EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

OPINION AND REPORT ON

BSE IN UNITED KINGDOM'S CATTLE BORN AFTER 31 JULY 1996 [BARBS]

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 10-11 APRIL 2003

BACKGROUND AND MANDATE

"BARB" BSE cases or "**B**orn **A**fter the **R**einforced [feed] **B**an" are BSE cases in UK cattle born after 31 July 1996. This is the date that the animal feed ban was reinforced and policed in the UK to such an extent that the inclusion of animal-derived proteins in the feed of any farmed animal, was considered to be excluded.

In its opinion of 30 November 2001 on the six BARB BSE cases in the UK since 1 August 1996, the Scientific Steering Committee (SSC) concluded that there was currently no reason for the SSC to assume an increased risk as compared to its assessments presented in previous opinions. The SSC therefore did not consider at that moment a revision of its Date Based Export Scheme (DBES) or other BSE related opinions.

Because a feed-borne origin of the BARB cases could not be excluded and because of the continuing presence of BSE cases in the Over-Thirty Months Scheme (OTMS) animals, it recommended a large and significant epidemiological testing program to last until there is sufficient evidence for reassurance of the safety in terms of human exposure of the UK DBES.

Should such program reveal a large number of (pre-clinical) BSE cases that cannot be attributed to maternal transmission or a number of cases that can directly be related to other sources of infection, or provide indications that the number of infected animals is higher than has been extrapolated from the model estimates, then the validity of the UK's Date Based Export Scheme (DBES) might have to be put into question. Also, if a new way of transmission other than feed or maternal would be strongly hypothesised or proven, it could indicate that the DBES alone is not sufficient anymore to guarantee the control of the disease in cattle and to prevent exposure of human beings.

Between 1 December 2001 and 1 December 2002, 24 UK-born BARB BSE cases were reported in the UK and the Commission Services invited the SSC to evaluate pro-actively the total number of BARB cases recorded in the UK since 1 August 1996. More precisely, it invited the SSC to:

i) Update its opinion of 29-30 November 2001 on the six BARB cases in the UK since 1 August 1996 in the light of the new BARB BSE cases;

ii) Judge whether it saw any reason to revise its earlier conclusion on the most likely route of infection or its assessment of the overall BSE risk in the UK and in particular related to the DBES.

On the basis of the report of the TSE/BSE *ad hoc* Group, the SSC concludes as follows:

OPINION

1. In the past, model-based estimates of the number of BARB cases that could be expected to occur have regularly been published in the scientific press. The models were based on the numbers of clinical BSE in the UK. The basis for the estimates was the assumption of that maternal transmission would be at the origin of such cases. These model-based estimates have been overtaken by two sources of subsequent intelligence.

   Firstly, models based only on UK's clinical BSE cases have seriously underestimated UK's number of BSE infections. BSE surveillance has continuously improved and rapid testing programmes have been introduced. These are likely to account for part of the more recently detected BARB cases and UK's BSE modelling is currently being re-visited.

   Secondly, maternal transmission, as commonly understood, is not an explanation for those BARBs whose dam survived for at least two years after the birth of the BARB and survived to at least six years of age without clinical signs or BSE-test positivity. In this context the SSC takes note of recent preliminary epidemiological analyses of Great Britain's confirmed cases of BSE in cattle born after 31 July 1996 which indicate that the geographical distribution of these BARBs is consistent with a widespread but low risk of exposure, and that the BARB cases show an epidemiology which is distinct from Great Britain's BSE epidemic prior to the initial feed ban in 1988 and from the epidemic in the inter-regnum between 1988 and 1996 feed bans[1].

[1] For some of the BARB cases it is not known whether maternal transmission can be fully excluded as it is not known whether the dam would still have been alive and in good health six months after the birth

An update is thus needed of the scientific basis of the DBES, taking into account the most recent (epidemiological) evidence and present revised BARB BSE projections. Because the key-assumption of the DBES is not valid, prudence is needed: a sensitive surveillance apparatus (tests) needs to be maintained to detect the BARB BSE cases, and these BARB BSE cases (in UK and elsewhere) need to be studied very carefully in order to find the reasons why they were contaminated in spite of a rigorously reinforced feed ban. BARB-controls studies should be instituted Europe-wide so that the natal, feed and dam history of BARBs and suitable controls can be directly compared. In addition the SSC recommends that the BSE incidence in risk stock[2] be analysed against the dates, types and scope of risk management measures taken in various Member States.

2. With regard to the most likely origin of the BARB cases and the routes of infection, currently available data do not permit final conclusions. The hypothesis emitted in the SSC opinion of November 2001 – that the route of infection of the BARB BSE cases has a probability to be feed-borne - seems to be further supported by the evolution to date in the number of BARB BSE cases in the UK and a recent peer-reviewed epidemiological analysis.

3. Other possibilities cannot be excluded, e.g., vertical transmission, environmental contamination, spontaneous occurrence for a small number of cases, etc. They should be further investigated.

4. Taking into account that:

   - meat products are produced according to the SSC's recommendations regarding animal source, age (30 months) and removal of SRMs and
   - there are so far no reasons to assume widespread and systematic inappropriate implementation of the current feed ban of 1996,

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of the BARB case. For example for some of the BARB cases, with available data about the dam, the dam was slaughtered or culled less than 6 months after the birth (less than six months post calving).

[2] This includes dead-on-farm animals ("fallen stock"), casualty animals (emergency slaughtered animals), and sick slaughter animals (animals sent for normal slaughter but found sick at the *ante mortem* inspection).

- in *absolute* terms and in relation to human exposure risk, the number of BARB cases remains below the upper limit set by the SSC in its opinion of November 2001,

the SSC considers that currently available data do not change its earlier risk assessment with regard to the UK DBES.

5. Both the implementation of feedbans (exact measures, their dates of implementation) and the surveillance of BSE differed until recently across the EU Member States and a large degree of harmonisation was reached in the course of 2001 and 2002 only. The comparison between Member States of numbers of BSE cases born after a feedban is therefore premature at this moment. The SSC considers that these numbers should continue to be monitored closely across all Member States and regularly evaluated.

REPORT ON BSE IN UNITED KINGDOM'S CATTLE BORN AFTER 31 JULY 1996 [BARBS]

Rapporteur: Sheila M. Bird: contributions from John W.Wilesmith

I. BACKGROUND AND MANDATE

In its opinion on the six BARB BSE cases in the UK since 1 August 1996 **(EC, 2001),** the Scientific Steering Committee (SSC) concluded in November 2001 that there was currently no reason for the SSC to assume an increased risk as compared to its assessments presented in previous opinions. The SSC did not consider at that moment a revision of its DBES or other BSE related opinions.

Because a feed-borne origin of the BARB cases could not be excluded and because of the continuing presence of BSE cases in surveys of the August 1966/July 1997 birth cohort (60+ month old) cattle in the Over-Thirty Months Scheme (OTMS) animals, the SSC recommended a large and significant epidemiological testing program to last until there is sufficient evidence for reassurance of the safety in terms of human exposure of the UK Date Based Export Scheme (DBES).

Should such program reveal a large number of (pre-clinical) BSE cases that cannot be attributed to maternal transmission, or a number of cases that can directly be related to other sources of infection, or provide indications that the number of infected animals around 30 months of age is higher than has been extrapolated from the model estimates, then the validity of the UK's DBES might have to be put into question. Active BSE surveillance has necessitated revision of UK's BSE modelling (Donnelly *et al*, 2002) and further work is being undertaken for UK's Risk Assessment Group who have the task of reviewing the OTM rule. As a possible practical guidance for deciding when the risk exceeds, independently from the source of infection, the level indicated in the SSC opinions of 1999 and 2000 on the UK DBES, the SSC indicated that if the number

of BARB cases would exceed the upper limit of approximately 55 cases[3] (all ages confounded) during a 12 months period in animals born after mid 1996, a new assessment would be required to identify possible new risks that were not taken into account in the SSC's opinions on the DBES. Also, if a new way of transmission other than feed or maternal would be strongly hypothesised or proven, it would indicate that the DBES alone is not sufficient anymore to guarantee the control of the disease in cattle and human security.

Between 1 December 2001 and 1 December 2002, 24 UK-born BARB BSE caseswere found in the UK, the highest number in any 12 months period so far.

The first BARB was reported on 8 May 2000 and there was then an almost 12 month gap with the second being reported on 1 June 2001. There is evidence that the 1997/8 cohort did not experience the same risk of exposure as the 1996/97 cohort. Commission Services nevertheless invited the SSC to:

i) Update its opinion of 29-30 November 2001 on the six BARB cases in the UK since 1 August 1996 in the light of the new BARB BSE cases;

ii) Judge whether it saw any reason to revise its earlier conclusion on the most likely route of infection or its assessment of the overall BSE risk in the UK and in particular related to the DBES.

To facilitate a judgement as to whether there is any reason to revise its earlier conclusion on the most likely route of infection or its assessment of the overall BSE risk in the UK and in particular related to the DBES, the SSC asked the TSE/BSE *ad hoc* Group to carry out a statistical evaluation of the BSE incidence in UK cattle born after 1 August 1996, and to compare it as far as possible with the BSE incidence in other EU Member States where (cross-)contaminated feed is still considered to be the main source of BSE.

[3] This is the upper limit of number of model-predicted cases for 2001, assuming an effective feed-ban and maternal transmission only. It corresponds with a human exposure risk in 2001 of less than 1 animal below 30 months of age and possibly and in the last 12 months of incubation. UK's modelling is under revision in 2003.

II. BARBS IN THE UK

II.1. DATA

Table 1 provides an overview of the 34 BARB-cases in the UK (Great Britain + Northern Ireland) between 1 August 1996 and end November 2002 which were reported by end January 2003 as having been identified clinically or by active surveillance.

In October 2002, Wilesmith (2002) reported on preliminary epidemiological analyses of *Great Britain's*[4] first 17 confirmed cases of BSE in cattle born after 31 July 1996. Sixteen were born in Great Britain plus one imported from the Republic of Ireland. Maternal transmission did not adequately account for GB's BARBs Their geographical distribution was consistent with widespread, but low-level, risk of exposure, and was distinct from Great Britain's two previous BSE epidemics - prior to the initial feed ban in 1988, and in the inter-regnum between 1988 and 1996 feed bans. Further analysis (J.W.Wilesmith, pers.communication: 16 January 2003) of the first 27 BARBs born in Great-Britain confirmed that the BARBs' geographical distribution was indicative of a wide-scale distribution of low-level BSE exposure.

[4] Northern Ireland's cases were not considered. NI's BARB incidence may have separate risk factors because of adjacency to the Republic of Ireland (ROI). NI's BARB incidence is disproportional, given the past BSE incidence in NI and GB. NI has experienced BSE in an animal born in 1999, as has the ROI. The putative incubation periods for these cases alone may suggest different exposure to that in GB. Contrariwise, active surveillance was comprehensive earlier in NI than in GB.

Table 1: UK BARBs to End November 2002 (sorted by date of birth of the BARB case)

Date of Birth	Region of birth and number of birth cohort	Target Group	*Clinical onset (CO), Slaughter/death (Sl)*	*Survival of Dam*	*Mater-nal?*
1996/09/10	NI 1	ACTIVE:CA	01/2001	Culled 30/10/98	open
1996/08/25	GB 1	SUSPECT	08/05/01 (Sl)	D.O.B: 21/09/91; Found death in trough (casualty) 14/11/96	M (3 months)
1997/05/20	GB 1	SUSPECT	24/05/01 (CO) 06/06/01 (Sl)	D.O.B: 01/12/89; Dam alive	No
1996/12/04	GB 1	SUSPECT	01/01/01 (CO) 28/06/01 (Sl)	Dam sold for further breeding 09/97; Slaughtered-OTMS 1/9/00 (udder damage)	No
1997/01/18	GB 1	SUSPECT	01/08/01 (Sl)	D.O.B: 09/01/92; Slaughtered OTMS 16/12/98 (barren)	?M
1997/04/25	GB 1	ACTIVE: CA	05/08/01 (Sl) Clinical signs evident	D.O.B: 31/07/90; Dam alive	No
1996/09/07	GB 1	ACTIVE: CA	11/11/01 (Sl)	D.O.B: 10/11/92; Dam slaughtered (casualty – lame) 25/11/99	No
1997/07/27	GB 1	ACTIVE: CA	16/11/01 (Sl) Clinical signs evident	Dam alive at 14/12/01 Age: > 6 years	No
1997/06/01	NI 1	ACTIVE: CA	20/11/01	?	?
1998/02/16	GB 2	ACTIVE: CA	05/12/01 (Sl)	Slaughtered OTMS 22/08/99 Age: > 4 years	?M
1997/01/04	GB 1	SUSPECT	11/01 (CO) 10/12/01 (Sl)	D.O.B: 26/08/91; Slaughtered OTMS 19/03/98 (barren)	?M
1997/03/09	GB 1	OTMS	18/12/01 (Sl)	No records	?
1997/02/12	GB 1	SUSPECT	01/12/01 (CO) 18/12/01 (Sl)	D.O.B: 14/02/93; Slaughtered OTMS 19/01/99 (barren)	?M
1997/07/30	GB 1	ACTIVE: CA	20/12/01 (CO) 24/12/01 (Sl)	D.O.B: 19/08/95; Dam slaughtered OTMS 01/09/97	M (2 months)
1999/05/25	NI 3	ACTIVE: CA	11/01/02	Slaughtered 01/09/99	M (4 months)
1996/09/29	ROI 1	ACTIVE: CA	31/01/02 (Sl)	Slaughtered in ROI for human consumption 01/05/98	?M
1997/04/27	GB 1	ACTIVE: CA	01/02/02 (CO) 06/02/02 (Sl)	D.O.B: 05/06/94; Dam alive	No

1997/06/28	GB 1	ACTIVE: FS	07/04/02 (SI)	Slaughtered as casualty NFI	?
1996/09/18	GB 1	SUSPECT	12/03/02 (CO) 08/04/02 (SI)	D.O.B: 31/01/86; Slaughtered OTMS 15/09/98	?M
1996/08/27	GB 1	ACTIVE: CA	01/04/02 (CO) 10/04/02 (SI) Clinical signs evident	D.O.B 06/03/88; Dam slaughtered as casualty (downer cow) 10/02/98	?M
1997/11/29	GB 2	SUSPECT	17/04/02 (CO) 23/04/02 (SI)	D.O.B: 26/08/93; Dam alive	No
1998/07/20	GB 2	ACTIVE: CA	02/07/02 (SI) Clinical signs evident	Born: pre 04/96; dead on CTS 11/10/00– no other records available	No
1998/03/04	GB 2	ACTIVE: CA	26/07/02 (SI)	D.O.B: 05/03/96 (imported from Holland); Dam alive	No
1998/07/21	GB 2	ACTIVE: CA	24/07/02 (CO) 02/08/02 (SI)	D.O.B: 04/07/93; casualty, calving problems 23/07/98;	M (0 months)
1997/09/28	NI 2	ACTIVE: CA	12/08/02 (NFI)	?	?
1996/08/22	GB 1	OTMS	10/09/02 (SI) Clinical signs evident	Culled before autumn 1998;	Open
1996/11/08	GB 1	OTMS	12/09/02 (SI) Death of owner	D.O.B: 1990; sold-dispersal; Slaughtered OTMS 01/07/97	M (8 months)
1997/02/21	GB 1	ACTIVE: FS	16/09/02 (SI) Clinical signs evident	removed 01/01/99 - No breeder's BSE1 (culled?)	Open
1997/09/17	GB 2	ACTIVE: CA	07/10/02 (SI)	Slaughtered OTMS 12/05/99 Age: > 5 years	?M
1996/10/04	GB 1	OTMS	14/10/02 (SI) 15/04/02 (CO)	Not recorded; No breeder's BSE1	?
1997/02/14	GB 1	SUSPECT	02/09/02 (CO) 11/11/02 (SI)	D.O.B: 08/12/89; Slaughtered (selective cohort cull) 18/05/97	M (3 months)
1997/02/12	GB 1	ACTIVE: CA	01/11/02 (SI) 23/10/02 (CO)	Slaughtered OTMS 07/03/97 Age: > 3 years	M (1 month)
1997/02/13	GB 1	OTMS	5/11/02 SI)	DOB: 10/10/94. Slaughtered OTMS 30/11/98	?M
1998/11/6	GB 3	OTMS	20/10/02 (C0) 22/11/02 (SI)	DOB: 01/90 Slaughtered/died 10/12/98 (sent to hunt kennels)	M (1 month)

Key:
- CA = casualty slaughter
- FS = fallen stock
- OTMS = over thirty months scheme
- NFI = No further information
- 1 = Birth cohort August 1996/July 1997
- 2 = Birth cohort August 1997/July 1998
- 3 = Birth cohort August 1998/July 1999

II.2. DISCUSSION

II.2.1. Great Britain's identification of BARBS

In Great Britain, BARBs have been identified ***either*** as clinical cases; ***or***, from 1 July 2001, by BSE screening of all cattle over 24 months either slaughtered as casualties or as fallen stock[5]; from 1 December 2001, by BSE screening in the Over Thirty Month Scheme of cattle from the August 1996/July 1997 birth cohort; and, from 24 August 2002, by BSE screening in the Over Thirty Month Scheme of all cattle aged over 42 months and born after 31 July 1996, which includes the 1996/1997 and subsequent birth cohorts. Cattle from the 1997/98 and 1998/99 birth cohorts would also have been subject to BSE screening ***if*** selected as part of UK's annual random sample of 40,000 post-July-1997 OTMS-slaughtered bovines. Thus, only from 24 August 2002 has UK's active BSE surveillance been comprehensive. [Note: from 1/12/2001 to 31/8/2002, 27,782 animals were tested in these later born cohorts. It looks to me that the sampling fraction was quite high as these animals would have been relatively young during this period for culling.]

During the **first three months of comprehensive surveillance** (September to November 2002), **nine** BARB BSE cases were identified, only one of which was a clinical suspect. Notice that clinical signs were evident at the time of slaughter or in retrospect for five of the remaining eight BARBs (at the time of slaughter: one OTMS, one fallen stock; in retrospect: two OTMS, one casualty). The number of confirmed BARBs slaughtered as clinical suspects in September to November 2002 may yet increase if confirmation delays are longer for clinical suspects than for BSE rapid test positives.

Future of comprehensive BSE surveillance in UK. As the number of similarly-BSE exposed post-July 1996 birth cohorts increases, some further increase in the number of UK (=GB + NI) BARBs per 12-months may be observed by dint of now-comprehensive, active BSE surveillance. For example, by January 2005,

[5] According to Wilesmith (2002). However, DEFRA's website suggests that surveillance of 25-30 month old fallen stock was not mandatory until 1 January 2002.

BARB-BSE cases may arise from six (not three) birth-cohorts ranging from August 1996/July 1997 (cohort 1, reference age 8 years) to August 2001/July 2002 (cohort 6, reference age 3 years).

II.2.2. Descriptive summary of UK's first 34 BARBS

Northern Ireland [4]: Four surveillance-detected BARBs were reported by Northern Ireland, two in 2001 (both from the August 1996 to July 1997 cohort, cohort 1 in **Table 1**) and two in 2002. The first NI BARB in 2002 (date of birth 1999/05/25, date of slaughter 2002/01/11) was a 32 month old casualty from the August 1998 to July 1999 birth cohort (cohort 3 in **Table 1**), the other (date of birth 1997/09/28, date of slaughter 2002/08/12) from the August 1997 to July 1998 birth cohort (cohort 2 in **Table 1**).

Great Britain [29 UK-born, one born in Ireland]: One 2002-slaughtered surveillance-detected BARB in GB was a January 2002 casualty which had been born in September 1996 in Republic of Ireland.

Twenty-two of Great Britain's 29 UK-born BARB BSE cases were from the August 1996 to July 1997 birth cohort (cohort 1 in **Table 1**), six from cohort 2 and one from cohort 3. Great Britain's first four GB-born BARBs in 2001 were all clinical suspects from the August 1996-July 1997 birth cohort (cohort 1 in **Table 1**). By contrast, the first GB BARB from the August 1997-July 1998 birth cohort (cohort 2 in **Table 1**) was a surveillance-detected 46 month old casualty (date of birth 1998/02/16, date of death 2001/12/05); and the first BARB BSE case from cohort 3 in **Table 1** was a surveillance-detected 36 month old in OTMS (date of birth 1998/11/06, date of slaughter 2002/11/22 with clinical onset one month earlier, at least in retrospect).

GB-born: slaughtered	Aug. 1996 – July 1997 birth cohort			Aug. 1997 – July 1998 birth cohort **[& cohort 3]**		
	Suspect	OTMS	Active: ca	Suspect	OTMS	Active: ca
2001	6	1	4	0		1
2002[end Nov]	2	4	5	1	**1 (cohort 3)**	4

30/34 BARBS were older than 48 months at slaughter; 13/30 were older than 60 months at slaughter; and 2/13 were older than 72 months, both OTMS-detected with evident or prior clinical signs.

For 29/34 BARBs there is information about the dam. In three of the 29 BARBs the available information about the dam leaves open the question about maternal transmission. For the 26 BARB BSE cases with sufficient data, the adjudication on maternal transmission is as follows: nine BARBs were **not** maternal transmissions because dam survived for at least two years after birth of BARB and to at least 6 years of age; in nine cases, the dam died within two years, but more than one year after, the BARB's birth so that maternal transmission cannot be ruled out, but is less likely; and the dam of eight BARBs was slaughtered within one year (0m,1m, 1m, 2m, 3m, 3m, 4m and 8m) of the BARB's birth (death of the dam: three in OTMS, three as casualty, one in selective cohort cull and one unspecified)

Finally, of 21 BARBs detected in GB by active surveillance of casualty or OTMS stock, 12 (or 57%: 95% confidence interval: 36% to 78%) had clinical signs either in evidence (6) or in retrospect (6).

II.2.3. Comparison of BSE positivity rates: GB, July 2001 to September 2002

By birth cohort and source of detection, 22 BARBs are summarized in **Table 2** for the notification period July 2001 to September 2002. The three birth cohorts represented in Tables 2a to 2c differ in reference age at time of slaughter and so their BSE positivity rates are not directly comparable between birth cohorts – except for *those shown in italics.* The latter are consistent with the hypothesis that the 1996/97 and 1997/98 birth cohorts have had similar low-level BSE exposure.

Pooled italicized data are [rate per 1 million]: *7/11993 risk stock*[6] *[584]; 1/17848 OTMS [56]*; and *3 clinical BSE*, so that incomplete active surveillance picked up an additional three BSE positives per clinical BSE. Overall, for the three surveillance periods documented in **Table 2**, there were five clinical BARBs to 17 BARBs detected by (only latterly fully comprehensive) active BSE surveillance.

Active surveillance of risk stock was, however, fully operational for all three birth cohorts during the notification periods in **Table 2**, from which we observe that similar numbers (roughly 24,000) of risk stock were slaughtered per birth cohort in the period July 2001 to September 2002 - notwithstanding that the birth cohorts differ in reference ages. Comparison of **bold rates for risk stock** in **Table 2** indicates that BSE positivity rate in risk stock is sharply age-dependent, as evidenced by non-overlapping confidence intervals **for reference ages 5 and 3 years**.

Because BSE positivity rate in risk stock is age-dependent, the BARB positivity rates shown in **Table 2** are not directly comparable with those reported by other Member States' active BSE surveillance of all risk stock over 24 or 30 months of age.

Cumulated over the three birth cohorts, which is reasonable if all three had similar low-level BSE exposure, UK's BSE positivity rate in the period July 2001 to September 2002 for risk stock born after 31 July 1996 was 13/ 71847 [181; 95% CI from 83 to 279]. This rate may increase as older-aged risk stock born after 31 July 1996 are screened.

However, the cumulative rate is unlikely to exceed the above pooled*italicised rate of 584*for approximately five year old risk stock.

Table 2a: August 1996 – July 1997 birth cohort {reference age = 5 years}

Period notified	**BSE positives [rate per 1 million]**				
	Risk stock [rate]: & 95% CI rate		OTMS [rate]: & 95% CI for rate		Clinical BSE
Jul – Dec. 2001	4/ 7484	*534: 146 to 1369*	1/12175	*82: 2 to 458*	*3*
Jan – Jun. 2002	4/11157		0/25512		1
Jul - Sept 2002	1/ 4404		2/13890		0
TOTAL: 96/97	**9/23045**	**391: 178 to 741**	3/51577	58: 12 to 170	4

Table 2b: August 1997 – July 1998 birth cohort {reference age = 4 years}

Period notified	BSE positives [rate per 1 million]				
	Risk stock [rate]: & 95% CI rate		OTMS [rate]: & 95% CI for rate		Clinical BSE
Jul – Dec. 2001	1/ 7820		0/ 717		0
Jan – Jun. 2002	0/11618		0/ 7776		1
Jul - Sept 2002	3/ 4509	*665: 137 to 1945*	0/ 5673	*nil: 0 to 649*	*0*
TOTAL: 97/98	**4/23947**	**167: 45 to 428**	0/14166	nil:0 to 260	1

Table 2c: August 1998 – July 1999 birth cohort {reference age = 3 years}

Period notified	BSE positives [rate per 1 million]				
	Risk stock [rate]: & 95% CI rate		OTMS [rate]: & 95% CI for rate		Clinical BSE
Jul – Dec. 2001	0/ 6884		1/ 784		0
Jan – Jun. 2002	0/12912		0/ 8883		0
Jul - Sept 2002	0/ 5059		0/ 5461		0
TOTAL: 98/99	**0/24855**	**nil 0 to 148**	1/15128	66: 2 to 368	0

III. INTERNATIONAL COMPARISON OF BSE POSITIVITY RATE IN RISK STOCK: BEFORE AND AFTER CONSTRAINT ON YEAR OF BIRTH OF RISK STOCK

III.1. INTRODUCTION

Comparisons between Member States and between the UK and other Member States have to be done with caution:

- When comparing incidences between countries, different scenarios may apply for the safeguarding of ruminant and animal feed: for example, UK's complete feed ban from 1 August 1996 (no MBM allowed for any animal) versus a ban on dead animals and SRM in the MBM processing and ban on MBM for ruminants, versus only the ban of MBM for ruminants. Also, most Member States only introduced in January 2001 a "real feed ban" comparable to the UK's "real feed ban" of 1 August 1996.
- Harmonised surveillance systems, involving also rapid testing of risk stock and applied to comparable age-classes, were achieved in the Member States at different times.

- Some BARB BSE cases could have resulted because their dam was late in her BSE incubation period and and therefore represented an enhanced risk for her calf. The percentage of dams in late BSE incubation when calved during August 1996 – July 1999 is directly linked to the size of the epidemic before 1996, which is non-comparable between countries, particularly for GBR IV versus III countries.

What precedes implies that the comparison between BSE incidence in UK cattle born after 1 August 1996 and the BSE incidence in other Member States can only have value in absolute terms and not for inferring either the origin of BSE cases in the various countries, or the efficacy of their risk management measures.

The fairest approach to compare BSE incidence between Member States that introduces the least errors is to compare BSE incidence in risk stock[6]. This approach is, however, not entirely free of bias:

- The proportion of the BSE cases detected through clinical surveillance or the screening programs at abattoirs of risk cattle varies between countries. Theoretically, this can occur because of geographical variation in the mortality of cattle, in BSE-associated culling, in the quality of active BSE surveillance, etc., but these factors are currently the subject of investigation by the EU's Community Reference Laboratory.
- The target groups considered as "risk stock" are clearly defined, but efficiency in detecting sick animals at ante-mortem may vary. This could lead to a reduction of the BSE positivity rate in risk stock and inflation of the rate in healthy slaughter animals. Also, UK's reimbursed OTMS may result in a reduced time-specific hazard for cattle to become risk stock after 30 months of age.

[6] This includes dead-on-farm animals ("fallen stock"), casualty animals (emergency slaughtered animals), and sick slaughter animals (animals sent for normal slaughter but found sick at the *ante mortem* inspection).

III.2. RESULTS AND DISCUSSION

Table 3 summarizes BSE positivity rates per 1 million risk stock for the six GBR III Member States which tested over 20,000 risk stock in January to June 2002 and for Ireland. UK's BSE positivity rates per 1 million testees in risk cattle born after 31 July 1996 conform with the BSE positivity rate for all risk stock in these six GBR III countries with more than 1 million adult cattle.

Table 4 presents BSE positivity during July 2001 to November 2002 in risk cattle born in 1996 or 1997-99 per million of adult cattle in the national herd. The chosen time period takes account of the fact that Member States' active BSE surveillance was not fully operational in the first semester of 2001 and had not started in UK because of its outbreak of Foot and Mouth Disease.

1996-born cattle include those born before the UK's real feed ban of 31 July 1996. The number of BSE positives in 1997 to 1999-born risk stock per 1 million adult cattle is therefore the better measure by which to compare UK's third-wave BSE epidemic (1) with the geographical BSE risk in other Member States' young stock. However, because the proportion of BSE cases detected through the screening of risk cattle varies between countries for reasons which include the quality of clinical surveillance, **Table 5** gives member states' total BSE positives in July 2001 to November 2002 for 1997 to 1999-born stock per 1 million adult cattle.

Table 3: BSE positivity rates for risk stock in Member States testing over 20,000 risk stock during January to June 2002

GBR III Member State:	Adult cattle (millions)	BSE positives in risk stock [rate per 1 million testees]	
Spain	3.38	34/ 44044	[770]
France	11.20	72/138131	[520]
Germany	6.57	27/139627	[190]
Belgium	1.49	11/ 22993	[480]
Netherlands	1.83	6/ 34342	[170]
Italy	3.40	8/ 44622	[180]
Ireland	3.43	118/ 49161	[2400]
UK	5.00	4/ 35687	[112]

Table 4: BSE positivity rate [July 2001 to November 2002] in risk cattle born in 1996 or 1997-1999 per 1 million adult cattle in national herd

Member State	Adult cattle (millions)	1996 born BSE +ves in risk stock [rate per 1m adult cattle]	1997-99 born BSE +ves in risk stock [rate per 1m adult cattle]
Spain	3.4	29 [8.5]	23 [6.8]
France	11.2	24 [2.1]	10 [0.9]
Germany	6.3	23 [3.6]	10 [1.6]
Belgium	1.5	5 [3.4]	3 [2.0]
Netherlands	1.7	5 [2.9]	5 [2.9]
Italy	3.4	14 [4.2]	6 [1.8]
Denmark	0.9	2 [2.3]	1 [1.1]
Luxembourg	0.1	1 [10.0]	0 [nil]
Ireland	3.6	40 [11.1]	2 [0.6]
Portugal	0.8	8 [10.4]	2 [2.6]
UK	5.0	30 [6.0]	15 [3.0]

Table 5: Total BSE positives (clinical + BSE rapid tested) for July 2001 to November 2002 in cattle born in 1996 or 1997-1999 per 1 million adult cattle in national herd

Member State	Adult cattle (millions)	1996 born BSE +ves in risk stock [rate per 1m adult cattle]	1997-99 born BSE +ves in risk stock [rate per 1m adult cattle]
Spain	3.4	38 [11.2]	36 [10.6]
France	11.2	53 [4.7]	16 [1.4]
Germany	6.3	65 [10.3]	21 [3.3]
Belgium	1.5	26 [17.6]	7 [4.7]
Netherlands	1.7	16 [9.1]	7 [4.0]
Italy	3.4	31 [9.2]	12 [3.6]
Denmark	0.9	5 [5.6]	2 [2.3]
Luxembourg	0.1	1 [10.0]	0 [nil]
Greece	0.3	1 [3.0]	0 [nil]
Austria	1.0	1 [1.0]	0 [nil]
Ireland	3.6	81 [22.6]	5 [1.4]
Portugal	0.8	33 [42.9]	13 [16.9]
UK	5.0	53 [10.6]	21 [4.2]

Table 4 is illuminating because a 95% lower bound on the Spanish rate for 1997 to 1999-born BSE positives in risk stock per 1 million adult cattle is 3.9 whereas the upper 95% confidence bound for Germany is 2.6. Spain apart, UK's 1997 to

1999-born cattle have the next highest BSE positivity rate in risk stock per 1 million adult cattle. However, UK's rate for 1997 to 1999-born cattle is not outlying in comparison with those for GBR III Member States.

Table 5, based on clinical plus screen-detected BSE positives in 1997 to 1999-born stock, affirms that UK's real feed ban of 1 August 1996 appears to have brought UK in line with other Member States before the effect of their feed bans of 1 January 2001 comes into evidence and despite UK's historically high BSE incidence.

IV. SUMMARY

1. Only from 24 August 2002 has UK's active BSE surveillance been comprehensive for cattle born after 31 July 1996. During the three months from September to November 2002, nine BARBs were confirmed, only one of which was a clinical suspect.

2. As the number of low-level similarly-BSE exposed post-July 1996 birth cohorts increases, some further increase in the number of UK BARBs per 12-months may be observed by dint of now-comprehensive, active BSE surveillance. Annual updating of this Opinion would be prudent.

3. BARBs detected by active surveillance outnumber clinical cases by at least three to one (17 to 5 during the period July 2001 to September 2002; the ratio was eight to one during September 2002 to November 2002 when UK's active BSE surveillance for cattle born after 31 July 1996 was comprehensive, but confirmation delays may be longer for clinical suspects than for surveillance detected BARBs).

4. UK's active surveillance of risk stock became effectively comprehensive in 2001. BSE positivity rate in the period July 2001 to September 2002 for UK risk stock born after 31 July 1996 was 13/ 71847 [181 per 1 million testees; 95% CI from 83 to 279].

5. The above BSE positivity rate per 1 million testees in UK risk stock born after 31 July 1996 conforms, in order of magnitude, with the BSE positivity rate (170, 180, 190, 480, 520, 770) for risk stock in six GBR III Member States with more than 1 million adult cattle which tested over 20,000 risk stock in January to June 2002; and is noticeably lower than Ireland's BSE positivity rate in risk stock (2400 per 1 million testees).

6. UK's age distribution of risk stock testees born after 31 July 1996, as above, is likely to be younger than for other Member States whose risk stock testees include older stock.

7. Number of BSE positives in 1997 to 1999-born risk stock per 1 million adult cattle is therefore a better measure by which to compare UK's third-wave BSE epidemic with the geographical BSE risk in other Member States' young stock.

8. 95% lower bound on the Spanish rate for 1997 to 1999-born BSE positives in risk stock per 1 million adult cattle is **3.9** whereas the upper 95% confidence bound for Germany's rate is 2.6 and the UK rate is 3.0 (with approximate 95% CI: 1.5 to 4.5).

9. Total (that is: clinical plus screen-detected) BSE positives in 1997 to 1999-born stock per 1 million adult cattle confirms that UK's real feed ban of 1 August 1996 has brought UK range in line with other member states (Portugal excepted) before the effect of their feed bans of 1 January 2001 comes into evidence. This comparability is despite UK's historically high BSE incidence with its attendant risk of maternally-related BSE exposure for 1997-1999 born stock.

10. There is no control group against which to compare the dam history for BARB BSE cases. Although maternal transmission has been ruled out in 9 out of 26 BARB BSE cases with sufficient data about the dam, in 8 of the 26 cases the dam died less than 12 months after giving birth to the BARB. In all of these 8 cases the dam's death preceded active BSE surveillance so that the dam's BSE status is not proven.

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APPENDIX: BSE incidence in young cattle, detected from July 2001 to November 2002

Healthy Slaughtered

	Cattle population	Number of cases in cattle born in:				Rate per million	
	>2 years (x 1000)	1996	1997	1998	1999*	1996	1997-1999
B	1475	17	4	0	0	11,5	2,7
DK	887	3	0	1	0	3,4	1,1
D	6339	30	4	2	0	4,7	0,9
E	3445	9	9	1	0	2,6	2,9
EL	331	1	0	0	0	3,0	0,0
F	11175	21	4	1	0	1,9	0,4
IRL	3590	10	0	0	0	2,8	0,0
I	3368	17	6	0	0	5,0	1,8
NL	1749	10	2	0	0	5,7	1,1
AU	1003	1	0	0	0	1,0	0,0
P	769	17	3	0	2	22,1	6,5
UK	5012	3	1	0	0	0,6	0,2

*: one Portuguese case was imported from Denmark and probably infected in Denmark

Suspects

	Cattle population	Number of cases in cattle born in:				Rate per million	
	>2 years (x 1000)	1996	1997	1998	1999	1996	1997-1999
B	1475	4	0	0	0	2,7	0,0
DK	887	0	0	0	0	0,0	0,0
D	6339	9	2	1	0	1,4	0,5
E	3445	5	5	0	0	1,5	1,5
F	11175	8	1	0	0	0,7	0,1
IRL	3590	30	2	0	0	8,4	0,6
NL	1749	1	0	0	0	0,6	0,0
P	769	8	5	1	0	10,4	7,8
UK	5012	20	5	0	0	4,0	1,0

Risk animals (detected by active monitoring)

	Cattle population	Number of cases in cattle born in:				Rate per million	
	>2 years (x 1000)	1996	1997	1998	1999	1996	1997-1999
B	1475	5	3	0	0	3,4	2,0
DK	887	2	0	1	0	2,3	1,1
D	6339	23	8	2	0	3,6	1,6
E	3445	29	19	4	0	8,4	6,7
F	11175	24	7	3	0	2,1	0,9
IRL	3590	40	2	0	0	11,1	0,6
I	3368	14	4	2	0	4,2	1,8
NL	1749	5	2	3	0	2,9	2,9
LUX	100	1	0	0	0	10,0	0,0
P	769	8	2	0	0	10,4	2,6
UK	5012	30	10	4	1	6,0	3,0

Culling cohorts

	Cattle population >2 years (x 1000)	Number of cases in cattle born in: 1996	1997	1998	1999	Rate per million 1996	1997-1999
D	6339	3	1	1	0	0,5	0,3
IRL	3590	1	0	0	1	0,3	0,3

Total

	Cattle population >2 years (x 1000)	Number of cases in cattle born in: 1996	1997	1998	1999	Rate per million 1996	1997-1999
B	1475	26	7	0	0	17,6	4,7
DK	887	5	0	2	0	5,6	2,3
D	6339	65	15	6	0	10,3	3,3
E	3445	38	31	5	0	11,0	10,4
EL	331	1	0	0	0	3,0	0,0
F	11175	53	12	4	0	4,7	1,4
IRL	3590	81	4	0	1	22,6	1,4
I	3368	31	10	2	0	9,2	3,6
NL	1749	16	4	3	0	9,1	4,0
LUX	100	1	0	0	0	10,0	0,0
AU	1003	1	0	0	0	1,0	0,0
P	769	33	10	1	2	42,9	16,9
UK	5012	53	16	4	1	10,6	4,2