EFSA
European Food Safety Authority

MINUTES OF THE 27TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS HELD IN PARMA ON 8 AND 9 NOVEMBER 2006

AGENDA:

1 Opening, apologies for absence
2 Adoption of the agenda
3 Declarations of interest
4 Official requests to EFSA
  4.1 Presentation of new mandates received from the Commission
  4.2 Organization of Working Groups
5 Discussion and possible adoption of opinions
  5.1 Cattle SRM related back-calculations
  5.2 Quantitative Risk Assessment for residual BSE risk in sheep
  5.3 Update GBR methodology (possible adoption of report to put forward for public consultation)
6 Progress reports and discussion on the following mandates
  6.1 Update on QRA tallow opinion diverging from opinion of BFR/FLI
  6.2 BSE in fishmeal
  6.3 ABP: Progress on process applications received
  6.4 Microbiological criteria, testing and other objectives
  6.5 Revision of the opinion on microbiological risks in infant formulae
  6.6 *Salmonella* in meat and meat preparations
7 Discussion on self tasking suggestions
  7.1 Antimicrobial resistance self mandate
  7.2 Other suggestions
8 Feed back from the scientific committee and from other WG
9 AOB
  9.1 Feedback on comments on the draft report of the 2005 Community Summary Report
10 Closure of the meeting

PARTICIPANTS

Panel Members:

Olivier Andreoletti, Herbert Budka, Sava Buncic, Pierre Colin, John D Collins, Aline De Koeijer, John Griffin, Arie Havelaar, James Hope (9 November), Günter Klein, Hilde Kruse, Simone Magnino, James McLauchlin, Christophe Nguyen-The, Birgit Noerrung, Miguel Prieto Maradona, Terence Roberts and Emmanuel Vanopdenbosch.

EFSA:

Biological Hazards (BIOHAZ): Bart Goossens, Marta Hugas (9 November), Fulvio Barizzone, Paolo Calistri, Tobin Robinson, Eirini Tsigarida Didier Verloo (8 November), (Scientific Staff); Angela Cohen, Cristiana Ventura (Administrative staff).

Pia Mäkelä and Frank Boelaert (Scientific Staff, Zoonoses unit) – item 9.1

European Commission (EC):

DG Health and Consumer Protection: Taina Sateri

1. OPENING, APOLOGIES FOR ABSENCE

The Chair welcomed everyone. Apologies were received from Marta Hugas (8 November), James Hope (8 November), Antonio Martínez López, Karsten Noeckler and Ivar Vågsholm. By way of an introduction to the other members of the Panel, Dr McLauchlin gave a brief outline of his career history as a public health microbiologist.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

There were no new declarations of interest.

4. OFFICIAL REQUESTS TO EFSA

4.1. PRESENTATION OF NEW MANDATES RECEIVED FROM THE COMMISSION

The following new mandates were received from the European Commission:

4.1.1. QUANTITATIVE RISK ASSESSMENT ON *SALMONELLA* IN SLAUGHTER AND BREEDER PIGS FOR PUBLIC HEALTH

Regulation (EC) No 2160/2003 on the control of zoonoses calls for targets for the reduction of the prevalence of *Salmonella* in pigs. The deadline for producing the opinion is the end of June 2008 for slaughter pigs and end of June 2009 for breeding pigs. The mandate was discussed by the Panel. Some common elements were identified between the mandate for QRA on *Salmonella* in Pigs, and the mandate on *Salmonella* in meat and meat preparations (see item 6.6). The composition of the WG was discussed.

4.1.2. PUBLIC HEALTH RISKS INVOLVED IN THE HUMAN CONSUMPTION OF REPTILE MEAT

Trade in reptile meat is not currently harmonised in the European Union (EU). The Panel is requested to assess the public health risks involved and the deadline for this mandate is 30 April 2007. A literature review will be carried out by EFSA as a basis for discussion. A Working Group will be set up at the December Plenary.

4.1.3. TSE TESTING – CRL REPORT ON BATCH TESTING RESULTS OF RAPID TESTS

EFSA received a new mandate from the European Commission asking for scientific advice on a report prepared by the Community Reference Laboratory (CRL) on the results of batch testing for BSE using approved TSE tests. The first meeting will be held on 4 December.

4.1.4. TSE TESTING – PROTOCOLS FOR TSE TEST EVALUATION

A number of scientific reports[1] on evaluations for Transmissible Spongiform Encephalopathy (TSE) were previously addressed and adopted by an Independent Expert Group on test evaluations. A new mandate has been received by the EC asking for a revision of the existing protocols (i.e. BSE testing in cattle; scrapie in small ruminants; live animal testing) for TSE testing. A WG under the panel will be established in order to undertake these revisions and prepare opinions which will be presented for possible adoption by the BIOHAZ Panel. It is intended to present these for adoption in March 2007. These opinions will assist the EC when preparing a new call for expression of interests for testing.

[1] www.efsa.europa.eu/en/science/tse_assessments/bse_tse.html

4.2. ORGANISATION OF WORKING GROUPS

Several WGs for items 4.1.1; 4.1.2; 4.1.3 ; 4.1.4. and 4.1.5 were established.

5. DISCUSSION AND POSSIBLE ADOPTION OF OPINIONS

5.1. CATTLE SRM RELATED BACK-CALCULATIONS

On the request of EFSA, the EC extended the deadline until the end of December 2006. A progress report was given by the Chair of the WG. The WG met on 17 October. Additional requested data on the epidemiology were provided by the EC Services. The first draft of the document will be presented at the December Plenary for comment. The WG will meet again in January 2007, and a draft opinion will be presented for adoption at the January Plenary.

5.2. QUANTITATIVE RISK ASSESSMENT FOR RESIDUAL BSE RISK IN SHEEP

The WG met on 18 October and a final meeting will be held on 1 December. The Chair of the WG presented a first reading of the draft opinion. It is foreseen that the draft opinion will be presented for adoption at the December Plenary.

5.3. UPDATE GBR METHODOLOGY (POSSIBLE ADOPTION OF REPORT TO BE PUT FORWARD FOR PUBLIC CONSULTATION)

The Chair of the WG outlined the main updates made to the document since the last Plenary. The Panel discussed the document in detail and approved the document for public consultation. The document will be on-line on the EFSA web for 6-8 weeks allowing all interested stakeholders to comment. The comments received from the public will be considered. A final opinion on the revision of the GBR methodology will then be prepared, taking account of the comments received, and will be presented for possible adoption during the March Plenary.

6. PROGRESS REPORTS AND DISCUSSION ON THE FOLLOWING MANDATES

6.1. UPDATE ON QRA TALLOW OPINION DIVERGING OPINION WITH BFR/FLI

The Panel were updated on the exchange of correspondence to date between BfR/FLI[2], EFSA and the EC. EFSA asked BfR/FLI for their concerns on the EFSA opinion on the "human and animal BSE risk posed by tallow with respect to residual BSE risk"[3] and is currently awaiting their response in writing. EFSA will formally update the EC of the current situation in due course.

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[2] German Bundesinstitut für Risikobewertung (BfR) and Friedrich-Loeffler Institut (FLI)

[3] www.efsa.eu.int/science/biohaz/biohaz_opinions/1110_en.html

6.2. BSE IN FISHMEAL

The Chair of the WG presented the draft opinion. The next WG meeting will be held on 22 November. The opinion is scheduled for presentation at the December Plenary and for possible adoption at the January Plenary.

6.3. ABP: PROGRESS ON PROCESS APPLICATIONS RECEIVED

6.3.1. Mandate on the evaluation of a process submitted by the European Lime Association (EULA)

At the last WG meeting which was held on 13 July with representatives from EULA, it was agreed that EULA would provide a timeframe for the submission of their results by 18 September. As EFSA still has not received the data requested from EULA, work on the mandate is suspended until the data are provided by EULA.

6.3.2. Treatment of animal by-products in mesophilic biogas fermenters

The ToR of the mandate were explained by the Chair of the WG. The EC asked EFSA to assess the risks related to the mesophilic process for biogas production and compost treatment plants. The ToR concern the generic process of mesophilic biogas fermenters but some further clarification on the ToR is needed. The first meeting of the WG will be held on 17 November.

6.3.3. Use of certain low risk Category 2 animal by-products[4]

A letter was sent to the EC, indicating that the subject of this mandate was not of relevance to the BIOHAZ Panel. EFSA is awaiting the reply.

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[4] An indicative summary of the Categories given in the ABP Regulation 1774/2002 and subsequent modifications is as follows:
Category 1: Animal by-products presenting a risk of contamination with BSE or scrapie agent, or with residues of prohibited substances (e.g. hormones used for growth promotion) or environmental contaminants (e.g. dioxins and PCBs) (Article 4).
Category 2: Animal by-products presenting a risk of contamination with other animal disease agents (e.g. animals which have died on the farm or were killed in the context of disease control measures on the farm) or at risk of residues of veterinary drugs (Article 5).
Category 3: Parts of slaughtered animals that are not consumed by humans but that come from animals declared fit for human consumption following veterinary inspection (Article 6).

6.3.4. Use of certain Category 1 and 2 animal by-products for technical purposes

EFSA replied by letter to the EC that the mandate could not be accepted as it is not related to food safety and thus not in the remit of EFSA. A reply is awaited.

6.4. MICROBIOLOGICAL CRITERIA, TESTING AND OTHER OBJECTIVES

The Chair of the WG reported that following comments received from the public consultation, the ToR have been amended and the title has been changed to: "Microbiological criteria and targets based on risk analysis". The changes were accepted by the Executive Director. The WG will meet on 22 November and a preliminary report will be prepared for the December Plenary.

6.5. REVISION OF THE OPINION ON MICROBIOLOGICAL RISKS IN INFANT FORMULAE

EFSA was asked to review the former opinion of the BIOHAZ Panel in the light of the recent report on risk assessment published by World Health Organisation (WHO) and the Food and Agriculture Organisation of the United Nations. The next WG meeting will be held on 16 November.

6.6. *SALMONELLA* IN MEAT AND MEAT PREPARATIONS

At the second WG meeting, held on 26 October, the EC provided further clarification on the mandate. During the last WG meeting a Table of Contents of the preliminary risk profile was defined and the main tasks distributed to the WG members. The next WG meeting will be held on 12 December.

7. DISCUSSION ON SELF TASKING ACTIVITIES

7.1. ANTIMICROBIAL RESISTANCE SELF MANDATE

A draft mandate was presented to the Panel. The Panel members discussed whether the ToR could be revised as the EC had requested an extension of the ToR to include further analysis. The Panel agreed that the requested additional request could not be accepted as it was too general and out of the scope of the mandate. Amendments to the text of the ToR were suggested by the Panel members and will be distributed to them before the next Plenary meeting.

7.2. OTHER SUGGESTIONS

Several suggestions for self-tasking activities will be sent to the Panel members before the December Plenary for discussion in December.

8. FEEDBACK FROM THE SCIENTIFIC COMMITTEE AND FROM OTHER WG

8.1. WORK PROGRAMME FOR 2007

The Scientific Committee (SC) met on 6-7 November[5]. The SC asked each Panel to review the section of the draft EFSA Work Programme for 2007 relating to that Panel's activities. The text on BIOHAZ was revised and agreed upon by the Panel.

8.2. TRANSPARENCY

The SC Transparency Committee requested from each Panel a summary of the type of actions made which enhance transparency for the public and stakeholders, for instance public consultations.

8.3. PANEL APPROACH TO RESPONDING TO URGENT QUESTIONS

The SC requested a summary of how each Panel responds to urgent questions. The distinction was made between urgent questions (e.g. when a rapid response on Avian Influenza[6] was provided by the BIOHAZ Panel) and emerging risks.

8.4. PANEL APPROACH TO EMERGING RISKS

The Panel under the first mandate[7] had been asked to identify up to six emerging risks. It is likely the SC will ask each Panel to submit a further list linked to the Panel. The definition of emerging risks can be found in the Opinion of the Scientific Committee related to the early identification of emerging risks (adopted on 4 July 2006)[8]. Furthermore, an Emerging Risk Unit is being set up at EFSA.

8.5. QUALIFIED PRESUMPTION OF SAFETY

The Qualified Presumption of Safety (QPS) approach is designed to facilitate the process of safety assessment, and in the first instance this approach is being applied to the safety assessment of microbial feed additives and crop protection agents. QPS is used to indicate if a microbial species could be considered for a simplified safety assessment for food chain applications.

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5 www.efsa.europa.eu/en/science/sc_commitee/sc_meetings.html

6 www.efsa.europa.eu/etc/medialib/efsa/science/biohaz/biohaz_documents/1412.Par.0001.File.dat/biohaz_report_ej74_avian_influenza_en2.pdf

7 The duration of the first mandate of the BIOHAZ Panel ran three years from its inaugural meeting of May 2003.

8 www.efsa.europa.eu/en/science/sc_commitee/sc_opinions/sc_op_ej375_emrisk.html

A range of organisms currently used are now being considered by the Scientific Committee who established a WG to address this procedure. The WG was formed into four sub-groups, each considering a different group of microorganisms. The four documents have a common structure and, following a public consultation in 2007, the final document will be produced.

8.5.1. QPS - GENUS *BACILLUS*

The draft opinion on "assessment of strains within the genus *Bacillus* with respect to a Qualified Presumption of Safety" was presented to the Panel. Comments from the Panel on the suitability of *Bacillus* species to be considered for QPS status were noted, and are to be transmitted to the WG of the Scientific Committee on QPS for their consideration.

8.6. BOTANICALS

The WG will meet on 23-24 November. It will be divided into three or four sub-groups to address different areas including one on the guidelines to assess the safety of botanicals and another on toxicological aspects.

8.7. AHAW – PIG WELFARE

The member of the BIOHAZ Panel involved in this mandate reported that the WG will be divided into three sub-WGs: on tail biting; on sows, boars and piglets welfare and on fattening pigs welfare. It was agreed by the AHAW and BIOHAZ Panels that BIOHAZ will produce a chapter on food safety related issues.

8.8. AHAW – FISH WELFARE

A member of the BIOHAZ Panel was nominated to be involved in this mandate. It was agreed by the AHAW and BIOHAZ Panels that BIOHAZ will produce a chapter on food safety related issues.

8.9. MEETING OF CHAIRS OF PANELS AND SCIENTIFIC COMMITTEES OF THE EU

The Chair attended the meeting of 24-25 October. Among the topics which were discussed were risk benefit, non-animal testing, and nanotechnology applications such as active and intelligent packaging. The EFSA 5th Year anniversary celebrations will be held in 2007.

9. AOB

9.1. FEEDBACK ON COMMENTS ON THE DRAFT REPORT OF THE 2005 COMMUNITY SUMMARY REPORT

The Unit on data collection of Zoonoses thanked the Plenary members for the comments received from the BIOHAZ Panel on the draft 2005 report. It is hoped to have the draft text of the report ready in mid-November.

9.2. PLENARY – SEPTEMBER 2007

It was confirmed that the BIOHAZ Plenary will be held in Rotterdam on 6 September 2007, starting at 9.00 and ending in the afternoon of 7 September.

9.3. EXTRANET

An extranet will be provided by EFSA for the BIOHAZ Panel by April 2007. The extranet will facilitate the exchange of working and meeting documents. A presentation will be given to the Panel members at the December or January Plenary.

10. CLOSURE OF THE MEETING

The meeting closed at 13.30.