Animal Nutrition Section

Brussels, 30 November 2005

In the Chair: Willem Penning, Head of Unit.

1. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisations of a new use of certain additives already authorised in feedingstuffs

This draft Regulation concerned the permanent authorisation of one micro-organism and one enzyme preparation. These products have been granted a provisional authorisation previously. Moreover, it concerned the provisional authorisation of three enzyme preparations for 4 years.

The identification number, the trade names of the preparations and the animal categories subject to the authorisations are as follows:

Authorisation without time limit:

a) micro-organisms:
- E 1705, Cylactin for piglets. It was given micro-organism preparation No 10 in the provisional authorisation.

b) Enzymes:
- E 1632, Finase for chickens for fattening. It was given enzyme preparation No 28 in the provisional authorisation.

Provisional authorisations for four years:
- enzyme preparation No 28, Finase for Laying hens
- enzyme preparation No 39, Porzyme 9100 for piglets
- enzyme preparation No 53, Kemzyme W DRY for turkeys for fattening

The vote was taken. The draft Regulation received a favourable opinion by qualified majority.

The French delegation made the following declaration:

« Au cours de l’évaluation du dossier de demande d’autorisation du Cylactin pour les porcelets, le pétitionnaire n’a pas répondu de façon satisfaisante aux questions des experts français sur l’efficacité du produit. Considérant les conclusions des experts, communiquées aux pétitionnaires par courrier le 30 septembre 2005, la France s’abstient. »

2. Discussion and possible request of opinion on a draft Commission Regulation amending Regulations (EC) N°s 2430/1999, 937/2001, 1852/2003 and 1463/2004 as regards the terms of the authorisation of certain additives in feedingstuffs belonging to the group of coccidiostats and other medicinal substances
This draft Regulation concerned a change of the terms of the authorisation of the below-
mentioned four coccidiostats authorised as feed additives for 10 years linked to a person 
responsible for putting them into circulation. The amendment concerned a change of the 
authorisation holder.

- E 764 Halofuginone hydrobromide 6 g/kg (‘Stenorol’), authorised for chickens for laying 
by Commission Regulation (EC) No 2430/1999;

- E 766 Salinomyc is sodium 120 g/kg (‘Sacox 120’), authorised for rabbits for fattening by 
Commission Regulation (EC) No 937/2001;

- E 766 Salinomycin sodium 120 g/kg (‘Sacox 120 microGranulate’), authorised for 
chickens reared for laying by Commission Regulation (EC) No 1852/2003 and

- E 766 Salinomycin sodium 120 g/kg (‘Sacox 120 microGranulate’), authorised for 

The vote was taken. The draft Regulation received a favourable opinion by qualified majority.


The draft Commission Directive proposes to establish new maximum levels for the sum of 
dioxins and dioxin-like PCBs in feedingstuffs. In order to ensure a smooth transition, for a 
transitional period the existing levels for dioxins will continue to apply in addition to the 
newly set levels for the sum of dioxins and dioxin-like PCB. The feed must comply during 
that period with the maximum levels for dioxins and with the maximum levels for the sum of 
dioxins and dioxin-like PCBs. Consideration will be given by 31 December 2008 to 
significantly reducing the maximum levels for the sum of dioxins and dioxin-like PCBs and to 
dispensing with the separate maximum level for dioxins.

In view of this review, operators need to make efforts to step up their decontamination 
capacity to remove effectively dioxins and dioxin-like PCBs from fish oil. Further efforts 
have to be done by the operators to investigate the different possibilities to remove dioxins and 
dioxin-like PCBs from fish meal and fish protein-hydrolysates. Once the decontamination 
technology is also available for fish meal and fish protein hydrolysates, operators will have to 
do efforts to provide for sufficient decontamination capacity.

Directive 2002/32/EC provides for the possibility of setting action levels. Therefore the action 
levels for dioxins are transferred from Recommendation 2002/201/EC to Annex II to 
Directive 2002/32/EC. Since the sources of dioxins and dioxin-like PCBs are different, 
separate action levels are determined for dioxins on the one hand and for dioxin-like PCBs on 
the other hand.

The extraction procedure used for the analysis of dioxins and dioxin-like PCBs has a large 
influence on the analytical result in particular on products intended for animal feed of mineral 
origin and it is therefore appropriate to determine before the date of application the extraction 
procedure to be used for the analysis of dioxins and dioxin-like PCBs.

After a comment made as regards the time needed to transpose the Directive into national law, 
it has been agreed that the new measures become only applicable 9 months after publication 
in the Official Journal.
One delegation indicated that they could only agree on the proposed measures if the extraction procedure was already determined.

The vote has been taken. The Committee expressed a favourable opinion by qualified majority on the proposed measures.

4. Possible request of opinion on a draft Commission Regulation amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs as regards dioxins and dioxin-like PCBs.

The draft Commission Regulation proposes to establish new maximum levels for the sum of dioxins and dioxin-like PCBs in foodstuffs. In order to ensure a smooth transition the existing levels for dioxins will continue to apply for a transitional period in addition to the newly set levels for the sum of dioxins and dioxin-like PCB. The foodstuffs must comply during that period with the maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs. Consideration will be given by 31 December 2008 to significantly reducing the maximum levels for the sum of dioxins and dioxin-like PCBs and to dispensing with the separate maximum level for dioxins.

In view of this review, operators need to make efforts to step up their decontamination capacity to remove effectively dioxins and dioxin-like PCBs from marine oil intended for human consumption.

The date of application will be the same as the date of application agreed for the proposed measures in feedingstuffs (9 months after publication in the Official Journal).

The measures foresee furthermore to extend the temporary derogation for Sweden and Finland until 31 December 2011 but to limit it to 6 fish species (salmon, herring, trout, char, river lamprey and roe of vendace). Furthermore the possibility for derogation is introduced for Latvia and Lithuania (in addition to Estonia for which the possibility for derogation was already foreseen in the Accession Treaty) under the same conditions as Sweden and Finland.

The vote has been taken. The Committee expressed a favourable opinion by qualified majority on the proposed measures.

Denmark made following declaration:

“Denmark appreciates the Commission’s effort to accelerate the legislation concerning dioxin and dioxin-like PCB. Like the Commission, we find it appropriate to reduce the intake in the population in general. However, from a toxicological point of view and combined with the intention of the Commission strategy on the issue, Denmark cannot support the proposal and vote against it.

According to the strategy, as mentioned in Regulation 2375/2001, the human exposure is to be reduced by at least 25% by the year 2006 in the Member States. To our understanding this is not achieved by allowing higher levels of dioxin-like PCBs in certain fish species compared to other fish species.

Previous derogations from legislation on dioxin-contamination, have been issued for certain countries only – and with a specific restriction, that
products not complying with the regulation could be traded on the home market only. With this proposal a higher limit for dioxin-like PCB in eel is framed as a Community limit, and not as derogation for specific countries with identified problems. Denmark finds it unacceptable since it will reduce the level of food safety and protection for the consumers in general in the Community.

For Danish Consumers the proposed limit for eel causes, those consumers, which already have high intake of dioxin and dioxin-like PCB, now risk an increase in their daily intake up to 11%. This ought to be considered along with the general advice from authorities to increase the intake of fish.”

Germany made following statement (courtesy translation provided by the German delegation):

“The German delegation thanks the Commission for its efforts to limit the presence of dioxins and PCBs in the food chain. We note with regret that there is currently no majority for the establishment of separate maximum levels for dioxins on the one hand and dioxin-like PCBs on the other hand for food and those stricter levels for WHO-TEQ are not enforceable at the moment. Moreover the German delegation is concerned about the maximum level for eel, which was raised from 8 pg/g fresh weight to 12 pg/g fresh weight.

Despite the concerns expressed above the German delegation endorses the Commission proposal for the following reasons:
* The maximum levels are defined in a way that allows for highly contaminated food to be taken off the market throughout Europe as from the moment the measures apply.
* The provisions for maximum levels in food and feed will come into effect simultaneously.
* The provisions for maximum levels of dioxins will no longer be suspended on 31 December 2007 as originally planned, but potentially be extended until 31 December 2008.
* It is foreseen to lower the levels for WHO-TEQ by 31 December 2008 at the latest.”

5. Exchange of views on a draft Commission Recommendation on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs

In order to encourage a proactive approach to reducing the dioxins and dioxin-like PCBs present in food and feed, action levels were set by Commission Recommendation 2002/201/EC of 4 March 2002 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs. Those action levels are a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures to reduce or eliminate it. Since the sources of dioxins and dioxin-like PCBs are different, separate action levels are determined for dioxins on the one hand and for dioxin-like PCBs on the other hand by this Recommendation for food and in Annex II to Directive 2002/32/EC for feed.

The Committee endorsed the draft Commission Recommendation.
6. Follow-up on EFSA opinions as regards undesirable substances endosulfan and HCH isomers

Taking into account the available information on occurrence and transformation factors, following changes to existing provisions were submitted to the Committee for consideration as regards endosulfan in oilseeds and products derived from the processing thereof:
- Oilseeds and products derived from the processing thereof with the exception of crude vegetable oil: 0.5 ppm
- Crude vegetable oil: 2 ppm.

A delegation indicated that extensive monitoring data indicated that a level of 2 ppm for crude vegetable oil is too high. The Commission indicated to verify with oilseed crushing industry if more data were available before continuing the discussion on this issue. Norway reiterated its comments as regards ongoing studies on the toxicity of endosulfan for farmed fish species.

As regards HCH, it can be concluded from the conclusions of the EFSA opinion, that the existing legal provisions as regards HCH-isomers in products intended for animal feed are appropriate to ensure that these products do not represent any danger to human health, animal health or adversely affect the livestock production. In order to provide more clarity as regards the term fats, the Committee was in favour of replacing the term “fats” by “fats and oils” (referring to the feed materials). This will include unequivocally fish oil, vegetable oil and animal fat.

7. Discussion on current legal provisions as regards ergot in view of the EFSA opinion on ergot alkaloids in animal feed.

It is considered appropriate for future monitoring purposes to determine the ergot alkaloids of relevance eventually combined with guidance values. A proposal was made by Germany to focus on the ergot alkaloids ergometrine, ergotamine and ergocryptine and for control purposes guidance values for these individual ergot alkaloids were proposed which correspond to the current maximum level for sclerotia. Nevertheless the delegation from Germany was requested to clarify why ergocristine was not identified as indicator ergot alkaloid in the proposal, while in the EFSA opinion ergocristine was identified to be the major ergot alkaloid present in sclerotia from rye, wheat and triticale.

The German delegation indicated that there were analytical problems with the determination of ergocristine and given the fact that only limited occurrence data exist on ergocristine, it is not possible to determine an appropriate guidance value. For ergometrine, ergotamine and ergocryptine, extensive monitoring data exist.

The Commission representative indicated to examine the analytical problems for the determination of ergocristine and requested the German delegation to submit their extensive data on the presence of ergometrine, ergotamine and ergocryptine in feedingstuffs for future consideration by the Committee.

8. Presence of high levels of aflatoxin B1 and free gossypol in whole cotton seed originating from West-Africa. Follow-up on request for reinforced controls
No information was provided by the delegations. It was noted that no notifications as regards high levels of aflatoxin B1 and/or free gossypol were transmitted by the Member States to the RASFF. One delegation referred to the problems incurred for identifying the consignments to control. The Commission representative indicated that it would be appropriate to submit the outcome of the controls in writing (a specific request will be addressed to the Member States) and reminded the competent authorities of the Member States to pay particular attention to this issue and to control the presence of aflatoxin B1 and free gossypol in whole cotton seed.

9. Feed additives


9.2 Community Register of Feed Additives

Following the first publication of the Register on 7 November, an exchange of views took place about its status, its maintenance and ways of improving its usability. The Register will be updated by the Commission whenever authorisations are granted, or modified. The Register has only informative purposes and does not replace Community legal acts. The Community legal acts concerning the authorisation of each additive entered in the Register constitute the legal basis for the placing on the market and use of the additives concerned.


9.3.1 Enzymes

9.3.1.1 “Kemzyrne W DRY”, preparation of endo-1,3(4)-beta-glucanase produced by Aspergillus aculeatus (CBS 589.94), endo-1,4-beta-glucanase produced by Trichoderma longibrachiatum (CBS 592.94), alpha-amylase produced by Bacillus amyloliquefaciens (DSM 9553), bacillolysin produced by Bacillus amyloliquefaciens (DSM 9554) and endo-1,4-beta-xylanase produced by Trichoderma viride (NIBH FERM BP 4842) (Enzyme No. 53).

Extension of use for animal category: laying hens. Rapp BE.

Second part of the evaluation period in clock 3 has been closed.

9.3. Coccidiostats

1.3.2 Clinacox 0.5% Active substance: Diclazuril (R064433) CAS 101831-37-2. Coccidiostat for rabbits for fattening and breeding. Application for an authorisation for ten years. Rapp.: BE. Clock has been stopped.

10. Swiss agreement

There was no discussion on this item.

11. Any other business.
11.1 Quality of translations

Considering the position systematically expressed by one delegation concerning the translation status and quality of the documents submitted to the Committee, the Chairman gave the following clarification: in order to preserve the necessary flexibility allowing committees to progress with their work, translations into all official languages are requested once the text of a draft measure becomes “stable”. Responsibility for linguistic and formal aspects of the text lies on the Directorate-General for Translation while the mention of substantial issues in the draft measure such as scientific data falls within the competence of the services author of the document. Along this line, measures published in the Official Journal of the E.U. may be subject to corrigenda in case of translation mistake and if this is judged necessary by the competent services.

11.2 Analytical method to determine phytase

Following requests of a delegation the Committee was informed of the following:
- the workshop on measurement uncertainty will be held mid January 2006.
- CEN is currently working on a standardised method for the determination of phytase in animal feed. Once finalised, this method has to be used for official control and this in accordance with the provisions of the Regulation 882/2004 on the official control of feed and food.
- the problem of the presence and control of aflatoxin B1 in imported peanuts used as wild bird feed will be tabled as agenda item for the meeting of the Committee in January 2006.
- co-ordinated control programs are not intended to serve scientific purposes. The Fusarium toxins T-2 and HT-2 toxin were included in the control programme 2006 because of the importance to gather data on the co-occurrence of the different Fusarium-toxins in animal feed.

11.3 Condroitin sulphate and glucosamine

A request from a company to determine for the legal status of these products was distributed to the delegations. The company aimed to amend Directive 93/74/EEC. A particular nutritional purpose for the support of cartilage function in case of articular wearing down was proposed to modify the Directive.

A representative from the Commission asked the delegations to examine the legal status of the two products and the possibility to introduce a new particular nutritional purpose. This issue will be discussed in the next meeting of the Standing Committee.

11.3 Legal Status of Haematoccocus pluvialis algae meal

A representative of the Commission informed the delegations that this product is to consider to be an additive falling within the scope of Regulation (EC) No 1831/2003. Member states agreed with this approach.

A company submitted an application for authorisation as additive and the product is under evaluation by the European Food Safety Authority.
Dr. Willem Penning