



**MINUTES OF THE 21st PLENARY MEETING OF  
THE SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS  
Held in Parma on 15 and 16 March 2006**

**AGENDA:**

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- 1 Opening, apologies for absence
- 2 Adoption of the agenda
- 3 Declarations of interest
- 4 Self tasking issues – discussion
  - 4.1 The 2004 Community Report on zoonoses: analysis about risk factors
  - 4.2 Avian influenza – food safety issues
- 5 Official requests to EFSA
  - 5.1 Presentation of new mandates received from the Commission
  - 5.2 Organization of Working Groups
- 6 Discussion and possible adoption of opinions
  - 6.1 Guidance document on antimicrobials for decontamination
  - 6.2 The risk of feeding farmed animals with ready-to-use milk-based products and milk-derived products (ABP)
  - 6.3 Risk reduction options of Salmonella in pig production
  - 6.4 Baseline survey study for Salmonella in pigs - Technical report
  - 6.5 Efficacy of decontamination for poultry carcasses:
    - 6.5.1 Lactic acid
    - 6.5.2 Acidic calcium sulphate
  - 6.6 Quantitative Risk Assessment for residual BSE risk. Opinion on di-calcium phosphate (DCP) and tri-calcium phosphate (TCP)
- 7 Progress reports and discussion on the following mandates
  - 7.1 Opinion on the update of the GBR methodology
  - 7.2 Microbiological testing, criteria and other objectives
  - 7.3 ABP: Progress on process applications received
  - 7.4 Quantitative Risk Assessment for residual BSE risk in sheep
  - 7.5 Breeding and TSE resistance in small ruminants
  - 7.6 BSE related risk from the use of skins and hides for technical purposes from cohort animals
  - 7.7 Visual inspection system in veal calves – TB aspects
  - 7.8 Quantitative Risk Assessment for residual BSE risk: Opinion on Vertebral Column.
- 8 Feedback by the chairman on subjects discussed in the SC of interest to the panel

- 8.1 Position paper on SC Committee and SC Panels
- 8.2 EFSA evaluation report
- 8.3 EFSA contribution to DGRTD 7WP
- 9 Feedback by the panel members attending WG from other panels
  - 9.1 Exposure Assessment: Draft opinion on uncertainties in dietary exposure assessment prepared by the Working Group Exposure of the Scientific Committee
  - 9.2 Qualified Presumption of Safety
  - 9.3 Farming systems for calves – Food safety aspects
- 10 Presentation by DG SANCO: main points of the hygiene package
- 11 EMEA public consultation on a reflection paper from CVMP on the use of Fluoroquinolones veterinary medicinal products in the EU
- 12 QMRA prospective project
- 13 Closure of the meeting
- 14 AOB

## **PARTICIPANTS**

### Panel Members:

Herbert Budka, Sava Buncic, Pierre Colin, John D Collins, James Hope, Mac Johnston, Günter Klein, Hilde Kruse, Ernst Lücker, Simone Magnino, Riitta Liisa Maijala, Antonio Martínez López, Christophe Nguyen-The, Birgit Noerrung, Servé Notermans, George Nychas, Maurice Pensaert, Ivar Vågsholm, Emmanuel Vanopdenbosch

### EFSA:

Marta Hugas, Bart Goossens, Eirini Tsigarida, Didier Verloo, Paolo Calistri, Fulvio Barizzone, Wolfgang Gelbmann (am 15 March), Torben Hallas-Moller (AFC<sup>1</sup> Panel am 15 March), Tobin Robinson, (Scientific Staff); Angela Cohen, Cristiana Ventura (Administrative staff)

### European Commission (EC):

DG Health and Consumer Protection: Ron Dwinger

## **1. OPENING, APOLOGIES FOR ABSENCE**

The Chair welcomed everyone. Apologies were received from Christian Ducrot and Terence Roberts. Dr Tobin Robinson was introduced to the Panel. He is a microbiologist and joined the Biological Hazards (BIOHAZ) unit on 1 March.

## **2. ADOPTION OF THE AGENDA**

The agenda was adopted.

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<sup>1</sup> AFC: Panel on food additives, flavourings, processing aids and materials in contact with food

### **3. DECLARATION OF INTEREST & MINUTES OF THE PREVIOUS PLENARY**

There were no new declarations of interest relating to the above agenda. The minutes of the Plenary of 17-18 January had been adopted by written procedure.

### **4. SELF-TASKING ISSUES - DISCUSSION**

#### **4.1. THE 2004 COMMUNITY REPORT ON ZOOSES: ANALYSIS ABOUT RISK FACTORS**

The Council of the European Union invited EFSA<sup>2</sup>, in collaboration with the European Centre for Disease Prevention and Control (ECDC) to present a detailed analysis of the risk factors on the basis of the annual Community Summary Report<sup>3</sup>. The BIOHAZ and AHAW<sup>4</sup> Panels had formally received the Terms of Reference (ToR) for the areas under their remit. The issues to be considered by the BIOHAZ Panel are *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, VTEC *E. coli*, *Yersinia*, *Trichinella*, *Echinococcus*, *Toxoplasma*, *Cysticercus*, antimicrobial resistance and food-borne outbreaks. The Panel decided to establish an *ad hoc* Working Group (WG) and the Chair and members were nominated.

#### **4.2. AVIAN INFLUENZA (AI) - FOOD SAFETY ISSUES**

A member presented a scientific report on avian influenza H5N1. The report addressed issues concerning the fate of highly pathogenic avian influenza viruses in avian species with particular reference to the possible transfer of AI H5N1 to mammals including humans via the food chain. The report was discussed and its publication was agreed.<sup>5</sup>

### **5. OFFICIAL REQUESTS TO EFSA**

#### **5.1. PRESENTATIONS OF NEW MANDATES RECEIVED FROM THE COMMISSION**

##### **5.1.1. Animal By-Products (ABP)**

Three mandates on ABPs had been received from the European Commission. A Working Group had been formed and will meet on 6 April to discuss the mandates on biofuel production and on lime treatment. A third mandate will be discussed following receipt of further data.

#### **5.2. ORGANIZATION OF WORKING GROUPS**

See item 5.1.1. relating to the new WG on ABP and 4.1 relating to the new WG on Zoonoses.

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<sup>2</sup> Council Conclusions from 6-7 December 2004 on Emerging Zoonotic Diseases

<sup>3</sup> [www.efsa.eu.int/science/monitoring\\_zoonoses/reports/1277\\_en.html](http://www.efsa.eu.int/science/monitoring_zoonoses/reports/1277_en.html)

<sup>4</sup> AHAW: Panel on animal health and welfare

<sup>5</sup> [www.efsa.eu.int/science/biohaz/biohaz\\_documents/1412/biohaz\\_report\\_ej74\\_avian\\_influenza\\_en2.pdf](http://www.efsa.eu.int/science/biohaz/biohaz_documents/1412/biohaz_report_ej74_avian_influenza_en2.pdf)

## **6. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS**

### **6.1. GUIDANCE DOCUMENT ON ANTIMICROBIALS FOR DECONTAMINATION**

The draft guidance document had been drafted following the self-tasking mandate of BIOHAZ with respect to the efficacy of decontaminating agents other than potable water. The European Commission requested that the evaluation of the safety of such substances be included in the guidance document. The draft had been written in cooperation with the AFC Panel and was put to the Panel. The Chair of the WG explained that, in particular, attention had been given to validation of the efficacy of the agent and its mode(s) of use.

The EC official welcomed the guidelines which will be of assistance to applicants and the EC with respect to the preparation and submission of dossiers for evaluation. To-date the EC was generally pleased with the draft. Clarification was requested as to whether the scope of the mandate considers the use of decontaminating agents when used only on raw food; the EC confirmed that this was the case. In addition, the EC gave clarification on various technical and legal points of the regulations<sup>6</sup>. The Panel agreed that following a few minor amendments, the document would be placed for public consultation on EFSA's website.

### **6.2. THE RISK OF FEEDING FARMED ANIMALS WITH READY-TO-USE MILK-BASED PRODUCTS AND MILK-DERIVED PRODUCTS (ABP)**

The Chair of the WG explained that the document prepared in reply to an EC question had addressed both animal health and public health and had been prepared as two draft opinions which shared a common part. The BIOHAZ opinion focuses on Public Health aspects while the AHAW opinion deals with Animal Health issues. The Chair of the WG outlined the draft opinion, in particular the chapters under the remit of the BIOHAZ Panel. A discussion on the text of the sections under the responsibility of the BIOHAZ Panel followed. Amendments were made to the conclusions and recommendations and an updated version was distributed to the members. The Panel adopted the opinion.

### **6.3. RISK REDUCTION OPTIONS OF *SALMONELLA* IN PIG PRODUCTION**

A comprehensive document had been prepared which took into account regulations such as Directive 2003/99/EC monitoring of zoonoses and Regulation (EC) No 2160/2003 on the control of *Salmonella* and other zoonotic agents<sup>7</sup>. The Rapporteur of the WG gave an overview of the draft opinion.

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<sup>6</sup> Regulation 852/2004: OJ L226/25.06.04, p3; Regulation 853/2004: OJ L226/25.06.04, p22

<sup>7</sup> Regulation 2160/2003: OJ L 325, 12.12.2003, p1

As a matter of procedure<sup>8</sup> the Chair of the Panel then handed over to one of the two Vice-Chairs who reviewed the draft with the members of the Panel in detail and addressed comments or requests for changes to the text. Following discussion the draft was amended and the Panel adopted the opinion.

#### **6.4. BASELINE SURVEY STUDY FOR *SALMONELLA* IN PIGS - TECHNICAL REPORT**

The technical report, which is a proposal for a baseline survey study, was tabled as an annex to the opinion (see 6.3) and was discussed. The discussion on the report was again chaired by the Vice-Chair, for the same reasons<sup>8</sup> as cited under Minute 6.3. The Panel agreed that it was appropriate that the annex be put to the Member States (MS) for discussion.

#### **6.5. EFFICACY OF DECONTAMINATION OF POULTRY CARCASSES:**

##### **6.5.1. Lactic acid**

The Chair of the WG presented the draft opinion on the evaluation of the efficacy of Lactic acid for carcass decontamination. The opinion was adopted by the Panel.

##### **6.5.2. Acidic calcium sulphate**

The application for the use as an antimicrobial agent of a formulation based on acidic calcium had been examined by a WG. The WG concluded that the data submitted were outside the scope of the mandate given to EFSA. This was because the studies submitted by the applicant concerned cooked food, whereas EFSA's mandate from the EC with respect to substances for the antimicrobial treatment of poultry is for use on raw food. The Panel concurred with the WG that the above-mentioned application on acidic calcium sulphate was outside the scope of the mandate given to the BIOHAZ Panel.

#### **6.6. QUANTITATIVE RISK ASSESSMENT FOR RESIDUAL BSE RISK. OPINION ON DI-CALCIUM PHOSPHATE (DCP) AND TRI-CALCIUM PHOSPHATE (TCP)**

The Chair of the WG reported that the draft opinion had been streamlined as requested by the Panel members at the previous Plenary of 17-18 January. Some further modifications were requested by the Panel in order to make the text clearer. Subsequently, the Panel adopted the opinion.

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<sup>8</sup> The person chairing the discussion leading to the potential adoption of an opinion cannot be the Chair of the WG.

## **7. PROGRESS REPORTS AND DISCUSSION ON THE FOLLOWING MANDATES:**

### **7.1. OPINION ON THE UPDATE OF THE GBR METHODOLOGY**

A member of the WG reported on the progress of the draft opinion. The group is reviewing factors considered in the established GBR<sup>9</sup> for assessing the BSE risk of imported MBM<sup>10</sup> and live animals (= external challenge). In addition the evaluation method of the “cattle system” (feeding, rendering, SRM removal, surveillance) is being reviewed for the purpose of updating. The group is also to review the categories which are currently used. Meetings are scheduled until July with the aim of producing a ‘stand alone’ report. A preliminary draft for the Panel’s consideration possibly at the May plenary is in preparation. A public consultation period is foreseen to be included.

### **7.2. MICROBIOLOGICAL TESTING, CRITERIA AND OTHER OBJECTIVES**

The WG met on 14 March to progress the document. The draft was reviewed by the Panel with emphasis on the conclusions and recommendations. It was agreed that the document would be made available for public consultation at EFSA’s website. Any feedback from the public will be considered for incorporation before the final document is published.

### **7.3. ABP: PROGRESS ON PROCESS APPLICATIONS RECEIVED**

See item 5.1

### **7.4. TSE DISCRIMINATORY TESTING IN SHEEP SAMPLES AND QUANTITATIVE RISK ASSESSMENT (QRA) FOR RESIDUAL BSE RISK IN SHEEP**

On 9 March EFSA had released a press statement on discriminatory scrapie/BSE testing of samples from one sheep from Cyprus and two sheep from France. An EFSA WG reviewed on 14 March 2006 the data in the report of the EU TSE Community Laboratory on the 3 cases. The EFSA WG agreed with the conclusions of the report and documented their findings. The Panel requested some modifications to the text, which were duly made. The Panel then agreed to issue the information as a statement from the Panel<sup>11</sup>. The results will be taken into account in the "QRA for residual BSE risk in sheep working group" which will meet for the second time on 23 March 2006.

The Chair of the WG reported on the progress of the draft opinion after the first meeting of 19 January 2006 including the different subjects to be considered: model for prevalence estimation, species barrier, infectious load and distribution

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<sup>9</sup> GBR: Geographical BSE Risk - [www.efsa.eu.int/science/tse\\_assessments/catindex\\_en.html](http://www.efsa.eu.int/science/tse_assessments/catindex_en.html)

<sup>10</sup> MBM: Meat and bone meal

<sup>11</sup> [www.efsa.eu.int/science/biohaz/biohaz\\_documents/1402/biohaz\\_statement\\_tsesheep\\_en1.pdf](http://www.efsa.eu.int/science/biohaz/biohaz_documents/1402/biohaz_statement_tsesheep_en1.pdf)

in tissues, human consumption level, transmission of BSE in sheep, examination of the previous Scientific Steering Committee (SSC) opinion and Commission clarification.

#### **7.5. BREEDING AND TSE RESISTANCE IN SMALL RUMINANTS**

The aim of the WG was to evaluate the current breeding programme to see if there were any adverse effects. A third meeting on 21 March will concentrate on the conclusions and recommendations of the draft opinion. A final meeting on 10 April is envisaged to prepare the document for presentation for possible adoption at the April plenary meeting.

#### **7.6. BSE-RELATED RISK FROM THE USE OF SKINS AND HIDES FOR TECHNICAL PURPOSES FROM COHORT ANIMALS**

Under Regulation (EC) No 999/2001 (the TSE Regulation), cohort animals must be killed and destroyed and no part of the animal may be used for any purpose. The mandate is to assess the BSE risk from hides and skins if cohort animals were allowed to be used for technical purposes (*i.e.* the production of leather). The first WG meeting was held on 10 February, a second meeting is scheduled for 22 March and it is expected that a third and final meeting will be held on 26 April to finalise the draft opinion in time for the BIOHAZ plenary in May.

#### **7.7. VISUAL INSPECTION SYSTEM IN VEAL CALVES – TB ASPECTS**

The Chair of the WG gave details of the letter sent to MS requesting further data on calf populations and movements. The deadline for replies was set for 24 March; some replies had already been received.

#### **7.8. QUANTITATIVE RISK ASSESSMENT FOR RESIDUAL BSE RISK: OPINION ON VERTEBRAL COLUMN.**

The draft opinion on vertebral column will be presented at the April plenary.

#### **8. FEED-BACK BY THE CHAIRMAN ON SUBJECTS DISCUSSED IN THE SC OF INTEREST TO THE PANEL**

The Scientific Committee (SC) met on 15-16 February.<sup>12</sup>

#### **8.1. POSITION PAPER ON SC COMMITTEE AND SC PANELS**

The Chair presented a position paper by the SC on the functioning of EFSA's SC and Panels.

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<sup>12</sup> [www.efsa.eu.int/science/sc\\_committee/sc\\_meetings/1344\\_en.html](http://www.efsa.eu.int/science/sc_committee/sc_meetings/1344_en.html)

## **8.2. EFSA EVALUATION REPORT**

Information on the evaluation report had been reported at the BIOHAZ Plenary of 17-18 January. Comments had been collected on the report.<sup>13</sup>

## **8.3. EFSA CONTRIBUTION TO DG RTD -7WP**

The SC had informed all Panels that DG Research (RTD) would consider research priorities identified by the Panels. The Panel was invited to send any suggestions for areas of research to EFSA so that these can be forwarded to DG Research. Emphasis could be made on research on basic questions as well as applied research.

## **9. FEED-BACK BY THE PANEL MEMBERS ATTENDING WG FROM OTHER PANELS**

### **9.1. EXPOSURE ASSESSMENT: DRAFT OPINION ON UNCERTAINTIES IN DIETARY EXPOSURE ASSESSMENT PREPARED BY THE WORKING GROUP EXPOSURE OF THE SCIENTIFIC COMMITTEE**

An EFSA official stated that any comments from the BIOHAZ Panel on the draft opinion can be provided to the SC. The member of the Panel in the WG presented the ToR on exposure assessment which is to identify uncertainties in exposure assessment as an area where guidance could be developed. The Panel agreed that the document can be referred to in BIOHAZ opinions where appropriate.

### **9.2. QUALIFIED PRESUMPTION OF SAFETY (QPS)**

The sub-Working Group had advanced their work covering *Bacillus*. The work on lactic acid and yeasts was in progress according to QPS working document. An opinion will be prepared for adoption by the SC and the species to be included in the QPS will be identified.

### **9.3. FARMING SYSTEMS FOR CALVES – FOOD SAFETY ASPECTS**

An AHAW report is being prepared on the effects of intensive farming systems on calf welfare. The BIOHAZ Panel has been asked to comment on food safety issues.

## **10. PRESENTATION BY DG SANCO: MAIN POINTS OF THE HYGIENE PACKAGE**

The European Commission official gave an overview of the hygiene package covering the legal framework; in particular the Hygiene Regulations (EC 178/2002 on general food law, 852/2004 on hygiene of foodstuffs, 853/2004 on hygiene rules for food of animal origin, 854/2004 on official controls (meat

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<sup>13</sup> [www.efsa.eu.int/mboard/catindex\\_en.html](http://www.efsa.eu.int/mboard/catindex_en.html)

inspection), and 882/2004 on official feed and food controls. Implementing measures, transitional arrangements and guidance documents were also presented. Guidance documents dealing with 852/2004, 853/2004, HACCP, import requirements, multi-annual control plans/auditing and official controls of microbiological criteria were currently being prepared by the EC. A CD ROM containing all the regulations and guidance documents in 20 languages will be available from April and placed on the EC website. Copies of the CD ROM will be sent to the Panel members.

## **11. EMEA PUBLIC CONSULTATION ON A REFLECTION PAPER FROM CVMP ON THE USE OF FLUOROQUINOLONES VETERINARY MEDICINAL PRODUCTS IN THE EU**

This item was mentioned for information only. A reflection paper was published by EMEA<sup>14</sup>. Any comments from Panel members could be sent either via EFSA or directly to EMEA on a personal basis.

## **12. QMRA PROSPECTIVE PROJECT**

A document which had been tabled at the Advisory Forum (AF) of 3 March was presented<sup>15</sup> by the secretariat. A number of recommendations and conclusions were highlighted. The document was supported by the AF and some MS expressed interest in undertaking a study on *Campylobacter*. EFSA has asked the Panel for its views and the matter is to be discussed further at the Plenary in April. DG SANCO supports the project and would like to discuss details with EFSA on how to approach it.

## **13. AOB**

### **13.1. FIRST MEETING OF THE SECRETARIATS OF EFSA AND MEMBER STATES DEALING WITH TSE/BSE ISSUES**

The objectives of the meeting were mainly to discuss how to avoid duplication/diverging opinions. The main conclusions and action list of the first meeting was tabled for information. The needs for networking and the avoidance of duplicating or divergent opinions were discussed. The follow up to the action list will be forwarded to the AF which is also working on networking issues. The next meeting is envisaged in September 2006.

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<sup>14</sup> [www.emea.eu.int/htms/vet/swp/srantimicrobial.htm](http://www.emea.eu.int/htms/vet/swp/srantimicrobial.htm)

<sup>15</sup> [www.efsa.eu.int/advisory\\_forum/adv\\_meetings/1375/af\\_noteqmra\\_16thmeet\\_en\\_3a1.pdf](http://www.efsa.eu.int/advisory_forum/adv_meetings/1375/af_noteqmra_16thmeet_en_3a1.pdf)

### **13.2. JOINT STATEMENT OF BFR AND FLI ON THE BSE RISK OF THE RE-ADMISSION OF THE FEEDING OF ANIMAL FATS OF RUMINANTS TO RUMINANTS**

A statement from BFR and FLI commented on the EFSA opinion on tallow was discussed. The Panel agreed that a reply be drafted by the Chair of the WG on QRA for the Panel's approval.

### **13.3. NEXT MEETINGS**

19-20 April 2006 and 17-18 May 2006 were confirmed. It was noted that the meeting of 17-18 May 2006 would be the final Plenary meeting under the current mandate.

### **14. CLOSURE OF THE MEETING**

The meeting closed at 13.00.