Opinion of the Scientific Panel on Biological Hazards of the European Food Safety Authority on the "Quantitative assessment of the Human BSE risk posed by Bovine Vertebral Column including Dorsal Root Ganglia with respect to residual BSE risk"[1]

(Question N° EFSA-Q-2003-099)

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1. SUMMARY

1.1. Residual BSE risk due to Bovine Vertebral Column

The European Food Safety Authority (EFSA) quantitative risk assessment (QRA) guidance document gives residual Bovine Spongiform Encephalopathy (BSE) risk assessments for by-products – tallow, gelatine and calcium phosphates – used in human food obtained from cattle fit for human consumption (EFSA QRA report, 2004). The effect of including vertebral column in the batch of raw materials used for the production of the by-products was calculated as part of separate risk assessments for these materials. The Commission Mandate to EFSA asked the Panel to review the "Opinion and report, assessment of the human BSE risk posed by bovine vertebral column including dorsal root ganglia (adopted on 16 May 2002)" in the light of their QRA on residual BSE risk and, if appropriate, revise the 2002 Opinion accordingly. This revision covers the by-products, tallow and gelatine, but does not consider the human risk from consumption of meat on the bone or the inclusion of bovine-derived phosphates as food additives, or the effect of changing the age limit for regarding vertebral column as specified risk material.

The EFSA Opinions on tallow and gelatine give descriptions of manufacturing processes, the various assumptions relating to their QRA and the background considerations relating to the interpretation of the output values. In this document we simply reproduce the relevant conclusions and recommendations of those opinions relating to the inclusion of vertebral column and the production of these by-products.

Some illustrative data is shown below for the range of median (P50) exposure estimates (units, Cattle oral infectious dose 50%, $CoID_{50}$/person/week)[2]. For detailed results see table 1 further in this document.

		GBR II†	GBR III	GBR IV
Tallow	De-Greasing bones	*	*	10^{-12} to 10^{-11}
	Mixture of tissues	*	*	10^{-12} to 10^{-10}
Gelatine	Acid & Alkaline	*	*	10^{-9} to 10^{-8}
	Heat & Pressure	*	*	10^{-11} to 10^{-10}

The logic of interpreting the $CoID_{50}$ units of exposure in terms of human risk is essentially that assuming a species barrier of 1, and all the other assumptions, an exposure value > 10^{-8} per time period may result in one or more cases of vCJD per time period. The only scenario in which the P50 values approach the 10^{-8} level is in the production of gelatine from bovine bones by the acid and alkaline method. Referring back to the gelatine opinion, this is a worst case consumption scenario where all the daily human dose of gelatine is assumed to be bovine bone derived (when it is more likely to be 1-5%). Similarly, for more realistic sourcing scenarios such as a GBR III country with reliable surveillance, even the P97.5 values only approach 10^{-8} for gelatine produced from bovine bones by the acid and alkaline method (and a worst case consumption input).

[2] * in this Table is defined as an exposure level of < 10^{-13} $CoID_{50}$ units/person/per week.
† GBR: Geographical BSE Risk

1.2. Conclusion of this revision

- Inclusion of vertebral column in the raw materials used to produce tallow and gelatine from bones or a mixture of tissues increases the level of human exposure by ~ 3-10 fold. However, the levels of residual BSE risk for these products calculated in the QRA are low and the increased risk factor due to inclusion of vertebral column is unlikely to translate into further cases of vCJD in the population. Therefore, in the case of tallow and gelatine, there appears to be no rationale for imposing an age-limit above which to exclude vertebral column from the batches of raw materials used to produce these by-products.
- The human risk from consumption of meat on the bone or the inclusion of bovine-derived phosphates as food additives could be estimated using the QRA model if the appropriate input data for human consumption were available.

1.3. Further recommendations of the BIOHAZ Panel during the adoption of this report at their Plenary Meeting, 17-18th May, 2006

- This is the final Report to be revised in the light of the EFSA BSE QRA guidance document (EFSA QRA report, 2004), and joins a series covering a range of residual BSE risk assessments on the cattle by-products : tallow, gelatin, and calcium phosphates. Each revision considers the separate effects of the QRA on the risk of exposure to human and/or cattle population for each by-product. The Panel recognised the need to evaluate the cumulative effect of each incremental change in exposure to the populations calculated in these revisions, and recommended that this "total" exposure assessment be carried out in the near future.
- "Gaps" in these residual risk assessments were inevitable due to the restricted scope of the original EFSA BSE QRA guidance document, and the Panel recommended that these gaps should be addressed by future Panel members using their "self-tasking mandate" option. For example, in the context of this vertebral column document, the QRA model could be used to estimate the human risk from consumption of meat on the bone or the inclusion of bovine-derived phosphates as food additives.
- The EFSA BSE QRA guidance document was written almost four years ago, and although some parts have been revised since then to accommodate new research findings, the methodology and nomenclature for defining the geographical BSE risk (GBR) input to the model is no longer appropriate. New methodology, under the auspices of the OIE, is under construction within the EU and EFSA and the Panel recommended that once these classifications had been finalised they should harmonised with those used in the EFSA BSE QRA guidance document. The Panel anticipated that this harmonisation may have a knock-on impact on the QRA calculations, conclusions and recommendations and that, again, future Panel members should review this, and other, inputs of the QRA and address this impact using their "self-tasking mandate" option.

KEYWORDS: phosphates, BSE, Quantitative Risk Assessment, QRA, BSE, vCJD, VC, vertebral column, tallow, gelatine, exposure assessment, GBR.

2. MANDATE AND TERMS OF REFERENCE

EFSA has received a formal mandate from DG SANCO of the European Commission requesting EFSA's Scientific Panel on Biological Hazards for an opinion on **the quantitative assessment of the residual BSE risk in certain bovine derived products and updating different SSC opinions on residual BSE risk in certain bovine derived products.**

Terms of Reference (ToR)
The European Food Safety Authority (EFSA) is invited to:

(1) Assess the validity of the outcome of a quantitative assessment of the residual BSE risk in bovine derived products, carried out for gelatine, tallow and dicalcium phosphate from bones, tallow from fat tissues and tallow from rendered mixtures of tissues, and for the presence of small amounts of meat-and-bone meal in feeding stuffs intended for ruminants.

(2) If the outcome is considered valid,

(a) review the SSC opinions* listed below in the light of the quantitative risk assessment.

*Relevant SSC opinions for which an update is requested:

- Updated opinion and report on the **safety of dicalcium phosphate (DCP) and tricalcium phosphate (TCP)** from bovine bones, used as an animal feed additive or as fertiliser (submitted to the SSC at its meeting of 6-7 March 2003).
- Updated opinion on the safety with regard to TSE risks of **gelatine** derived from ruminant bones or hides (adopted by the SSC at its meeting of 6-7 March 2003).
- Opinion and report, assessment of the human BSE risk posed by **bovine vertebral column** including dorsal root ganglia (adopted on 16 May 2002).
- Revised opinion and report on the safety of **tallow** obtained from ruminant slaughter by-products (adopted on 28-29 June 2001, editorial clarifications introduced at the meeting of 6-7 September 2001).
- Report and Scientific Opinion on **mammalian derived meat and bone meal** forming a cross-contaminant of animal feedstuffs adopted by the Scientific Steering Committee at its meeting of 24-25 September 1998.

(b) advise on how to interpret the results of the calculation in view of making an estimation of the number of potential BSE and vCJD cases expected per year in a population.

Part (1) of the above ToR has been finalised and the validity of the working document was accepted by the Experts of the Scientific Panel on Biological Hazards recognising the dynamics of such report. The working document, including the assumptions and the calculations, as carried out by a joint WG and DNV consulting are now used as basic

guidance in updating the SSC opinions. This guidance document has now been published on-line (EFSA QRA Report, 2004: www.efsa.eu.int/science/biohaz/biohaz_documents/1280_en.html).

The current opinion addresses **part (2) of the ToR** to provide the European Commission with updates of the requested opinions and concerns specifically the:

- Opinion and report: assessment of the human BSE risk posed by **bovine vertebral column** including dorsal root ganglia (adopted on 16 May 2002).

The QRA guidance document (EFSA QRA report, 2004) gives residual BSE risk assessments for by-products used in human food – tallow, gelatine and calcium phosphates – obtained from cattle fit for human consumption. Therefore this revision of the SSC 2002 opinion is restricted to tallow and gelatine and does not include consideration of the risk from consumption of meat on the bone. The QRA model can be used for this purpose in the future by including further data.

We start below by summarising the SSC Opinion 2002 (Section 2) and the relevant analyses in the EFSA`QRA Report 2004 (Section 3). Essentially, the effect of including vertebral column in raw materials used for production of tallow and gelatine has been calculated as part of the separate risk assessments for these products. Hence those documents should be consulted for a description of manufacturing processes, the various assumptions relating to their QRA and the background considerations relating to the interpretation of the output values. Here, in sections 4 and 5, we simply reproduce the relevant conclusions and recommendations of those opinions relating to vertebral column and the production of tallow and gelatine.

3. SUMMARY OF THE OPINION OF THE SCIENTIFIC STEERING COMMITTEE (2002)

The Scientific Steering Committee (SSC) was asked, in the light of (a) the results of the BSE monitoring carried out so far (2002) and in particular the age distribution of positive BSE cases and (b) the recent assessment of the possible risk posed by bovine dorsal root ganglia in Ireland:

(1) to assess a recent quantitative assessment of risk from possible BSE infectivity in dorsal root ganglia, produced for the Food Safety Authority in Ireland.

(2) to give a quantitative assessment of the BSE risk [for human consumers] posed by bovine vertebral column including dorsal root ganglia.

(3) to address the question of whether evidence can be found to justify an increase of the current age limit of 12 months for treating vertebral column as SRM in bovine animals and if so, to what extent and under which conditions? If no, what would be the conditions for increasing the age limit?

The Opinion and Report (EC 2002) addressed issues relevant to both consumption of meat on the bone and residual risk from bovine by-products. It considered specifically the scientific

merit of a quantitative assessment of risk from infectivity in DRG produced for Ireland (DNV 2001) and compared this to the previous similar report based on UK data (DNV 1997).

The previous assessments indicated that, assuming that 1 Cattle oral ID_{50} = 1 human oral ID_{50}, in the UK, the 95% percentiles for the range of individual exposure risk in 1997 were $4x10^{-13}$ to $1x10^{-6}$ human oral ID_{50} units and that in Ireland, the 95% percentiles for the range of individual exposure risk in 2000 were $2x10^{-11}$ to $4x10^{-5}$ human oral ID_{50} units. While the SSC considered these results valid, the assessments were considered not applicable to other Member States, similar assessments for which would require country specific data on consumption patterns and BSE incidence. However, it was acknowledged that risks in subsequent years from most other European Countries (EU 15) (Portugal excepted) would have been less.

One key element of the risk assessment was recognized as the time in the incubation period when the spinal cord and dorsal root ganglia can contain infectivity. The limited data provided by the UK experimental study of the pathogenesis of BSE were not considered to be sufficient to generalise with regard to the relative proportion of the incubation period at which infectivity might first be detected in the central nervous system.

Regarding parts (1) and (2) of their mandate, the SSC considered that the risk assessment produced for the Food Safety Authority in Ireland was scientifically sound but applied only to Ireland. The risk estimates could not be applied to other countries because of differences in consumption patterns and BSE incidence. The preparation of similar assessments for other countries, or for the EU's continental part as a whole, would require the collection of the appropriate information, some of which would require further surveys.

With respect to part (3) of the mandate the SSC view was that evidence to justify an increased age limit above 12 months for treating vertebral column as SRM in bovine animals, could come only from assessment by the various Member States of the human exposure risk over time (before and after the implementation of consecutive risk management measures as listed in the Opinion of 12 January 2001, including the total feedban).

The Opinion considered that an evaluation for the whole EU would become possible and the SSC would be able to revisit and update its opinion on human BSE risk related to Specified Risk Materials, including dorsal root ganglia.

4. ANALYSIS OF THE RESIDUAL RISK QUANTIFICATION IN RELATION TO MANUFACTURE OF BY- PRODUCTS USING BOVINE VERTEBRAL COLUMN IN RAW MATERIALS

The EFSA QRA Report, 2004 provides analysis of the residual BSE risk in various bovine derived products. In the context of the SSC 2002 Opinion, it analyses the effects of removal of the vertebral column from the raw materials used to produce tallow and gelatine and this analysis can be used as the basis for a partial revision of Q2 of the SSC 2002 Opinion:

(2) to give a quantitative assessment of the BSE risk [for human consumers] posed by bovine vertebral column including dorsal root ganglia

The residual BSE exposure for various risk scenarios considered by the EFSA QRA are given in Table 1 (Table 7 of the EFSA QRA Report 2004) in terms of weekly human consumption of $CoID_{50}$ units[3], and these calculations are discussed in more detail for each relevant scenario below:

[3] $CoID_{50}$ is cattle oral infectious dose 50%; if the species barrier is taken as 1 (the worst case, see discussion EFSA QRA Report, 2004) then this is equivalent to human oral infectious dose 50% ($HoID_{50}$).

Table 1: Summary of Human Exposure to BSE Infectivity($CoID_{50}$ per person per week)[4]

a) Median and 95 percentile values

	Case	GBR II		GBR III		GBR IV	
		Reliable	Unreliable	Reliable	Unreliable	Reliable	Unreliable
1	**Tallow from bones (filtration 0.02%)**						
1.1	skull and vertebral column removed - P50	0	0	0	1.4E-13	1.2E-12	5.0E-12
	P97.5	0	0	5.1E-12	1.7E-11	4.6E-11	1.5E-10
1.2	only skull removed - P50	0	0	0	0.0E+00	1.0E-11	4.7E-11
	P97.5	0	0	4.4E-11	1.5E-10	4.1E-10	1.4E-09
1.3	skull and vertebral column **not** removed - P50	0	0	0	0.0E+00	1.4E-11	7.1E-11
	P97.5	0	0	7.1E-11	2.4E-10	6.4E-10	2.1E-09
2	**Tallow from fat tissues (filtration 0.02%)**						
2.1	Carcass fats before splitting - P50	0	0	0	0	0	0
	P97.5	0	0	0	0	0	0
2.2	Fats before and after splitting - P50	0	0	0	0	0	3.6E-11
	P97.5	0	0	4.3E-11	1.8E-10	4.4E-10	1.3E-09
3	**Tallow from mixture of tissues tissues (0.02%)**						
3.1	No SRMs removed - P50	0	0	0	0	0	1.9E-10
	P97.5	0	0	2.0E-10	1.3E-09	3.6E-09	1.1E-08
3.2	SRMs removed, except vertebrae - P50	0	0	0	0	0	8.2E-12
	P97.5	0	0	9.4E-12	5.8E-11	1.6E-10	5.1E-10
3.3	All SRMs removed - P50	0	0	0	0	0	2.8E-12
	P97.5	0	0	3.3E-12	1.8E-11	4.9E-11	1.6E-10
4	**Gelatine from bovine bones (acid & alkaline)**						
4.1	skull and vertebral column removed - P50	0	0	0.0	0	0.0E+00	1.7E-09
	P97.5	0	0	2.1E-09	8.0E-09	2.0E-08	6.4E-08
4.2	only skull removed - P50	0	0	0	0	0.0E+00	1.5E-08
	P97.5	0	0	1.4E-08	6.7E-08	1.9E-07	6.0E-07
4.3	skull and vertebral column **not** removed - P50	0	0	0	0	0	2.1E-08
	P97.5	0	0	2.3E-08	1.2E-07	3.2E-07	9.2E-07
5	**Gelatine from bovine bones (heat pressure)**						
5.1	skull and vertebral column removed - P50	0	0	0	0.0E+00	0.0E+00	1.7E-11
	P97.5	0	0	2.1E-11	7.7E-11	1.9E-10	6.3E-10
5.2	only skull removed - P50	0	0	0	0.0E+00	0.0E+00	1.5E-10
	P97.5	0	0	1.5E-10	6.8E-10	1.8E-09	5.8E-09
5.3	skull and vertebral column **not** removed - P50	0	0	0	0.0E+00	0	2.1E-10
	P97.5	0	0	2.1E-10	1.2E-09	3.0E-09	9.3E-09

b) Mean values

1	**Tallow from bones (filtration 0.02%)**						
1.1	skull and vertebral column removed - Mean	7.5E-15	1.9E-14	5.6E-13	2.1E-12	6.2E-12	2.3E-11
1.2	only skull removed - Mean	2.1E-13	2.8E-13	5.9E-12	2.0E-11	6.0E-11	2.2E-10
1.3	skull and vertebral column **not** removed - Mean	4.1E-13	4.6E-13	9.8E-12	3.3E-11	9.5E-11	3.4E-10
2	**Tallow from fat tissues (filtration 0.02%)**						
2.1	Carcass fats before splitting - Mean	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00	0.0E+00
2.2	Fats before and after splitting - Mean	4.0E-14	2.2E-13	5.0E-12	1.8E-11	5.2E-11	1.8E-10
3	**Tallow from mixture of tissues tissues (0.02%)**						
3.1	No SRMs removed - Mean	1.9E-12	2.0E-12	4.4E-11	1.5E-10	4.6E-10	1.6E-09
3.2	SRMs removed, except vertebrae - Mean	4.2E-14	2.4E-13	1.8E-12	6.1E-12	1.9E-11	6.7E-11
3.3	All SRMs removed - Mean	4.0E-15	8.0E-14	6.7E-13	2.1E-12	6.3E-12	2.2E-11
4	**Gelatine from bovine bones (acid & alkaline)**						
4.1	skull and vertebral column removed - Mean	3.2E-12	1.6E-11	2.5E-10	8.7E-10	2.5E-09	8.7E-09
4.2	only skull removed - Mean	9.7E-12	1.3E-10	2.3E-09	8.0E-09	2.3E-08	8.3E-08
4.3	skull and vertebral column **not** removed - Mean	1.1E-11	1.2E-10	3.7E-09	1.3E-08	3.7E-08	1.3E-07
5	**Gelatine from bovine bones (heat pressure)**						
5.1	skull and vertebral column removed - Mean	2.8E-14	1.5E-13	2.5E-12	8.7E-12	2.5E-11	8.8E-11
5.2	only skull removed - Mean	1.2E-13	2.1E-12	2.8E-11	8.9E-11	2.5E-10	8.5E-10
5.3	skull and vertebral column **not** removed - Mean	1.2E-13	1.3E-12	3.4E-11	1.3E-10	3.8E-10	1.3E-09

[4] "0" in this Table means that there is a >50% (P50) or >97.5% (P97.5) probability of no exposure per person per week.

4.1. Tallow

4.1.1. Production of tallow from bones (employing 0.02% filtration)

- For **country scenario GBR II** at P97.5 levels there is no residual BSE risk. Thus for at least 97.5% of the time there would be no exposure to BSE infectivity through consumption of tallow. The mean residual risk for 0.02% filtration varies from $5x10^{-13}$ $CoID_{50}$ to $8x10^{-15}$ including both reliable and unreliable surveillance. The effect of removal of the skull and vertebral column on the mean residual risk is two orders of magnitude, with reliable surveillance and less than one order of magnitude with unreliable surveillance. Removal of the skull alone provides an immeasurable difference, irrespective of reliability of surveillance.
- For **country scenario GBR III**, the median value (P50) of the residual risk is zero for all three options with reliable surveillance and with unreliable surveillance it is estimated to be less than $1x10^{-13}$ $CoID_{50}$. The worst case P97.5 values are 7×10^{-11} with reliable surveillance and $2x10^{-10}$ $CoID_{50}$ with unreliable surveillance. As for GBR II countries, the mean values for residual risk for GBR III countries, with and without removal of skull and vertebral column represent approximately one order of magnitude. The P97.5 values also indicate a similar difference, with again reliable surveillance also contributing a single order of magnitude reduction. Also, removal of skull alone makes no measurable difference in risk.
- The results for a **GBR IV country scenario** are a factor of 10 or more greater than those for GBR III, with the median value (P50) of the residual risk estimated to be $7x10^{-11}$ if the skull and vertebral column is not removed, reducing to $5x10^{-12}$ with removal of the skull and vertebral column (both for unreliable surveillance).
- From the mean values it can be seen that the residual risk for a GBR III country is between 1 and 2 orders of magnitude greater than that for a GBR II country, with a GBR IV country being about one order of magnitude greater than a GBR III.
- The P97.5 value of the residual risk from tallow produced from bovine bones is estimated to be a weekly consumption of $4x10^{-10}$ $CoID_{50}$ units for a GBR IV country with the skull removed and $5x10^{-11}$ $CoID_{50}$ units with both the skull and vertebral column removed if there is reliable surveillance. If there is not reliable surveillance these values increase to $1x10^{-9}$ and $2x10^{-10}$ $CoID_{50}$ units respectively. The potential infectivity for humans would be further reduced by the cattle to human species barrier.

4.1.2. Production of tallow from bones (employing 0.15% filtration)

The P97.5 value for the residual risk from tallow is greater by approximately 10 fold for all scenarios of comparison with 0.02% filtration for both **GBR III and GBR IV countries** irrespective of the reliability of surveillance. As for the 0.02% filtration, 0.15% filtration makes no difference to the zero P97.5 value for GBR II countries.

4.1.3. Production of tallow from bones (employing steam and pressure)

Risks are correspondingly greater than reduction of risk by filtration (0.15%) by a factor of up to 10 fold when skull and vertebral column are not removed.

4.1.4. Production of tallow from mixture of tissues

The residual BSE risks are very dependent on the degree to which SRMs are removed. If all SRMs are removed the mean residual BSE risk ranges from $4x10^{-15}$ for a GBR II country to $6x10^{-12}$ $CoID_{50}$ units for a GBR IV country, both with reliable surveillance. If no SRMs are removed the BSE risk increases by about a factor of 100-500. The maximum residual BSE risks are for a GBR IV country with unreliable surveillance when no SRMs are removed; estimated to be less than $1x10^{-8}$ $CoID_{50}$ units per week for 97.5% of the time.

Excluding vertebral column from the list of SRM makes a ~3-fold decrease in P97.5 exposure values (Table 1, sections 3.2 and 3.3) for all scenarios (GBR III and GBR IV, reliable and unreliable surveillance) for tallow by-product produced from a mixture of tissues.

4.2. Gelatine production from bones

The residual risk from gelatine made from bovine bones is influenced by the production treatments of acid and alkaline applications or heat pressure. The results for the heat pressure process are about a factor of 100 less than for the acid or alkaline processes. The following comments refer to the heat treatment process. The results are similar to those for tallow, in terms of no residual infectivity present in human consumption, at the P50 and P97.5 levels for GBR II countries. For country scenario GBR III with reliable surveillance, the P97.5 value of including the skull and vertebrae is estimated to be $2x10^{-10}$ $CoID_{50}$ units reducing to $2x10^{-11}$ if both the skull and vertebrae are removed (Table 1, sections 5.1 and 5.3)

These values increase to $1x10^{-9}$ and $8x10^{-11}$ if surveillance is not reliable. The results for a GBR IV country would be about a factor of 10 greater risk than those for GBR III. The P97.5 value of the residual risk from gelatine produced with the heat pressure process is estimated to be a weekly consumption of $9x10^{-9}$ $CoID_{50}$ units for a GBR IV country with unreliable surveillance, assuming that both the skull and vertebrae are not removed. The potential infectivity for humans would be further reduced by the cattle to human species barrier.

5. DISCUSSION

This section is given more detailed treatment in each of the corresponding sections of: Update of Report on Assessment of The Human and Animal BSE risk posed by Gelatine, with respect to Residual BSE Risk and Update of the Opinion & Report on Assessment of the Human and Animal BSE Risk posed by Tallow with respect to Residual BSE Risk.

5.1. Tallow from bones

With respect to the production of tallow from bones using filtration (0.02%), the worst scenario, that of the failure to remove skull and vertebral column in a GBR IV country with unreliable surveillance (P97.5 value $2.1x10^{-9}$) differs only by a factor of 100 reduction in risk when the axial skeletal elements are removed under conditions of reliable surveillance. Removal of these structures in a GBR III country with reliable surveillance provides a further 10 fold reduction in risk. However, the worst possible scenario with respect to production of tallow from bones would result from production with treatments confined to steam and pressure, with skull and vertebrae not removed in a GBR IV country with unreliable surveillance (P97.5 = $1.1x10^{-8}$). This exposure would theoretically represent a less than 2.5% probability that there is an exposure of one person in 100 million to 1 or more $CoID_{50}$ units

per week or similarly that one person will be exposed to $1x10^{-8}$ $CoID_{50}$ units per week less than 2.5% of the time or that one person in 10^8 will be exposed to 1 $CoID_{50}$ unit per week less than 2.5 % of the time. Consumption patterns, the species barrier, host susceptibility and other factors would almost certainly reduce the risk of infection from such exposure and the risk of developing disease is further reduced by age at infection, etc… Conversely, the maximum risk reduction provided by reliable surveillance, filtration of 0.02% and skull and vertebral column removed in a GBR IV country (P97.5 = $4.6x10^{-11}$) would theoretically represent the corresponding exposure to one person in one hundred- thousand million.

5.2. Tallow from a mixture of tissues

The dilution factor evident with tallow produced from a mixture of tissues reduces the influence of removal of vertebra on the exposure risk assuming other SRMs are removed. The equivalent worst scenario to that proposed in 6.1 above, that of a GBR IV country, with unreliable surveillance with only steam and pressure treatment gives an exposure risk of P97.5 = $8.1x10^{-9}$ (one person in a billion exposed to 1 $CoID_{50}$ unit per week for 97.5% of the time). The risk contributed by vertebrae is P97.5 = 1.8 x 10^{-8} compared to $5.6x10^{-7}$ when no SRM are removed.

5.3. Gelatine from bones

Given that the alkaline and acid processing provides the least risk reduction in the production of gelatine from bones the worst scenario assessment for a GBR IV country with unreliable surveillance and skull and vertebrae not removed (P97.5 = $9.2x10^{-7}$) provides a slightly greater risk to that for tallow from bones, though this is less than a ten fold increase. Reliable surveillance does not improve on this significantly. Removal of the skull alone provides no difference in risk suggesting that the ten fold reduction in risk resulting from removal of skull and vertebrae is contributed entirely by the latter.

The WG was asked to consider what effect inclusion of vertebral column in the raw materials used in the manufacture of gelatine would have on the residual BSE risk to humans of bone-derived gelatine. This was considered in detail in Update of Report on Assessment of The Human and Animal BSE risk posed by Gelatine, with respect to Residual BSE Risk. The latter report also concludes that removal of specified risk materials (SRM) significantly decreases the risk of vCJD infection by bovine bone gelatine. Removal of the skull with brains, eyes and trigeminal ganglia, and the spinal cord decreases the risk by a factor of 12 to 15 (GBR II) or 21 (GBR III and GBR IV). Additional removal of the vertebral column with the DRG decreases the risk further by a factor of 8 to 10 (GBR III and IV) or 3 (GBR II with reliable surveillance).

5.4. Specific risks posed by DORSAL ROOT GANGLIA

In considering the residual risk aspects of the vertebral column, the QRA does not address the specific risks posed by Dorsal Root Ganglia (DRG) compared to the remaining spinal cord attached to vertebrae. In the calculations, retention of 5g of spinal cord for 1% of vertebral columns is assumed, whereas the entire weight of the DRG (30g) will be retained in all cases where the vertebrae are not removed. Thus, dependant upon age of animal, it may be concluded that the DRG represent the major contribution to infectivity in the vertebral column. If this is the case, it should be possible to use the QRA model to assess the risk of

DRG in meat on the bone which is an issue not discussed here but one that needs to be considered to complement update of the Opinion.

6. THE CURRENT AGE LIMIT FOR TREATING VERTEBRAL COLUMN AS SPECIFIED RISK MATERIALS IN BOVINE ANIMALS (OPINION TOR 3)

The EFSA BSE QRA guidance document does not consider an age limit above which vertebral column would be regarded as specified risk materials (SRM) and excluded from the food chain. Essentially, the scenarios on which calculations of exposure risk were made included or excluded vertebral column as part of raw source materials irrespective of age. Hence, the exposure figures in the guidance document reproduced in Table 1 of this report can be considered as "worst case" with respect to this risk factor. Refinement of the QRA model incorporating an age-stratified cattle population may be possible in the future and the details required for this amendment are currently under review by an EFSA BIOHAZ Panel work group following on from their previous Opinion on "the assessment of the age limit in cattle for the removal of certain Specified Risk Materials (SRM)", adopted on 28 April 2005 (EFSA 2005).

In the context of this current report, it should be noted that any risk management refinement imposing an age limit above which vertebral column would be excluded from batches of raw materials would leave risk of exposure estimates either unchanged or reduced.

7. CONCLUSIONS

- Inclusion of vertebral column in the raw materials used to produce tallow and gelatine from bones or a mixture of tissues increases the level of human exposure by ~ 3-10 fold. However, the levels of residual BSE risk for these products calculated in the QRA are low and the increased risk factor due to inclusion of vertebral column is unlikely to translate into further cases of vCJD in the population. Therefore, in the case of tallow and gelatine, there appears to be no rationale for imposing an age-limit above which to exclude vertebral column from the batches of raw materials used to produce these by-products.
- The human risk from consumption of meat on the bone or the inclusion of bovine-derived phosphates as food additives could be calculated using the QRA model if the appropriate input data for human consumption were available.

8. SCIENTIFIC PANEL MEMBERS

Herbert Budka, Sava Buncic, Pierre Colin, John D Collins, Christian Ducrot, James Hope, Mac Johnston, Günter Klein, Hilde Kruse, Ernst Lücker, Simone Magnino, Riitta Liisa Maijala, Antonio Martínez López, Christophe Nguyen-The, Birgit Noerrung, Servé Notermans, George-John E Nychas, Maurice Pensaert, Terence Roberts, Ivar Vågsholm, Emmanuel Vanopdenbosch.

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