

**MINUTES OF THE 68<sup>TH</sup> PLENARY MEETING  
OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN  
ANIMAL FEED (FEEDAP)**

**(PARMA, 25-27 MAY 2010)**

**(AGREED ON 22 JUNE 2010)**

**PARTICIPANTS**

Panel Members

Gabriele Aquilina, Georges Bories, Paul Brantom, Andrew Chesson, Pier Sandro Cocconcelli, Joop de Knecht (1<sup>st</sup> and 2<sup>nd</sup> days), Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Reinhard Kroker, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen (1<sup>st</sup> and 2<sup>nd</sup> days), Alberto Mantovani (1<sup>st</sup> and 2<sup>nd</sup> days), Miklós Mézes (1<sup>st</sup> and 2<sup>nd</sup> days), Derek Renshaw and Maria Saarela.

Apologies

Joop de Knecht (3<sup>rd</sup> day), Anne-Katrine Lundebye Haldorsen (3<sup>rd</sup> day), Alberto Mantovani (3<sup>rd</sup> day), Miklós Mézes (3<sup>rd</sup> day).

EFSA

Claudia Roncancio-Peña, Jaume Galobart, Maria Vittoria Vettori, Montserrat Anguita, Matteo Innocenti, Rosella Brozzi (scientific staff), Giulia Frattini (administrative staff).

European Commission

Marta Ponghellini (DG SANCO), Christoph von Holst (DG JRC, 2<sup>nd</sup> and 3<sup>rd</sup> day).

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**1. WELCOME AND APOLOGIES FOR ABSENCE**

The Chair opened the meeting and welcomed the participants to the 68<sup>th</sup> Plenary meeting of the FEEDAP Panel.

Members not able to attend the meeting had sent their apologies (see under participants).

**2. ADOPTION OF THE AGENDA**

The agenda was adopted.

**3. DECLARATIONS OF INTEREST**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this

meeting.

#### 4. ADOPTION OF THE DRAFT MINUTES OF THE 67<sup>TH</sup> PLENARY MEETING

The minutes of the 67<sup>th</sup> Plenary meeting of the Panel held on 7-8 April 2010 were reviewed and agreed.<sup>1</sup>

#### 5. WORK PROGRAM

##### 5.1. Discussion and possible adoption of the following scientific opinions

- **Avatec<sup>®</sup> 150G (lasalocid sodium) for pheasant, partridges, quails and guinea fowl (EFSA-Q-2008-080)**

The Rapporteur from the Working Group (WG) presented the question and the draft opinion. This question refers to an application for authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Avatec 150G as a coccidiostat for minor poultry species.

The draft opinion was discussed. The Panel identified some issues that need further clarification. Therefore, a request for supplementary information will be sent to the applicant.

- **AviPlus (citric acid, sorbic acid and thymol) for weaned piglets (EFSA-Q-2008-701)**

The Rapporteur presented the question and the draft opinion. This question refers to an application for authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product AviPlus as a zootechnical additive for piglets.

The draft opinion was discussed. The Panel considered that vanillin, which was not originally included in the specifications of the additive by the applicant, is an integral part of the additive. The additive is considered safe for the target species, consumers and the environment. Protective measures for users are recommended given the potential for irritation/sensitisation. The Panel also concluded that the product is efficacious at the minimum recommended dose.

The opinion was adopted.<sup>2</sup>

- **Ronozyme NP (6-phyase) for sows (EFSA-Q-2009-00536)**

The Rapporteur presented the question and the draft opinion. This question refers to an application for authorisation under Article 4 of Regulation (EC) No 1831/2003 of the product Ronozyme NP as a zootechnical additive for sows.

The draft opinion was discussed. The Panel concluded that the additive is safe and efficacious when used in diets for sows under the recommended conditions.

The opinion was adopted.<sup>3</sup>

- **Biosprint<sup>®</sup> (*Saccharomyces cerevisiae*) for horses (EFSA-Q-2009-00753)**

Not discussed due to lack of time.

- **Bonvital (*Enterococcus faecium*) for chickens for fattening (EFSA-Q-2010-00070)**

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<sup>1</sup> <http://www.efsa.europa.eu/en/events/event/feedap100407-m.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1633.htm>

<sup>3</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1634.htm>

The Chair of the WG presented the question and the draft opinion. EFSA has been requested to deliver an opinion on the efficacy and safety of Bonvital when used as a zootechnical additive for chickens for fattening. In a previous opinion,<sup>4</sup> the Panel could not conclude on the safety for the target species and the efficacy of this additive. The applicant has now provided new tolerance and efficacy studies.

The draft opinion was discussed. The Panel concluded that the product is safe for chickens for fattening and that there is evidence of the potential efficacy of the additive in chickens for fattening at the minimum recommended dose.

The opinion was adopted.<sup>5</sup>

- **Vitamin E for all species (EFSA-Q-2009-00816)**

The Rapporteur presented the question and the draft opinion. This question refers to an application for the re-evaluation (Article 10) and for the authorisation of a new use (Article 4) of the product vitamin E as a nutritional additive for all animal species under Regulation (EC) No 1831/2003.

The draft opinion was discussed. The dossier contained information for three active substances (all-rac- $\alpha$ -tocopheryl acetate, RRR- $\alpha$ -tocopheryl acetate and RRR- $\alpha$ -tocopherol). The Panel concluded that vitamin E at current use levels is safe for the target species, consumers and the environment. No concern for user safety is expected from the use of Vitamin E feed additives. The Panel also concluded that the three active substances are efficacious in all species in satisfying the requirements for vitamin E.

The opinion was adopted.<sup>6</sup>

## 5.2. Discussion of the following scientific opinions

- **Clinacox<sup>®</sup> 0.5% (diclazuril) for chickens for fattening (EFSA-Q-2008-749)**

Not discussed due to lack of time.

- **Clinacox<sup>®</sup> 0.5% (diclazuril) for guinea fowl (EFSA-Q-2009-00968)**

Not discussed due to lack of time.

## 6. PROGRESS REPORT ON ONGOING WORK

- The Panel was informed that the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) has an electronic Working Group developing a discussion paper on the "Factors taken into account in connection with establishing the ADI and the current process of recommending MRLs". Due to the importance and relevance of this issue to the Panel activities EFSA will liaise directly with the EC to get further information and prepare a close collaboration with the EC.

EFSA has also been in contact with the European Medicines Agency (EMA) to identify current activities in this area and potential collaboration.

- The Panel has identified that some of the guidance documents adopted by the Panel need revision and updating in order to provide clarification in some areas and further guidance in

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<sup>4</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/990.htm>

<sup>5</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1636.htm>

<sup>6</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/1635.htm>

others. Therefore, a self-task will be proposed to the Executive Director in order to proceed to the revision and update of the guidance documents identified in need of updating.

- A technical meeting with industry is scheduled for the 8<sup>th</sup> June to present the proposal of the Panel on the modifications of the guidance for technological additives to take into account the requirements for the new functional group “substances for the reduction of contamination of feed by mycotoxins”.
- The Head of Unit (HoU) informed the Panel on several activities that have been undertaken by the unit in the last months to prepare for the re-evaluation of feed additives.

## 7. FEEDBACK FROM THE SCIENTIFIC COMMITTEE

The Scientific Committee has established a WG on default assumptions. A member of the Panel will participate to this WG.

## 8. NEW REQUESTS TO EFSA

### 8.1. New applications under Regulation (EC) No 1831/2003

The Commission has forwarded to EFSA the following new applications of feed additives seeking authorisation under Regulation (EC) No 1831/2003 since the last Plenary meeting. These applications were presented to the Panel, who accepted them, and are currently being checked for completeness:

Additive	EFSA-Q-Number
Ronozyme <sup>®</sup> HiPhos (M/L)(6-phytase) for all pigs and poultry	EFSA-Q-2010-00769
Bentonite (dioctahedral montmorillonite) (Mycifix <sup>®</sup> Secure) for all animal species	EFSA-Q-2010-00770
Calsporin <sup>®</sup> ( <i>Bacillus subtilis</i> C-3102) for turkeys for fattening, ducks, geese, pigeons and other game birds for meat production, ducks, geese, pigeons, game birds, ornamental and sporting birds for rearing to point of lay, turkeys reared for breeding and chickens reared for laying	EFSA-Q-2010-00814
Chemically defined flavourings from Flavouring Group 18 – allylhydroxybenzenes: 4 substances for all animal species and categories	EFSA-Q-2010-00815
Chemically defined flavourings from Flavouring Group 31 – Aliphatic and aromatic hydrocarbons: 17 substances for all animal species and categories	EFSA-Q-2010-00816
<i>Bacillus subtilis</i> PB6 ( <i>Bacillus subtilis</i> ATCC PTA-6737) for chickens for fattening	EFSA-Q-2010-00768

### 8.2. Valid applications under Regulation (EC) No 1831/2003 since the previous meeting

Applications considered valid for the start of the assessment:

#	Additive	EFSA-Q-Number	Valid on
1	Biogalactosidase BL (alpha-galactosidase and 1,4-beta-glucanase) for chickens for fattening	EFSA-Q-2009-00534	07/04/2010
2	Sel-Plex (organic form of selenium produced by <i>Saccharomyces cerevisiae</i> ) for all animal species	EFSA-Q-2009-00752	21/04/2010
3	Ecobiol <sup>®</sup> and Ecobiol <sup>®</sup> plus ( <i>Bacillus amyloliquefaciens</i> ) for chickens for fattening	EFSA-Q-2009-00825	18/05/2010
4	Coxidin (monensin sodium) for chickens for fattening and turkeys	EFSA-Q-2009-00915	07/04/2010
5	Astaxanthin for salmon and trout, ornamental fish and birds, crustaceans and other fish	EFSA-Q-2009-00947	06/04/2010

6	Clinacox 0.5 % (diclazuril) for guinea-fowl	EFSA-Q-2009-00968	28/04/2010
7	Fecinor and Fecinor Plus ( <i>Enterococcus faecium</i> ) for chickens for fattening	EFSA-Q-2009-00969	18/05/2010
8	GalliPro <sup>®</sup> Tect ( <i>Bacillus licheniformis</i> ) for chickens for fattening	EFSA-Q-2009-00970	20/04/2010
9	Cylactin <sup>®</sup> /Cernivet <sup>®</sup> ( <i>Enterococcus faecium</i> ) for calves, lambs and kids for rearing and fattening	EFSA-Q-2010-00009	18/05/2010
10	Chemically defined flavourings from Chemical Group 02 - Branched-chain primary aliphatic alcohols/aldehydes/acids, acetal and esters with esters containing branched-chain alcohols and acetals containing branched-chain aldehydes: 34 substances	EFSA-Q-2010-00701	11/05/2010
11	Chemically defined flavourings from Chemical Group 01 - Straight-chain primary aliphatic alcohols/aldehydes/acids, acetal and esters with esters containing saturated alcohols and acetals containing saturated aldehydes: 86 substances	EFSA-Q-2010-00702	11/05/2010
12	Bentonite (dioctahedral montmorillonite) (Mycofix <sup>®</sup> Secure) for all animal species	EFSA-Q-2010-00770	21/05/2010

These applications were assigned to the working group on Enzymes (#1), Trace elements (#2), Micro-organisms (# 3, 7, 8 and 9), Coccidiostats (#4 and 6), Colourings agents (#5), Feed flavourings (#10 and 11) and Mycotoxin detoxifying agents (#12).

## 9. GENERAL INFORMATION FROM EFSA

- The HoU updated the panel on the arrangements for the June plenary, which will take place in Geel (Belgium) at the premises of the CRL.
- Two presentations were given to the panel, one on the library support to the work of the panels and units, and another one on the EFSA's strategy for the identification of emerging risks in the food/feed chain.

## 10. MISCELLANEOUS

- Dr. von Holst, gave a presentation on the "Key aspects of the method validation according to Commission Decision 2002/657/EC"
- The Panel was reminded about the monthly reports from the Information Exchange Platform (IEP) which contain information regarding risk assessment activities done by the Member States and which may be relevant to the work of the Panel.
- Discussion took place on the assessment of the safety for the consumer for astaxanthin. It was agreed that a request for supplementary information would be sent to the applicant.
- The HoU informed the Panel of an open call for a junior scientific staff (grade AD5) for the unit.<sup>7</sup>
- The HoU also informed the Panel on the status of the replacement of the experts that resigned from the Panel.
- The Panel agreed on the plenary dates for 2011: 1<sup>st</sup> - 3<sup>rd</sup> February, 15<sup>th</sup> - 17<sup>th</sup> March, 12<sup>th</sup> - 14<sup>th</sup> April, 11<sup>th</sup> - 12<sup>th</sup> May, 14<sup>th</sup> - 16<sup>th</sup> June, 12<sup>th</sup> - 14<sup>th</sup> July, 6<sup>th</sup> - 8<sup>th</sup> September, 11<sup>th</sup> - 13<sup>th</sup>

<sup>7</sup> <http://www.efsa.europa.eu/en/vacancies/vacancy/efsaxad2010005.htm>

October, 15<sup>th</sup> - 17<sup>th</sup> November and 13<sup>th</sup> - 15<sup>th</sup> December.