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HANDBOOK

FOR THE ASSESSMENT OF THE

GEOGRAPHICAL BSE-RISK

ANNEX 4

Example of a Report

On the Assessment

Of the Geographical BSE-Risk

Of

<a hypothetical Country[9]>

[9] The example text for a hypothetical country is deliberately not fully consistent. However, any real report should be fully consistent, comprehensive and logic. Experts are invited to include graphics if needed. Even hand-made drawings are useful.

Overall assessment

<*Country*> is regarded to have a geographical BSE risk level <A, B, C, D>.

Justification

Completeness of the dossier

Guidelines for the experts:
If the dossier is not sufficiently complete, describe the gaps and the additional sources of information used. (Copies of the additional information sources have to be added to the dossier stored by DG XXIV.) Interpolations that have been made and/or assumptions used have to be summarised, details should be given under the corresponding headings. Indicate if and how the country could improve the basis for assessment (not necessary the result) by providing additional information (specify).

Example text:
The dossier was responding to all points on which information was requested. In general it lacked appropriate time series.
With regard to population structure the age distribution at slaughter was incomplete or lacking for most periods. Information on husbandry systems and the number of cattle and their age in these systems was to general to provide more then a general impression. Information on sheep and goats was lacking. Gaps where closed by using EUROSTAT and other community databases.
Trade statistics where rather complete until 1993 but information on the use made from the imported animals, semen and embryos was incomplete. Assumptions where made on the basis of experience available to the FVO and after discussion with the Country expert.
The information on animal feed was abundant but the key information, i.e. on MBM-fed to ruminants was neither convincing nor consistent nor complete. The situation for sheep and goats was even worse then for cattle. Import/export figures where incomplete, in particular as regard to composite feed containing mammalian protein. Assumptions had to be made because no alternative information sources could be identified. Also the country-expert could only provide estimates. The assumptions are described below.
The information on the MBM-and SRM-bans was felt to be complete, except for compliance figures and on cross-contamination. For compliance it was assumed to have reached 60% within the first year after implementation, 80% in the second year, 90% in year 3 and 95% since.
The information on surveillance was very well presented but did not respond sufficiently to the methodological aspects of BSE-diagnosis. Based on information from the FO it was assumed that only histopathological methods have been used until recently.
On rendering and feed processing the information was very detailed but not fully consistent. Evidence on compliance with the existing regulation was absent. The relative importance of different rendering systems and their respective raw-material sources could only be indirectly concluded on. Based on information from the FVO it was assumed that the compliance is not above 80% and that only 50% of the rendered material is exposed to the harsh conditions needed to reduce BSE-infectivity.

The information on culling is not fully complete but remains theoretical because it was never applied until now.

Discussion of the eight factors influencing the propagation and processing risk

Summarise the factor by factor analysis.

Guidelines for the experts:
Here the result of the qualitative factor-by-factor analysis should be presented and summarised. It gives the main reasons for the geographical BSE-Risk level proposed above.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Estimating the impact of the eight factors on the propagation and processing risk showed a general trend towards a lower risk. Since 5 years all risk indicators point to a certain capacity to reduce or control any remaining risk. However, the information on MBM feeding to ruminants did not allow to assume that MBM was not fed to cattle until rather recently. Even after the MBM ban of 1994 cross-contamination of ruminant feeds where still found until late 1996. The rendering system is still showing weaknesses, despite all improvements. The surveillance is now good but doubts are raised on the capacity to discover in-frequent BSE-cases in the past.
Hence the experts came to the conclusion that the geographical BSE-risk level is < A or B or C or D>.

Factor by factor discussion

1. Structure and dynamics of the bovine, ovine and caprine animal populations

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. Address the impact on the propagation and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

The cattle population is characterised by a high proportion of adult dairy cattle (more then 30% of the cattle population are dairy cows older than >24 months). These dairy cows are normally intensively managed and receive rather high amounts of supplementary feed. A decrease in overall population indicates a period of higher than normal age of the cattle, in particular as the figures for calves slaughtered increase in the same period of time ….
The impact on the propagation and processing risk was rather constant over time.

2. Animal trade

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. Address the impact on the propagation and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

In the period 1985 to 1992 several thousand of life-cattle where imported from the UK every year. However, most have been slaughtered and processed at very young age and in the year of import and of the few surviving, 2 out of 6 developed subsequently BSE. Due to the relatively small number (in comparison to the national cattle population) the impact on the processing risk remained rather marginal.
MBM was not officially imported but no guarantee could be found that it was not semi-legally imported in composite feed etc. The source of the latter imports could not be identified. Together with the imported animals, which finally also enter the rendering system, the impact

of the potential import of MBM on the propagation risk was felt to have been marginal. However, a certain import could not be excluded and a risk, that BSE was imported exists.

3. Animal feed

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. Address the impact on the propagation and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

The dossier demonstrated convincingly that feeding MBM to ruminants was never common practice. However, it could not proof that high-yield dairy cattle would not receive it as part of their normal diet. Given the price advantage of MBM over vegetable-protein in the early 90th, it has to be assumed that MBM was imported, including (illegally) from the UK and that hence the high yield cattle population was exposed to (potentially contaminated) MBM in the early 90th (1990-1994).
The possibility that cattle were fed MBM until end 1994 or even beyond points to an enhanced propagation risk. It can be assumed that MBM is not any more fed to cattle since end 1994. Hence the propagation risk is dramatically reduced, even if cross-contamination may still take place occasionally.

4. Meat and bone meal (MBM) bans

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. Address the impact on the propagation and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

A ruminant to ruminant ban was first established in 1992 but enforcement was not convincing before 1994 when it was enlarged to an MBM-ban. Even in 1996 MBM was still found in 6% of the samples taken from "MBM-free" feed and it therefore has to be assumed that cattle were stile exposed to potentially MBM as late as 1996/97.

5. Specified bovine offal (SBO) and specified risk materials (SRM) bans

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. If possible address also the impact on the cattle exposure risk, the propagation risk and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

An SRM-ban was introduced in 1992, at the beginning only including Brain and Spinal cord and only since 1996 also including other SRMs. The information on compliance is incomplete but from the FVO mission reports it can be concluded that the compliance was only gradually improving. Today the compliance is assumed to be good (>90%).

6. Surveillance of TSE, with particular reference to BSE and scrapie

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. If possible address also the impact on the cattle exposure risk, the propagation risk and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Current situation: The current surveillance for TSEs is seen to be adequate and able to identify even very low level of incidence of BSE. However, no plans for active surveillance exist
Historical development: The surveillance system was not able to identify BSE-suspect cases until the introduction, in 1997, of obligatory laboratory verification of cattle brains from all cattle with CNS-disorders. Even if BSE was a notifiable disease since 1990, the insufficient compensation (less than the market price) and the obligatory culling of entire herds renders full compliance unlikely.
The laboratory procedures to verify for BSE where inappropriate until 1993, when a central laboratory was set-up and histopathological training was provided. Since 1997 also immunoblot methods are used and the current verification can be assumed to be as good as currently possible.

7. Rendering and feed processing

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. If possible address also the impact on the cattle exposure risk, the propagation risk and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Current situation: The country has ZZ rendering facilities of which currently XX work in accordance with the rendering standard (133/20/3). These facilities provide YY% of the national MBM-production. The remainder must be regarded to be unsafe. If BSE would enter it the rendering process would not be able to reduce significantly the infectivity.
Historical development: Before 1973 all rendering facilities operated in batch modus and at conditions close to or more severe than 133°C, 20min. Subsequently to the first oil crisis more energy efficient methods (continuos, lower temperature and pressure, and shorter process duration) where introduced. This implies that the ability of the rendering system to reduce BSE-infectivity decreased significantly. In the period 1980 to 1994 most rendering facilities did not apply appropriate rendering procedures and only in 1994 a part of the capacity was switched to the required conditions (133/20/3). This part of the rendering facilities was dealing with the so-called high risk materials while the other materials where continued to be processed at lower temperatures and pressures. A significant part of the rendering system is still not operating at 133/20/3. In relation with the MBM-feeding habits the insufficient rendering lead to significant propagation risk during a long period of time (roughly 1975 to 1996).

8. BSE or scrapie related culling

Guidelines for the experts:
Description of key characteristics and their importance for the geographical BSE-risk. If possible address also the impact on the cattle exposure risk, the propagation risk and the processing risk.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Current situation: An effective culling system, including offspring of cases is in place but has not been applied to cattle, yet.
Historical development: No culling was yet necessary in the context of BSE but since 1990, when BSE became a notifiable disease, it is foreseen to cull the entire herd in which a BSE-case is confirmed. Plans for a cohort culling exist since 1996 and the required tracing system is in place since the same year.

Scrapie culling has been executed at three occasions in 1992, 1995, and 1997. The entire herds where culled in which the scrapie cases where found. In addition the herds of origin where placed under surveillance and in one case culled as a new scrapie occurred there.

Dynamics of the propagation and processing risk

Guidelines for the experts:
Present the dynamics of the processing and propagation risk over time (graphic) and explain the main conditions responsible for it. Events, which are assumed to have been of particular importance, have to be described.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Figure <n> shows the development of the different risk factors over time, Figure <n+1> shows the related development of the processing and propagation risk over time.
Comments on figure <n>:
The risk factor "animal feed" shows a strong risk enhancement potential until 1994, when the first feed-ban was introduced. Currently it is regarded to be unlikely that cattle receive MBM and hence the factor has a risk reduction potential. (Similar text on the other risk factors).

Comments on figure <n+1>:
As the rendering efficiency is still not sufficient, the propagation risk was rather high until 1995 when the MBM ban became really effective. As the processing risk is related to the propagation risk of the past it is currently still rather high. (In case that a semi-quantitative estimation of the processing risk was carried out, this curve should be compared to the one produced from the qualitative factor by factor assessment and differences should be addressed.)

Concluding remarks (should be in line with the summary given above)

Guidelines for the experts:
Summarise the main arguments leading to the proposed level of the geographical risk on the basis of the discussion of each risk-factor, as given above.

EXAMPLE TEXT REFERRING TO A HYPOTHETICAL COUNTRY

Given the shortcoming in the data presentation and the risk enhancement capacity of the risk factors MBM, animal feed and rendering which is still existing (rendering) or was only recently rectified (MBM, feed), the foreseeable geographical BSE-risk is seen to be considerable. As it can not be fully excluded that BSE has been imported and as the system has the tendency to propagate it, it has to be assumed that this significant risk continues to exist for the next years.
However, the risk is not regarded to be high because until now no BSE has been seen and the likelihood that BSE has been imported is not regarded to be high, neither.
Due to the shortcomings mentioned, the geographical BSE-risk level is proposed to be <A or B or C or D>

HANDBOOK

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GEOGRAPHICAL BSE-RISK

ANNEX 5

Guidelines for the semi-quantitative estimation of the cattle exposure risk (CER) and the processing risk (PR)

Guidelines for estimating the cattle exposure risk (CER) and the processing risk (PR)

The cattle exposure risk

The cattle exposure risk is defined as the probability that a cattle is exposed to an infective dose of the BSE agent, within a given time period.

However, currently the infective dose of BSE for cattle is not known, the effect of cumulative small doses is not clear and the infective load of potentially contaminated cattle feed is not evaluated. It is therefore necessary to define the exposure risk as the probability that any exposure to the BSE-agent took place.

For the purpose of the risk assessment the exposure risk should be estimated for each year. If the exposure risk is assumed to remain stable, several years might be summarised to periods.

To estimate the exposure risk four steps are to be taken:

1. The fraction of the cattle population that is likely to have received supplementary feed should be estimated because these feeds are the most probable source of an exposure to the BSE-agent.
2. The fraction of the supplementary feed given to cattle which could have contained mammalian (or better: ruminant) protein should be estimated. This will allow to estimate the fraction of the cattle population likely to be exposed to the BSE-agent via its feed.
3. The degree to which the mammalian (ruminant) proteins could be contaminated with the BSE-agent has to be assessed.
4. From the estimation of the cattle population exposed to mammalian (ruminant) proteins and the estimation of the BSE-contamination of these protein the Cattle Exposure Risk can be derived.

Estimating the fraction of the cattle-population which have been fed supplementary feed[10].

Supplementary feed is given to cattle depending on their necessity or (perceived) usefulness. Among others, traditions and habits but also climatic factors and production targets will determine this practice.

Special emphasis should be attached to concentrates given as additional protein source. In the past they often contained mammalian protein, depending on the types of proteins needed and the relative price in relation to other protein sources.

The evaluator is asked to determine the fraction of cattle that have been fed supplementary feed for the beef and dairy cattle, in age classes below 2, 2-3, and above 3 years. The table below gives a fictive example how this should be presented An empty table is attached at the end of this annex.

[10] Supplementary feed includes for example calf-starters, milk replacers and concentrates. They are given in the context of calf rearing or for production purposes.

Year:_____19xx___

Type	**<24 months**	**24-36 months**	**> 36 months**	**All ages**
Beef	5%	20%	n.a.	12.5%
Dairy	50%	80%	95%	49.5%
All types	27.5%	76%	95%	31.7

Example for fraction of cattle, expressed in % of all cattle of that type in a given age class that in a given year has received supplementary feed.

It should be noted that dairy cattle below 24 months are the most important class of cattle because they are the only cattle that are likely to live long enough after the exposure to develop BSE:

- Beef cattle will normally be slaughtered before being 3 years old. It is therefore unlikely that any beef cattle will develop BSE before being slaughtered.
- Adult dairy cattle (above 2 years) will normally be slaughtered before the end of the incubation period, which mostly turns around 4 to 6 years.

To estimate the fraction in each cattle class that received supplementary feed, the evaluator should use the data from table 1 and 2 in annex 2 (model input tables).

If the data which should be included into that tables are not complete, the following should be taken into consideration:

- It is more likely that a dairy cattle receives composite feed than beef cattle. Therefore it can be assumed that the fraction of all cattle receiving supplementary feed increases with the fraction of dairy in the whole cattle population.
- Highly productive milk cows (5000kg milk/year and more) must receive supplementary feed because this productivity can hardly be reached by grass-feeding alone. The fraction of cattle receiving supplementary feed therefore increases with the fraction of highly productive milk cows in the cattle population.
- As it is likely that calves in highly productive dairy herds will receive similar feed as the adult animals. It therefore can be assumed that these calves receive relative high rations of supplementary feed.
- If no information on the fraction of highly productive milk cows is available, the average productivity of milk cows can be taken as a indicator for supplementary feeding. The latter will increase with increasing average productivity.
- If no other data are available assume that all dairy calves receive supplementary feeding.

For information: UK-figures indicate that 98% of all diary herds receive regularly supplementary feed but only 45% of all beef suckler herds receive from time to time some rations of it.

The information on the husbandry system, which was requested from applicant countries, could be used for qualifying the assumptions made above:

- Intensive husbandry, with high numbers of animals per hectare grassland, will have a tendency to use more composite feed than extensive husbandry system with larger areas of grassland per cattle.
- Climatic factors, such as very harsh winters, may require concentrates being given, even if the productivity figures seems not to indicate this.
- The production of pigs and cattle in the same geographical area and during the same period of time is also an indicator for a potentially increased risk of cross contamination. This risk increases with the intensity of both production systems.
- The price of MBM in relation to the price for other protein sources would be a good indicator for the economic incentive to replace plant proteins by animal (ruminant) proteins. It is worth knowing that before the BSE-crisis feed producers took the relative price, together with the technical parameters of the protein, as main criterion for the protein source in a composite feed.

Estimating the fraction of this supplementary feed that could have contained mammalian (ruminant) derived proteins.

Supplementary feeds like calf starter and milk replacer could include mammalian (ruminant) proteins but only in small quantities. These quantities are likely to be insignificant in comparison with the amount of these proteins that could be fed via concentrate feeds.

It would then be important to estimate the possible MBM-content of these concentrates. The appropriate data could be found in table 2 of annex 2.

If no information, or only incomplete information were available, it would be appropriate to assume the following worst case values:

- 1980-1990:
  All concentrate feeds contain MBM. The MBM content is around 5% of the total concentrate feed. (Reduce this figure if a MBM ban was in place and/or MBM was not a competitive protein source or any other plausible reason is identified (explain!) For information: more than 5% would probably reduce the palatability of the feed and would therefore normally not been surpassed.)
- since 1990 :
  60% of the concentrate rations contain MBM . The MBM content is below 5%, more likely between 2% and 0.5%. If cross-contamination can not be excluded the MBM content may be assumed to be always above 1%.

  From the date of introduction of a MBM-feed-ban onwards, it can be expected that the values will decrease. If no other information is available it is to be assumed that the fraction of concentrate rations containing MBM will fall very quickly to 50-60% and decrease then slower over time with an assumed target value of about 5%, to be reached after 5 years. This decrease might be faster if the implementation is convincingly carried out and policed, and vice versa. If cross contamination is not efficiently avoided the MBM content in those rations which contain MBM will always remain around 1%. Increase if price of MBM was relatively low and if feed ban was not in place.

The result of this reflection leads to an assumed contamination rate of the supplementary feed with mammalian (ruminant) protein. If it is possible to differentiate between different supplementary feeds, this should be done but it is assumed that normally a ball-park figure has to be used for the entire supplementary feed.

Estimating the BSE-contamination of the mammalian (ruminant) derived proteins contained in the supplementary feed given to cattle.

This is the third element needed to develop a good estimate of the exposure of cattle to the BSE-agent in a given year. The information to respond to this task could normally be derived from tables 3,4,5 and 6 in annex 2.

If no direct information can be found in the country dossier, an estimation should be developed applying the following considerations:

a) The contamination of MBM with the BSE-agent depends on the infective load (with BSE) of the material from which the MBM was produced and the ability of the production processes (rendering) to reduce/eliminate this infective load[11].

- The average infective load of the raw material entering the rendering process depends of the average infective load of the animals from which it originates (= the processing risk). This is strongly influenced by the age of these animals. Cattle, which are processed at an age of <30 months, would hardly carry any significant infectivity, even if it were infected with BSE at birth.
  - A low fraction of cattle older than 30 months when slaughtered would allow assuming that the average amount of BSE-agent being possibly processed when processing one infected animal would be rather low. The following threshold value is defined: The fraction of "old" cattle at slaughter is **low** if it is lower than 20% and **high** if it is 20% or higher.
  - The exclusion of SRMs from animals, in particular from those being older than 30 months at slaughter, can also be assumed to reduce the amount of infectivity processed. And hence the potential infectivity of the products derived from it. The SSC has presented figures showing that the exclusion of the CNS (Brain and Spinal Cord) alone would already significantly reduce the infective load of a full-blown BSE-case (between 80 and 90 %of the entire infective load). For the sake of the risk assessment SRM can be assumed to be excluded from rendering if an SRM-ban is fully implemented which ensures that no brain (incl. eyes) and spinal cord enters the food or feed chain ("**SRM-out**"). It would be even better if also the DRG and TRG (Dorsal Root Ganglia and Trigeminal Ganglia) and small intestine are excluded.
  - If an existing SRM – ban exists but is not well implemented (or is only excluding the brain, or is only excluding the SRMs from the food chain but not from the feed chain, or if no SRM – ban exists at all, it has to be assumed that a significant, if not all SRM are rendered and could hence raise the infectivity of the produced materials **("SRM-in").**
- The ability of the rendering system to reduce or better eliminate the BSE-agent from the processed material is depending of the process conditions applied. A rendering system,

[11] This relation is also a key parameter for the mathematical model of the propagation risk.

which applies the appropriate or even more severe combination of temperature, time and pressure (133°C / 20min / 3Bar), can be assumed to reduce the infectivity in the MBM by a factor of 1000 **("good rendering").** If this can not be guaranteed, e.g. in most, if not all, continuous systems, this factor is lower, e.g. around 100 or less ("**bad rendering**").

- It is obvious that the import of potentially contaminated MBM could also be a significant source of exposure. It is therefore important to get information on imports of MBM, MBM-containing concentrates, and other concentrates. If these products have been imported from countries/regions with known incidence of BSE, a contamination with BSE can not be excluded. In the absence of better information the following worst case assumptions are proposed:
- In the period 1985 to 1995 all MBM traded in Europe carried a significant but unknown risk to be contaminated with BSE. This assumption is mainly based on the known fact that UK born MBM was exported to many European countries but not necessarily remained there. It will therefore not be able to conclude with certainty on the origin of any MBM internationally traded in that period.
- Since 1996 it can be assumed that the European MBM ban showed significant effects and the overall risk that MBM was contaminated, declined.
- The impact of imports on the average potential BSE-contamination of the entire MBM in a given country and a given year depends on the size of these imports in relation to the internal consumption and the BSE-risk carried by the imports. Given the assumptions made on the average risk of international traded MBM, and if the consumption of MBM is known, imports are regarded to be **significant** if the surpassed 2% of the entire consumption. If no consumption figures are known, imports are regarded to be significant if they surpass 2% of the internal production.

For simplification it is proposed to conclude on the potential degree of contamination of MBM with BSE by assuming that each of the factors described above falls into one of two large categories.

1. Fraction of "old" cattle slaughtered	**low**	**high**
2. Treatment of SRM	**SRM-out**	**SRM-in**
3. Rendering system	**good**	**bad**
4. Significant imports of potentially contaminated MBM	**no**	**yes**

These parameters may occur in 16 different combinations. To each of these combinations an indicator is assigned which represents the BSE-contamination class of the MBM at the market in the year under consideration, 1 being the best, 5 the worst value. The assessor may interpolate between the above given yes/no alternative if he/she feels the need to do so. Accordingly, the following table provides an orientation rather than a iron rule.

The expert may deviate from the BSE contamination class proposed for a given combination of factors. This could, for example, be necessary because of a relative dominance of one factor that reaches more extreme values than assumed when proposing the categories above. A perfect rendering system, for example, would probably be able to outweigh a high average age at slaughter. However, it should be noted that in proposing the BSE-contamination classes, the relative weight of the factors has been taken into account.

AGE		**SRM**		**Rendering**		**Imports**		**BSE cont. class**
<30	^{3}**30**	**Out**	**in**	**Good**	**bad**	**no**	**Yes**	
X		X		X		X		**1**
X		X		X			X	**2**
X		X			X	X		**2**
X		X			X		X	**3**
X			X	X		X		**2**
X			X	X			X	**3**
X			X		X	X		**4**
X			X		X		X	**4**
	X	X		X		X		**2**
	X	X		X			X	**3**
	X	X			X	X		**3**
	X	X			X		X	**4**
	X		X	X		X		**3**
	X		X	X			X	**4**
	X		X		X	X		**5**
	X		X		X		X	**5**

<u>The evaluator is asked to estimate the BSE-contamination class per yer or the same periods used for the estimation of the fraction of the cattle population exposed to the BSE-agent (via feed). It is necessary that any deviation from the assumptions presented above are explained.</u>

Estimating the cattle exposure risk

The risk that cattle are exposed to the BSE-agent (exposure risk) is largely depending of the fraction of the cattle population (or sub-population) which received MBM during the period/year under consideration, and the BSE-contamination class for that year/period.

If the exposure risk is represented at a scale of 0 (no risk) to 10 (maximum risk), the following relationship between the fraction of cattle exposed to mammalian protein (mainly via MBM), the BSE-contamination-class, and the cattle exposure risk shall be applied:

BSE **contamination class**	**Fraction of cattle population exposed to MBM [%]**				
	0	<1	<5	<10	≥10
1	**0**	**0**	**0**	**1**	**1**
2	**0**	**2**	**3**	**4**	**5**
3	**0**	**4**	**6**	**8**	**9**
4	**0**	**6**	**8**	**9**	**10**

5	**0**	**8**	**9**	**10**	**10**

Table: Exposure risk in relation to BSE-contamination class and cattle exposure.

Estimating the maximum processing risk from the cattle exposure risk

Definition:

> *The processing risk is defined as the probability that, within a given time period, an infectious animal (or material thereof) is processed either in a slaughterhouse or directly in a rendering plant with a view to be used as food or feed.*

The basic assumption is that the processing risk of today is proportional to the exposure risk in the past.

For concluding from the exposure risk on the processing risk the following considerations have to be taken into account:

- Whether or not an exposure leads to infection depends of factors such as the individual susceptibility of animals, the existence (or not) of threshold values below which no infection takes place, the role of repeated doses, other factors which might influence the individual susceptibility, etc. These factors are currently not known. It is therefore assumed, for the purpose of this risk assessment, that no threshold dose exists and that hence each exposure event has the potential to lead (sooner or later) to an infection.
- It is assumed that the maximum processing risk, which would result from the exposure risk alone, is directly proportional to the cattle exposure risk in the preceding years.
- However, in reality not all animal exposed and, according to the assumption made, infected, will develop BSE. Many of them will die (being slaughtered or otherwise) before the end of the incubation period. It therefore is assumed that the processing risk is lower than the maximum processing risk.
- One factor reducing the impact of the exposure risk on the processing risk is the life expectation of the animals after their initial exposure. Assuming infection at birth, this live expectation is equal to the age at which the animals are slaughtered or die otherwise. This age can be roughly assumed as follows:
  - beef-cattle will normally be slaughtered before 24 months of age and only exceptionally get older than 3 years;
  - dairy-cattle will normally get 4 to 5 years old but significant fractions will get older.

  If it is possible to stratify the Cattle Exposure Risk by type (beef or dairy) and within dairy by below and above 2 years of age, estimating the maximum processing risk should follow the following pattern:

  For

- beef cattle, it is only important to take into account the CER of this class of animals in the previous **3** years;
- dairy-cattle, exposed at an age older than 2 years for the first time in their live to BSE, it would be important to take into account the CER of this class of animals in the previous **6** years;

- dairy cattle, exposed at an age below 2 years to BSE, it would be important to take into account the CER of this class of animals in the previous **8 to 10** years.

Estimating the current maximum processing risk from the CER of the past

The following considerations have to be taken into account:

- The exact relationship between infection event and incubation period is not known but the majority of UK-cases occurred between 4 and 6 years of age. Assuming that most of the exposure events which lead to these cases took place close to birth, it can hence be assumed that an exposure event would lead to a maximum number of cases between 4 and 6 years later. This incubation period is also backed by the pathogenesis experiment in the UK where cattle challenged by high doses of raw BSE-brain developed clinical signs 36 to 48 months after challenge. *Note: The incubation period should be taken as a stochastic variable that does not change over time.*
- Based on the above a matrix was developed which, for a given CER, indicates the relative Maximum Processing Risk (rMPR) in the 10 following years. This risk will follow the incubation period pattern ($rMPR_{a+x}=f(CER_a)$).
- The Maximum Processing Risk for a given class of cattle (MPRc) is then arrived at by adding all resulting rMPRc.
- The maximum processing risk of the entire cattle population can be calculated by multiplying each MPRc with the fraction of the total cattle population that class represents and by adding up the products.

CER	MPR in year X, X years after the CER										MPR Dairy [12]young	MPR Dairy [13]adult	MPR [14]Beef
	1	2	3	4	5	6	7	8	9	10	In year X		
0	0	0	0	0	0	0	0	0	0	0	**0**	**0**	**0**
1	0	0	0	1	1	1	0	0	0	0	**3**	**3**	**0**
2	0	0	0.5	1.5	2	1.5	0.5	0.25	0.1	0	**6.35**	**5.5**	**0.5**
3	0	0	0.75	2	3	2	0.75	0.45	0.2	0.1	**9.35**	**7.75**	**0.75**
4	0	0	1	2.5	4	2.5	1	0.65	0.3	0.2	**12.15**	**10**	**1**
5	0	0	1.25	3	5	3	1.25	0.85	0.4	0.3	**15.05**	**12.25**	**1.25**
6	0	0.25	1.5	3.5	6	3.5	1.5	1.05	0.5	0.4	**18.2**	**14.75**	**1.75**
7	0	0.25	1.75	4	7	4	1.75	1.25	0.6	0.5	**21.1**	**17**	**2.0**
8	0	0.25	2	4.5	8	4.5	2	1.45	0.7	0.6	**24.0**	**19.25**	**2.25**
9	0	0.5	2.25	5	9	5	2.25	1.65	0.8	0.7	**27.15**	**21.75**	**2.75**
10	0	0.5	2.5	5.5	10	5.5	2.5	1.85	0.9	0.8	**30.05**	**24.0**	**3**

[12] MPR Dairy Calves = the MPR resulting from exposing dairy calves to BSE. Ten years to be taken into account.
[13] MPR Dairy adults = MPR resulting from first exposure of adult dairy cows. Six years to be taken into account.
[14] MPR-Beef = the MPR resulting from exposing beef-cattle to BSE. Three years to be taken into account.

Table: Illustration of the assumed relation between the cattle exposure risk (CER) and the maximum processing risk (MPR) for dairy cattle exposed before 24 months of age (dairy young), dairy cattle exposed after 24 months of age (dairy adult) and beef.

The last columns in the table give the MPR of the cattle class, which would result if the cattle exposure risk of that class would remain constant over a period of 10 years (Dairy young), 6 years (dairy adult) or 3 years (beef).

For example, if a country had a cattle exposure risk for the young dairy cattle of 7 over the last 10 years, the current maximum processing risk would be 21.1. If the same exposure would be valid for Beef, only the last three years have to be taken account of and the MPR would be 2.0.

Note: The MPR is represented by another scale as the CER. For the MPR the highest risk is represented by a value of 30 and not 10.

The combined MPR of the three Cattle classes (beef, young and old dairy) can be estimated by multiplying the respective MPR with the fraction the respective class represents of the total cattle population and adding up the resulting values.

Example:

In a given year the beef class represents roughly 50% of the total cattle population. Hence the multiplier for beef is 0.5.

If young cattle are 35% and old cattle are 15% the respective multipliers are 0.35 and 0.15.

In the same year the MPR_{beef} is 10; MPR_{yC} is 25, and MPR_{oC} is 30.

The resulting total MPR would be:

(10*0.5)+(25*0.35)+(30*0.15) = 5+8.75+4.5 =**18.25**

A table into which the respective multipliers can be noted is attached to this annex.

Reduction of the processing risk below the theoretically possible maximum

Several factors may prevent the overall maximum processing risk from occurring, in particular the age of the animals at slaughter, and a good surveillance incl. culling.

- **Age:**

If the age at slaughter is lower than assumed for the different cattle classes, the Processing Risk (PR) will be lower than the Maximum Processing Risk (MPR) because the infective load of the slaughtered cattle will be lower. Because the infective load remains very low until at least 2 years after initial infection, the age of older cattle at slaughter is the most important. The following reduction is foreseen:

- If more than 90% of all cattle older than 2 years at slaughter are less than 4 years when they are culled, reduce the MPR by **3**.
- If less than 90% but more than 75% of all cattle older than 2 years at slaughter are less than 4 years when they are culled, reduce the MPR by **2**.
- If less than 76% but more than 60% of all cattle older than 2 years at slaughter are less than 4 years when they are culled, reduce the MPR by **1**.

- **Surveillance and culling strategy:**

A "good" surveillance system will identify and verify all/nearly all BSE-suspect cases and ensure that confirmed cases are not processed. Because of the exponential growth of the infective load excluding cattle with early clinical symptoms from processing has an over-proportional impact on the processing risk.

If suspect cases, even if not finally confirmed, are excluded the reduction might even be higher because of the persisting difficulties with diagnosing BSE.

The processing risk can be further reduced by means of an appropriate culling strategy which excludes from processing all animals which are likely to have been subject to the same exposure as confirmed cases as well as their (first generation) offspring.

Before defining reduction factors the characteristics of a "good" surveillance system have to be identified. A "good" surveillance system must include the following

- compulsory notification;
- training and awareness raising measures for farmers, vets and other actors;
- targeted monitoring of "risk-populations", i.e. older cattle (>24 months) with CNS symptoms, high-yielding, intensively managed cattle who receive lots of supplementary feed enriched with protein, etc.;
- technically appropriate verification methodology (laboratory, combination of histopathology and immunoblot, etc.), able to recognise BSE, in combination with sufficient numbers of brains verified annually.

  Note: It is obvious that a better surveillance system would increase the likelihood of identifying BSE cases. This would obviously increase the BSE-incidence in the country in question but at the same time reduce the processing risk because these cases are excluded from processing. As they would also not be recycled, the propagation risk would also be reduced. It is worth noting that higher incidence figures could thus correspond to a lower geographical BSE-risk.

Reduction factors:

- If the surveillance system (SS) is "good" during the past 10 years, and suspect cases where excluded from processing as long as no alternative diagnosis was confirmed and an appropriate culling system was in force: reduce MRP by **5**.
- If the SS is "good" only since 5 years, but BSE is already notifiable since 8 years: reduce MRP by **4**.
- If the SS is currently good and was so since less than 5 years but BSE became notifiable 8 years ago: reduce MRP by **3**.
- If the SS is currently good and was so since less than 5 years but BSE became notifiable only 5 years ago: reduce MRP by **2**.
- If the SS is currently good and was so since less than 3 years but BSE became notifiable only less than 5 years ago: reduce MRP by **1**.

Other risk reducing factors

The expert may identify other factors that in his/her mind reduce the processing risk. These may be taken into account and additional points may be subtracted from the MPR to reach the assumed PR in a given year. These additional factors have to be mentioned in the evaluation report and their impact must be described.

The maximum reduction of the MPR by one single other risk reducing factor should not be larger than 2.

Note: With the above-proposed values, the Processing risk MPR could by reduced by up-to 8 points or more. This could lead to negative values or values that are unrealistically low. It is therefore proposed to compare the resulting value for PR with the value for the cattle exposure risk (0 to 10) and to take in any case the higher one of these two values. (The numeric value of PRF is hence ³ the numeric value of the cattle exposure risk. If this minimum is chosen, it still indicates, thanks to the different scale, a reduction of the processing risk to 1/3 of the cattle exposure risk).

Trade and the processing risk

The processing risk may be influenced by imports. If infected cattle are imported and processed sometime after, they will increase the processing risk above the MPR, i.e. the theoretical maximum processing risk resulting from exposure of native cattle to contaminated MBM.

However, this potential increase is proportional to the cattle exposure risk in the country of origin, the size of imports in relation to the local population, the age and type of cattle imported, the fate of the imported animals, etc.

The CER of the country of origin, which has to be taken into account, is the CER in each year since birth. The processing risk which imported cattle are carrying when imported, has to be seen accordingly as a function of the CER since birth in the country of origin. If this is not known, the following values shall be used:

- imports from the UK in the period 1980-1990:	10
- imports from the UK in the period 1991-1995:	08
- imports from the UK in the period since 1996:	04
- imports from other countries in the period 1980 to 1990:	05
- imports from other countries in the period 1990 to 1995:	03
- imports from other countries in the period since 1996:	02

On the basis of their estimated CER the MPR of the imported animals can be calculated.

This import-MPR contributes to the overall MPR in relation to the relative size of the imports in comparison to the total n° of slaughtered animals. This relative size is calculated by dividing the number slaughtered cattle, imported as life cattle, by the total number of slaughtered cattle.

Example:

- The imports are about 1% of the processed population = the derived factor would be 0.01.
- The CER in the country of origin was 10 since several years, i.e. the import MPR was 30.
- The overall MPR would increase by 30*0.01=0.3

The imported animals will contribute to the processing risk in the year when they are processed. It is therefore important to know the fate of the imported animals as well as their age at import.

- Imports of animals for slaughter in the year of import would increase the processing risk in the same year in relation to the import MPR as shown above.

- Animals kept alive for several years would contribute to the processing risk in their year of slaughter, not the year of import.

Overview table for the calculating the CER per type of cattle and year							
Year	**Type of Cattle**	**Fraction per age class (months)** **<24**	**24-36**	**> 36**	**All ages**	**BSE cont. class**	**CER**
1980	Beef						
	Dairy						
	All types						
1981	Beef						
	Dairy						
	All types						
1982	Beef						
	Dairy						
	All types						
1983	Beef						
	Dairy						
	All types						
1984	Beef						
	Dairy						
	All types						
1985	Beef						
	Dairy						
	All types						
1986	Beef						
	Dairy						
	All types						
1987	Beef						
	Dairy						
	All types						
1988	Beef						
	Dairy						
	All types						
1989	Beef						
	Dairy						
	All types						

Overview table for the calculating the CER per type of cattle and year

Year	Type of Cattle	Fraction per age class (months) <24	24-36	> 36	All ages	BSE cont. class	CER
1990	Beef						
	Dairy						
	All types						
1991	Beef						
	Dairy						
	All types						
1992	Beef						
	Dairy						
	All types						
1993	Beef						
	Dairy						
	All types						
1994	Beef						
	Dairy						
	All types						
1995	Beef						
	Dairy						
	All types						
1996	Beef						
	Dairy						
	All types						
1997	Beef						
	Dairy						
	All types						
1998	Beef						
	Dairy						
	All types						

Overview table for calculating the MPR

Year	Fractions of cattle population			MPR per cattle class			Overall MPR
	Beef	Young dairy	Adult dairy	Beef	Young dairy	Adult dairy	
example	*0.5*	*0.35*	*0.15*	*10*	*25*	*30*	*18.25*
1980							
1981							
1982							
1983							
1984							
985							
1986							
1987							
1988							
1989							
1990							
1991							
1992							
1993							
1994							
1995							
1996							
1997							
1998							
1999							
2000							
2001							
2002							
2003							