



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

**SUMMARY RECORD OF THE
STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH
HELD ON 27-28 NOVEMBER 2008 IN BRUSSELS
(Section Animal Nutrition)
(Section Animal Health and Welfare)**

President : Mr Willem PENNING

All Member States were represented, except Malta

1. Feed Additives

1.1. Applications under Regulation (EC) No 1831/2003 Art. 4

1.1.1. New application (1)

1.2. Applications under Regulation (EC) No 1831/2003 Art. 25

1.2.1. Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) from *Penicillium funiculosum* (IMI SD101) (enzyme 30), for piglets (weaned). Application for permanent authorisation

Expiry of provisional authorisation : 20.12.2008. Rapp : UK

A discussion took place.

1.2.2. Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) from *Penicillium funiculosum* (IMI SD101) (enzyme 30), for ducks for fattening. Application for permanent authorisation

Expiry of provisional authorisation : 20.12.2008. Rapp : UK

A discussion took place.

1.2.3. Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma longibrachiatum* (IMI SD 135) (enzyme 17) for laying hens.

Application for permanent authorisation. Rapp : UK

A discussion took place.

1.2.4. Endo-1, 4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma longibrachiatum* (IMI SD 135) (enzyme 17) for piglets.
Application for permanent authorisation . Rapp : UK

A discussion took place.

1.2.5. Endo-1, 4-beta-xylanase (EC 3.2.1.8) produces by *Bacillus subtilis* (LMG S-15136) (enzyme 51) for laying hens.
Application for permanent authorisation.
Expiry of temporary authorisation : 06.03.2009. Rapp : BE

A discussion took place. The annex entry was submitted.

2. Discussion on a draft Regulation amending Regulation (EC) No 1137/2007 concerning the authorisation of *Bacillus subtilis* (O35) as a feed additive (Document SANCO/3675/2008)

The annex was discussed.

3. Discussion on a draft Regulation (EC) amending Regulation (EC) No 600/2005 concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs (Document SANCO/3674/2008)

The annex was discussed.

4. Discussion on a draft Regulation concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc47 linked to the holder of authorisation Société Industrielle Lesaffre (Document SANCO/3739/2008)

The annex was discussed.

5. Discussion on EFSA opinion on "Safety and efficacy of Advastat (containing 10% acarbose, produced by *Actinoplanes utahensis* CBS 961.70), as feed additive for cattle for fattening and dairy cows"

A discussion took place. It was decided to ask for more information to the company.

6. Exchange of views on activities relating to future work in Codex Alimentarius relating to animal feed

The Commission provided background about the status of the work of the Codex electronic Working Group about this issue. Denmark also provided some further elements. A discussion followed about the future work that could be undertaken in

Codex. The EU Member States participating in the electronic Working Group who had not yet contributed to the text, could send their comments to the document prepared by the Chair of the Working Group.

7. Exchange of views on amending aspects of Regulation (EC) No 378/2005 relating to the tasks and duties of the CRL Feed additives authorization

A first exchange of views took place about the possibilities of updating Regulation (EC) No 378/2005 in particular when considering the work of evaluation of multi-analyte methods. The case of re-evaluation process of chemically defined flavourings because of their likely safety evaluation in groups of chemically related families, their big number and the specific requirements foreseen in Regulation (EC) No 429/2008 seemed to be a good case to apply this procedure. A number of elements were raised for further consideration at a next meeting.

8. Discussion on Draft Commission Directive amending Directive 2002/32/EC on undesirable substances in feed as regards arsenic

The Commission representative mentioned that the draft Commission Directive was not yet drafted but that the stakeholder organisations have been consulted on the following proposed changes of the maximum levels of arsenic mentioned in Annex I of Directive 2002/32/EC.

- for fish meal, fish oil and other feedingstuffs derived from fish and other marine organisms: 25 mg/kg
- for fish feed and feed for fur animals: 10 mg/kg.

The current footnote requiring that, upon request of the competent authority, the responsible operator must perform an analysis to demonstrate that the content of inorganic arsenic is lower than 2 mg/kg remains applicable for both abovementioned indents.

Following maximum levels on total arsenic are proposed to be added

- iron particles used as tracer: 50 mg/kg
- additives belonging to the functional group of compounds of trace elements 30 mg/kg except
 - copper sulphate pentahydrate and copper carbonate: 50 mg/kg
 - zinc oxide, manganous oxide and copper oxide: 100 mg/kg.

A large majority of the Committee agreed to the proposed changes. These amendments to current legislation will be notified to WTO for comments, in accordance with the SPS agreement.

9. Discussion on mercury in feed. Follow-up on EFSA opinion

In accordance with the conclusions of the EFSA opinion on mercury as undesirable substance in animal feed, the following possible changes to current legislation were put forward by the Commission representative for discussion :

- reduction of the existing maximum level of mercury in feed for cats, given that cats are very sensitive to (methyl)mercury and that the current maximum level of 0.4 mg/kg provides only a small margin of safety;

- the level in feed for fish (0.1 ppm) is not in correspondence with the established maximum levels in fish oil and fish meal (0.5 ppm). For other heavy metals, such as arsenic, lead and cadmium, the ratio between the maximum level for fish oil/fish meal and fish feed is about 2 to 2.5 while for mercury this ratio is 5. In order to bring this ratio for mercury in line with the provisions for other heavy metals, two options were discussed: lowering the levels for fish oil and fish meal or increasing the levels for fish feed. The majority of the Committee was in favour of lowering the levels for fish oil and fish meal;

- feed for mink, given that mink has been identified as a very sensitive species for (methyl) mercury. As the existing maximum level of 0.1 ppm provides a sufficient margin of safety, no changes to current legislation are proposed;

The Commission representative indicated to work out a concrete proposal on amendments to the current provisions on mercury in feed taking into account the different views expressed during the meeting. The discussion continues at the next meeting of the Standing Committee.

10. Discussion on non-dioxin like PCBs in feed. Follow-up on EFSA opinion

The Committee was informed on the ongoing discussions as regards possible maximum levels for non dioxin-like PCBs in food. These discussions are close to finalisation and therefore it is appropriate to initiate the discussions on provisions for non dioxin-like PCBs in feed. It was mentioned that the levels currently discussed are strict and that this might have as consequence that low levels in feed could be allowed. In particular, the expected difficulties to comply with these levels, in particular for beef, in flooded areas was highlighted.

11. Discussion on other topics related to undesirable substances in feed

a) tropane alkaloids

The CONTAM Panel from EFSA adopted on 9 April 2008 a scientific opinion on tropane alkaloids as undesirable substance in animal feed¹. One of the conclusions is that pigs have been shown to be among the most sensitive species to *Datura* poisoning. A worst case exposure estimate indicated that adverse pharmacological effects in pigs following exposure to *Datura ferox* seeds, mainly containing scopolamine, can not be entirely excluded at the current statutory limits of 3000 mg/kg feed. However, the limited data also suggested that it is not likely that the presence of *Datura stramonium* impurities in animal feed up to the current statutory level of 1000 mg/kg would present a risk to animal health.

¹ Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Tropane alkaloids (from *Datura* sp.) as undesirable substances in animal feed. *The EFSA Journal* (2008) 691, 1-55
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/contam_op_ej691_tropane_alkaloids_en,0.pdf?ssbinary=true

Following that conclusion, it appears to be appropriate to extend the current limitation of 1000 mg/kg for seeds and unground and uncrushed fruits from *Datura stramonium* to all *Datura* spp. (including *Datura ferox*). The Committee raised no objections to this proposed modification.

Work will be undertaken to have routine method available for the analysis of tropane alkaloids (hyoscyamine, scopolamine and atropine) in feed in view of a possible future review of the legislation based on these toxic substances.

b) theobromine

The CONTAM Panel from EFSA adopted on 10 June 2008 a scientific opinion on theobromine as undesirable substance in animal feed². One of the conclusions is that the current EU regulations on maximum levels (ML) of theobromine in feed material (300 mg/kg for complete feedingstuffs with the exception of 700 mg/kg for complete feedingstuffs for adult cattle) may not be fully protective for some target animal species, e.g. as effects on milk production in dairy cows and adverse effects in pigs may occur. Owing to the recognized susceptibility to theobromine toxicity, feed manufacturers do not include by-products of cocoa manufacture or confectionary by-products in feeds for dogs and horses.

The Commission representative indicated that following this opinion, it seems appropriate to reduce the current maximum levels for theobromine in particular for pigs, dairy cattle, dogs and horses given the sensitivity of these animal species for theobromine. The Committee raised no objections to such a reduction and the Commission representative indicated to present at the next meeting a concrete proposal for discussion.

c) ricin

The CONTAM Panel from EFSA adopted on 10 June 2008 a scientific opinion on ricin (from *Ricinus communis*) as undesirable substance in animal feed³. One of the recommendations is that more information is needed on the occurrence of seeds *Ricinus communis*, *Croton tiglium*, *Abrus precatorius* and *Jatropha curcas* as botanical impurities in feed materials.

The Committee agreed that more information is needed on the occurrence of these seeds as botanical impurities in feed materials.

Furthermore it should be discussed to have the same provisions for *Ricinus communis*, *Croton tiglium* and *Abrus precatorius* in current legislation.

Work will be undertaken to have routine method available for the analysis of ricin, abrin and crotin I in feed in view of a possible future review of the legislation based on these toxic substances.

² Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on theobromine as undesirable substances in animal feed. *The EFSA Journal* (2008) 725, 1-66. [http://www.efsa.europa.eu/cs/BlobServer/Scientific Opinion/contam_op_ej725_theobromine_en.0.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific%20Opinion/contam_op_ej725_theobromine_en.0.pdf?ssbinary=true)

³ Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on ricin (from *Ricinus communis*) as undesirable substances in animal feed. *The EFSA Journal* (2008) 726, 1-38. [http://www.efsa.europa.eu/cs/BlobServer/Scientific Opinion/contam_op_ej726_ricin_en.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific%20Opinion/contam_op_ej726_ricin_en.pdf?ssbinary=true)

12. A.O.B.

Melamine

Reference was made that Commission Decision 2008/798/EC of 14 October 2008 imposing special conditions governing the import of products containing milk and milk products originating in or consigned from China and repealing Commission Decision 2008/757/EC⁴ provides that Member States following provisions relevant for feed :

- shall sample and analyse all consignments of composite products, including feed, containing milk products originating in or consigned from China;
- may carry out random checks prior to importing other feed and food products with a high protein content originating from China;
- shall take the necessary measures to ensure that composite products containing milk and milk products and feed and food with a high protein content originating in or consigned from China which are already placed on the market are subject to an appropriate level of controls.

These provisions are applicable since 26 September 2008, when the interim safeguard measures as regards the import of products containing milk or milk products originating in or consigned from China were adopted by the Commission by Decision 2008/757/EC⁵ which have been replaced since 14 October 2008 by the abovementioned Decision 2008/798/EC.

Following the findings of high levels of melamine in soya meal/flakes, a note was sent on 10 November 2008 to the Heads of Delegation of the Committee with the request to increase significantly the controls on the presence of melamine in feed originating in or consigned from the People's Republic of China. It was stressed that feed includes compound feed, pet food, medicated feed, feed additives and feed materials.

During the exchange of views, the delegations of France, Netherlands and UK highlighted the findings of high levels of melamine in soybean meal/flakes originating from China.

Following the exchange of views, the Commission announced to consider amending Commission Decision 2008/798/EC by including the 100 % testing at import requirement for feed and food containing soya and soya products⁶.

⁴ OJ L 273, 15.10.2008.

⁵ OJ L 259, 27.9.2008.

⁶ Information *a posteriori* of the Committee: Commission decision 2008/921/EC of 9 December amending Decision 2008/798/EC. (OJ L331, 10.12.2008, p. 19)

**13. Exchange of views and possible opinion on a draft Regulation (EC) amending Regulation (EC) No 1800/2004 as regards the terms of the authorisation of the feed additive "Cycostat 66G" in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances
(Document SANCO/3721/2008)**

A discussion took place and the vote was taken.
The draft Regulation received a favourable opinion by qualified majority.

Spain declaracion :

*"La delegación española se abstiene en la votación del producto en este punto, ya que los Límites Máximos de Residuos propuestos no permiten el control analítico del tiempo de espera propuesto en base a las modificaciones de las características organolépticas de los tejidos de los animales tratados.
En consecuencia, deben ser solicitados de la compañía una nueva propuesta de LMR, teniendo en cuenta el efecto organoléptico y fijar un tiempo de espera verificable mediante un control analítico."*

**14. Exchange of views and possible opinion on a draft Regulation (EC) concerning a permanent authorisation of an additive in feedingstuffs
(Document SANCO/3673/2008)**

A discussion took place and the vote was taken.
The draft Regulation received a favourable opinion by qualified majority.

Déclaration de la France :

*"Les éléments scientifiques fournis pour la demande d'autorisation définitive d'un additif de la catégorie des micro-organismes à base d'Enterococcus faecium destinés aux chiens sont suffisants pour pouvoir statuer sur l'efficacité de l'additif sur la consistance des fèces chez le jeune chien à la dose maximale revendiquée. L'efficacité de l'additif en tant que stabilisateur de la microflore intestinale reste à démontrer à la dose minimale revendiquée chez le chien adulte ou âgé.
Les éléments scientifiques fournis pour la demande d'autorisation définitive d'un additif de la catégorie des micro-organismes à base d'Enterococcus faecium destinés aux chats sont insuffisants pour pouvoir statuer sur l'efficacité de l'additif en tant que stabilisateur de la microflore intestinale notamment par son impact sur la microflore et la consistance des fèces.
Considérant les conclusions des experts communiquées aux pétitionnaires, la France s'abstient sur le projet de règlement SANCO/3673/2008."*

**15. Exchange of views and possible opinion on a draft Commission Directive amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels of unavoidable carry-over of coccidiostats or histomonostats in non-target feed
(Document SANCO/3024/2008)**

Reference was made at the extensive discussions which have taken place at previous meetings.

After discussion following modifications were made to the text:

- date of application on 1 July 2009
- revision of the Annex by 1 July 2011
- separate provisions in the Annex for feed materials and compound feed
- specific provisions for chickens reared for laying (> 12/16 weeks)
- maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50 % of the maximum levels established in the feed when the instructions for use of the premixture are followed.

The vote was taken and the draft Directive received a favourable opinion by qualified majority.

Denmark could not agree on the proposed provisions as they cannot agree with the levels provided for in food of animal origin for halofuginone and nicarbazin. As they consider the levels in feed and food as one package a same voting attitude is taken for this draft Directive as the voting attitude for the draft Regulation (see point 16 for the voting declaration).

Czech Republic had some reservations given the fact that no reference is made to methods of analysis to control these levels (see point 16 for the voting declaration).

**16. Exchange of views and possible opinion on a draft Commission Regulation setting maximum levels for coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed
(Document SANCO/3417/2008)**

Reference was made at the extensive discussions which have taken place at previous meetings.

After discussion following modifications were made to the text :

- date of application on 1 July 2009
- revision of the Annex by 1 July 2011
- addition of a specific provision indicating that in case of a finding of a significant residue below the maximum level, it is appropriate for the competent authority to carry out investigations to confirm that the residue is present as a consequence of unavoidable carry over in the feed and not as the consequence of illegal administration of the coccidiostat or histomonostat.
- addition of specific provision that foodstuffs complying with the maximum levels shall not be mixed with foodstuffs which exceed these maximum levels.
- following the comments of CRL Berlin as regards the analytical achievability of the level, the levels for lasalocid sodium in milk, for salinomycin sodium in other food and for semduramycin and maduramycin the levels were increased to the lowest level which can be analytically determined with sufficient reliability.
- following comments, the levels for halofuginone in eggs, milk and other food were decreased as well the level for nicarbazin in eggs.

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

Following declarations were made :

Denmark declaration :

"Denmark appreciates the Commissions effort to solve the problems at EU –level on unavoidable carry-over of authorised coccidiostats or histomonostats into non-target feed.

However, from a toxicological point of view and in order to protect the consumers, Denmark cannot support the proposal as regards the inclusion of the substances Nicarbazin and Halofuginone as these substances are likely to pose a risk to human health.

As regards the substance Halofuginone the proposed maximum level will increase the daily estimated intake. Halofuginone is already authorised as a veterinary medicinal product to cattle not producing milk for human consumption. When establishing the MRL for this substance the daily estimated intake did not include milk, as the substance is not authorised for milk producing cattle intended for human consumption. Setting a maximum level for milk can without taking into account the daily estimated intake of this substance might cause a risk to human health especially children as they drink a lot of milk and dairy products.

As regards the substance Nicarbazin, Denmark finds it questionable to establish a maximum level for carry-over due to unsatisfactory toxicological dossier. Especially the incomplete studies on genotoxicity might cause a risk to human health given the fact that it is not possible for the FEEDAP Panel to establish an ADI on the base of data available. The fact that an ADI has not been established due to a lack of satisfactory data should invoke the precautionary principle laid down in Art 7 of the Community Food regulation 178/2002 and the proposed maximum level for carry over of Nicarbazin should be deleted.

Denmark finds the substances unacceptable since they will reduce the level of food safety and protection for the consumers in general in the Community."

Czech Republic declaration :

"Taking into account the fact that the maximum residues of coccidiostats in food of animal origin established in draft Commission Regulation SANCO/3417/2008 do not result from toxicological studies, but are calculated, respectively extrapolated;

That the assessments leading to establishment of the maximum content of residues of coccidiostats in foodstuffs derived from the non-target species has not been harmonized with the assessment of maximum residue limits according to the Regulation (EC) 2377/90 for the same substances, since the European Medicines Agency (EMA) and the European Food Safety Authority use different ADI, respectively safety factor;

That distribution of tissues in consumer basket differs according to this proposal from Regulation 2377/90;

That the proposal SANCO/3024/2008 lacks reference to analytical methods taking into account measurement uncertainty as it is for example in the case of lead and cadmium;

That the established maximum levels of cross-contamination in non-target feed does not reflect different physical-chemical characteristic of coccidiostats and levels in target feed;

That verification is missing as to whether it is possible by currently existing procedure for sampling according to first Commission Directive 76/371/EEC of 1 march 1976 establishing Community methods of sampling for the official control of feedingstuffs, to take objectively sample of compound feed for example with content of 0.01 mg/kg of diclazuril;

With respect to these reasons, the Czech Republic cannot support the proposed drafts."

Belgium declaration :

"België stemt tegen het bovenvermelde voorstel (SANCO/3417/2008 – rev. 1) van Verordening van de Commissie tot vaststelling van maximumgehalten voor coccidiostatica of histomonostatica in voedingsmiddelen ten gevolge van de onvermijdelijke overdracht van deze stoffen in voeders voor niet-doeldieren.

België is akkoord dat in dit specifieke geval nultolerantie niet realiseerbaar is en bijgevolg zijn wij voorstander voor het vaststellen van normen voor de aanwezigheid van residuen van coccidiostatica in voeders voor niet-doeldieren en de voedingsmiddelen van dierlijke oorsprong hiermee geproduceerd.

Wij zijn echter van oordeel dat de voorgestelde maximumgehalten voor voedingsmiddelen van dierlijke oorsprong onvoldoende realistisch en arbitrair zijn aangezien een solide wetenschappelijke basis '(=overdrachtsgegevens van feed naar food) hiervoor in vele gevallen ontbreekt. Het risico bestaat dat dit, bij toepassing van deze normen in de praktijk, aanleiding zal geven tot juridische problemen (vaststelling van verantwoordelijkheden bij overschrijding van norm).

Ten einde dit te vermijden is België voorstander voor het vaststellen van meer realistische normen voor voedingsmiddelen van dierlijke oorsprong in afwachting van meer wetenschappelijk onderbouwde gegevens, zonder hierbij de gezondheid van de consument ook maar enigszins in gevaar te brengen."

Hungary declaration :

"I, Szabolos Pásilov, representative of Hungary at the Animal Nutrition section of SCoFCAH has abstained from vote on agenda item 16 on the 27-28 November 2008 meeting. The reason for my abstention is that significant new amendments have been introduced to the draft text which I have been unable to discuss with our experts on the subject."

Poland declaration (courtesy translation provided by the Polish delegation) :

"The Polish side has voiced concerns regarding the limit values on coccidiostats in food, included in the draft document SANCO/3417/2008, which result from unavoidable carry-over of these substances to non-target feed. Pursuant to the opinion delivered by the Polish National Veterinary Institute in Pulawy (the reference laboratory) maintaining such levels in food will be very difficult in practice. Therefore the Polish delegation votes against the draft document SANCO/3417/2008 – rev. 2."

17. Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1266/2007 as regards conditions for movements within the same restriction zone and the conditions for exempting animals from the exit ban provided for in Council Directive 2000/75/EC

(Document SANCO/3647/2008)

The document submitted by the Commission was discussed. Two topics were subject to intensive discussion: the routine surveillance that should be in place in the "lower risk" zones in which vaccination would be applied in the absence of virus circulation and the need of testing of vaccinated animals before they are moved from these "lower risk" zones to zones with a better status. The vote was postponed.

Bernard Van Goethem,
Director (signed)