



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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FAX

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A L'ATTENTION DE TOUTES LES REPRESENTATIONS PERMANENTES
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SUMMARY MINUTES OF THE MEETING OF THE STANDING
COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

ANIMAL NUTRITION SECTION

Brussels, 7 & 8 June 2007

1. Feed Additives

1.1. Application under Regulation (EC) n°1831/2003

1.1.1. **Monensin sodium (Elancoban/Sylvata).** As coccidiostat for calves for rearing.

A discussion took place.

1.2. Setting timetable for additives (Art 25 of Regulation (EC) n° 1831/2003)

1.2.1. Microorganism

1.2.1.1. **Oralin** *Enterococcus faecium* DSM 10663/NCIMB 10415
animal categories: turkeys for fattening Application for **permanent**
authorisation
(The expire of **temporary authorisation 18.10.2007**) **Rapp : DE**

A discussion took place.

1.2.1.2. **Lactobacillus Acidophilus D2/CSL** *Lactobacillus Acidophilus*
D2/CSL CECT 4529, animal categories: laying hens
Application for **permanent** authorisation
(The expire of **temporary authorisation 14.12.2007**) **Rapp : IT**

A discussion took place.

1.2.2. Enzymes

1.2.2.1 **“Hostazym C”** endo 1,4-beta glucanase EC 3.2.1.4 (E 1616) produced
by *Trichoderma longibrachiatum* (IMI SD 142). Animal category: piglets.
Application for permanent authorisation. The provisional authorisation expires
on 30/06/2004. **Rapp : UK**

A discussion took place.

1.2.2.2. “Kemzyme 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 longi-brachiatum* (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)

Animal category: laying hens. Request for provisional authorization **Rapp: BE Annex entry**

A discussion took place.

1.2.3. Coccidiostat

1.2.3.1. Kokcisan” (KRKA) Salinomycin sodium for chickens for fattening. Rapp : UK

A discussion took place.

1.3 Draft Guidelines on feed additives under Regulation 1831/2003 (Document SANCO/426/2005/REV3)

A discussion took place.

2. Circulation of products containing L-theanine

The issue was initially raised by a Member State stating that products containing synthetic L-theanine could currently neither be circulated in the EU as veterinary drug nor as feed. The Member States shared the view that the products would have to be either classified as veterinary drug or as feed additive. As there is no authorisation for such products in the EU the circulation would be illegal. The Commission representative called on the Member States to be vigilant in the control of their national markets for not authorised products. It was concluded that for a classification of such products more information would be necessary.

3. Export to third countries of feed additives which are not authorised in the EU

A representative of the Commission indicated that the matter was governed by Article 3(1) of Regulation (EC) No 1831/2003 in conjunction with Article 12 of Regulation (EC) No 178/2002. As already mentioned in the Summary Minutes of the meeting of the Committee held on 24-25 April 2006, any product placed on the Community market, processed or used as a feed additive prior to export to third countries has to be authorised and labelled in accordance with the requirements laid down in Regulation (EC) No 1831/2003. The opinion of the Legal Affairs unit of DG Health and Consumer Protection will also be sought.

4. Follow up on recent contamination incidents in feed

The delegations were informed that the discussed possible measures as regards the presence of very high levels of cadmium in zinc sulphate originating from China are currently under consideration in the Commission services in the light of recent other contamination incidents. An extensive discussion took place as regards the possible presence of melamine and structurally related compounds such as cyanuric acid in protein-rich ingredients used for feed and food.

Reference was made by the Commission representative to the note of 2 May 2007 of Mrs Paola Testori Coggi to the heads of delegation of the Standing Committee on the Food Chain and Animal Health, section Animal Nutrition and section Toxicological Safety of the Food Chain requesting the competent authorities to control consignments of wheat gluten, corn gluten, corn meal, soy protein, rice bran and rice protein concentrate originating from third countries, in particular from China, for the presence of melamine and related compounds (cyanuric acid, ammeline, ammelide) and to report the results of the control (both favourable and unfavourable) to the Commission through the RASFF. Unfavourable results should be notified without delay. Favourable results may be reported on a weekly basis.

For the time being, 3 findings of contaminated consignments were notified to the RASFF - finding by Germany of melamine in **dog feed** originating from South Africa. Origin of ingredients for making the feed not yet known. Analytical result obtained from a control sample. The dog feed was already recalled in November - December 2006 because of the presence of ethylene glycol.

- finding by Greece of melamine and structurally related compounds in **rice protein concentrate from China**. The consignment has been rejected and has been re-dispatched to the country of origin, China.

- finding by Poland of melamine in **corn gluten from China**. The feed material (corn gluten) has been withdrawn from the market as well as the feeds made with the feed material in question. At the meeting, the delegation of Poland provided more precise information and mentioned that this lot was part of a larger consignment, which is blocked and samples are taken for analysis.

At the meeting, extensive information was provided by several delegations on their investigations. In line with the findings in the US, it was confirmed that the product labelled as "rice protein concentrate" was in reality a wheat flour. Although it was generally acknowledged that the analysis is not a major challenge and that analytical capacity in the EC is sufficient, one delegation mentioned that because the analysis of melamine was previously not routinely carried out, time is required to put the analytical method in place in the official feed control laboratory.

The Commission has sent a request to EFSA on 8 May 2007 to obtain an urgent opinion on the risks for animal health and public health of the presence of melamine and structurally related compounds in feed and food.

EFSA has issued on 8 June 2007 a statement related to melamine and structurally related compounds such as cyanuric acid in protein rich ingredients used for feed and food (**available at**

http://www.efsa.europa.eu/etc/medialib/efsa/science/contam/contam_statements/contam_statement_melamine.Par.0001.File.dat/contam_statement_melamine_en.pdf)

EFSA provisionally recommends to apply a TDI of 0.5 mg/kg b.w. per day for the total of melamine and its analogues (ammelina, ammelide, cyanuric acid). Because of a lack of toxicity data in domestic animals, EFSA provisionally recommends to apply this tolerable intake level as established for humans also to domestic animals.

Taking into account the conclusions of the EFSA statement the Committee agreed to follow following approach in case of a finding of presence of melamine and related compound (ammelina, ammelide, cyanuric acid):

- the batches of feed materials, in which the presence of melamine and related compounds, has been found, cannot be used for animal feeding (it goes without saying that the material can also not be used for human consumption) and has to be re-dispatched to the country of origin or to be disposed of safely.

- in case food producing animals have been fed with feed contaminated with melamine and related compounds, there is for the protection of public health, taking into account the conclusions of the EFSA statement, no need to take restrictive measures as regards the animals which have been fed with contaminated feed and as regards food of animal origin originating from animals fed with contaminated feed.

- the appropriateness of restrictive measures as regards compound feed containing a contaminated feed material and the extent of an eventual recall of compound feed, has to be decided on a case by case basis, taking into account the levels of melamine and related compounds, the incorporation ratio of the contaminated feed material, ...etc. In any case, it must be ensured that the animals are not exposed to levels of melamine and related compounds higher than 0.5 mg/kg b.w. a day, and this in accordance with the conclusions of the EFSA statement.

It was also agreed to assess at each future meeting of the Committee the situation and to decide on the appropriateness of continuing the increased monitoring on the presence of melamine and related compounds.

5. Follow up of recent scientific opinions as regards undesirable substances in feed

Reference was made to three recent EFSA opinions as regards undesirable substances in feed

- cyanogenic compounds (adopted on 23 November 2006)
- pyrrolizidine alkaloids (adopted on 25 January 2007)
- heptachlor (adopted 26 April 2007)

a) The **main conclusions of the EFSA assessment as regards cyanogenic compounds** were already presented at the meeting on 26 March 2007 (agenda item 3.1).

b) The **main conclusions as regards the EFSA assessment on pyrrolizidine alkaloids** are:

Pyrrolizidine alkaloids (PAs) represent a large group of chemically diverse plant metabolites and more than 6000 plants have been identified as potential sources of PAs, but the actual concentrations of common PAs occurring in feed materials remains largely unknown.

Animal exposure to PAs results from the direct ingestion of PA containing plants with fodders. The highest risk to livestock seems to be associated with ingestion of plant materials from *Senecio*, *Heliotropium*, *Trichodesma* and *Symphytum* species, and in certain geographic regions also from *Echium* spp. Grazing animals avoid PA containing plants and consume them only if no other feed is available. The recognition of toxic plant materials is lost in preserved feeds such as hay and silage. Contamination of grains and other components used in concentrates by seeds of weeds containing PAs is the other route leading to animal exposure. It is generally recognized that rodents, as well as pigs, poultry, cattle and horses are very sensitive to PA intoxication, whilst sheep, goats and rabbits are not. Experimental data on the carry-over into edible tissue suggest that residues of PA metabolites do not occur in muscle tissue, but transfer of PAs and/or their metabolites into milk and eggs, is likely, albeit at a low rate. In addition, honey is found regularly to be contaminated with PAs. The levels of PA metabolites found in milk, eggs and honey are significantly lower than the measurable levels in herbs and spices that are used in the human diet.

c) The **main conclusions as regards the EFSA assessment on heptachlor** are:

Heptachlor shows moderate acute toxicity and heptachlor epoxide and photoheptachlor are more toxic than heptachlor. Heptachlor is classified by IARC as possibly carcinogenic to humans (group 2B). Heptachlor is moderately or highly toxic to fish exposed via water, but no data from feeding studies with fish feed containing heptachlor have been found.

Amongst the species studied, the domestic hen is the most sensitive species and egg production and hatchability are the critical endpoints. Total heptachlor (sum of heptachlor and heptachlor epoxide) is not frequently found in feed commodities. When present, it is mostly in fish derived products and only very infrequently in feed materials of plant origin. Heptachlor epoxide is the predominant contaminant. The concentrations found in feed are in the low µg/kg range and thus well below those that have been found to cause adverse effects in animals. Following heptachlor exposure, only heptachlor epoxide is found in milk and eggs. The present dietary exposure of the adult population to total heptachlor is below 1 ng/kg b.w. per day, which is two to three orders of magnitude below the tolerable daily intake of 0.0001 mg/kg b.w. as established by WHO in 2006.

Taking into account the conclusions of the EFSA opinions, the representative of the Commission presented possible amendments to the current provisions in the Annex to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed and other possible measures to be taken at EU level. However it was recognised that there was no sufficient time to discuss in detail and therefore it was agreed to organise a specific meeting of the expert group "Undesirable substances" as working party of the Standing Committee to discuss these issues in detail.

6. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the permanent and provisional authorisation of additives in feedingstuffs (Document SANCO/824/2007) (Hostazym X, Feedlyve AXC, Aquasta)

This draft Regulation concerns the permanent authorisation for the use of the following additives:

- endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (MUCL39203) for chickens for fattening as enzyme;
- the preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) for turkeys as enzyme;

and the provisional authorisation for the use of the following additive:

- preparation Astaxanthin-rich *Phaffia rhodozyma* (ATCC SD-5340) for salmon and trout as colorant.

A discussion took place.

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 des dossiers de demande d'autorisation des additifs Aquasta, additif de la catégorie des colorants destiné aux truites et saumons, et Hostazym X, additif de la catégorie des enzymes destiné aux dindes, les pétitionnaires n'ont pas répondu de façon satisfaisante aux questions des experts français sur le risque environnemental du colorant d'une part et sur l'efficacité de l'enzyme d'autre part.

Considérant les conclusions des experts, communiquées au pétitionnaire par courrier en dernier lieu respectivement les 14 avril et 6 juin 2007, la France s'abstient sur le projet de règlement SANCO/824/2007."

7. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the authorisation of *Bacillus cereus* var. *toyoi* (Toyocerin) as a feed additive (Document SANCO/969/2007)

This item was cancelled from the agenda before the meeting.

8. Examination and possible opinion on a Draft Commission Regulation amending Commission Regulation (EC) No 378/2005 on detailed rules for the implementation of Regulation 1831/2003 of the European Parliament and of the Council as regards the duties and the tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (Doc SANCO/2007/1196 rev. 1)

This draft Regulation concerns the amendment of Regulation (EC) No 378/2005 as regards essentially the updating of the fee, as foreseen in that Regulation.

The Commission submitted a slight revision of the text with a clarified legal basis and some minor modifications in the recitals. A discussion took place. Minor amendments to the list of laboratories in the Annex as regards their name in the original language were brought.

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

Consideration will be given in future updates of the amount of fee to further detail the accompanying justification of the structure of the costs involved in the operation of the CRL and of the laboratories participating in the Consortium assisting the CRL for the tasks supported by the fee. The possibility of fixing different fees for different types of applications, as provided for in Regulation (EC) No 378/2005, will also be taken into account on the occasion of future updates of the amount of the fee. To this end, the Commission services will invite the CRL and the consortium of NRLs to develop criteria for differentiated fees.

9. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of benzoic acid (Vevovital) as a feed additive (Document SANCO/1415/2007) Annex entry

A discussion took place.

10. Discussion on a draft Regulation (EC) concerning the authorisation of an enzyme preparation of endo-1-4-beta-xylanase) (Natugrain Wheat) as a feed additive (Document SANCO/1478/2007) Annex entry

A discussion took place.

11. Discussion on a draft Regulation (EC) concerning the authorisation of an enzyme preparation of 3-phytase (Rovabio PHY AP/LC) as a feed additive (Document SANCO/1479/2007) Annex entry

A discussion took place.

12. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of L-Arginine as feed additive (Document SANCO/825/007) Annex entry

A discussion took place.

13. Discussion on a draft Regulation (EC) concerning the authorisation of a preparation of Natuphos Wheat TS (endo-1-4-beta-xylanase) as feed additive (Document SANCO/1480/2007) Annex entry

A discussion took place.

14. Exchange of views on the use of feed additives in water under Regulation 1831/2003

The Commission services had circulated a working document where several options and proposals were presented. An exchange of views followed. Some Member States asked for further time to consider the paper more in detail. The item will be discussed in a forthcoming meeting.

15. Exchange of views on the situation of certain flavourings in the Community Register of Feed Additives

Following communications from some Member States and the consultation from stakeholder FEFANA regarding several of the flavouring compounds included in the Register of Feed Additives, it was concluded that the following products should be considered for withdrawal from the Register:

1) Products belonging to

Category: 2 (sensory additives)

Functional group: b (flavouring products)

Subclassification: natural products – botanically defined

| Additive |
|---|
| <i>Aristolochia cymbifera</i> L.: Jarrinha absolute / Jarrinha extract / Jarrinha oil / Jarrinha tincture |
| <i>Aristolochia serpentaria</i> L. : Serpentry root powder CoE 58 / Serpentry oil COE 58 / Serpentry extract CoE 58 |
| <i>Prunus amygdalus</i> Batsch: Bitter almond absolute CoE 367 / Bitter almond oil CoE 367 / Bitter almond tincture CoE 367 |
| <i>Prunus armeniaca</i> L.: Apricot concentrate CoE 368 / Apricot distillate |

| |
|---|
| CoE 368 / Apricot extract CoE 368 / Apricot kernel oil CAS 72869-69-3 FEMA 2105 CoE 368 / Apricot essence oil CoE 368 |
|---|

2) Products belonging to

Category: 2 (sensory additives)

Functional group: b (flavouring products)

Subclassification: natural or corresponding synthetic chemically defined flavourings

| Additive |
|--|
| CAS No. 83-67-0 / Theobromine / Flavis No. 16.032 |
| CAS No. 94-3-3 / Propyl 4-hydroxybenzoate / Flavis No. 09.915 |
| CAS No. 404-86-4 / N-(4-Hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide / Flavis No. 16.014 |

In addition the participants agreed to further consider other issues in the working document circulated by the Commission and also the relationship between some flavourings and certain undesirable substances and other uses of in particular certain plants. This would be in view of the re-evaluation of 2010 and the priorities which may be established for this re-evaluation.

Miscellaneous

- One delegation presented its position on the issue of the application of Article 15(5) of Regulation (EC) No 882/2004 concerning official controls on feed and food of non-animal origin. Works are ongoing on this matter under the competence of Unit E2 of DG Health and Consumer Protection, to whom the information given during the meeting will be referred to.

- Following enquiries by some delegations, the Commission took the opportunity to thank the delegations who had already sent contributions for the report foreseen in Article 11 of Regulation (EC) No 1831/2003 and announced its intention to discuss further this issue at forthcoming meetings.

Bernard VAN GOETHEM,
Director
(signed)