permanent authorisation.** Animal category: cattle for fattening. The provisional authorisation will expire on 30.06.2004. Rapp: B

11.7 “MLB” – *Lactobacillus acidophilus* DSM 13241– **Application for provisional authorisation.** Animal category: cats (*Day O* 28.08.2003, end of sixty-day period under article 4 par 4 of Dir. 70/524/EEC: **27.10.2003**) Rapp: DK

11.8. Belfeed B1100 MP/ML (Preparation of Endo-1,4-beta-xylanase, EC 3.2.1.8, produced by *Bacillus subtilis* (LMG S-15136), Enzyme N° 51). Animal category: chickens for fattening (solid/liquid form). **Application for permanent authorisation.**

**Expiration of temporary authorisations:** a) for solid form **17.07.2004**, b) for liquid form **1.1.2007**. Rapporteur: BE.


11.11. Allzyme PT. Preparation of endo-1,4-beta xylanase EC 3.2.1.8, produced by *Aspergillus niger* (CBS 520.94). Animal category: chickens for fattening. **Application for permanent authorisation.** **Expiration of temporary authorisation 30.06.2004.** Rapp: IE


13. Other business
2. Bioproteins

NUTRIGROW: yeast cells (*Candida guillermondii*) from the production of citric acid. Rapporteur: IRL
A representative of the Commission stated that a request had been submitted to the European Food Safety Authority for a risk assessment.

3. Particular nutritional purposes

Request from DK to modify the particular nutritional purpose “Reduction of the risk of milk fever”.
The dossier was briefly discussed pending the opinion of the EFSA.

4. Information about the agreement on scientific and technological cooperation with the Swiss Confederation. State of play.

A representative of the Commission explained the tasks that needed to be performed in connection with this agreement and, in particular, the provisions in Swiss legislation that could be regarded as identical to EU provisions and therefore were to be incorporated in the Annex to the Agreement


The Codex Secretariat asked for comments before 1 December 2003.
A representative of the Commission asked the delegations whether they could support the agreement reached in the Codex Alimentarius Commission in July 2003 on traceability, GMO labelling and the definition of additives. A majority of delegations could in principle support the approach.
A co-ordination meeting would be held in the Council in order to co-ordinate the EC position before 1 December 2003.
Denmark stated that a meeting of the Task Force on Animal Feeding would take place in Copenhagen on 17-19 May 2004.

6 Exchange of views on a Commission Decision on the establishment of a list of feed materials whose circulation or use for animal nutrition is restricted or prohibited. (SANCO/3358/2003)

A preliminary discussion took place. The main comments referred to the necessity to ensure coherence with other Community legislation, in particular Regulation 1774/2002 on animal by-products not intended for human consumption.
A representative from the Commission invited the delegations to submit comments within 15 days.

Any other business:

Nifursol: French request
France reported an increase in the mortality of turkeys following the prohibition of nifursol. The French delegation also stated that no other substance was available on the market to treat histomonosis. 
The Presidency made a "tour de table" on this subject and, apart from France, only two more Member States reported economic problems for the turkey industry possibly due to histomonosis. 
The Presidency asked all Member States to find and communicate to the Commission data on any increase in the mortality of turkeys caused by histomonosis.

**Directive 2002/2: Open Declaration — Belgian request**

The Belgian interpretation of the application of Directive 2002/2 (open declaration) was confirmed by the Commission services and accepted by all other Member States. Furthermore, in reply to a question from Belgium, the Commission stated that any fixing of a threshold below which the indication of the percentage would not be required would not be possible under current EU law.