1. Discussion of and possible opinion on a draft Commission Regulation concerning the provisional authorisation of new uses of additives in feedingstuffs: SANCO/2003/4236

The draft Commission Regulation was presented and discussed. It concerned potassium diformate as a growth promoter for piglets and pigs for fattening; the person responsible for putting into circulation had changed and new data had been submitted in order to obtain approval for higher maximum concentrations of this additive in feed.

A vote was taken: the draft was approved by qualified majority.

2. Discussion of and possible opinion on a draft Commission Regulation amending the conditions for authorisation of an additive in feedingstuffs: SANCO/2003/00678

The draft Commission Regulation was presented and discussed. It concerned an enzyme preparation, endo-1, 3(4)-beta-glucanase EC 3.2.1.6, endo-1,4-betaxylanase EC 3.2.1.8: new data were submitted to apply for authorisation without a time limit.

A vote was taken: unanimous approval.

2.a Discussion of and possible opinion on a draft Commission Regulation concerning the provisional authorisation of a new additive in feedingstuffs: SANCO/2003/1156

This point was an addendum to the initial agenda. The document concerned had been sent to the delegations in advance of the meeting.

The draft Commission Regulation was presented and discussed. It concerned the microorganism Enterococcus faecium DSM 7134 for piglets and pigs for fattening.

A vote was taken: unanimous approval.


Document SANCO/2003/79 Rev.2, a draft Commission Regulation on the authorisation of a new additive and amending the conditions for authorisation of additives in feedingstuffs, was examined.

The Commission representative proposed amending the draft Regulation in order
to maintain only the authorisation for manganomanganic oxide. The legal framework for establishing maximum levels for undesirable substances in additives was Directive 2002/32/EC.

A majority of delegations agreed with the Commission. One Member State expressed its reluctance to authorise this product due to the level of lead.

4. SETTING TIMETABLE FOR ADDITIVES


4.2. “Bio-feed plus” (endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,4-beta-glucanase EC 3.2.1.4 produced by *Humicola insolens* (strain No DSM 10442), animal categories: chickens for fattening. Rapp.: Denmark. The provisional authorisation for the product “Bio-feed plus” would expire on 30 June 2004.


4.4. Rovabio™ Excel LC &AP (Endo-1,3(4)-betaglucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8) produced from *Penicillium funiculosum* (IMI SD101) (solid/liquid form); extension of use to animal categories: piglets. (*Day 0 29 January 2003*; end of sixty-day period as laid down by Article 4(4) of Directive 70/524/EEC: 30 March 2003) Rapp.: UK.

4.5. Rovabio™ Excel LC &AP (Endo-1,3(4)-betaglucanase EC 3.2.1.6, Endo-1,4-beta-xylanase EC 3.2.1.8) produced from *Penicillium funiculosum* (IMI SD101) (solid/liquid form); extension of use to animal categories: ducks for fattening. (*Day 0 18 February 2003*; end of sixty-day period as laid down by Article 4(4) of Directive 70/524/EEC: 19 April 2003) Rapp.: UK.

4.6. Coccidiostats


“Avatec 15%” Lasalocid sodium: chickens for fattening, chickens reared for laying. Rapp.: F (Article 9g). Clock 3 (second part) was stopped today.

“Sacox 120 mg microgranulate” Salinomycin sodium; animal category: chickens for fattening. Rapp.: UK (Article 9g). Clock 3 (first part) was stopped today.
5. Report by Member States on measures taken to avoid contamination of food industry by-products as a result of drying processes

All delegations from Member States and EFTA countries provided information on the implementation of measures regarding Annex II (contamination of certain industrial by-products with dioxins as a result of drying or other types of processing) to the Commission Recommendation of 10 February 2003 on the co-ordinated inspection programme in the field of animal nutrition for the year 2003 in accordance with Council Directive 95/53/EC. In addition, the delegates reported the adoption of additional measures such as specific monitoring studies, reinforcement of control programmes, information sent out to the feed and food sectors, identification of types of by-products used as feed and on-the-spot checks of dried by-products. Samples tested so far had not shown particularly high levels of dioxins.

The possibility of adopting legal measures had been discussed. Member States would report further results when these became available.

6. Exchange of views on a draft harmonised model for the annual report on official feed controls

The draft harmonised model for reporting the results of official feed controls was close to its final stage. All delegations had contributed to the improvement of this draft document. The Commission would present a final version soon.

7. Use of sodium butyrate as an ingredient in animal feedingstuffs

A discussion took place on this subject. The delegations were asked to study the issue and to present their views at the next meeting.

. "Nifursol" Sulfiride 50DF Turkey. Evaluation of the dossier

The Chairman reminded the Committee of the background to the dossier and provided information on the current situation, including the updated opinion of the SCAN adopted on 17 March 2003. This opinion, which was distributed to the members of the Committee, concluded that the complementary data supplied by the petitioner did not enable the SCAN to conclude that Nifursol was non-genotoxic in vivo, did not enable an ADI and human exposure to be established, and therefore made it impossible to draw a conclusion as to the safety of this product.

A discussion took place, and most of the Member States agreed with the updated SCAN opinion. Some Member States, however, considered that the level of acceptability of the risk concerned should be carefully re-examined, notably in view of the divergent interests at stake.

The issue of controls on imports once Nifursol was withdrawn from the Community market was also raised by several Member States.

The Chairman indicated that the Commission would be ready to proceed as quickly as possible with the re-authorisation of Nifursol only on the basis of a favourable opinion from the SCAN or the European Food Safety Authority. He explained that this new authorisation would have to be granted in accordance with the procedure laid down in Article 4 of Directive 70/524/EEC.

9. Miscellaneous
The Chairman denounced the growing pressure from companies directly on the Commission in order to push for quick authorisations of products. This was unacceptable, and companies should be reminded that the evaluation and authorisation procedures laid down in the relevant Community legislation must be respected and applied to all parties concerned without discrimination.

Further to remarks made by several delegations, the Chairman asked each Member State to communicate to the other Member States and to the Commission the list of approved and registered establishments and intermediaries, and the place of publication where appropriate, in accordance with Directive 95/69/EC.

W. Penning