

SUMMARY MINUTES OF THE MEETING OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

ANIMAL NUTRITION SECTION

Brussels, 26 March 2007

1. Feed Additives

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

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 expiry of **temporary authorisation 18.10.2007**) **Rapp: DE**

Discussion took place and the current status of the authorisation procedure was updated.

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

Discussion took place and the current status of the authorisation procedure was updated.

1.2.2. Enzymes

1.2.2.1. "Hostazym X". Endo 1,4-beta xylanase EC 3.2.1.8 (EC number 1617)
produced by *Trichoderma longibrachiatum* (IMI SD 135). Animal category:
turkeys. Application for permanent authorisation. The provisional authorisation
expired on 30/06/2004. **Rapp: UK**

Discussion took place and the current status of the authorisation procedure was updated.

1.2.2.2. “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 expired on 30/06/2004. **Rapp: UK.**

Discussion took place and the current status of the authorisation procedure was updated.

1.2.2.3. Feedlyve AXC Preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (MUCL 39203) (Enzyme 21). Animal category: **chickens for fattening**. Request for **permanent** authorisation. Expiry of temporary authorisation 30 June 2004. **Rapp: FR**
Annex entry

Discussion took place and the current status of the authorisation procedure was updated.

Annex entry was discussed during the Committee.

1.2.3. Colourants

1.2.3.1. Astaxantin-rich. Active substance : Phaffia rhodozyma (ATCC SD-5340). Colourant for trout and salmon. Rapp: BE Permanent authorisation. Annex entry

Discussion took place and the current status of the authorisation procedure was updated.

Annex entry was discussed during the Committee.

2. Follow-up on the request for collaboration of Member States on the collection of data regarding the use of coccidiostats as feed additives and of available alternatives

Member States indicated that it might be difficult to deliver all data requested, but agreed to do their best to provide their responses.

A new dead-line was established for mid-May.

3. A.O.B.

3.1. Follow-up on EFSA-opinions as regards undesirable substances and update on activities of EFSA on issues related to undesirable substances in feed

a) Follow-up to the opinion of the Scientific Panel on Contaminants in the Food chain on a request from the Commission related to hydrocyanic acid as undesirable substance in animal feed, adopted on 23 November 2006

Hydrogen cyanide (HCN) is formed following the enzymatic hydrolysis of cyanogenic glycosides, which are produced as secondary metabolites by various plant species. In the intact plant these cyanogenic compounds are stored separated from hydrolytic enzymes. Crushing of plant materials either by technical processes or by chewing by animals obliterates this separation and initiates the enzymatic hydrolysis of cyanogenic compounds, resulting ultimately in the formation of HCN. Hydrolysis to release HCN can also be accomplished by micro-organisms in the digestive tract.

Cyanogenic glycosides are widely distributed in the plant kingdom. Typical feed materials that contain cyanogenic glycosides are linseed (flax), cassava root and the green parts of sorghum species. Linseed is presented as animal feed mainly as extraction cake, being a by-product in the production of linseed oil. The same applies to the seeds of various *Prunus* species, of which the press- or extraction cake is used as feed material. Cassava roots are commonly processed into chips, which are exported to Europe as feed material for pigs.

In general, ruminants are regarded as the most vulnerable to intoxication by cyanogenic feeding stuffs due to the more efficient hydrolysis of the cyanogenic glycosides.

Exposure to cyanide may lead to acute, fatal intoxications. More frequently, however, chronic intoxications are observed, characterized by growth depression and neurological symptoms resulting from tissue damage in the central nervous system.

Within the group of ruminants, goats appear to be the most susceptible to cyanide. Based on the available data the following intake (mg hydrogen cyanide (HCN) equivalents/kg b.w. per day) seems to be tolerated by the following animal species: pigs (2.9 mg/kg per day), poultry (2.8 mg/kg per day), ruminants (on the basis of goat studies) (0.25 mg/kg per day), and horses (0.4 mg/kg per day), respectively.

No studies on carry over of cyanogenic glycosides or of any of their degradation products have been performed. Cyanogenic residues have been found in the liver of a fatally intoxicated goat. However, provided the animal is not intoxicated with hydrogen cyanide, based on kinetic considerations and a common metabolic pathway of degradation of cyanide, the levels in meat, or eggs intended for human consumption can be expected to be very low in all food producing animals. Carry over of cyanogenic residues into milk has been demonstrated in intoxicated animals. Based on similar considerations as above, levels are expected to be very low.

The Panel also identified the need for up-to-date analytical methods that allow the determination of the total cyanogenic potential.

The Commission representative informed the Committee in the draft Regulation compiling all existing methods of analysis in feedingstuffs, the existing method for hydrogen cyanide has been not taken up as it has demonstrated that the method is generating false positive results. The European Standardisation Committee (CEN – Comité Européen de Normalisation) Technical Committee (TC) CEN/TC 327 Animal Feedingstuffs – methods of sampling and analysis is currently working on the elaboration and validation of an updated method for the determination of hydrocyanic acid, in execution of the mandate from the Commission to CEN.

Upon request of a Member State, the Commission representative indicated that the draft regulation compiling all existing methods of analysis is foreseen to be submitted to the Committee for opinion at the meeting in June.

The Committee agreed to examine in detail the conclusions of the European Food Safety Authority opinion and to discuss at a future need possible modifications, if necessary, to

the current provisions on hydrocyanic acid in feedingstuffs as provided for by Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

b) Dioxins in copper sulphate from Canada.

The Committee was informed of a very high level of dioxins (211, 95 ng WHO-TEQ/kg) in copper sulphate originating from Canada. The legal limit is 1.0 ng WHO-PCDD/F-TEQ/kg. The information has been distributed through the RASFF system on Friday 23 March 2007 (Notification 2007.0228). The copper sulphate was integrated into a premixture at a level of about 26-27 %. Three batches of in total 24,550 tonnes have been imported into Ireland. The Irish delegation provided a detailed overview of the distribution from Ireland to other countries (United Kingdom, Hungary, Poland, Spain and Turkey). Most of the quantities could still be blocked at the premises concerned.

The exact source of the contamination of copper sulphate is not yet known. The Commission requested the delegation of Ireland to keep the Member States informed through the RASFF and urged the Member States to take urgent action upon information received given the seriousness of the contamination.

c) Cross contamination of non target feedingstuffs by coccidiostats authorised for use as feed additive.

Upon request of a delegation the Commission representative provided following information.

Coccidiostats are authorised for use as feed additive for the production of feedingstuffs for target species according to the conditions of authorisation. However this can result through carry over in residues from these coccidiostats in feedingstuffs for non target species produced after a feedingstuff in which the coccidiostats have been used.

Of major importance is the application by the feed operator of good manufacturing practices to avoid to the largest extent possible the carry over of residues of coccidiostats in subsequent batches of compound feedingstuffs. However, even if all prevention measures are applied, including the use of rinsing batching the carry over of residues is unavoidable.

Therefore, the possibility to set tolerances for these unavoidable residues of coccidiostats in feedingstuffs for non-target species will be considered in the frame of Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed.

Such tolerances for feedingstuffs for non target species will be set following the ALARA principle (As Low As Reasonably Achievable) taking into account good manufacturing practices.

Such tolerances in feedingstuffs for non-target species should not have a pharmacological activity and not endanger animal health and public health, as in some cases the tolerances for feedingstuffs for non target species could result in residues in products of animal origin.

Therefore the Commission has asked EFSA to provide an opinion of the risks involved for animal health and public health as the consequence of carry-over of coccidiostats

authorised as feed additive into non target feeds, which cannot be avoided under practical production conditions. In this opinion the following aspects have to be addressed:

- the risks for animal health for non target species are assessed;
- the adverse effects as the consequence of the carry over of coccidiostats into non target feeds;
- on the basis of the available information, an estimate of the level of residues present in food of animal origin from non target species as the consequence of cross contamination is performed.
- the possible risks for human health as the consequence of the presence of such residues in food of animal origin (eggs, milk, meat, edible offal) from non target species are assessed.

The work within EFSA is already well progressed. It is the intention to adopt and publish the opinions for the 11 authorised coccidiostats simultaneously. It can be expected that the opinions will be finalised later this year and once the opinions are available the Commission services will immediately initiate the discussions on tolerances.

d) Decision on protective measures with regard to milk powder intended for animal nutrition imported from Ukraine.

Reference was made to Commission Decision 2002/805/EC of 15 October 2002 concerning certain protective measures with regard to certain products of animal origin for animal nutrition and imported from Ukraine. (Official Journal, L278, 16.10.2002).

This Decision provides that Member States shall subject each consignment of milk powder or artificial milk replacer made from milk powder, intended for animal nutrition and imported from Ukraine, to a sampling and analysis in view of detecting the presence of chloramphenicol. The results of the results have to be submitted through the RASFF.

The Decision also provides that the Decision shall be reviewed on the basis of the guarantees provided by the competent Ukrainian authorities and of the results of the tests.

It is to be noted that since the date of application (October 2002), only one notification of non-compliance has been transmitted through the RASFF (in November 2002). Since December 2002, no notifications of non-compliance have been received.

Therefore it seems appropriate to consider if the protective measures are still necessary and appropriate. The Commission representative indicated to contact the competent official within the Commission, responsible for the follow-up of Decision 2002/85/EC and to inform the Committee on the follow-up that will be given.

3.2. Discussion on a draft Regulation (EC) concerning the authorisation of a microbiological preparation of *Bacillus subtilis* var. *toyoi* (Toyocerin) as a feed additive (Document SANCO/2560/2007) Annex entry

Discussion took place.

3.3. Monensin sodium (Elancoban/Sylvata). As coccidiostat for calves for rearing: supplementary information provided by company.

The Commission Representative requested to have comments of the Member States on the supplementary information provided by company to assess the monensin sodium for calves.

3.4. *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 (E1700): change of carrier

Concerning the carrier for the preparation, the Commission noted that no comments have been made with regard to the use of the new carrier. Therefore the Commission sees no objections for this carrier to be used.

4. Opinion on draft Commission Decision on the Community position on the amendment of the Appendices to Annex 5 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products (Document SANCO/10825/2006)

This draft Decision concerns modifications of appendix 1 to recognise that the legislative provisions of the Parties on feed hygiene are as achieving the same effects and of appendix 2 to update the lists of legislative provisions on feed additives and certain products used in animal nutrition.

A discussion took place.

The vote was taken. The draft Decision received a favourable opinion by unanimity.

5. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the permanent authorisation of additives in feedingstuffs (Document SANCO/554/2007)

The draft Regulation concerns the authorisation without a time limit, under the transition period (for on-going Directive 70/524/EEC applications at the time of entry into application of Regulation (EC) 1831/2003) for the use of the following additives:

- an acidity regulator of benzoic acid for pigs for fattening
- a preservative preparation of sodium benzoate, propionic acid and sodium propionate for cattle for fattening.

A discussion took place.

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

6. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the authorisation of 6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L) as a feed additive (Document SANCO/3692/2006)

The draft Regulation concerns the authorisation of a new use of the preparation of 6-phytase EC 3.1.3.26 produced by *Schizosaccharomyces pombe* (ATCC 5233) (Phyzyme

XP 5000G Phyzyme XP 5000L), as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, and sows to be classified in the additive category “zootechnical additives”.

A discussion took place.

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

7. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the authorisation of endo-1,4-beta-mannanase EC 3.1.3.78 (Hemicell) as a feed additive
(Document SANCO/3945/2006)

The draft Regulation concerns the authorisation of the preparation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell), produced by *Bacillus lentus* (ATCC 55045), as a feed additive for chickens for fattening, to be classified in the additive category “zootechnical additives”.

A discussion took place.

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

8. Exchange of views and possible opinion of the Committee on a draft Regulation (EC) concerning the authorisation of selenomethionine as a feed additive
(Document SANCO/243/2007)

The draft Regulation concerns authorisation of the preparation selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as a feed additive for all species, to be classified in the additive category “nutritional additives”.

A discussion took place.

The vote was taken. The draft Regulation received a favourable opinion by qualified majority (316 votes in favour, 29 against).

The German delegation has made to following declaration:

"Deutschland stimmt aufgrund von Bedenken für die Tiergesundheit gegen den Verordnungsvorschlag der Kommission. Die deutschen Experten sind der Auffassung, dass die Zulassung der Selen-Hefe-Zubereitung auf die Zieltierarten beschränkt werden sollte, für die das Antrag stellende Unternehmen Effizienz- und Sicherheitsstudien vorgelegt hat (Geflügel, Schweine und Rinder). Nachdem die Bioverfügbarkeit und der Metabolismus von anorganischem und organisch gebundenem Selen sehr unterschiedlich ausfallen, hierzu keine Erkenntnisse bei anderen als den genannten Tierarten vorgelegt wurden und die Europäische Behörde für Lebensmittelsicherheit sich in Ihrem Gutachten vom 05. Dezember 2006 zur Sicherheit der Zubereitung bei anderen als den genannten Tierarten nicht äussert, ist unter den nun vorgesehenen Verwendungsbedingungen eine Gesundheitsgefährdung von bestimmten Zieltierarten (Fische, Equiden, Hunde und andere) nicht ausgeschlossen."

Bernard VAN GOETHEM,
Acting Director
(signed)