Standing committee

1. Exchange of views and possible opinion on a draft Commission Decision authorising the placing on the market of foods and food ingredients produced from genetically modified maize line GA21 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (doc SANCO:3885 REV1).

The Commission presented the Draft Commission Decision on the authorisation of genetically modified Roundup Ready maize line GA21 as novel foods or novel food ingredients. The vote was taken and no opinion was given by 98 votes in favour (9 Member States), 62 against (5 Members States) and 139 abstaining (8 Member States) Three Member States were not present (22 votes).

The Danish delegation has made the following declaration:

“Denmark does not have reasoned scientific objections against the approval. However, due to the political attention related to GMOs, we find, that the decision should be taken in Council. Thus Denmark abstains from voting in this committee.”

The French delegation has made the following declaration:

« Considérant les éléments suivants, la France s’oppose à l’adoption de la décision autorisant la mise sur le marché d’aliments et d’ingrédients alimentaires produits à partir de la lignée de maïs génétiquement modifié Roundup ready GA21 en tant que nouveaux aliments ou nouveaux ingrédients alimentaires :

En avril 2000, la France avait émis une objection à la commercialisation du maïs GA21 et de ses dérivés au motif notamment que leur instance nationale d’évaluation, l’AFSSA, avait demandé la conduite d’un essai de toxicité 90 jours sur rats pour confirmer l’absence de toxicité de la protéine modifiée. Cette demande n’a pas été reprise par le Comité scientifique de l’alimentation humaine qui a procédé à l’évaluation alors que la réalisation d’un essai de toxicité sur rats avec la protéine nouvellement synthétisée figure désormais dans les lignes directrices de l’AESA en matière d’évaluation de novembre 2004."
La France n’est pas favorable à ce que certains OGM soient autorisés uniquement pour une filière déterminée (alimentation humaine ou animale) compte tenu de la difficile séparation des filières. L’AESA, dans son avis du 24 septembre 2004 relatif au maïs TC1507, a émis les mêmes réserves.

The Belgian delegation made the following declaration:

« L’article 27.1 du règlement 1829/2003 précise que lorsqu'un produit est susceptible d’être utilisé à la fois comme denrée alimentaire et comme aliment pour animaux, une demande unique est introduite.


La délégation belge demande donc que lors de la demande de renouvellement des produits existants du maïs GA21 (dérivés pour le feed), cette demande intègre tous les usages de l’OGM (food + feed), conformément à l’article 27.1 du règlement 1829/2003.

(signé) Martine DELANOY »

2. Exchange of views and possible opinion on a draft Commission Regulation concerning the urgent authorisation of an additive in feedingstuffs (SANCO/934/05).

This point was withdrawn from the agenda to the Standing Committee for technical reasons.

3. Discussion and possible request of opinion on a draft Commission Regulation concerning the permanent authorisations of certain additives (SANCO/472/05)

This draft Regulation concerned the granting of authorisations without a time limit within the meaning of Directive 70/524 for uses of 6 enzyme preparations previously authorised provisionally for 4 years. These preparations and their authorised uses are the following:

- Preparation of endo-1,3(4)-beta-glucanase, EC 3.2.1.6 ; endo-1,4-beta-xylanase, EC 3.2.1.8, alpha-amylase EC 3.2.1.1, trade name Porzyme SP. Animal category: piglets.
- Preparation of endo-1,3(4)-beta-glucanase EC 3.2.1.6 ; endo-1,4-beta-xylanase EC 3.2.1.8 ; alpha-amylase EC 3.2.1.1 ; polygalacturonase EC 3.2.1.1.15, trade name Porzyme TP100. Animal category : piglets.
- Preparation of endo-1,4-beta-xylanase, EC 3.2.1.8, produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin, EC 3.4.21.62, produced by
Bacillus subtilis (ATCC 2107), trade name Porzyme 8300. Animal category: piglets.

- Preparation of endo-1,3(4) beta-glucanase, EC 3.2.1.6, from Trichoderma longibrachiatum (ATCC 2106) and endo-1,4 beta xylanase, EC 3.2.1.8, from Trichoderma longibrachiatum (ATCC 2105), trade name, Porzyme 9100. Animal category: pigs for fattening.

- Preparation of endo-1,4-beta-xylanase, EC 3.2.1.8, produced by Trichoderma longibrachiatum (ATCC 2105), trade name Avizyme xylanase. Animal category: chickens for fattening.

- Preparation of endo-1,4 beta xylanase, EC 3.2.1.8, from Trichoderma longibrachiatum (ATCC 2105), and endo-1,3(4) beta-glucanase, EC 3.2.1.6, from Trichoderma longibrachiatum (ATCC 2106), trade name Avizyme 1210, Animal category: chickens for fattening.

The vote was taken. The draft regulation was adopted with qualified majority. Two Member States abstained and four were not represented.

The German delegation made the following declaration:

„Die Zulassungsvoraussetzungen für eine endgültige Zulassung der Zusatzstoffe E-1624 (Endo-1,3(4)-beta-glucanase, Endo-1,4-beta-xylanase, Alpha-Amylase) und E-1625 (Endo-1,3(4)-beta-glucanase, Endo-1,4-beta-xylanase, Alpha-Amylase, Polygalacturonase) in der Tierernährung für die Tierkategorie abgesetzte Ferkel sind nach der Auffassung Deutschlands nicht erfüllt. Bei beiden Zusatzstoffen lässt sich aus den Ergebnissen der Studien, in denen die Wirksamkeit der beantragten Formulierungen geprüft worden ist, ein eindeutiger Wirksamkeitsnachweis nicht ableiten. Daher kann Deutschland einer unbefristeten Zulassung dieser Zusatzstoffe nicht zustimmen.“

4. Feed additives


New application on Selplex (organic Selenium from Saccharomyces caerevisiae) as additive under categories trace elements and other zootechnical additives for dairy cows, calves and cattle for fattening, poultry and pigs.

4.2 Setting timetable for additives (Art 25 Regulation (EC) No 1831/2003):

4.2.1 Micro-organisms

4.2.1.1“Levucell SB20” (Saccharomyces cerevisiae CNCM I-1079)

4.2.1.2 Biacton (Lactobacillus farciminis CNCM MA 67/4R)
Animal Category: Chickens for fattening and laying hens (seeking provisional authorisation), turkeys, (seeking permanent authorisation) Application for extension of use Rapporteur: FR. The clock has been stopped.

4.2.2 Enzymes


The clock is stopped on 27 April 2005.

4.2.2.3. Avizyme 1500. Endo-1, 4-beta-xylanase (EC 3.2.1.8) from Trichoderma longibrachiatum (ATCC 2105), endo-1, 3(4)-beta-glucanase and alpha-amylase, EC 3.2.1.1, from Bacillus amyloliquefaciens (DSM 9553), subtilisin produced by Bacillus subtilis (ATCC 2107), and polygalacturonase (EC 3.2.1.1.5) produced by Aspergillus aculeatus (CBS 589.94). Extension of use for animal category: Ducks. Rapp: UK. Day O: 3.12.2004.

The clock is stopped on 27 April 2005.


The clock is stopped on 27 April 2005.


The clock is stopped on 27 April 2005.


The clock is stopped on 27 April 2005.
4.2.2.7. **Grindazym GP**, preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94). Extension of use for animal category ducks for fattening. Rapp DK. Day O: 3.12.2004

The clock is stopped on 27 April 2005.

4.3. **Trace elements**

4.3.1. Chelated forms of the trace elements iron, copper, manganese and zinc with chemically synthesised aminoacids: request for authorisation under Article 4 of Directive 70/524/EEC

The clock is stopped on 26-04-2005. The company must submit complementary data to answer the questions raised by the Member States.

5. **Iodine**

Following the opinion of the European Food Safety Authority on the use of iodine in animal nutrition (adopted on 25 January 2005), a representative of the Commission informs that a proposal will be drafted for discussion and possible adoption in the next standing committee. The aim is to reduce the maximum permitted levels in dairy cows and in laying hens.


6.1 L-Histidine monohydrochloride monohydrate

Following the opinion of the European Food Safety Authority on the use of this product in animal nutrition (adopted on 2 of March 2005), a representative of the Commission informs that a proposal will be drafted for discussion and possible adoption in the next standing committee.

6.2 Vitalys® liquid and Vitalys® dry, l-lysine-sulphate (produced by fermentation with corynebacterium glutamicum). Rapporteur DK

A representative of the Commission informed that a question will be submitted immediately to EFSA for the assessment of this product. One delegation informed on its intention to submit comments soon. The company has already responded to three delegations that must examine the answer.

7. **Directive 94/39/EC**

Reduction of risk of milk fever Rapporteur SE

A representative of the Commission informed that it is examining this dossier carefully to verify the compliance with Directive 94/39/EEC

8. **Legal status of methylsulfonylmethane**

A short discussion taken place on the legal status of this product. The discussion is ongoing.

Few Member States have sent their annual reports to the Commission. The delegations have been reminded to send the reports as a matter of urgency. In particular, results of the feed ban controls might be an important input for the debate on zero-tolerance in the BSE feed ban.

10. Undesirable substances

* Continuation of the discussion on possible measures as regards the presence of deoxynivalenol, zearalenone and ochratoxin A.

This point has not been discussed

* Discussion on extraction procedure for fluorine in feed of mineral origin

Maximum levels for fluorine have been established by Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. No Community method of analysis has been established for the official control. The extraction method has a large influence on the analytical result obtained in particular in case of feed materials/feed additives of mineral origin. This issue has been extensively discussed at the expert meeting on 07 March 2005 and at the meeting of the Expert Committee “Methods of analysis in feedingsstuffs” on 11 April 2005. Different extraction methods are used in the Member States and it is urgent to determine at EU level an extraction method to be used for official control in order to ensure a harmonised control European wide. After discussion, the extraction procedure with hydrochloric acid 1 N for 20 minutes at ambient temperature was proposed. One Member State could not agree on this proposal.

As regards an extraction procedure for dioxins in feed materials and feed additives of mineral origin the Committee was informed that a comparative trial would be organised to verify if the currently applied extraction procedures provide comparable results.

* Discussion on the follow-up EFSA opinions on Camphechlor and Arsenic

A short exchange of views has taken place.

As regards camphechlor, it was indicated that further discussions should focus primarily on the presence of camphechlor in fish oil, fish meal and fish feed.

As regards arsenic, it was indicated that it is necessary to develop and validate a method of analysis to determine the presence of inorganic arsenic in feed materials, feed additives and compound feedingsstuffs. For the time being, maximum levels in Directive 2002/32/EC refer to total arsenic as this can be routinely analysed. From a toxicological point of view, organic arsenic is less toxic than inorganic arsenic.
**Other issues**

- High levels of cadmium in zinc sulphate originating from China. (RASFF notification 2005.AWR) Information from Norway

Norway informed the Committee extensively on this contamination incident. Levels of 11-17 mg/kg of cadmium in feed from two feed mills (feed for ruminants and pigs) were found in the beginning of March 2005 following analysis of samples taken in the frame of a surveillance programme showed.

Investigations on the ingredients used, identified the premixture as the common source of contamination and that cadmium most probably originated from zinc sulphate imported from China as the other ingredients from the premixture were found not to be contaminated.

High levels of cadmium were also found in samples from compound feedingstuffs for fish. The premixture used contained zinc sulphate of the same origin.

Analysis of premixture available at the end of March showed a cadmium content up to 30000 mg/kg. This gives an estimated content of 7 – 8 % cadmium, i.e. 70 – 80,000 mg/kg. All zinc sulphate from the concerned batch were already used for the production of premixtures. Measures were taken to prevent further use of the premixture and products thereof and to withdraw products already sold to farmers.

Most of the imported zinc sulphate was used for the production of mineral premixture for use in compound feedingstuffs for ruminants and fish. Minor amounts have been used in premixtures for pigs, but cross contamination to premixtures for pigs and poultry has been identified as a problem. No unacceptable levels of cadmium have been found in meat of animals exposed to the contaminated feed (levels were complying with Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs). However levels of cadmium not complying with the maximum levels laid down in Commission Regulation 466/2001 have been found in the kidneys and livers of exposed pigs and ruminants. Therefore it has been decided to remove at the slaughterhouse the liver and kidneys from exposed pigs and ruminants from the food chain. Analysis performed on fish muscles, liver and kidneys has shown compliance with the maximum levels in force.

The Commission representative indicated that a similar contamination of cadmium in zinc sulphate originating from China at these extreme high levels has already been observed in 2000 and 2002. Following the finding in 2000, Member States were requested to increase the frequency of controls on the presence of cadmium in zinc sulphate from China. The control on the presence of cadmium in trace elements has been taken up in the coordinated inspection programme in animal nutrition for the years 2001 and 2002. Furthermore it was mentioned that a maximum level of 10 mg/kg of cadmium in trace elements, including zinc sulphate is currently under discussion.

A delegation referred to the application of Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector. In this context, it was noted that zinc sulphate is not always imported as feed additive but for technical
purposes and it is only when it is on the EU market that it is converted for use as feed additive.

The correct application of HACCP principles by feed business operators was mentioned as the way forward to avoid that future contaminated batches would enter the feed chain. The presence of cadmium in zinc sulphate (originating from China) has to be identified as critical control point for which effective, systematic monitoring is essential to prevent or eliminate a hazard (Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene).

The competent authorities of the Member States were requested to monitor systematically the presence of cadmium in zinc sulphate originating from China. The Commission representative indicated to address the issue with the Chinese authorities.

* Presence of high levels of aflatoxin B1 and gossypol in cotton seeds originating from West Africa.

The Commission representative informed the Committee that information was received that whole cotton seed originating from West Africa (Benin, Togo, Ivory Coast, Burkina Faso and Mali) imported into the EU would apparently not comply with the maximum levels established for aflatoxin B1 and free gossypol in Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. The competent authorities of the Member States were requested to pay particular attention to this issue and to control the presence of aflatoxin B1 and free gossypol in whole cotton seed.

11. Any other business

- **Zero tolerance in the BSE feed ban.**

A member State has presented the difficulties raised by the application of a zero-tolerance policy in the BSE feed ban, in particular with regard to bone fragments in sugar beet pulp. It forwarded arguments to consider derogation for "cropping- and harvest-induced contaminations". The Commission representative replied that an option of EFSA on a quantitative assessment of the risk posed by cross-contamination should be awaited before a final decision is taken. The Commission is reflecting if provision provisions can be proposed pending the EFSA opinion. It is likely that such provisions would be restricted to tuber and root crops and feedingstuffs containing such raw materials and include a case by case risk assessment.

Dr. Willem Penning
Chairman