Opinion on Monitoring Some Important aspects of the evolution of the Epidemic of BSE in Great-Britain (Status, April 1999)

Adopted by the Scientific Steering Committee at its meeting of 27-28 May 1999

Text subject to possible further editorial changes

(The table in annex was amended on 3 June 1999)

Report of the Working Group

1. The questions:

In its Opinion of 8-9 December 1997 on *The UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases*, the Scientific Steering Committee considers that " *the combination of both proposals, if properly implemented and taking into account the requests made by the SSC in the above report, will lead to a major risk reduction of human exposure to the BSE agent*. (...)"

The SSC further considered that " *The above conclusions should be reviewed if the decline in the current epidemic fails to conform to predictions or if new facts indicate that other risk factors may be involved*."

In March 1999, the Commission therefore requested Scientific Steering Committee was requested to address the following questions:

1. How does the SSC assess the current and expected (1999-2004) evolution of the number of BSE cases in the UK?

2. Is the current number of cases in line with the scientific expectations?

3. If not, what are the most probable explanations for the difference between the observed and the predicted values (e.g. routes of transmission, problems in the statistical models on which the predictions are based)?

4. What is the significance of the observed development of the epidemic in terms of consumer health protection?

5. In the light of the above, would an extension of the Selective Cull Scheme to currently not covered birth cohorts reduce the risk, and if yes to what extent, that BSE-infected animals enter the food chain?

6. In the light of the above, would the continuation of the OTM Scheme for animals falling under the Date-based Export Scheme reduce the risk, and if yes to which extent, that BSE-infected animals enter the food chain?

A special working group was created, which prepared the evaluation hereafter.

2. Evaluation

2.1 *P reamble*:

For the monitoring of the evolution of an epidemic, availability of information on the clinical and pathological profile of the population is needed to determine whether the disease persists at an endemic level or whether there is evidence of a trend that might indicate the fading out of the infection. In this context the age structure of the sampled animals is the key point for understanding the evolution of the disease. Results should be reported avoiding the mere large data set of incidence in the whole population and maintaining age structured data according to age classes.

However, recent data on the age structure were not available to the SSC, and this aspect is therefore not addressed in the present opinion.

2.2. The evolution of the BSE epidemic in Great Britain (more precisely England, Wales and Scotland, excluding the Channel Islands and Northern Ireland), is shown in the first part of Annex 1.

Predictions from several available models have been compiled in the subsequent parts of Annex 1.

The Working group comments as follows on Annex 1:

2.3. Some general aspects that are crucial for the interpretation and comparison of such predictions should be considered:

- Formulation and estimation of a prediction model is based on assumptions. Therefore one should consider which assumptions have been made. Are they valid with regard to scientific and administrative knowledge? Do they reflect the future situation? Which assumptions are mere guesses without quantifiable uncertainty?
- Concerning model estimation the goodness-of-fit and the structure of unexplained residuals could be of interest. On the other hand there might be some problems with so-called overfitting the data. This danger occurs when complicated models with many parameters are estimated to fit a comparatively low number of data points.
- As the prediction model is estimated to fit past data it must be considered when the predictions were made, i.e. on which observed data the forecast is based. There might be new developments and changes in circumstances that could not be foreseen at the time when predictions were made.
- When comparing the predictions with the actual data observed for instance for 1998 one should compare them with prediction intervals, not only with 'mean predictions' as these do not reflect and account for uncertainties in parameter estimates and unexplained residual deviations from the prediction model as such intervals do. The width of these intervals is depending on the distance between the point in time at which the prediction was made as well as on the point in time for which a prediction is calculated. This reflects the growing uncertainty the longer the observed development is projected to the future.
- For 1998, the upper 95% confidence limit estimate of the UK Central Veterinary Laboratory (CVL)-model appears to be more close to the observed number of cases than the central estimate. This effect may result from a systematic bias due to the lack of data in the model from the last 6 months before the date of the prediction. This lag period is necessary to ensure a reasonable complete case ascertainment from the suspect cases being investigated. This effect is thought to be more and more severe as the size of the number of cases decreases, and as the predictions become increasingly sensitive to the lack of data on the most recent observations.

2.4. BSE case numbers in Great Britain have been falling until 1998, i.e. as far as data are available right now. However, there is not such a rapid decline as suggested by simple point-predictions made from the Oxford-model on the basis of data available in 1996 (this model seems to give central estimates which are somewhat lower than the observed numbers).

With regard to prediction intervals, however, there is agreement of the 1998 incidence with predicted numbers. Furthermore, there is consistency of the predicted numbers in the different models for 1999- 2001, showing a relatively similar degree of decline for all assumptions (1999: min. 456; max. 2409; 2000: min. 172; max. 1555; 2001: min. 72; max. 1012). Unless new unforeseeable events interfere, the SSC is reasonably confident that the decline will proceed as predicted (supposing that the Over-Thirty-Months Scheme (OTMS) will be continued as planned and that the hypothetical presence of BSE in sheep is carefully monitored, so that possible negative effects on BSE in cattle can be excluded).

Obviously, estimates of prevalence will become available if large scale testing with validated tests is applied, especially in targeted populations (fallen stock, emergency slaughter, etc).

2.5. The predictions for 1998 listed in the table are partly in line with the current number, partly they deviate depending on when the predictions were given and on the assumptions made. The 'Oxford'-model (Anderson *et al*, 1996) for instance gives different prediction intervals for different scenarios.

Different predictions, using the same assumptions (i.e. 10% maternal transmission for 6 months - no horizontal transmission (2 predictions), and 10% maternal transmission for 12 months - no horizontal transmission (2 predictions)) differ to a certain extent presumably depending on the year when the predictions were given, but they are mostly all in agreement within the range of confidence for the observed cases in 1998. Only two predictions were lower than the observed incidence of 3,161 cases in 1998. For a 10% maternal transmission for the last 6 months of the maternal incubation period and no horizontal transmission, Ferguson *et al* (1997) predict the following values for 1998: minimum: 1,450; mean: 1,741; maximum: 2,098. For a 10% maternal transmission for the last 12 months of the maternal incubation period and no horizontal transmission, they predict: minimum: 1,568; mean 1,929; maximum: 2,370.

One could conclude that the predictions in most models were in line with the 3,161 observed cases in 1998.

2.6. Uncertainties in the models:

- Models are based on assumptions on alternative ways of transmission and on different degrees of maternal transmission and genetic factors.
- The contribution of other species to continuing contamination of animal feed with the BSE agent (e.g. sheep) or other routes of transmission is not clear.
- The degree of underreporting can not be quantified. Underreporting may become more significant at the tail end of the epidemic because of decreasing disease awareness.
- The effect of variations in the clinical presentation of BSE is only partly known. Pathological lesions diagnostic for BSE have been found not only in clinical cases, but also in cohort animals that showed no clinical signs, but which were considered to be in the late stage of incubation. On a more theoretical note: how significant are silent or atypical clinical forms? Have they become more significant towards the end of the epidemic?
- The last two factors appear to be far more important than previously thought in the Swiss epidemic, as it has recently been reported on the basis of systematic testing of fallen livestock (M.Vandevelde, pers.comm.)
- Additionally there are some assumptions in the 'Oxford'-model that could be questioned, for instance the modelled infectivity of feed-stuff which seems to be estimated to fit the observed case numbers up to 1993 and set simply to 0 since then. There are some doubts whether this assumption really holds. The decrease in the cattle and calves population sizes that could be observed between 1985 and 1995 is incorporated in the model. However, which assumptions are made on such developments for the future to base predictions on is not clear.
- The CVL-model seems to be somewhat more 'data-driven' than the 'Oxford'-model as it does not introduce as many effects with biological interpretations. However, it is difficult to tell how far the model estimates really disagree, as predictions from the different models in the table were made at different points in time. However, the differences in estimates are not that large, as the 'Oxford'-model is estimated with close reference to the observed numbers of cases as well. For effects like infectivity of feed-stuff or incubation time distributions there is no independent information but they seem to be estimated from case numbers and ages at onset.
- When it comes to predicting future numbers of BSE cases, one weakness of the CVL-model is that it is based on absolute numbers of cases, not on relative frequencies accounting for demographic factors like decreases in cattle population size. So the CVL-predictions may not account for changes in such developments in the future.

2.7. There is evidence that the possibility of meat-and-bone meal (MBM) inclusion in feed rations for bovines has become remote since 1996. Culling offspring of BSE animals should reduce the effect of maternal transmission (if it occurs) on the BSE epidemic considerably. These two measures tend to reduce concerns about uncertainties in the models. However, it needs to be stressed that the assumption of no possibly infected MBM having been fed to cattle, is a highly crucial factor in the future evolution of the BSE epidemic.

The models all predict a continued decline of the epidemic and the rate at which the decline takes place seems acceptable. Thus there is no reason to consider taking more action at this point. Moreover, we have no idea by which means to speed up the decline further. Model exercises suggest that other possible (future) interventions may appear to be not very effective.

2.8. However, before the decline is not anymore going as expected or not anymore at an acceptable rate, it is worthwhile to consider how such a change in decline will be detected. When the expected number of cases is low, stochasticity will

influence the observed numbers of cases and thus it is not sufficient to see that the number of cases exceeds the expected numbers. In part, the indecisiveness resulting from stochasticity can be avoided by only studying longer time periods. Right now weekly observations do fluctuate too much to be useful to base decisions on. In the future, the time period on which decisions about the future evolution can be made will become much longer. It is therefore worthwhile to consider how statistical methods can be used to test for a change in decline, because that will increase the power for detecting a change early and give a formal framework by which to decide that such a change has taken place.

In the paper by De Koeijer *et al.* (1999) the reproduction ratio R (expected number of new cases per case) due to transmission via feed is calculated from experimental data on infectivity and effects of rendering. The data of the BSE epidemic is then used to quantify the other infection routes. In the 'absence' of the feed route R is below 1 and thus the number of cases will decrease steadily. The predicted rate of decrease from that work could be used as basis for statistical testing whether the observed number of cases is still decreasing as expected. The information used to make these calculations is the number of cases in the past, the distribution of the time from infection to clinical onset, and the reproduction ratio R. Two major elements of variation play a role: uncertainty in the parameter values of the model and stochasticity in the case numbers when these are low. The former is known from the data analysis and the latter could be assumed to follow a Poisson distribution. If the number of cases at any moment in time would be more than expected from this stochastic model within the 95% confidence limits, the situation with respect to BSE should be studied more careful to find causes for the deviation.

3. Opinion

On the basis of the above evaluation by the Working Group, the Scientific Steering Committe answers as follows to the questions of the mandate:

3.1. Question 1: *How does the SSC assess the current and expected (1999-2004) evolution of the number of BSE cases (epidemic) in the UK?:*

The current and expected evolution of number of BSE cases in the UK (1999-2004) are in line with all models, but the tail of the epidemic will not necessarily present a constant decline, certainly not when small numbers are involved; a reassessment can be needed if by applying better diagnostic measures and an improved quality of surveillance a much higher than expected number of cases is revealed (potential problem of underreporting). In the latter context it is mentioned that the relative importance of underreporting may increase as the incidence decreases at the tail-end of an epidemic.

3.2 Question 2: *Is the current number of cases in line with the scientific expectations?:*

Current numbers of cases are in line with the scientific expectations.

3.3 Question 3: *If not, what are the most probable explanations for the difference between the observed and the predicted values (e.g. routes of transmission, problems in the statistical models on which the predictions are based)?:*

Not applicable: no significant difference between observed and predicted values.

3.4. Question 4: *What is the significance of the observed development of the epidemic in terms of consumer health protection?:*

In view of all the evidence, it remains difficult to answer question 4 in concrete terms since the transmission of BSE to humans is influenced not only by the current state of the epidemic but also by many other factors. All that can be said is that, in line with the predicted and observed decline of the epidemic, it seems to be plausible to expect that the risk of exposure of the consumer to the BSE agent (as reported in MAFF, 1998b, 1998c, 1998d, 1998e) is likely to decline also. However, to determine the relationship between a level of change of the epidemic and the corresponding level of change in consumer health protection requires very detailed, case specific analysis.

A special Working Group "Human Exposure Risk" of the SSC is presently assessing the risks resulting from the exposure of humans (individuals and populations) to various levels of possible residual infectivity in cattle-derived

products. One of the major problems faced by this Working Group is to make realistic assumptions regarding the initial infectivity in the raw material, the dilution and the clearance during processing, the consumption pattern, etc., which vary highly between member states and between production plants.

3.5. Question 5: *In the light of the above, would an extension of the Selective Cull Scheme to currently not covered birth cohorts reduce the risk, and if yes to which extent, that BSE-infected animals enter the food chain?*

The question on the Selective Cull is rather complex and requires some more reflection. The SSC will provide an answer on this point at its next meeting.

3.6. Question 6: *In the light of the above, would the continuation of the Over-Thirty-Months Scheme (OTMS) for animals falling under the Date-based Export Scheme (DBES) reduce the risk, and if yes to what extent, that BSE-infected animals enter the food chain?.*

This question is again difficult to answer because too many factors are involved. In general, the OTMS is assumed to significantly reduce the risk that animals could reach human consumption being in a late stage of BSE-incubation. This is only relevant as long as it can not be excluded that BSE-incubating animals are slaughtered. For answering the question it is therefore necessary to assess the efficiency of the real total ban which became effective on 1 August 1996.

As long as the presence of BSE can only be verified on the basis of clinical symptoms, the SSC is of the opinion that a final conclusion as to the risk of animals falling under the DBES to develop BSE can not be drawn before August 2001. At that time, 5 years after the critical date, the majority of animals infected shortly after that date, should show clinical signs. Waiting longer would increase the validity of zero-incidence. [1]

If methods are available to detect pre-clinical BSE-cases, such a conclusion may be drawn earlier. The precise conditions (sampling size etc.) have to be determined once the test-method(s) is (are) known.

The SSC is therefore of the opinion that for the time being the OTMS reduces the risk that might continue to exist due to possible failures in the implementation of the ban and/or maternal transmission.

An active surveillance of animals falling under the OTMS and in particular those being born after 01.08.96 might help to confirm the effectiveness of the real total ban. If a 100% effectiveness can be proven, no reason would be seen to continue the OTMS in its present form for animals born after the ban. As long as this 100% effectiveness is not proven the SSC sees the OTMS as a necessary additional safeguard.

4. Acknowledgements

5. Non-exhaustive list of the consulted literature and documents

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Annex 1. **BSE Epidemic in Great Britain: Number of cases observed (Ref. 1) and predicted (Ref. 2 to 6) according to different available models (see references below table)**

Great Britain			Observed BSE incidence (confirmed cases) in Great Britain										
			Value	1996	1997	1998	04.98 - 03.99	1999 (on: 28.05)	2000	2001	2002	2003	2004
1			Number:	8016	4312	3176	2872 (3 pen-ding)	(793) (74 pen-ding)			?	?	?
Great Britain			Predicted trends in BSE incidence (and higher and lower 95% prediction interval)										
Ref	Model's key elements/ variables / assumptions	Period ahead	Value	1996	1997	1998	04.98 - 03.99	1999	2000	2001	2002	2003	2004
2	Age-period-cohort model, ignoring last 6 month's data. Predictions for 1996 and 1997 based on model run 03.96.	3 years	Lower	8093	4860	2957	2370	1597	743				
			Expect.	8271	4999	3066	2724	1891	951				
			Higher	8449	5138	3175	3078	2185	1159				
3	10% maternal transmission (6months) - no horizontal Transmission.	6 years	Lower	6541	3006	1153		388	128	45			
			Expect.	7386	4111	1864		682	221	72			
			Higher	8856	7664	7025		5909	3660	1592			
4.	10% maternal transmission (6 months) - no horizontal transmission.	6 years	Lower	7356	3583	1450		534	198	76			
			Expect.	8075	4197	1741		641	235	89			
			Higher	8944	4944	2098		772	280	105			
3.	10% maternal transmission (12 months) - no horizontal transmission.	6 years	Lower	6085	2559	960		357	140	56			
			Expect.	6740	3145	1247		456	172	68			
			Higher	8291	6904	6365		5417	3388	1499			

Ref	Model's key elements/ variables/ assumptions	Period ahead	Value	1996	1997	1998	04.98-03.99	1999	2000	2001	2002	2003	2004
	10% maternal transmission	6 years	Lower	7363	3677	1568		628	259	111			
4.	(12 months) - no horizontal transmission.		Expect.	8126	4404	1929		764	309	131			
		Year	Higher	9054	5289	2370		930	370	156			

Great Britain			Predicted trends in BSE incidence (and higher and lower 95% prediction interval)										
Ref	Model's key elements/ variables/ assumptions	Period ahead	Value	1996	1997	1998	04.98-03.99	1999	2000	2001	2002	2003	2004
	No maternal transmission	6 years	Lower	8383	5624	3683		2356	1517	988			
4.	but horizontal transmission		Expect.	8654	5792	3765		2409	1555	1012			
	for the last 6 months.	Y	Higher	9440	6413	4069		2569	1669	1094			
	No maternal, no horizontal	6 years	Lower	7044	3774	1654		560	152	34			
3	Transmission.		Expect.	7988	5573	3644		1896	744	225			
			Higher	9306	8369	7762		6545	4042	1728			
	No maternal, no horizontal	6 years	Lower	7673	4136	1819		659	211	63			
4	Transmission		Expect.	8452	5125	2628		1090	380	118			
			Higher	9355	6381	4011		2169	943	337			
5	Not specified	7 years	Expect.	-	-	2320		1125	675	405	243	146	88
6, 7	Estimation of basic reproduction ratio R_o, taking into account: UK risk management measures prior to June1996 (SRM bans, feed bans, ...) [measures after June 1996 unlikely to have large effects before 2000)]; age distribution of cases; awareness, surveillance and reporting not changed since 1990; underreporting before 1990.*	3 years (and with decreas. confid. for up to 10 years)	Expect.	7006	4251	3037		2201	1141				

* *Remark* : Misjudging the speed and rate of implementation of the control measures and the period after which they will effectively have results, may have a rather large impact on the estimated new prevalence.

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[1] The SSC would like to underline that small numbers of born-after-the-ban cases might be unavoidable because of the possible existence of maternal transmission. Any such case should, however, be very carefully analyzed in order to identify flaws in the ban.