European Food Safety Authority

SCIENCE

ASSESSMENT OF SAFETY WITH RESPECT TO CONSUMPTION OF GOAT PRODUCTS IN RELATION TO BSE/TSE

(Update on the State of affairs on 12 January 2005)

1. The French authorities informed the Commission (28 October 2004) of a high suspicion of BSE in a goat that was slaughtered in 2002 and had since undergone a series of confirmatory tests. Following this, EFSA has received a formal mandate from DG SANCO of the European Commission requesting EFSA's Scientific Panel on Biological Hazards for advice and an update of the opinions related to **"**Assessment of safety with respect to consumption of goat products in relation to BSE/TSE". The opinion should be delivered preferably before end of June 2005. In the meantime a statement has been sent to COM related to the safety of milk and milk products in relation to TSE in goats.

2. The direct and medium-term consequences for the EFSA and its Scientific Panel on Biological Hazards will be, pending the results following the evaluation as carried out by the Community Reference laboratory (CRL), to update previous opinions (*e.g.* SSC opinion April 2002 on safe sourcing of small ruminant products) related to the BSE risk of consumption of goat products (and sheep) in case BSE is confirmed in this goat.

3. At the meeting (25 November 2004) organised under auspices of COM, the experts of the CRL came to the following conclusion: "The Expert Group considered that because of the incomplete nature of available data, specifically with regard to bioassay and IHC, this prevented a definitive interpretation at this time. Despite the strength of the WB, ELISA and bioassay results in transgenic mice already available it felt that the interpretation required review of additional data from RIII and C57Bl mice. This is expected to be available end of January 2005. Following the CRL meeting, SANCO issued a media statement regarding the CRL conclusions. This statement can be found at the SANCO website: http://europa.eu.int/comm/food/library/press006_en.pdf.

4. In the attached pages, an overview is given of actions taken by EFSA and the subsequent results of these actions and consultations.

(Bart Goossens, Scientific Coordinator)

Annex 1.

SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

Overview of actions taken by EFSA and the subsequent replies

1. A feasibility study (see attached Terms of Reference) was launched shortly after the announcement of the suspected case to check the availability and usefulness of existing or new scientific data and to collect other information as the basis for a quantitative assessment of the risks involved in the consumption of goat products.

   Progress: A report of both consulted experts has been delivered to EFSA before end of December 2004 and was discussed at the first WG meeting of 11 January 2005.

2. Question to the European Commission.
   The services of the EC (DG Sanco) were invited to supply EFSA with the relevant data related *to point 1) of the ToR*. Data should cover both goats and sheep and for sheep also more particular for points *c to h* also including data for positive sheep of both the non-resistant and resistant genotypes.

   Progress: This information as compiled by the COM has been supplied to EFSA and is also part of the documents which were discussed at the first meeting of the WG of 11 January 2005. *Some additional info will be requested following the meeting of 11 January 2005.*

3. Letter to the Advisory Forum of EFSA in order to request the MS and their national reference laboratories and different research institutes to provide EFSA with an update on any planned or on-going scientific research at national level linking BSE and small ruminants, including studies on the infectivity of milk.

   Progress: different MS have up to today (10 January 2005) supplied information to EFSA: Ireland, Portugal, Sweden, Luxembourg, Germany, UK, Cyprus, Latvia, Belgium, Finland and Italy. Also Norway and Iceland supplied info. However still the following countries have not submitted any form of communication on the above questions despite a reminder sent: France, Spain, Denmark, Greece, The Netherlands and Austria and all accession countries with the exception of Latvia and Cyprus. *Some additional info will be requested following the meeting of 11 January 2005.*

4. Letter to different experts with question on update of scientific knowledge related to different opinions on the subject available and request to examine the current scientific literature in order to provide us with the results of any new findings, currently ongoing research project on the subject and if available intermediate results or indication of timing for available results.

   Progress: A summary of the contribution has been prepared and was discussed at the first WG meeting of 11 January 2005. As the mandate from COM had

slightly changed (ref new mandate: D(2004) KDS/cm/421319) compared to the first mandate received shortly after the announcement of the suspected case, this consultation needed to be updated during the meeting on 11 January 2005. The first mandate concentrated more on the safety of milk whereas the second one included the safety of goat products in general.

5. Involvement of the EFSA Scientific Panel on Biological Hazards

   The Scientific Expert Working group of the EFSA Biohaz panel published a preliminary statement on the safety of goat milk and derived products with regards to TSEs on 26 November 2004 and this statement can be found at: http://www.efsa.eu.int/science/biohaz/biohaz_documents/catindex_en.html.

   At the plenary meeting of the Biological Hazards Panel (1-2 December 2004) this state of affairs was discussed and the composition of a WG was agreed. Date for first meeting was set at 11 January 2005 which was then anticipating the second meeting of the CRL strain typing group. In the meantime this first meeting took place and a summary of the conclusions is attached (annex2). The further actions will involve the adoption of an opinion on the safety of goat and sheep products. It is anticipated that this will be adopted latest at the plenary meeting of July 2005 (12-13 July).

FEASIBILITY STUDY OF THE AVAILABILITY AND USEFULNESS OF EXISTING SCIENTIFIC DATA AND OTHER INFORMATION AS THE BASIS FOR A QUANTITATIVE ASSESSMENT OF THE RISKS INVOLVED IN THE CONSUMPTION OF GOAT PRODUCTS.

TERMS OF REFERENCE

To advise on approaches to enable a quantitative risk assessment of human exposure to products from goats should BSE be confirmed in goats:

The study should provide information on the availability and usefulness of existing scientific data and other information from Member States and third countries which would allow for a quantitative assessment of the human health risks involved in the consumption of goat meat and milk and products made thereof. Such a quantitative risk assessment would be based on a probabilistic approach and would provide for the timely assessment of the human health risks, in case BSE would be confirmed in goats.

The data requested should include, but not necessarily be limited to:

1. The following surveillance data (per country) on goats:
    a. Population data;
    b. Numbers of goats slaughtered annually and age distribution;
    c. Numbers of goats tested for scrapie out of total goats tested and age distribution;
    d. Number of positive scrapie cases;
    e. Number of doubtful positive scrapie cases;
    f. How many of these doubtful cases had been further submitted to a molecular confirmatory test;
    g. How many cases, confirmed by the molecular test had been submitted to a bio-assay;
    h. If cases were submitted to the bio-assay test; provision of likely timetable when the results of such testing would become available.

2. An overview of available research data from the scientific literature and, as appropriate, from separately reported cases, including the suspected French BSE case, on:
    a. Distribution of infectivity in the different organs of goats (experimentally) infected with BSE;
    b. Distribution of infectivity in the different organs of goats (experimentally) infected with scrapie;
    c. Susceptibility of goat kids versus adult goats for scrapie infections;

3. An overview of available scientific human epidemiology literature and, as appropriate, reported case studies on:
    a. The occurrence of variant Creutzfeldt Jakob Disease (vCJD) in Member States and third countries;
    b. Occurrence of vCJD in specified groups of society respecting particular dietary habits with respect to meat consumption.
    c. Causal relationships between TSE in animals and vCJD in humans.