資料１

ＯＩＥ／ＢＳＥコード改正について

資料１　　ＢＳＥコードの改正について

資料２　　ＯＩＥ：ＢＳＥコード及びＢＳＥサーベイランス基準改正に関する主要論点

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参考資料①　ＢＥＳに関する国際基準の改正について

参考資料②　食肉のと畜検査を通じた家畜衛生及び公衆衛生上のハザードコントロールのためのガイドライン（概要）

農林水産省

資料　1

ＢＳＥコードの改正について

現時点で加盟国に対して提案されている改正案の概要は以下の通り。

１　無条件物品（ＢＳＥステータスに関わらず条件を課さずに輸入を承認すべき物品）に関する条件の変更

骨なし牛肉に課されている条件のうち、「30カ月齢以下」及び「BSE感染の疑いがなく、もしくは感染が確認されていない」との条件を削除。

２．各カテゴリーに区分するための要件の変更

「無視できるリスク」の国が満たすべき要件のうち、「自国産牛における最終発生が７年以上前に報告されたこと」を「いかなる自国産牛におけるBSE発生例も８年以上前に出生していること」に変更。

３．サーベイランス基準の変更

（１）「管理されたリスク」の国においては、A型サーベイランス（１０万頭に１頭の感染牛を摘発できる水準）を実施すべきとされているが、一旦その目標ポイントを達成した場合には、「無視できるリスク」の国が実施することとされているB型サーベイランス（５万頭に１頭の感染牛を摘発できる水準）に移行することができる旨の規定を追加。

（２）累積ポイント（各国のサーベイランス実績に基づき算出されるポイントの総計）にかかわらず、全ての臨床的に疑わしい牛は検査されるべき旨の規定を追加。

（３）サーベイランスの対象牛群４区分のうち、「緊急と殺牛等」と「死亡牛」について、どちらに区分すべきか判別が困難な場合を想定して両群の統合を可能とする旨の規定を追加。

４．その他

（１）コホート（BSE感染牛確認の際に処分が必要な牛）の範囲の変更

コホートの範囲から、「BSE臨床症状発病前２年以内又は発病後にBSE感染雌牛から生まれた全ての産子」を削除。

（２）リスクアセスメントの対象の変更

リスクアセスメントの対象をBSE病原体の存在の有無（従前はTSE）、輸入された反芻動物（従前は生体動物）にそれぞれ変更。

資料　2

ＯＩＥ：ＢＳＥコード及びＢＳＥサーベイランス基準改正に関する主要論点
第74回OIE総会（06年5月21～26日、パリ）

1　無条件物品（ＢＳＥステータスに関わらず条件を課さずに輸入を承認すべき物品）に関する条件の変更

骨なし牛肉に課されている条件のうち、「30カ月齢以下」及び「BSE感染の疑いがなく、もしくは感染が確認されていない」との条件が削除されているが、

①　「30か月齢以下」という要件を課すことには科学的根拠がないという提案についてどう考えるか。また、月齢要件そのものを撤廃することについてどう考えるか。

②　「BSE感染の疑いがなく、もしくは感染が確認されていない」という要件は、同一文中の「生前／生後検査の合格」によってそのような牛は自動的に排除されることから不要であるという提案についてどう考えるか。

また、この場合、生前／生後検査の具体的な実施内容は、国が行うリスク評価の結果によって国毎に異なる場合があるが、このことについてどのように考えるか。

2．各カテゴリーに区分するための要件の変更

国が「無視できるリスク」に区分されるために満たすべき要件のうち、「自国産牛における最終発生が７年以上前に報告されたこと」を「いかなる自国産牛におけるBSE発生例も８年以上前に出生していること」に変更することとされているが、

①　発生の確認時期からBSE感染牛の出生時期に変更するのは、肉骨粉給与規制の効果に着目したものと考えられるが、このことについてどのように考えるか。

②　８歳以上の高齢牛のみでBSEの発生が確認されている国は、「無視できるリスク」の要件を満たす可能性が出てくる。この場合、現行規定ではＳＲＭ除去等の貿易条件が課されないこととなるが、このことについてどう考えるか。

３．サーベイランス基準の変更

① Ａ型、Ｂ型サーベイランスの摘発水準（Ａ型：１０万頭に１頭、Ｂ型：５万頭に１頭）については、加盟各国の実行可能性を考慮して設定された水準であるが、この水準についてどう考えるか。

② 全ての臨床的に疑わしい牛については、累積ポイントにかかわらず検査されるべき旨の提案についてどう考えるか。

③ サーベイランスの対象牛群４区分に関して、「臨床症状牛」はBSEの摘発率において優位性があるため単独で存続させるものの、「緊急とさつ牛等」と「死亡牛」については、どちらに区分すべきか判別が困難な場合を想定して両群の統合は可能とするという提案についてどう考えるか。

４．その他

（１）コホートの範囲から、「BSE臨床症状発病前２年以内又は発病後にBSE感染雌牛から生まれた全ての産子」を削除するという提案についてどう考えるか。

（２）リスクアセスメントの対象について、BSE以外のTSEがBSE病原体によるリスクを決定するという疫学情報がないことから、従来の「TSE病原体の存在の有無」を「BSE病原体の存在の有無」に、「輸入された生体動物」を「輸入された反芻動物」にそれぞれ変更するということとされているが、このことについてどう考えるか。

仮　訳

資料３－①

ＯＩＥ：ＢＳＥコード改正案（２００６年）

原文	仮　訳
Article 2.3.13.1.	**第 2.3.13.1 条**
The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.	本章に述べる勧告は、牛（*Bos taurus*及び*B. indicus*）における、牛海綿状脳症（BSE）病原体の存在に関わる人と動物の健康に対するリスクの管理を目的としている。
1)When authorising import or transit of the following *commodities* and any products made from these commodities and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country, *zone* or *compartment*:	1）以下に掲げる物品及びこれらの物品から製造され、それら以外の牛由来の組織を含有しない製品の輸入又は経由を承認するに当たって獣医当局は、輸出国、地域又はコンパートメントにおける牛群の BSE リスクに係るステータスにかかわらず、BSE に関連したいかなる条件をも要求すべきではない。
a)*milk* and *milk products*;	a)乳及び乳製品
b)semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;	b)精液及び国際受精卵移植学会の勧告にしたがって採取され、取り扱われた生体培養牛受精卵
c)hides and skins ;	c)獣皮（hides）及び皮革(skins)
d)gelatin and collagen prepared exclusively from hides and skins ;	d)獣皮及び皮革からのみ製造されたゼラチン及びコラーゲン
e)protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;	e)タンパクを含有しない獣脂（不溶性不純物の最大重量濃度は0.15%）及びその製品（derivatives）
f)dicalcium phosphate (with no trace of protein or fat);	f)第２リン酸カルシウム（蛋白又は脂肪が検出されないもの）、
g)deboned skeletal muscle *meat* (excluding mechanically separated meat) from cattle ~~30 months of age or less~~, which were not subjected to a stunning process,	g)と殺に先立って、器具を用いて頭蓋腔への圧縮空気又はガスを注入する方法を用いたスタンニング行程又は脊髄の破壊法（ピッシング行程）が行われ

prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, and which passed ~~were subject to~~ ante-mortem and post-mortem inspection ~~and were not suspect or confirmed BSE cases;~~ and which has been prepared in a manner to avoid contamination with tissues listed in Article 13.

h)blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2)When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone* or *compartment.*

Standards for diagnostic tests are described in the *Terrestrial Manual.*

ておらず、と殺前及び、と殺後検査に合格しを受け、~~BSE感染の疑いがなく、もしくは感染が確認されていない、~~また、第13条に列挙されている組織で汚染されないように前処理されている~~30ヶ月齢かそれ未満の~~牛に由来する脱骨された骨格筋肉（機械的除去肉を除く。）

h)と殺に先立って、器具を用いて頭蓋腔への圧縮空気又はガスを注入する方法を用いたスタンイング行程又はピッシング行程が行われていない牛由来の血液及び血液製品

2）本章に記載されている他の物品の輸入又は経由を承認するに当たって、獣医当局は、輸出国、地域又はコンパートメントにおける牛群の BSE リスクに係るステータスに対応した本章に記載されている要件を要求すべきである。

診断テストの基準は「陸生動物診断マニュアル」に記載されている。

Article 2.3.13.2.

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1)the outcome of a *risk assessment* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

a)Release assessment

Release assessment consists of assessing the likelihood that the BSE ~~a transmissible spongiform encephalopathy (TSE)~~ agent has been introduced into the cattle population from a pre-existing BSE ~~TSE~~ in the indigenous ruminant population or via *commodities* potentially contaminated with a BSE ~~TSE~~ agent, through a consideration of the following:

i)the presence or absence of the BSE agent ~~animal TSE agents~~ in the country, *zone* or *compartment* and, if present, evidence regarding ~~their~~ its prevalence

第２条

国、地域又はコンパートメントにおける牛群の BSE リスクに係るステータスは、以下に掲げる基準に基づき決定されるべきである。

1）1．3 章に基づくＢＳＥの発生及びそれらの歴史的背景に係る全ての潜在的要因を特定するためのリスク評価（毎年見直される）の結果、

a)侵入評価

侵入評価は、以下に掲げる事項を考慮して、自国産の反すう動物群に潜在する（pre-existing）BSE ~~TSE~~ から、又は、BSE ~~TSE~~ 病原体により潜在的に汚染している物品を通して、BSE ~~TSE~~ 病原体が牛群に導入されてきた可能性の評価から成り立つ。

i）国、地域又はコンパートメントにおける BSE 病原体 ~~動物の TSE 病原体~~の存在又は不在、及び、存在する場合には、その有疫率の根拠~~サーベイラ~~

based on the outcomes of surveillance;

ii) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

iii) imported *meat-and-bone meal* or *greaves*;

iv) imported live ruminnts animals;

v) imported animal feed and feed ingredients;

vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13 and may have been fed to cattle;

vii) imported products of ruminant origin for *in vivo* use in cattle.

The results of any Surveillance and other epidemiological investigations into the disposition of the *commodities* identified above (especially surveillance for BSE conducted on the cattle population) relevant to the above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

~~ランスの結果に基づくそれらの有病率~~；

ii）自国産反すう動物群由来の肉骨粉又は獣脂かす（graves）；

iii）輸入された肉骨粉又は獣脂かす；

iv）輸入された生体の反すう動物~~動物~~；

v）輸入された動物飼料及び飼料原料；

vi）食用に供される反すう動物由来であって、第 2.3.13.13 条に掲げられる組織を含んでいるでおり、かつ、それが牛に給与されてきたかもしれない輸入製品；

vii）牛の体内(in vivo)利用に供される反すう動物由来の輸入製品；

~~上記に関連のあるサーベイランス及び他の~~ 上記に示された物品の処分に対するいかなる疫学的調査結果も ~~(特に牛群を対象として実施された BSE サーベイランス)~~ は、評価を実施する場合、考慮に入れられるべきである。

b）暴露評価

仮に侵入評価でリスク病原体が特定された場合、以下に掲げる事項を考慮して、牛への BSE 病原体の暴露の可能性を評価することから成り立っている暴露評価が実施されるべきである：

i）牛が、肉骨粉又は獣脂かす若しくはこれらにより汚染した他の飼料又は飼料原料を摂取することを通じた BSE 病原体の循環及び増幅；

ii）反すう　動物の屠体（枝肉）（死廃牛からのものを含む。）、副産物及び と畜場廃棄物の利用、レンダリング工程及び動物用飼料の製造方法に係るパラメーター；

iii)the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;	iii）動物用飼料の交差汚染防止のための措置を含めて、反すう動物由来の肉骨粉及び獣脂かすの反すう動物の給餌の有無；
iv)the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance.	iv）牛群を対象に、その時点までに実施された BSE サーベイランスのレベル及び当該サーベイランスの結果。
2)on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;	2）附則第3. 8. 4条に規定されているターゲット亜群（target sub-populations）におけるBSE様症状（clinical signs consistent with BSE）を呈するすべての事例の報告を促すための、獣医師、農家並びに牛の輸送、販売及びと殺に関わる従業員を対象とした継続的な周知プログラム；
3)the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;	3）BSE様症状を呈するすべての牛の調査及び届出義務；
4)the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.	4）前述のサーベイランス及びモニタリング制度の枠組みの中で収集された脳又は他の組織に対する承認された研究所での検査。
When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.	リスク評価~~（上述の侵入及び暴露評価において言及したサーベイランスを考慮に入れている）~~が「無視できるリスク」を証明した場合、~~無視できるリスクではないことを証明する場合、~~当該国は別添 3.8.4 に基づくタイプ B のサーベイランスを実施すべきである。
When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible~~ fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.	リスク評価~~（上述の侵入及び暴露評価において言及したサーベイランスを考慮に入れている）~~が「無視できるリスク」を証明できない場合、当該国は別添 3.8.4 に基づくタイプ A のサーベイランスを実施すべきである。
Article 2.3.13.3. **Negligible BSE risk**	**第 2.3.13.3 条** 無視できる BSE リスク
Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent, should the following conditions be met:	次に掲げる条件に合致すれば、国、地域又はコンパートメントの牛群由来の物品が、BSE 病原体の伝達に関して無視できるリスクであることを示す。

1)*a risk assessment,* as described in point 1) of Article 2.3.13.2, has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage ~~all risk~~ each risk identified;

2)the country has demonstrated that Type B surveillance in accordance with Appendix 3.8.4. is in place and the relevant points target, in accordance with Table 1. has been met;

3)EITHER:

a)there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:

i)the criteria in points 2) to 4) of Article 2.3.13.2 have been complied with for at least 7 years; and

ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

b)~~the last indigenous *case* of BSE was reported more than 7 years ago~~ any indigenous case of BSE was born more than 8 years ago; and

i)the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii)it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and

iii)all BSE *cases*, as well as:

~~-all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~

1)第 2.3.13.2 条の 1）に記載されたリスク評価が、歴史的な及び現存するリスク要因を特定するために実施されており、当該国は、各々の~~すべての~~特定されたリスクを管理するため、適切かつ特定された~~包括的な（generic）措置~~が、以下に定義された妥当な期間、講じられていたことが証明されていること；

2)別添 3.8.4 に準拠した B 型サーベイランスを実施していることを当該国が証明しており、表 1 に適合した相当する目標ポイントを満たしていること；

3)かつ：

a)BSE の発生がないこと、又はいかなる BSE 感染事例も輸入されたものであることが証明されており、かつ、完全に処分（destroy）されたこと、並びに：

ｉ）第 2.3.13.2 条の 2）から 4）までに掲げられている基準が、少なくとも 7 年間遵守されていること；及び

ii）適切なレベルの管理（control）と査察（audit）を通じて、少なくとも 8 年間、反すう動物由来の肉骨粉又は獣脂かすが反すう動物に給餌されていないことが証明されていること；

又は

b)~~自国産牛における最終発生が 7 年以上前に報告されたこと~~ いかなる自国産牛における BSE 発生例も 8 年以上前に出生していること；及び

ｉ）第 2.3.13.2 条の 2）から 4）までに掲げる基準が、少なくとも 7 年間遵守されていること；及び

ii）適切なレベルの管理（control）と査察（audit）を通じて、少なくとも 8 年間、肉骨粉及び獣脂かすが反すう動物に給与されていないことが証明されていること；及び

iii）すべての BSE 感染牛、及び：

~~－ BSE 臨床症状発病前 2 年以内又は発病後に BSE 感染雌牛から生まれたすべての産子、及び~~

-all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or -if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*, if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.	－生後１年の間に、生後１年までBSE感染牛とともに飼育され、かつ、調査により当該期間に同じ汚染した可能性のある飼料を摂取したことが示されたすべての牛、又は －調査の結果が得られない場合には、感染牛と同じ群において、感染牛が生まれた前後１２ヶ月の間に生まれたすべての牛、 が、国、地域又はコンパートメント内で生存している場合には、これらの牛は永久に識別され、かつ、移動が管理され、並びにと殺又は死亡時に完全に処分されること。
Article 2.3.13.4 **Controlled BSE risk** *Commodities* from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent, should the following conditions be met: 1)a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken, but have not been taken for the relevant period of time to manage all risks identified ~~the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified~~; 2)the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4 is in place; Type B surveillance may replace Type A surveillance once the relevant points target, in accordance with Table 1. is met; 3)EITHER a)there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves*	**第 2.3.13.4 条** **管理された BSE リスク** 国、地域又はコンパートメントの牛群由来の物品が次に掲げる条件に合致すれば、BSE 病原体の伝達に関してリスクが管理されていることを示す。 1)第 2.3.13.2 条の 1）に記載されたようなリスク評価が、歴史的な及び現存するリスク要因の特定のために実施されており、また、当該国は適切な措置が行われているものの、特定されたすべてのリスクを管理するための妥当な期間措置が行われてきたわけではないことを証明してきたこと~~当該国は、すべての特定されたリスクを管理するため、適切な包括的（generic）措置が以下に掲げる妥当な期間、講じられていたことが証明されていないこと~~； 2)当該国が、別添 3.8.4 に基づき A 型サーベイランスを実施していることを証明していること；一旦、表１に相当する目標ポイントを満たした場合には、タイプ A サーベイランスをタイプ B サーベイランスに置き換えることが出来ること。 3)かつ、 a)BSE の発生がないこと、又はいかなる BSE 感染事例も輸入されたものであり、かつ、完全に処分されたことが証明されていること、第 2.3.13.2 条の 2）から 4）に掲げる基準が遵守され、適切なレベルの管理及び査察を通して、反すう動物由来の肉骨粉及び獣脂かすが反すう動物に給与されていないこと

derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:

i)the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii)it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

b)there has been an indigenous *case* of BSE ~~reported~~, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:

i)the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii)it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

iii)all BSE *cases*, as well as:

~~-all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~

-all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

-if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

が証明できるが、以下に掲げる２つの条件のうちの一つが少なくとも当てはまること：

ｉ）第 2.3.13.2 条の 2）から 4）までに掲げる基準が 7 年間遵守されていないこと；

ii）反すう動物由来の肉骨粉又は獣脂かすの反すう動物への給与に係る管理（control）が 8 年間実施されてきたことを証明することができないこと；

又は

b)自国産牛での発生事例~~の報告~~がこれまでにあり、第 2.3.13.2 条の 2）から 4）までに掲げる基準が遵守されており、かつ、適切なレベルの管理と査察を通して、反すう動物由来の肉骨粉及び獣脂かすが反すう動物に給与されていないことが証明できるが、以下の２つの条件のうちの、少なくとも一つが当てはまること：

ｉ）第 2.3.13.2 条の 2）から 4）までに掲げる基準が 7 年間遵守されていないこと；

ii）反すう動物由来の肉骨粉及び獣脂かすの飼料給与に係る管理が 8 年間実施されていることを証明することができないこと；

及び

iii）すべての BSE 感染牛、及び：

－ ~~BSE 臨床症状発病前２年以内又は発病後に BSE 感染雌牛から生まれたすべての産子、及び~~

－生後１年の間に、生後１年までBSE感染牛とともに飼育され、かつ、調査により当該期間に同じ汚染した可能性のある飼料を摂取したことが示されたすべての牛、又は

－調査の結果が得られない場合には、感染牛と同じ群において、感染牛が生まれた前後１２ヶ月の間に生まれたすべての牛、

が、国、地域又はコンパートメント内で生存している場合には、恒久的に

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed ;	識別され、かつ、移動が管理され、並びにと殺又は死亡時に完全に処分されること。
Article 2.3.13.5. **Undetermined BSE risk** The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.	**第 2.3.13.5 条** 不明の **BSE** リスク 他のカテゴリの要件を満たしていることを証明することができない場合、国、地域又はコンパートメントの牛群は、不明の BSE リスクであることを示す。
Article 2.3.13.6. When importing from a country, *zone* or *compartment* posing anegligible BSE risk, *Veterinary Administrations* should require:for all *commodities* from cattle not listed in point 1) of Article2.3.13.1. the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.	**第 2.3.13.6 条** 無視できる BSE リスクを引き起こす国、地域又はコンパートメントから輸入する場合、 獣医当局は、第 2.3.13.1 条の 1）に掲げられていないすべての牛由来の物品について、当該国、地域又はコンパートメントが第 2.3.13.3 条の条件を満たしていることを証明している国際獣医証明書の提示を要求すべきである。
Article 2.3.13.7. When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require: for cattle the presentation of an *international veterinary certificate* attesting that: 1)the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.; 2)cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3)b) iii) of Article 2.3.13.4.; 3)in the case of a country, *zone* or *compartment* with an indigenous case, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.	**第 2.3.13.7 条** 管理された BSE リスクを有する国、地域又はコンパートメントから輸入する場合、 獣医当局は、生体牛について、次に掲げる事項が証明されている国際獣医証明書の提示を要求すべきである： 1）当該国、地域又はコンパートメントが第 2.3.13.4 条に掲げる条件を満たしていること； 2）輸出用に選抜された牛は、母牛及び原産牛群までさかのぼることができる恒久的な個体識別制度によって識別されており、かつ、第 2.3.13.4 条の 3）b）iii）に記載されるような暴露牛でないこと； 3）自国産牛において BSE 感染事例がある国、地域又はコンパートメントの場合、輸出用に選抜された牛は、反すう動物由来の肉骨粉又は獣脂かすの反すう動物への給与禁止措置が効果的に施行された日の後に出生したものであること。

Article 2.3.13.8.	第 2.3.13.8 条
When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require: for cattle the presentation of an *international veterinary certificate* attesting that:	不明の BSE リスクの国、地域又はコンパートメントから輸入する場合、獣医当局は、生体牛について、次に掲げる事項が証明されている国際獣医証明書の提示を要求すべきである。
1)the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;	1)反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給与が禁止されており、かつ、当該禁止措置が効果的に実行されていること；
2)all BSE *cases*, as well as:	2)すべての BSE 感染牛、及び：
a)~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~	a)~~BSE 臨床症状発病前 2 年以内又は発病後に BSE 感染雌牛から生まれたすべての産子、及び~~
b)all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or	b)生後１年の間に、生後１年までBSE感染牛とともに飼育され、かつ、調査により当該期間に同じ汚染した可能性のある飼料を摂取したことが示されたすべての牛、又は
c)if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,	c)調査の結果が得られない場合には、感染牛と同じ群において、感染牛が生まれた前後12ヶ月の間に生まれたすべての牛、
if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;	が、国、地域又はコンパートメント内で生存している場合には、恒久的に識別され、かつ、移動が管理され、並びにと殺又は死亡時に完全に処分されること；
3)cattle selected for export:	3)輸出用に選抜された牛は：
a)are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;	a)母牛及び原産牛群までさかのぼることができる永久個体識別制度によって識別されており、かつ、BSE 患畜又は疑似患畜の産子でないこと；
b)were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was	b)反すう動物由来の肉骨粉及び獣脂かすの反すう動物への給与禁止措置が効果的に実行された日から少なくとも２年経過後に出生したものであること。

effectively enforced.	
Article 2.3.13.9. When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require: for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.:) the presentation of an *international veterinary certificate* attesting that: 1)the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.; 2)the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate~~;	**第 2.3.13.9 条** 無視できる BSE リスクを有する国、地域又はコンパートメントから輸入する場合、 獣医当局は、第 2.3.13.1 条（第 1 項で掲げられた物品以外）に記載されている牛由来の生鮮肉及び肉製品について、次に掲げる事項が証明されている国際獣医証明書の提示を要求すべきである： 1) 当該国、地域又はコンパートメントは、第 2.3.13.3 条の条件を満たすこと； 2) 生鮮肉又は肉製品が由来する牛がと殺前後の検査に合格していること~~生鮮肉又は肉製品の原料に供されるすべての牛に対して、と殺前後の検査(inspection)が実施されたこと~~；
Article 2.3.13.10. When importing from a country, *zone* or *compartment* posing a controlled BSE risk , *Veterinary Administrations* should require: For *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.) the presentation of an *international veterinary certificate* attesting that: 1)the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4; 2)the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate~~; 3)cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device	**第 2.3.13.10 条** 管理された BSE リスクを有する国、地域又はコンパートメントから輸入する場合、 獣医当局は、第 2.3.13. 1 条（第 1 項で掲げられた物品以外）に記載されている牛由来の生鮮肉及び肉製品について、次に掲げる事項を証明している国際獣医証明書の提示を要求すべきである： 1) 当該国、地域又はコンパートメントは、第 2.3.13.4 条に掲げる条件を満たすこと； 2) 生鮮肉又は肉製品が由来する牛がと殺前後の検査に合格していること~~生鮮肉又は肉製品の原料に供されるすべての牛に対して、と殺前後の検査(inspection)が実施されたこと~~ ； 3) 輸出用の生鮮肉又は肉加工品の原料に供される牛は、と殺に先立って、器具を用いて頭蓋腔へ圧縮空気又はガスを注入する方法を用いたスタンニング行

injecting compressed air or gas into the cranial cavity, or to a pithing process;	程又は脊髄の破壊法（ピッシング行程）が行われていないこと；
4)the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:	4)生鮮肉及び肉製品は：そのような製品が以下のものを含まず、かつ汚染されていないことを証明する方法によって生産され、管理されていること：
a)the tissues listed in Article 2.3.13.13.,	a)第 2.3.13.13 条に掲げる組織、
b)mechanically separated meat from the skull and vertebral column from cattle over 30 months of age, all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.	b)30 ヵ月齢を超えた牛由来の頭蓋骨及び脊柱から機械的に除去された肉、 これらはすべて生鮮肉及び肉製品の汚染を防止する方法で完全に除去されていること。
Article 2.3.13.11.	**第 2.3.13.11 条**
When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require: for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.) the presentation of an *international veterinary certificate* attesting that:	BSE リスクが不明の国、地域又はコンパートメントから輸入する場合、獣医当局は、第 2.3.13.1 条（第 1 項に掲げられた物品以外）に記載されている牛由来の生鮮肉及び肉製品について、次に掲げる事項が証明されている国際獣医証明書の提示を要求すべきである：
1)the cattle from which the *fresh meat* and *meat products* originate:	1)生鮮肉及び肉製品の原料に供される牛は：
a)~~are not suspect or confirmed BSE cases~~;	a)~~BSE の疑似患畜又は患畜ではないこと~~；
b)have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;	b)反すう動物由来の肉骨粉又は獣脂かすを給与されたことがないこと；
c)~~were subjected to~~ passed ante-mortem and post-mortem inspections;	c)と殺前後の検査（inspection）に合格したこと~~従ったこと~~；
d)were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;	d)と殺に先立って、器具を用いて頭蓋腔へ圧縮空気又はガスを注入する方法を用いたスタンニング行程又は脊髄の破壊法（ピッシング行程）が実施されていないこと；
2)the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:	2)生鮮肉及び肉製品は：そのような製品が以下のものを含まず、かつ汚染されていないことを証明する方法によって生産され、管理されていること：

a)the tissues listed in Article 2.3.13.13.,	a)第 2.3.13.13 条に掲げる組織、
b)nervous and lymphatic tissues exposed during the deboning process,	b)脱骨行程中に露出する神経組織及びリンパ組織、
c)mechanically separated meat from the skull and vertebral column from cattle over 12 months of age, all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.	c)12 か月齢を超えた牛由来の頭蓋骨及び脊柱から機械的に除去された肉、 これらはすべて生鮮肉及び肉製品の汚染を防止する方法で完全に除去されていること。
Article 2.3.13.12. Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.	**第 2.3.13.12 条** 反すう動物由来の肉骨粉又は獣脂かす、若しくはこれらの製品を含有するすべての物品であって、第 2.3.13.4 条及び第 2.3.13.5 条において規定されている国、地域又はコンパートメント由来のものは、貿易すべきでない。
Article 2.3.13.13. 1)From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.	**第 2.3.13.13 条** 1)第 2.3.13.4 条及び第 2.3.13.5 条において規定する国、地域又はコンパートメント原産のすべての年齢の牛由来の次に掲げる物品及びこれらによって汚染されているすべての物品は、食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具を製造する目的で貿易すべきでない：すなわち、扁桃および回腸遠位部、並びにこれら由来の蛋白製品。これらの物品を用いて製造された食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具も同様に貿易すべきでない。
2)From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article2.3.13.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.	2)第 2.3.13.4 条において規定される国、地域又はコンパートメント原産であって、と殺時の月齢が 30 ヵ月を超えている牛由来の次に掲げる物品及びこれらによって汚染されているすべての物品は、食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具を製造する目的で貿易すべきでない：すなわち、脳、眼、脊髄、頭蓋骨、脊柱及びこれら由来の蛋白製品。これらの物品を用いて製造された食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具も同様に貿易すべきでない。
3)From cattle that were at the time of slaughter over 12 months of age originating	3)第 2.3.13.5 条において規定される国、地域又はコンパートメント原産であっ

from a country, *zone* or *compartment* defined in Articles 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

て、と殺時の月齢が 12 ヵ月を超えている牛由来の次に掲げる物品及びこれらによって汚染されているすべての物品は、食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具を製造する目的で貿易すべきでない：すなわち、脳、眼、脊髄、頭蓋骨、脊柱及びこれら由来の蛋白製品。これらの物品を用いて製造された食料、飼料、肥料、化粧品、医薬品（生物学的製剤を含む。）又は医療用器具も同様に貿易すべきでない。

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1)a country, *zone* or *compartment* posing a negligible BSE risk; or

2)a country, *zone* or *compartment* posing a controlled BSE risk; and

a)skulls and vertebrae (except tail vertebrae) have been excluded;

b)the bones have been subjected to a process which includes all the following steps:

i)pressure washing (degreasing),

ii)acid demineralisation,

iii)prolonged alkaline treatment,

iv)filtration,

v)sterilisation at ≧ 138°C for a minimum of 4 seconds,

or to an equivalent process in terms of infectivity reduction.

第 2.3.13.14 条

輸入国の獣医当局は、骨由来のゼラチン及びコラーゲン並びに食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医療用器具に使用することを目的としたゼラチン及びコラーゲンについて、当該物品が以下の場所由来であることを証明する国際獣医証明書の提示を要求すべきである：

1)無視できる BSE リスクを有する国、地域又はコンパートメントであること；又は

2)管理された BSE リスクを有する国、地域又はコンパートメントであること；及び

a)頭蓋骨及び脊椎（尾椎を除く。）が除去されていること；

b)骨が以下に掲げるすべての段階を含む工程に従ってきたこと；

i）加圧洗浄（脂肪除去）、

ii)酸脱塩処理、

iii)長時間アルカリ処理、

iv)濾過、

v）１３８℃以上４秒以上の煮沸消毒、

又は感染性を削減する観点からこれらと同等である処理。

Article 2.3.13.15. *Veterinary Administrations* of *importing countries* should require: for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices the presentation of an *international veterinary certificate* attesting that ~~it originates~~ from: 1)a country, *zone* or *compartment* posing a negligible BSE risk, or 2)a country, *zone* or *compartment* posing a controlled BSE risk, and it originates from cattle which have ~~been subjected~~ passed to ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in point 1 and 2 of Article 2.3.13.13.	**第 2.3.13.15 条** 輸入国の獣医当局は、食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品又は医療用器具に使用することを目的とする獣脂（タロー）及び第2リン酸カルシウム（第2.3.13.1条において定義される蛋白を含有しない獣脂（protein-free tallow）以外）について、以下の場所由来であることを証明する国際獣医証明書の提示を要求すべきである。 1)無視できる BSE リスクに該当する国、地域又はコンパートメントであること；又は 2)管理された BSE リスクに該当する国、地域又はコンパートメントであること、及びと殺前後の検査（inspection）に~~供された~~合格した牛由来であって、かつ、第 2.3.13.13 条の第 1 項及び第 2 項に掲げられた組織を使用して製造されていないこと。
Article 2.3.13.16. *Veterinary Administrations* of *importing countries* should require: for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices the presentation of an *international veterinary certificate* attesting that: 1)they originate from a country, *zone* or *compartment* posing a negligible BSE risk, or 2)they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.	**第 2.3.13.16 条** 輸入国の獣医当局は、食品、飼料、肥料、化粧品、生物学的製剤を含む医薬品または医療用器具に使用することを目的とした獣脂由来製品（第2.3.13.1条において定義される蛋白を含有しない獣脂から製造されたもの以外）について、以下のことを証明する国際獣医証明書の提示を要求すべきである： 1)無視できる BSE リスクに該当する国、地域又はコンパートメント由来であること、又は 2)高温高圧の加水分解、鹸化又はエステル交換反応によって製造されたものであること。

仮　訳

ＢＳＥサーベイランス基準【２００６年改正案】

原文	仮　訳
Article 3.8.4.1. **Introduction** 1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy(BSE), surveillance for BSE may have one or more goals: a)detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*; b)monitoring the evolution of BSE in a country, *zone* or *compartment*; c)monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing ; d)supporting a claimed BSE status; e)gaining or regaining a higher BSE status. 2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size: a)cattle not exposed to the infective agent; b)cattle exposed but not infected; c)infected cattle, which may lie within one of three stages in the progress of BSE: i)the majority will die or be killed before reaching a stage at which BSE is detectable by current methods; ii)some will progress to a stage at which BSE is detectable by testing before clinical signs appear; iii)the smallest number will show clinical signs. 3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.	第 3.8.4.1 条 序文 1) BSE サーベイランスは、国、地域又はコンパートメントの牛海綿状脳症（BSE）についてのリスクカテゴリーに応じて、一つ又はそれ以上の目的を有している： a)国、地域又はコンパートメントにおける事前に決定された目標とすべき有病率での BSE の摘発 b)国、地域又はコンパートメントにおける BSE の進展（evolution）をモニタリングすること c)査察と連動して、飼料規制及び／又はその他のリスク低減措置の有効性をモニタリングすること d)BSE ステータスの主張を裏付けること e)より高い BSE ステータスを獲得、又は回復すること 2)BSE 病原体が、国又は地域に存在している場合、規模が大きい順に、牛群は以下のセクターを包含する： a)感染因子に暴露されていない牛； b)暴露したが感染していない牛； c)BSE の進行に係る 3 段階うちの一つに置かれている感染牛： i)大多数は、死亡し、又は現行手法で BSE を検出可能な段階に達する前に殺処分される； ii)いくつかの牛は臨床症状を発現する前に検査によって検出し得る段階に進行する； iii)ごく少数の牛が臨床症状を呈する； 3)国、地域又はコンパートメントの BSE ステータスは、サーベイランス計画のみによって決定することができるものではなく、第 2.3.13.2 条に掲げられるすべての要因にしたがって決定されるべきである。サーベイランス計画は、上記のセクターに関連した診断方法の限界及び感染牛の相対的な分布を考慮に入れるべきである。

4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

a)cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

b)cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter or downer cattle);

c)cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock);

d)cattle over 36 months of age at routine slaughter.

5) A gradient is used to describe the relative value of surveillance applied to each subpopulation.Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. ~~All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1 on general guidelines for animal health surveillance.

6) When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficults include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

4)上記に掲げるセクター内でのBSE病原体の分布及び発現に関連して、次に掲げる4つの牛群がサーベイランスを目的として識別されていること：

a)BSE様の行動又は臨床症状（臨床的に疑わしい症状）を呈する30ヶ月齢を超えた牛；

b)歩行困難、横臥状態、および補助なしでは歩行及び起立することができない30ヶ月齢を超えた牛；切迫と殺又はと殺前検査で廃用となった30ヶ月齢を超えた牛（死亡牛、切迫と殺牛又はダウナー牛）；

c)農場、輸送中又は食肉処理場における死亡牛であって30ヶ月齢を超えるもの（fallen stock）；

d)通常と殺で36ヶ月齢を超える牛。

5)各牛群に対し適用されるサーベイランスの相対的な価値を表現するため、勾配（gradient）が使用される。サーベイランスは、最初の牛群に焦点を当てるべきだが、他の牛群の調査は、国、地域又はコンパートメントのBSEの状況の正確な評価を提供することを補助するであろう。~~すべての国は、4つの牛群のうちの少なくとも3つからサンプリングを実施しなければならない。~~このアプローチは、動物衛生のサーベイランスに関する附則3.8.1に合致するものである。

6) サーベイランス手法を構築する際には、当局は農場における採材入手における特有の問題点について考慮し、これを克服する必要がある。これらの問題には、高コストであること、畜主に対して教育を行い動機付け行うことが必要であり、社会経済上の負のインプリケーションに対処することが含まれる。

Article 3.8.4.2.

Description of cattle subpopulations

1) Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects).

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are

第3.8.4.2条

牛群に係る説明

1) BSE様の行動又は臨床症状（臨床的に疑わしい症状）を呈している30ヶ月齢を超える牛

難治な疾病に罹患している牛、興奮、搾乳時における持続的なキッキングのような進行性の行動上の変化、牛群内における上下関係（hierarchical status）の変化、扉、ゲート及び柵壁に対する躊躇及び感染の徴候を有さない進行性の神経症状を呈している牛は、検査の候補となる。これらの行動上の変化は非常に微

candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

妙なものであるため、日常的に動物を取り扱っている者によって、もっとも良く確認される。BSE は、特徴的な臨床症状を引き起こさないことから、牛群を有するすべての国は、BSE 様症状を呈している個々の牛を観察することになるであろう。感染牛は、これらの症状のいくつかしか発現しないかもしれないし、程度が異なる可能性もあるが、そのような動物も、潜在的に BSE に罹患している動物として、引き続き観察するべきである。このような疑わしい事例が起こり得る確率は、疫学的状況によって異なり、そのために確実性を持って予測することはできない。

This subpopulation, ~~particularly cattle over 30 months of age,~~ is the one exhibiting the highest prevalence. ~~The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.~~ The accurate recognition, reporting and classification of such animls will depend on the ongoing owner/ veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

この牛群、~~特に３０ヶ月齢を超える牛~~は、最も高い有病率を有している。~~その確認は、経営者の意識及び擬似患畜の観察に大きく依存している。農場でのこれら擬似患畜の報告は、経費及び社会経済的な影響に基づく経営者の意欲（motivation）に依存するであろう。~~ そのような牛を正確に確認、報告、分類することは実施中の畜主及び獣医師に対する周知プログラムの次第であろう。このこと及び獣医当局によって導入されている調査・研究検査システム（第2.3.13.2条）はサーベイランスシステムの信頼性確保の為に不可欠である。

2) Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

2) 歩行困難、横臥状態、補助なしでは歩行及び起立することができない 30 ヶ月齢を超えた牛；切迫と殺に仕向けられ、又はと殺前検査で廃用となった 30 ヶ月齢を超えた牛（事故死牛、切迫と殺牛又はダウナー牛）

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

これらの牛は、上述の臨床症状のいくつかを示したが、BSE 様症状として認識されなかった可能性がある。BSE が確認された国における経験により、この群は2番目に高い有病率を示すことを示唆している牛群である。このような理由により、BSE を検出するための対象とするのに2番目に最適な牛群である。

3) Cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock)

3) 農場段階、輸送途上又は食肉処理場での死亡が認められ 30 ヶ月齢を超える牛（fallen stock）

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where

これらの牛は、死亡前に上述の臨床症状のいくつかを示したかもしれないが、BSE 様症状として認識されなかった可能性がある。BSE が確認された国におけ

BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.	る経験により、この牛群は3番目に高い有病率を示すことを示唆している。
4) Cattle over 36 months of age at routine slaughter Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2). ~~Within each of the above subpopulations, countries may wish to target cattle identifiable as imported from countries or *zones* not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.~~ ~~When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.~~	4) 通常と殺で36ヶ月齢を超える牛 BSE が確認された国における経験により、この亜群はもっとも低い有病率を示す牛群であることを示唆している。このような理由により、BSE を検出するための対象としてはもっとも妥当性の低い牛群である。しかしながら、この牛群からのサンプリングは、疾病流行のプロセス及び採用している防疫措置の有効性をモニタリングする上での一助となり得る。なぜならば、牛群の既知の種類（class）、年齢構成及び地理的由来への継続的なアクセスを提供するからである。36 ヵ月齢よりも若い通常と殺牛のルーティン検査の有効性は、相対的に非常に小さい。（表2） ~~上記の各牛群内において、各国は、BSE 非清浄国又は地域から輸入されたものとして識別し得る牛、BSE 非清浄国又は地域から輸入された潜在的に汚染を受けた飼料を摂取した牛、BSE 感染牛の産子及び他の TSE 病原体により潜在的に汚染された飼料を消費した牛、を標的とすることを望むことも可能である。~~ ~~サーベイランス戦略を策定する場合、当局は農場においてサンプルを取得する上での特有の障害を考慮に入れなければならない。これらの障害には、高いコスト、経営者の教育と意欲の必要性、潜在的にネガティヴな社会経済的影響の克服が含まれる。当局は、これらの障害を克服する方法を見いだきなければならない。~~
Article 3.8.4.3. ~~1)~~ Implementation of ~~Type A~~ surveillance In order to implement efficiently a surveillance strategy for BSE, a country must use ~~good quality data (or reliable estimates)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of ~~it's~~ the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*. ~~The application of the following procedure will allow the detection of BSE prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.~~ The approach assigns 'point values' to each sample, based on the subpopulation from	第 3.8.4.3 条 ~~1)~~ ~~A~~型サーベイランスの実施 効率的に BSE に対するサーベイランス戦略を実行するため、各国は~~質の高いデータ（又は信頼できる推計）~~文書化された記録又は当該国、地域又はコンパートメント内の成牛群における年齢分布及び年齢区分別、牛群別の BSE 検査頭数~~に係る~~の信頼できる推計を使用しなければならない。~~次に掲げる手続の適用は、関連した国、地域又はコンパートメントにおいて、95%の信頼性で、成牛群における少なくとも 10 万頭に 1 頭の BSE 有病率の検出を可能にするであろう。~~ サンプルが収集された牛群及び当該牛群における感染牛の摘発の可能性に基づ

which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

き、アプローチは各々のサンプルに評価ポイント（point value）を割り当てる。サンプルに割り当てられるポイントの数は、サンプリングされた牛群及びサンプリングされた動物の年齢により決定される。ポイントの蓄積の総計は、国、地域又はコンパートメントに対するポイントの目標数と定期的に対比される。

A ~~country should design its~~ surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

~~国は、~~サーベイランス戦略は、そのサンプルが国、地域又はコンパートメントにおける牛群を代表するよう計画されるべきである。また、生産タイプ及び地理的位置のような統計上の要素、及び文化的に独特な畜産の慣習による潜在的な影響を考慮に入れるべきである。使用されるアプローチ及び設定された仮定は、完全に記録され、かつ、当該記録は7年間保持されるべきである。

The points targets and surveillance point values in the appendix were obtained by applying the following factors to a statistical model:

附則中のサーベイランス目標ポイント及びサーベイランス評価ポイントは、統計学的モデルに次に掲げるファクターを適用することによって得られた。

a) ~~π~~ the design prevalence for Type A or Type B surveillance ~~of one case per 100,000 of the adult cattle population~~;

a) A型もしくはB型サーベイランスの為の~~成牛群における10万頭に1頭の~~有病率の設定；

b) a confidence level of 95%;

b) 95％の信頼限界；

c) the pathogenesis, and pathological and clinical expression of BSE:
   i) sensitivity of diagnostic methods used;
   ii) relative frequency of expression by age;
   iii) relative frequency of expression within each subpopulation;
   iv) interval between clinical pathological change and clinical expression;

c) BSEの病因論、ならびに病理学的及び臨床学的発現：
   i) 使用された診断方法の感度；
   ii) 年齢による相対的な発現頻度；
   iii) 各群内における相対的な発現頻度；
   iv) 臨床的病理学的変化及び臨床的発現の間の期間；

d) demographics of the cattle population, including age distribution;

d) 年齢分布を含む牛群の頭数統計；

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

e) 4つの群を通した牛群からの牛の淘汰又は頭数削減（attrition）に対するBSEの影響；

f) percentage of infected animals in the cattle population which are not detected.

f) 摘発されていない牛群における感染牛の割合；

Although the procedure accepts very basic information about a cattle population, and

この手順は、牛群に関する極めて基礎的な情報を受け入れ、かつ、予測および正確性が比較的低いデータとともに使用することができるが、慎重なデータの

can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are: a) cattle population numbers stratified by age; b) the number of cattle tested for BSE stratified by age and by subpopulation.	収集と記録は、それらの価値を大幅に高める。臨床的疑似患畜から採取されたサンプルは、健康牛や原因不明の死亡牛から採取されたサンプルよりも何倍もの情報を提供することから、入力データに対してよく注意することは、手続上の経費及び必要とされるサンプル数を実質的に低減することができる。必須の入力データとは： a) 年齢によって階層分類された牛群の頭数； b) 年齢と亜群によって階層分類された BSE 検査牛の頭数；
This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.	本附則は、望ましいサーベイランスの目標ポイント（point target）及び収集されたサーベイランスのサンプルの評価ポイント（point value）を決定するために表１及び表２を活用する。
Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.	上記の各牛群内において、各国は、BSE 非清浄国や地域から輸入されたものとして識別し得る牛、BSE 非清浄国又は地域から輸入された潜在的に汚染を受けた飼料を摂取した牛を標的とすることを望むことも可能である。
All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.	全ての臨床的に疑わしいケースは蓄積されたポイントの数に係らず、検査を行われるべきである。更に、その他の牛群のものも検査をされるべきである。
1) Type A surveillance The application of Type A surveillance will allow the detection of BSE around a design prevalence[47] of at least one case per 100,000 in the adults cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.	1) A 型サーベイランス A 型サーベイランスの適用は、少なくとも95%の信頼度で、当該国、地域及びコンパートメント内の成牛群において少なくとも10万頭に１頭の BSE 有病率の検出を可能とするものである。
2) Type B surveillance The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%. Type B surveillance may be carried out by countries, *zone* or *compartment* of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusion of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors	2) B 型サーベイランス B 型サーベイランスの適用は、少なくとも95%の信頼度で、当該国、地域又はコンパートメント内の成牛群において少なくとも5万頭に１頭の BSE 有病率の検出を可能とするものである。 B 型サーベイランスは例えば、特定されたいずれのリスクも低減させる措置の有効性の実証によって、或いは、それらの措置の失敗を検出する可能性を最大限に高めることを目的としたサーベイランスを通じて、リスクアセスメント

identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries, *zone* or *compartments* of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

~~For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk without commodity-specific risk mitigation measures', surveillance should continue at a reduced, maintenance level.~~

~~In order to implement efficiently a maintenance surveillance strategy for BSE,a country must use good quality data(or reliable estimates) concering the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation.The applicaion of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population,at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.~~

~~Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment*'s BSE status (to a maximum of 7 years).~~

の結論を確認するために、無視できる BSE リスクのステータス（第 2.3.13.3 条）の国又は地域において実施可能である。

B 型サーベイランスは、A 型サーベイランスを活用して得られた相当する目標ポイントの達成に続ける形で、A 型サーベイランスを通じて獲得された知見の信頼度を維持する目的で、管理された BSE リスクのステータス（第 2.3.13.4 条）の国、地域又はコンパートメントにおいても実施可能である。

~~リスクアセスメント（サーベイランスを含む。）を通して、「物品特異的なリスク低減措置を伴わない無視できるリスク」の要件に合致していることを示している国については、サーベイランスは、縮小した維持レベルで継続されるべきである。~~

~~BSE のための維持サーベイランス計画を効果的に実行するために、国は、国内の成牛群の月齢分布及び月齢や群によって階層化されたＢＳＥ検査された牛の頭数に関する良質なデータ（もしくは信頼性のある概算）を用いなければならない。以下の手順を適用すれば、当該国、地域、またはコンパートメントにおいて、95%の信頼度で、少なくとも50,000頭中に1頭の BSE 有病率感染牛を発見することができる。本附則では、望ましいサーベイランス目標ポイントと採取されたサーベイランスサンプルの価値を決定するために、表１と２を用いる。~~

~~維持サーベイランスは、比較的高い有病率の群（特に臨床的疑似患畜）に焦点を当てるべきである。毎年得られる臨床的疑似患畜からのサンプルは、国、地域又はコンパートメントにおける BSE ステータスに達するまでに要した期間（最大限７年間）中の臨床的疑似患畜から年間を通して採取されるサンプル数に近似させるべきである。~~

Article 3.8.4.4.

1) Selecting the points target

The desired surveillance points target ~~is~~ should be selected from Table 1, which shows target points for adult cattle populations of different sizes. ~~A country's~~ The size of the adult cattle population ~~size~~ of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point

第 3.8.4.4 条

1) 目標ポイントの選択

望ましいサーベイランスの目標ポイントは、成牛の頭数規模ごとに目標ポイントを示している表 1 から選択されるべきである。国、地域またはコンパートメントにおける成牛群の規模は、指定されるか 100 万頭にセットすることができるが、これは、統計学的な理由により、100 万頭は、サンプルサイズが群サイ

beyond which sample size does not further increase with population size. ~~The target depends on the design prevalence chosen by the country.~~

ズに伴ってこれ以上増加しないポイントの水準となっている。~~対象は、国によって選択されたデザイン有病率の設定によって変化する。~~

DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

有病率の設定(DP)は目標ポイントにおいて示されているサーベイの対象の規模を決定するために用いられている。もし、実際の有病率が設計上の選択されたものよりも高い場合、サーベイではより BSE が検出されやすくなる。

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* ~~which has not identified any BSE cases~~

表 1 ~~BSE 感染牛が確認されていない~~国、地域又はコンパートメントにおける成牛群のサイズに応じた採材目標ポイント

~~Points Target for country, zone or compartment with 0 cases, 95% confidence~~		
Adult Cattle Population Size (24 months and older)	**Type A Surveillance 1/100,000**	**Type B Surveillance 1/50,000**
≧ 1,000,000	300,000	150,000
800,000 - 1,000,000	240,000	120,000
600,000 - 800,000	180,000	90,000
400,000 - 600,000	120,000	60,000
200,000 - 400,000	60,000	30,000
100,000 - 200,000	30,000	15,000
50,000 - 100,000	15,000	7,500

~~DP is the maximum possible prevalence or "design prevalence".~~

~~BSE 事例がゼロである~~国、地域又はコンパートメント~~に係る (信頼性 95%)~~ 目標ポイント		
成牛群のサイズ (24 ヵ月齢以上)	**Type A Surveillance** 1/10 万	**Type B Surveillance**[1] 1/5 万
≧ 1,000,000	300,000	150,000
800,000 -1,000,000	240,000	120,000
600,000 - 800,000	180,000	90,000
400,000 - 600,000	120,000	60,000
200,000 - 400,000	60,000	30,000
100,000 - 200,000	30,000	15,000
50,000 - 100,000	15,000	7,500

[1] ~~DP とは、最大可能有病率又はデザイン有病率。~~

2) Determining the point values of samples collected

2) 採取されたサンプルの評価ポイントの決定について

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

表 2 は、採取されたサーベイランスサンプルの評価ポイントの決定に用いることができる。この手法は、サンプルが採取された群及びサンプルを採取した牛の年齢に基づき、感染を摘発する可能性に応じて各々のサンプルに評価ポイントを設定する。この手法は、附則3. 8. 1条に記載されているサーベイランスの一般原則及び BSE の疫学を考慮に入れている。

Because precise aging of the animals that are sampled may not be possible, Table 2

サンプリングされた牛の正確な年齢の決定が不可能かもしれないため、表 2 は、

combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise cllasefication of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~In addition, countries should sample at least three of the four subpopulations.~~

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

評価ポイントを5つの年齢カテゴリーにまとめている。各々のカテゴリーのポイント推定値は、グループを構成する年齢幅の平均として決定された。年齢グループは、BSE の潜伏期に関する科学的知見と及び世界的な BSE に係る経験に準じた BSE 発現の相対的な可能性に基づいて選択された。サンプルは、あらゆる群及び年齢のコンビネーションから選択することができるが、国、地域又はコンパートメントの牛群の頭数統計を反映するべきである。

もし、国、地域又はコンパートメントが自らの牛群の年齢分布及び疫学的特徴に基づいて、'事故死牛、切迫と殺牛及びダウナー牛'と'死亡牛群'の正確な分類は不可能であると判断するのであれば、これらの牛群をひとくくりにすることも可能である。そのようなケースではひとくくりにされた牛群のサーベイランスの評価ポイントは'死亡牛群'のものが適用される。

~~さらに、国は、4牛群中少なくとも3牛群から採材するべきである。~~

収集されたサンプルの合計ポイントは、表1の中で決定された目標ポイントを達成するため、最長連続7年間にわたって累積することが可能である。

Table 2 Surveillance point values for samples collected from animals in the given subpopulation and age category

Surveillance subpopulation			
Routine slaughter 1	**Fallen stock** 2	**Casually slaughter** 3	**Clinical suspect** 4
age ≧ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≧ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≧ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≧ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≧ 9 years (aged)			
0.0	0.1	0.2	45

1 See point 4) of Article 3. 8. 4. 2.

表 2 特定の牛群及び年齢区分における牛から収集されたサンプルのサーベイランス評価ポイント

サーベイランス群			
通常と殺*	死亡牛**	事故牛***	臨床上の疑似患畜****
1歳以上2歳未満			
0.01	0.2	0.4	N/A
2歳以上4歳未満（若い成牛）			
0.1	0.2	0.4	260
4歳以上7歳未満（中間的な成牛）			
0.2	0.9	1.6	750
7歳以上9歳未満（高齢の成牛）			
0.1	0.4	0.7	220
9歳以上（老齢牛）			

1 第3. 8. 4. 2条の第4項参照。

2 See point 3) of Article 3.8.4.2. 3 See point 2) of Article 3.8.4.2. 4 See point 1) of Article 3.8.4.2.	2 第3.8.4.2条の第3項参照。 3 第3.8.4.2条の第2項参照。 4 第3.8.4.2条の第1項参照。
Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).	サーベイランスポイントは、7年間有効である。(潜伏期間の95番目のパーセンタイル)
~~Article 3.8.4.5.~~ ~~To monitor the evolution of BSE in a country, zone or compartment once it is detected~~ ~~To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.~~	~~第3.8.4.5~~ ~~BSEが摘発された国、地域又はコンパートメントにおけるBSEの進展のモニタリング~~ ~~一度BSEが摘発された国、地域又はコンパートメントにおけるBSEの進展をモニタリングするためには、BSEの有病率を決定するためのより集中的なサンプリング手法が必要とされる。国内の牛群においてBSEが存在していることが決定している国に対しては、サーベイランスの目標は、摘発からBSEの程度と進展のモニタリング、飼料規制及び特定危険部位除去政策のような防疫措置の有効性のモニタリングに移行する。~~

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
September 2005

REPORT OF THE MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 19-30 September 2005

The OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission) met at the OIE Headquarters in Paris from 19 to 30 September 2005.

The members of the Terrestrial Code Commission are listed in Appendix I. The agenda adopted is given in Appendix II.

The Director General of the OIE, Dr B. Vallat, welcomed the members and thanked them all for their willingness to participate in this important OIE work. He recalled the significant changes to the meeting timetable of the two Code Commissions in that the OIE was reverting to a two-year cycle for the preparation and adoption of standards, except in the case of international crises. He hoped that the changed timetable would further improve coordination in standards work between the Terrestrial Code Commission and the other Commissions.

Dr Vallat recalled the commitments made to Member Countries at the 73rd General Session regarding progress on some important texts which had been adopted on the understanding that outstanding Member Countries' comments would be addressed. This included surveillance for bovine spongiform encephalopathy (BSE) (which would allow the official recognition of BSE status under the new chapter), bluetongue surveillance, the newly adopted standards on animal welfare, the 'under study' parts of the avian influenza chapter, and compartmentalisation. Dr Vallat also noted the need to address the recommendations arising from Regional Commission and other OIE meetings, including suggestions for improving the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) chapters on Veterinary Services (including statutory body responsibilities, rapid response capability and auditing mechanisms).

Dr Vallat encouraged the Terrestrial Code Commission and the Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) to continue their collaborative work on harmonisation of the two *Codes*.

The President of the Terrestrial Code Commission considered that the meeting was an appropriate time to examine the ways in which the Terrestrial Code Commission was operating and how procedures could be improved, particularly in relation to the other Commissions and the revised meeting schedule.

The Terrestrial Code Commission examined various *Terrestrial Code* texts in the light of Member Countries' comments received just prior to and following the 73rd General Session. The outcome of the Terrestrial Code Commission's work is presented as appendices to this report. Amendments made to existing chapters and previously circulated drafts are shown as double underlined text, with deleted text in strikeout.

The Terrestrial Code Commission thanked the following Member Countries for providing comments: Argentina, Australia, Botswana, Brazil, Canada, Chile, the European Union (EU), Japan, New Zealand, the Southern Cone countries of South America, Sudan, Switzerland, Taipei China, Thailand and the United States of America (USA).

The Terrestrial Code Commission strongly encouraged Member Countries to participate in the development of the OIE's international standards by sending comments on this report in sufficient time for them to be considered by the Commission. It would assist the Terrestrial Code Commission if comments were submitted as specific proposed text changes, supported by a scientific rationale.

Comments need to reach the OIE Headquarters by 17 February 2006 in order to be considered at the next meeting of the Commission in March 2006. However, in order to meet the deadlines for meetings of the Animal Production Food Safety Working Group and the Scientific Commission on Animal Diseases (hereafter referred to as the Scientific Commission) comments on Appendices VII, XII, XXIV and XXV should reach the OIE Headquarters by 3 January 2006.

Member Countries should note that, unless stated otherwise, all texts submitted for comment in this report (Part A) may be proposed for adoption at the 74th General Session. Depending on the nature of the comments received on each text, the Terrestrial Code Commission will indicate in its March 2006 meeting report whether a particular text will be proposed for adoption or held over for further work.

A. TEXTS WHICH ARE SUBMITTED FOR MEMBER COUNTRY COMMENT

1. General definitions (Chapter 1.1.1.)

After examining a comment from Australia on the definition of '*Case*', the Terrestrial Code Commission reconfirmed its previous position that limiting the pathogen by referring to 'listed by the OIE' would not be wise in order to encourage reporting of diseases not listed by the OIE, notably emerging diseases.

The suggestion by the EU to modify '*Outbreak of disease or infection*' to be serially numbered was not adopted as the Terrestrial Code Commission believes that every Member Country has its own system of numbering and any numbering system OIE suggests may cause confusion.

After considering the comment by Portugal during the 73rd General Session, the definition of '*Quarantine station*' was modified to accommodate disease specific conditions.

A set of definitions proposed by the Working Group of Animal Welfare was reviewed and endorsed by the Terrestrial Code Commission with some minor modifications.

Suggested changes are at Appendix III for the comment of Member Countries.

2. Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.)

The Terrestrial Code Commission received from the President of the *ad hoc* Group a draft revised text of Chapters 1.3.3. and 1.3.4. on the evaluation of Veterinary Services. This revision included recommendations on the evaluation of the Veterinary Statutory Body and on a procedure whereby a Member Country can request the OIE to organise an evaluation of its Veterinary Services.

The Terrestrial Code Commission also reviewed the tool (*Performance, Vision, Strategy* [PVS] *Instrument*) developed by the OIE and the Inter-American Institute for Cooperation on Agriculture (IICA) for the evaluation of Veterinary Services. This evaluation tool has been tested in the Americas and later reviewed and updated on the basis of this experience for a broader application. The *Instrument* was designed to indicate the areas of strength and weakness of a Veterinary Service (with a view to the allocation of resources) rather than to pass or fail it. The Terrestrial Code Commission was of the opinion that this tool could be used as a guide for self-evaluation by a Member Country of its Veterinary Services and for evaluation by the OIE of a Member Country's Veterinary Services on a voluntary basis.

Suggested changes to the chapters are at Appendices IV and V for the comment of Member Countries. The current version of the *PVS Instrument* is attached for the comment of Member Countries (Appendix VI).

3. Zoning and compartmentalisation (Chapter 1.3.5.)

Comments received from Member Countries as well as issues raised during the 73rd General Session were examined.

Paragraphs in the articles on 'Introduction' and 'General considerations' were reorganised to address the issues more logically. The Terrestrial Code Commission also clarified the commitment of the Veterinary Administration by modifying the last paragraph of Article 1.3.5.2.

The Terrestrial Code Commission was concerned that the concept of compartmentalisation was not yet well understood. It noted that the application of compartmentalisation was not mandatory and it should be used in a similar manner to zoning, depending on the epidemiology of the disease. While the primary criteria for zoning are related to geography, those for compartments relate to biosecurity management measures; however, the application of zoning includes some biosecurity elements and compartmentalisation will involve a spatial element for some diseases.

The Terrestrial Code Commission also discussed some issues on compartmentalisation with the *ad hoc* Group on Epidemiology which is preparing an explanatory paper on the concept in order to provide guidance to Member Countries.

The revised Chapter 1.3.5. is submitted at Appendix VII for the comment of Member Countries.

4. General guidelines for animal health surveillance (Appendix 3.8.1.)

The Terrestrial Code Commission was advised that the Scientific Commission will review the work of the *ad hoc* Group on Epidemiology at the Commission's meeting in January 2006 and present a revised appendix for consideration at the Terrestrial Code Commission's meeting in March 2006. The Terrestrial Code Commission has requested the Scientific Commission to take into account comments received from Member Countries.

The Terrestrial Code Commission has also requested that some guidelines on surveillance for vectors be included in the appendix.

5. Criteria for listing diseases (Chapter 2.1.1.)

The Terrestrial Code Commission met with Dr K. Ben Jebara, Head of the OIE Animal Health Information Department, to discuss the comments from Member Countries on the criteria for listing diseases. Minor changes were made to Article 2.1.1.1. and the decision tree in Article 2.1.1.2. was amended accordingly. Member Countries' proposals for the inclusion to or deletion from the OIE list of diseases will be considered by the *ad hoc* Group on Animal Disease Notification. Member Countries are reminded that they need to submit a supporting statement (addressing the relevant criterion) with each proposal.

The revised text at Appendix VIII is submitted for the comment of Member Countries.

6. Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7.)

The following modifications, in addition to some minor changes, were made to the chapter on foot and mouth disease (FMD) in response to Member Countries' comments.

After examining a comment from the EU, the Terrestrial Code Commission modified the conditions for "Recovery of free status" in Article 2.2.10.7. to clarify that it also applies to country, not only to zone. After examining a comment from New Zealand, the Terrestrial Code Commission clarified point 5) of Article 2.2.10.8. The Terrestrial Code Commission discussed the comment from the EU regarding the need to certify the vaccination status of an animal and decided to ask the Scientific Commission to further examine the need for such a requirement in Articles 2.2.10.9. and 2.2.10.10.

The Terrestrial Code Commission decided to send the comments from the EU on the milk and milk products for animal feeding in Article 2.2.10.24. and on skins and trophies from wild susceptible animals in Article 2.2.10.29. to the Scientific Commission, for further examination.

The Terrestrial Code Commission noted that the revised Appendix 3.8.7. prepared by the Scientific Commission did not include the concept of compartmentalisation. As a result, the Terrestrial Code Commission did not incorporate the concept into the chapter as requested by some Member Countries.

Some surveillance issues raised by Member Countries were referred to the Scientific Commission for consideration.

The revised chapter and appendix are presented at Appendices IX and X for the comment of Member Countries.

7. Bluetongue (Chapter 2.2.13.)

After reviewing comments from New Zealand, the Terrestrial Code Commission modified the southern latitude boundary in Articles 2.2.13.1. and 2.2.13.2.

After examining comments from the EU on the distance from the infection front in which surveillance was required, the Terrestrial Code Commission modified the paragraph to give more flexibility, with a linkage to the proposed surveillance appendix on bluetongue.

The newly developed surveillance appendix was received from the Scientific Commission and is presented unchanged to Member Countries.

The revised chapter and appendix are presented at Appendices XI and XII for the comment of Member Countries.

8. Bovine tuberculosis (Chapter 2.3.3.)

The Terrestrial Code Commission reviewed comments from the EU and New Zealand. The Terrestrial Code Commission decided to forward all comments to the Scientific Commission for examination, including the proposal from some Member Countries to expand the scope of this chapter or develop a new chapter to include bison, deer and wildlife.

9. Bovine spongiform encephalopathy (Chapter 2.3.13. and Appendix 3.8.4.)

a) Chapter 2.3.13.

The Terrestrial Code Commission recalled the discussion at the 73rd General Session where some Member Countries were opposed to inclusion of muscle meat and blood products in the list of commodities which can be traded safely. However, arguments were largely based on studies using laboratory strains of transmissible spongiform encephalopathy (TSE) in laboratory animals, and many scientific papers have confirmed that different TSEs behave differently in various animal models. With respect to BSE, cattle provide the appropriate model to study the distribution of the agent in cattle. A number of studies has failed to demonstrate the presence of BSE in muscle meat or in the blood of experimentally infected cattle not showing clinical signs of BSE.

The Terrestrial Code Commission also took into account information arising from a recent World Health Organization (WHO) Consultation on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies, but noted that, in many cases, this was preliminary information requiring further validation. The meeting also referred to an equivocal result for muscle meat (semitendinosus muscle) arising from a clinically affected cow. The Terrestrial Code Commission did not believe that any changes in this regard were required to the current text, but it would continue to monitor the progress in the research.

Comments from New Zealand and the Southern Cone countries of South America, which were endorsed by the *ad hoc* Group on Surveillance for BSE, were taken into account and references to other TSEs was deleted from the BSE chapter, because there is little evidence that surveillance information on other TSEs is necessary to determine the risks presented by the BSE agent. Any risks presented by other TSEs are addressed by the application of measures such as feed bans.

The Terrestrial Code Commission has been concerned for some time that up-to-date recommendations needed to be developed for other commodities, and will ask the Director General to convene an expert group to examine the safety of gelatine and tallow.

It also considered the issue of the specifications in point g) of Article 2.3.13.1 and "...30 months of age or less..." was removed because there is no scientific basis for this age restriction. The reference to "...and were not suspect or confirmed BSE cases..." was also deleted as the ante-mortem and post-mortem inspection specified in the same sentence would automatically exclude such animals. Likewise, in Article 2.3.13.11, point 1)a) was deleted, as point 1)c) precludes any suspect or confirmed BSE cases.

The Terrestrial Code Commission did not agree with the EU comment that the requirement for annual review of the risk assessment in Article 2.3.13.2.was onerous. It noted that the requirement was that documentation be provided to indicate whether the situation had changed in the previous 12 months.

In revising Articles 2.3.13.3. and 2.3.13.4., the Terrestrial Code Commission took into consideration comments from Canada, the EU, New Zealand and Switzerland, as well as recommendations made by the *ad hoc* Group on Surveillance for BSE. Point 2) of Article 2.3.13.4. was modified to incorporate references to Type B surveillance. In response to a submission from New Zealand and after considering advice from an expert, the reference to progeny was deleted from point 3)b)iii) of Articles 2.3.13.3. and 2.3.13.4. and point 2 a) of Article 2.3.13.8.

The Terrestrial Code Commission is working with an expert to update the existing supporting document on BSE.

The revised chapter is at Appendix XIII for the comment of Member Countries.

b) Appendix 3.8.4.

The report of the second meeting of the *ad hoc* Group on Surveillance for BSE is at Appendix XXXIII for the information of Member Countries.

The Terrestrial Code Commission examined the appendix proposed by the experts and endorsed it with minor changes.

The Appendix on surveillance for BSE is at Appendix XIV for the comment of Member Countries.

c) Appendix 3.8.5.

The Terrestrial Code Commission recognised that, as a result of changes made in the Appendix 3.8.4., Appendix 3.8.5. needs to be revised. It will work on this and present the draft as a part of the report of its March 2006 meeting.

10. Classical swine fever (Chapter 2.6.7. and Appendix 3.8.8.)

At the request of several Member Countries, the Terrestrial Code Commission worked on the chapter on classical swine fever (CSF) to incorporate the concept of compartmentalisation. The chapter was modified in order to better harmonise various articles, including with equivalent articles in the FMD chapter. However, new science was not introduced.

The chapter now does not make specific reference to countries or zones where there is a different health status of the domestic and wild pig populations, unless compartmentalisation is applied to maintain separation of domestic from wild pigs.

Requests from New Zealand and Japan to refer to surveillance in point 2)b) of Article 2.6.7.4. have been addressed as a result of the revision of the article.

The prescriptive text was deleted from Article 2.6.7.6., as it was considered inappropriate to prescribe such conditions which should be developed on a case-by-case basis.

The Terrestrial Code Commission is submitting the modified chapter for Member Countries' comment (Appendix XV), and will also submit it to the Scientific Commission to allow it to make the necessary changes to the appendix on surveillance. Among the changes required in the appendix, particular emphasis will need to be placed on the type of surveillance necessary to support the establishment and maintenance of a free compartment within infected countries or zones.

The Terrestrial Code Commission is awaiting advice from the Scientific Commission regarding commodities which could be safely traded regardless of the CSF status of the exporting country.

11. Avian influenza (Chapter 2.7.12. and Appendix 3.8.9.)

a) Chapter 2.7.12.

During the 73rd General Session, a revised *Terrestrial Code* chapter on avian influenza was adopted by the OIE International Committee. This revised chapter and the comments received from Argentina, Australia, Chile, the EU, the International Egg Commission, Japan, New Zealand and an expert were considered by the Terrestrial Code Commission. Among a number of general comments, in particular, comments on compartmentalisation and vaccination were taken into account when addressing specific articles.

New Zealand proposed that a new first article be drafted stating that eggs and poultry meat for human consumption can be freely traded from flocks not free from low pathogenic avian influenza (LPAI). The Terrestrial Code Commission did not think such an article was possible at this stage; however, it expanded on recommendations within relevant articles.

Japan proposed that the chapter should distinguish between "NAI free with vaccination" and "NAI free without vaccination". Comments from Argentina and Chile appeared to support the Japanese proposal. The Terrestrial Code Commission noted that Appendix 3.8.9. addressed the issue and inserted reference to this appendix in the text.

New Zealand proposed that Article 2.7.12.6. be deleted. The Terrestrial Code Commission did not accept this proposal because live birds other than poultry pose an avian influenza risk to poultry.

b) Appendices

The Terrestrial Code Commission had a meeting with the *ad hoc* Group on Epidemiology to discuss their recommendations from their May 2005 meeting. The *ad hoc* Group confirmed that comments made by New Zealand had been considered, but had not resulted in changes to the text.

Following a comment submitted by an expert, the fifth paragraph of Article 3.8.9.7. was reorganised to better demonstrate how to distinguish vaccinated from infected poultry.

The Terrestrial Code Commission made some modifications to point 2)a) of Article 3.8.9.2., point 1) of Article 3.8.9.3. and Article 3.8.9.5. for clarification or consistency of terminology.

The Terrestrial Code Commission drafted a new appendix on procedures for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus. The information in the appendix was compiled from a published paper and from a manuscript in press, provided by an expert. There are:

- SWAYNE D.E. & BECK J. R. (2004). - Heat inactivation of avian influenza and Newcastle disease viruses in egg products. *Avian Pathology*, 33 (5), 512-518.

- SWAYNE D.E. . - Microassay for Measuring Thermal Inactivation of H5N1 High Pathogenicity Avian Influenza Virus in Naturally-Infected Chicken Meat.

A revised chapter and appendix, and the new appendix on virus inactivation, are presented (Appendices XVI, XVII and XVIII) for the comment of Member Countries.

12. Semen and embryo related matters (Appendix 3.2.1)

The Terrestrial Code Commission accepted the comment from the EU and clarified point 1) of Article 3.2.1.3.

After examining the comment from Australia, the Terrestrial Code Commission modified Articles 3.2.1.5. and 3.2.1.6. to clarify that testing is unnecessary for animals in free countries.

In response to the comments from Australia, the Terrestrial Code Commission agreed to delete caseous lymphadenitis and border disease from point 1) of Article 3.2.1.6., as such diseases are not considered transmissible by semen.

After examining the comment from Australia, point 3) of Article 3.2.1.10. was modified to give further security to semen stored for export.

The revised appendix is at Appendix XIX for the comment of Member Countries.

13. Small hive beetle of honey bees (*Aethina tumida*) (Section 2.9.)

The Terrestrial Code Commission recalled the request from some Member Countries that a new chapter on this beetle be developed. The Terrestrial Code Commission examined a draft text prepared by the EU and a risk assessment prepared by a New Zealand expert, and decided to ask the Scientific Commission to develop a chapter on the small hive beetle of honey bees for consultation with Member Countries.

14. Animal welfare (Section 3.7.)

The Terrestrial Code Commission examined and endorsed the work of the Working Group on Animal Welfare in revising the four adopted chapters on animal welfare, taking into account comments received from Member Countries prior to the 73rd General Session, and the discussion at the General Session. The report of the fourth meeting of the Working Group on Animal Welfare is at Appendix XXXV for the information of Member Countries.

The Terrestrial Code Commission noted that some technical issues raised with experts in the *ad hoc* groups had not yet been responded to, but it expected that these should be finalised in time for the next meeting of the Terrestrial Code Commission in March 2006.

The four revised chapters are at Appendices XX, XXI, XXII and XXIII for the comment of Member Countries.

15. Animal production food safety

The Terrestrial Code Commission examined the report of the March 2005 meeting of the Working Group on Animal Production Food Safety and decided to circulate it for the information of Member Countries (Appendix XXXVI).

The Terrestrial Code Commission noted the work of the Food and Agriculture Organization (FAO) on good agricultural practice and recommended that, with regard to the Working Group document 'Guide to good farming practices', the OIE and the FAO coordinate their work with the aim of the information being published by both organisations for the guidance of Member Countries and the public.

Using a detailed discussion paper developed by the Working Group, the Terrestrial Code Commission drafted guidelines for the control of hazards of animal health and public health importance through ante- and post-mortem meat inspection. It is the Commission's intention that this text become a *Code* chapter in a new section on food safety. The draft is at Appendix XXIV for Member Countries' comment.

The Terrestrial Code Commission examined briefly some draft international health certificates, developed under the Working Group's work programme. The Terrestrial Code Commission noted that the Working Group would be examining these draft certificates at its next meeting at the end of January 2006.

16. Animal identification and traceability

The Terrestrial Code Commission noted the report of the *ad hoc* Group on Animal Identification and Traceability which is at Appendix XXXIV for the information of Member Countries. The Terrestrial Code Commission supported the recommendation of the *ad hoc* Group that the general principles form a part of a horizontal chapter on animal identification and traceability, in conjunction with more detailed articles on essential elements. The Terrestrial Code Commission noted the importance of coordination with the Codex Commission during the development of these standards.

The Terrestrial Code Commission made some modifications to the proposed definitions and general principles for animal identification and traceability, and is presenting the modified text at Appendix XXV for Member Countries'comment.

17. Carcass disposal

The Terrestrial Code Commission received from the Scientific Commission for Animal Diseases a revised text on the disposal of carcasses. The original text had been circulated for Member Countries' comment in 2004. The Terrestrial Code Commission proposed significant changes to the text (including to the title) and decided that the changes should be reviewed by the Scientific Commission before being circulated for further comment by Member Countries.

18. Paratuberculosis (Chapter 2.2.6.)

The Terrestrial Code Commission recalled the discussion on paratuberculosis at the 68th General Session in which Member Countries expressed their concern over possible trade implications of a proposed revised text. The text previously circulated for comment is at Appendix XXXVII for information.

As the current *Terrestrial Code* chapter is without technical content, the Terrestrial Code Commission is seeking advice from Member Countries on how to proceed in the development of an up-to-date chapter on paratuberculosis, with recommendations which do not unnecessarily disrupt trade.

19. Equine diseases (Section 2.5.)

After consultation with OIE Reference Laboratories on some equine disease chapters in need of updating, the Terrestrial Code Commission modified chapters on equine infectious anaemia, equine piroplasmosis, equine rhinopneumonitis, glanders and equine viral arteritis. The modified texts, at Appendices XXVI, XXVII, XXVIII, XXIX and XXX, are presented for comment by Member Countries.

The Terrestrial Code Commission examined a proposed revised chapter on African horse sickness prepared by a group of experts, and made some appropriate changes. The proposed revision (which is based on the bluetongue chapter), is circulated as clean text at Appendix XXXI for the comment of Member Countries. It will also be sent to the Scientific Commission for consideration.

20. Bovine viral diarrhoea-mucosal disease

The President of the Commission met some European experts on bovine viral diarrhoea-mucosal disease (BVD-MD) to discuss the BVD-MD situation, control efforts in Europe and possible future steps to make the European experience known internationally. As a result, the Terrestrial Code Commission discussed how guidance on the disease could be provided to Member Countries. It noted that a chapter had not been developed, but that some recommendations were present in the chapter on bovine and small ruminant semen.

The Terrestrial Code Commission recognised that BVD-MD has a worldwide distribution, but that, under certain circumstances, it can cause economic loss. It also recognised that, if certain procedures are followed, the disease could be controlled and eventually eradicated at a herd or regional level. The Terrestrial Code Commission concluded that it would not be appropriate to develop a specific chapter, but that guidance on control could be offered to Member Countries.

The Terrestrial Code Commission is therefore seeking advice from Member Countries as to how the OIE could address diseases such as BVD-MD and listeriosis, using alternative mechanisms to those currently used in the *Terrestrial Code* or *Manual* for such diseases, in order to provide Member Countries with useful guidance on managing such diseases without causing unjustified disruptions to trade.

21. International transfer of pathogens (Chapter 1.4.5.)

In consultation with the Terrestrial Code Commission, the Biological Standards Commission (hereafter referred to as the Laboratories Commission) decided to update Chapter 1.4.5. of the *Terrestrial Code* and the relevant sections of the *Terrestrial Manual.* The Terrestrial Code Commission expects to review revised text at its next meeting.

22. Future work programme

The Terrestrial Code Commission reviewed its work programme, taking into account the outcomes of the 73rd General Session, submissions received from Member Countries, and input from the Scientific Commission and the Laboratories Commission. A table summarising planned future activities for the Terrestrial Code Commission is at Appendix XXXII for the comment of Member Countries.

B. REPORTS OF WORKING GROUPS AND *AD HOC* GROUPS

The following reports are for the information of Member Countries:

- ***Ad hoc* Group on Surveillance for Bovine Spongiform Encephalopathy** (Appendix XXXIII)
- ***Ad hoc* Group on Animal Identification and Traceability** (Appendix XXXIV)
- **Animal Welfare Working Group** (Appendix XXXV)
- **Animal Production Food Safety Working Group** (Appendix XXXVI)

C. OTHER DOCUMENT

The following document is for the information of Member Countries: Chapter 2.2.6. on paratuberculosis proposed in 2000 (Appendix XXXVII).

The list of chapters and appendices circulated for the comment of Member Countries is in Section A of this report.

.../Appendices

Appendix I

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 19-30 September 2005

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Appendix II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 19-30 September 2005

Agenda

Item 1 General definitions (Chapter 1.1.1.)

Item 2 Evaluation of Veterinary Services (Chapters 1.3.3. and 1.3.4.)

Item 3 Zoning and compartmentalisation (Chapter 1.3.5.)

Item 4 General guidelines for animal health surveillance (Appendix 3.8.1.)

Item 5 Criteria for listing diseases (Chapter 2.1.1.)

Item 6 Foot and mouth disease (Chapter 2.2.10. and Appendix 3.8.7.)

Item 7 Bluetongue (Chapter 2.2.13. and surveillance appendix)

Item 8 Bovine tuberculosis (Chapter 2.3.3.)

Item 9 Bovine spongiform encephalopathy (Chapter 2.3.13. and Appendix 3.8.4.)

Item 10 Classical swine fever (Chapter 2.6.7. and Appendix 3.8.8.)

Item 11 Avian influenza (Chapter 2.7.12. and Appendix 3.8.9.)

Item 12 Semen and embryo related matters (Appendix 3.3.5. and Appendix 3.2.1.)

Item 13 Small hive beetle on honey bees (Section 2.9.)

Item 14 Animal welfare (Section 3.7)

Item 15 Animal production food safety

Item 16 Animal identification and traceability

Item 17 Carcass disposal

Item 18 Paratuberculosis (Chapter 2.2.6.)

Item 19 Equine diseases (Section 2.5.)

Item 20 Bovine viral diarrhoea-mucosal disease

Item 21 International transfer of pathogens (Chapter 1.4.5.)

Item 22 Work programme

Item 23 Others

Appendix XIII

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatin and collagen prepared exclusively from hides and skins;

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle ~~30 months of age or less,~~ which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which ~~were subject to~~ passed ante-mortem and post-mortem inspections ~~and were not suspect or confirmed BSE cases~~, and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2. When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.2.

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

Appendix XIII (contd)

1. the outcome of a *risk assessment* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

   a) Release assessment

   Release assessment consists of assessing the likelihood that the BSE ~~a transmissible spongiform encephalopathy (TSE)~~ agent has been introduced into the cattle population from a pre-existing agent ~~TSE~~ in the indigenous ruminant population or via *commodities* potentially contaminated with the BSE ~~a TSE~~ agent, through a consideration of the following:

   i) the presence or absence of ~~animal TSE agents~~ the BSE agent in the country, *zone* or *compartment* and, if present, evidence regarding ~~their~~ its prevalence ~~based on the outcomes of surveillance~~;

   ii) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

   iii) imported *meat-and-bone meal* or *greaves*;

   iv) imported live ruminants ~~animals~~;

   v) imported animal feed and feed ingredients;

   vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

   vii) imported products of ruminant origin for *in vivo* use in cattle.

   The results of any ~~surveillance and other~~ epidemiological investigation into the disposition of the *commodities* identified above ~~(especially surveillance for BSE conducted on the cattle population) relevant to the above~~ should be taken into account in carrying out the assessment.

   b) Exposure assessment

   If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

   i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

   ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

iv) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance;

2. on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;

3. the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4. the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible~~ fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent, should the following conditions be met:

1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate ~~generic~~ specific measures have been taken for the relevant period of time defined below to manage ~~all risks~~ each risk identified;

2. the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

3. EITHER:

   a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:

      i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

      ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

b) ~~the last indigenous *case* of BSE was reported more than 7 years ago~~ any indigenous *case* of BSE was born more than 8 years ago; and

i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and

iii) all BSE *cases*, as well as:

- ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent, should the following conditions be met:

1. a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate measures are being taken, but have not been taken for the relevant period of time to manage all risks identified ~~the country has not demonstrated that appropriate genetic measures have been taken for the relevant period of time defined below to manage all risks identified;~~

2. the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. is in place; Type B surveillance may replace Type A surveillance once the relevant points target, in accordance with Table 1, is met;

3. EITHER

a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

b) there has been an indigenous *case* of BSE ~~reported~~, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

iii) all BSE *cases*, as well as:

- ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.3.13.6.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

Appendix XIII (contd)

Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;

2. cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;

3. in the case of a country, *zone* or *compartment* with an indigenous *case*, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 2.3.13.8.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1. the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2. all BSE *cases*, as well as:

   a) ~~all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and~~

   b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

3. cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

   b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.9.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate~~.

Article 2.3.13.10.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;
2. the cattle from which the *fresh meat* and *meat products* were derived passed ante-mortem and post-mortem inspections ~~ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate~~;
3. cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
4. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
   a) the tissues listed in Article 2.3.13.13.,
   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

   all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.11.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

Appendix XIII (contd)

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1. the cattle from which the *fresh meat* and *meat products* originate:

   a) ~~are not suspect or confirmed BSE *cases*~~;

   b) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;

   c) ~~were subjected to~~ passed ante-mortem and post-mortem inspections;

   d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2. the *fresh meat* and *meat products* ~~do not contain~~ were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:

   a) the tissues listed in Article 2.3.13.13.,

   b) nervous and lymphatic tissues exposed during the deboning process,

   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age,

   all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.12.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Article 2.3.13.13.

1. From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2. From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3. From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1. a country, *zone* or *compartment* posing a negligible BSE risk; or

2. a country, *zone* or *compartment* posing a controlled BSE risk; and

   a) skulls and vertebrae (except tail vertebrae) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1. a country, *zone* or *compartment* posing a negligible BSE risk; or

2. a country, *zone* or *compartment* posing a controlled BSE risk, and ~~it originates~~ from cattle which have ~~been subjected to~~ passed ante-mortem and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 2.3.13.13.

Appendix XIII (contd)

Article 2.3.13.16.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1. they originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2. they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

— text deleted

APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

1. Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2. When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

   c) infected cattle, which may lie within one of three stages in the progress of BSE:

      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

      iii) the smallest number will show clinical signs.

3. The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4. With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

Appendix XIV (contd)

a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);

b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle);

c) cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock);

d) cattle over 36 months of age at routine slaughter.

5. A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. ~~All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

6. When establishing a surveillance strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 3.8.4.2.

Description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation~~, particularly cattle over 30 months of age,~~ is the one exhibiting the highest prevalence. ~~The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.~~ The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

~~Within each of the above subpopulations, countries may wish to target cattle identifiable as imported from countries or *zones* not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.~~

~~When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.~~

Article 3.8.4.3.

~~1)~~ **Implementation of ~~Type A~~ surveillance**

In order to implement efficiently a surveillance strategy for BSE, a country must use ~~good quality data (or reliable estimates)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of ~~it's~~ the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*. ~~The application of the following procedure will allow the detection of BSE at a prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.~~

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

Appendix XIV (contd)

A ~~country should design its~~ surveillance strategy should be designed to ensure that samples are representative of the herd of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this appendix were obtained by applying the following factors to a statistical model:

a) ~~a~~ the design prevalence for Type A or Type B surveillance ~~of one case per 100,000 of the adult cattle population~~;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between clinical pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

a) cattle population numbers stratified by age;

b) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a country may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

The application of Type A surveillance will allow the detection of BSE around a design prevalence[47] of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

2. ~~Maintenance (~~Type B~~)~~ surveillance

The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95%.

Type B surveillance may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

~~For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', should continue at a reduced maintenance level.~~

~~In order to implement efficiently a maintenance surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.~~

~~Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment*'s BSE status (to a maximum of 7 years).~~

Article 3.8.4.4.

1. Selecting the points target

The ~~desired~~ surveillance points target ~~is~~ should be selected from Table 1, which shows target points for adult cattle populations of different sizes. ~~A country's~~ The size of the adult cattle population ~~size~~ of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size. ~~The target depends on the design prevalence chosen by the country.~~

[47] DP (design prevalence) is used to determine the size of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

Appendix XIV (contd)

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* ~~which has not identified any BSE cases~~

Points targets for country, *zone* or *compartment* ~~with 0 cases, 95% confidence~~		
Adult cattle population size (24 months and older)	**Type A surveillance**	**Type B surveillance**
≥ 1,000,000	300,000	150,000
800,000 – 1,000,000	240,000	120,000
600,000 – 800,000	180,000	90,000
400,000 – 600,000	120,000	60,000
200,000 – 400,000	60,000	30,000
100,000 – 200,000	30,000	15,000
50,000 – 100,000	15,000	7,500

~~DP is the maximum possible prevalence or "design prevalence".~~

2. Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*.

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~In addition, Countries should sample at least three of the four subpopulations.~~

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2 Surveillance point values for samples collected from animals in the given subpopulation and age category

Surveillance subpopulation			
Routine slaughter[1]	Fallen stock[2]	Casualty slaughter[3]	Clinical suspect[4]
Age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

1 See point 4) of Article 3.8.4.2.
2 See point 3) of Article 3.8.4.2.
3 See point 2) of Article 3.8.4.2.
4 See point 1) of Article 3.8.4.2.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

~~Article 3.8.4.5.~~

~~**To monitor the evolution of BSE in a country, zone or compartment once it is detected**~~

~~To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.~~

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Appendix XXXIII

Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal

Original: English
September 2005

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON BSE SURVEILLANCE

Paris, 14-16 September 2005

The OIE *ad hoc* Group on Surveillance for Bovine Spongiform Encephalopathy (BSE) met for the second time at the OIE Headquarters from 14 to 16 September 2005. The members of the *ad hoc* Group and other participants are listed in Appendix I. The Agenda adopted is given in Appendix II.

On behalf of Dr B. Vallat, Director General of the OIE, Dr D. Wilson welcomed the participants and thanked them for their willingness to continue working on improving the BSE surveillance guidelines in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code)*. It was recalled that a significantly revised BSE chapter and surveillance appendix had been adopted at the 2005 General Session, but that the section in the appendix dealing with type B surveillance had been the subject of significant debate. Comments on the appendix had been received from Member Countries (Canada, Switzerland, Japan, New Zealand, the Southern Cone countries of South America, Australia and the EU) which informed the *ad hoc* Group's discussions. A peer review conducted by two OIE Collaborating Centres on the BSurvE model was also taken into account.

Due to the comments received and the new information available, and to the essential linkage between the *Terrestrial Code* BSE chapter and appendix, the *ad hoc* Group decided to review both documents.

The *ad hoc* Group noted the significantly different approach accorded to BSE surveillance compared to surveillance for other diseases such as foot and mouth disease (FMD) and avian influenza (AI), and recommended that, in the longer term, the OIE promote a similar approach to BSE surveillance as for other diseases. It recognised however that, in the short term, its task was to refine the current BSE surveillance approach to meet the practical needs of Member Countries.

The *ad hoc* Group considered that type B surveillance conducted by countries, *zones* or *compartments* of negligible BSE risk status had the following goals:

a) to show whether BSE was occurring despite the applied risk mitigating measures;

b) to contribute to maintain confidence that BSE risk remained negligible, irrespective of the means by which that status was achieved;

c) to contribute to the evaluation of the effectiveness of veterinary and farmer education programmes, and reporting and diagnostic systems.

Appendix XXXIII (contd)

Point 3) b) of Article 2.3.13.3 of the chapter was modified to reflect the importance of the date of birth of an indigenous case rather than the date the case was reported, as the date of birth is more reflective of the time of exposure than the date of reporting. A BSE case in an animal born after the imposition of a feed ban is far more important in assessing the effectiveness of measures imposed than a BSE case in an animal born before the feed ban was imposed.

Article 2.3.13.4 of the chapter was modified to clarify the wording in the chapeau concerning the generic measures.

The *ad hoc* Group noted that, in the current BSE chapter, the prevalence of the disease in a BSE-affected country was not a factor in the categorisation of a country, *zone* or *compartment*, except in general terms of a type A surveillance being in place. Unless the results of the surveillance will be used to compartmentalise part of the cattle population (for example by age or husbandry type), conducting surveillance at a high level at that point does not add useful information.

The *ad hoc* Group believed that greater resources should be directed towards mitigating the factors identified in the risk assessment rather than in conducting high levels of surveillance, as this would be commensurate with their relative contributions to addressing public health risks. This would be particularly relevant when, as a result of compartmentalisation, different risk mitigating strategies are in place. Assurances regarding public health derive more from risk mitigating measures than from detailed knowledge of BSE prevalence.

The *ad hoc* Group believed that the characteristics of BSE epidemiology lend the disease to compartmentalisation, for example the brief susceptibility window and the means of transmission. It recognised that compartmentalisation had been used in managing the risks associated with BSE in the United Kingdom (UK), using 'date of birth' in relation to the date of implementation of an effective feed ban as the separator. The *Terrestrial Code* recommendations on compartmentalisation should be used to provide guidance. The *ad hoc* Group believed that the focus could be on compartments rather than countries as a whole if groups of animals can be shown to have different epidemiologic characteristics that result in differing levels of BSE risk.

The *ad hoc* Group noted the importance of the linkage from the risk assessment to the recommended surveillance. The results of the risk assessment determines the type of surveillance needing to be carried out (and the target subpopulations selected) and the mitigating measures needing to be put in place, according to the risk factors identified. Selection of the target subpopulations should aim at validating the effectiveness of the mitigating measures.

The *ad hoc* Group confirmed that, where negligible risk had been demonstrated, type A surveillance would be unnecessary and type B surveillance would provide the level of confidence required.

The *ad hoc* Group considered that, in line with the General Guidelines for Animal Health Surveillance, there should be an indication in the *Terrestrial Code* of the circumstances under which surveillance for BSE could conclude.

As in all countries except the UK, cases appear to be the result of a Member Country's import policy, the *ad hoc* Group discussed whether it may be appropriate for countries demonstrating negligible risk to redistribute their risk mitigation measures from the interior to their external borders.

The *ad hoc* Group recognised that, under the current 4 sub-population system, there were advantages of testing animals in the 'clinical suspect' category compared to the fallen stock and emergency slaughter categories. It wanted to retain the differential between 'clinical suspects' and other animals, because of the contribution the former sub-population makes to knowledge of the BSE situation. The *ad hoc* Group also discussed whether the casualty or emergency slaughter or downer cattle, and fallen stock sub-populations should be combined but decided that this would be a matter for a Member Country to determine based on the demographics and epidemiological characteristics of its cattle population. In such a case, the score accorded to that combined subpopulation would be that of 'fallen stock'.

The *ad hoc* Group considered that all clinical suspects should be investigated, regardless of the number of points accumulated, in a similar fashion to the other diseases for which Member Countries have reporting obligations.

A detailed explanation of the manner in which the figures in the tables in the appendix were derived may be found in the report of the first meeting of the *ad hoc* Group which was attached to the report of the Terrestrial Code Commission meeting of January 2005. At that meeting, the *ad hoc* Group had made use of a background document developed by the OIE Collaborating Centre for Risk Analysis and Surveillance. The origin of the values referred to in the model (showing the relative effectiveness and efficiency of one stream vs another in the detection of BSE) may be found on the European Commission Web site http://europa.eu.int/comm/food/food/biosafety/bse/monitoring_en.htm. An examination of the pathogenesis of BSE and the performance of diagnostic tests determined the relative effectiveness and efficiency of testing animals according to age. The two parameters described, age and subpopulation, form the basis of the points distribution in the BSurvE model. Table 2 in the appendix was the result of a compression of these age categories; this compression was to accommodate the fact that Member Countries do not generally have the degree of age detail required in the BSurvE model.

At this meeting, the *ad hoc* Group modified Table 1 to make the points targets applicable to any country, no matter the number of BSE cases. The emphasis in the table was on a high level of confidence of diagnosing the first case. The *ad hoc* Group believed that, where a first case of BSE had been detected, it was unnecessary to increase the level of surveillance to maintain the same confidence that the true prevalence was less than the design prevalence. The precise determination of prevalence through an increase in surveillance beyond type A surveillance was considered to be less important than the application of relevant risk mitigating measures.

Consistent with this position, Article 3.8.4.5 was deleted.

The point values in Table 2 are derived from the pathogenesis of BSE and from the composite surveillance experience of countries in Europe, at a certain stage in the BSE epidemic (the only data source at the time). While several Member Countries, based on individual national experience, have questioned their relevance regarding the current stage of the epidemic in Europe or elsewhere, the point value distributions are believed to be most sensitive to the detection of an epidemic in its growth phase. The *ad hoc* Group considered that epidemics in their growth phase represent the greatest detection challenge. The *ad hoc* Group considered that the points values in Table 2 should be reviewed in line with changes in knowledge and diagnostic techniques, and with revisions in the BSurvE model.

As the *Terrestrial Code* BSE appendix had been derived from the BSurvE model, the *ad hoc* Group considered that, where a country had sufficient data to be able to use the BSurvE model and the expertise to do so, the outcome would be equivalent to the results obtained from using the *Terrestrial Code* appendix. The *ad hoc* Group considered that Member Countries could apply this flexible alternative to incorporate defensible national values for the key parameters on which the model is structured. The *ad hoc* Group noted that selection of this option carries the responsibility of defending scientifically the parameters selected.

The *ad hoc* Group's proposed revised texts are at Appendices III and IV.

.../Appendices

Appendix I

SECOND MEETING OF THE OIE *AD HOC* GROUP ON BSE SURVEILLANCE

Paris, 14-16 September 2005

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Appendix II

SECOND MEETING OF THE OIE *AD HOC* GROUP ON BSE SURVEILLANCE

Paris, 14-16 September 2005

Adopted Agenda

1) Update on BSE surveillance activities

   a) BsurvE peer review

2) Update on discussions at the General Session and the January meeting of the Terrestrial Code Commission

3) Review of the text of Appendix 3.8.4

4) Other issues

5) Further work programme

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins;

   d) gelatin and collagen prepared exclusively from hides and skins;

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat);

   g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, and which were subject to ante-mortem and post-mortem inspections and were not suspect or confirmed BSE *cases*; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

   h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

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Article 2.3.13.2.

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

1) the outcome of a *risk assessment* (which is reviewed annually), based on Section 1.3., identifying all potential factors for BSE occurrence and their historic perspective:

   a) Release assessment

      Release assessment consists of assessing the likelihood that the BSE ~~a transmissible spongiform encephalopathy (TSE)~~ agent has been introduced into the cattle population from a pre-existing agent ~~TSE~~ in the indigenous ruminant population or via *commodities* potentially contaminated with the BSE ~~a TSE~~ agent, through a consideration of the following:

      i) the presence or absence of ~~animal TSE agents~~ the BSE agent in the country or *zone* or *compartment* and, if present, evidence regarding ~~their~~ its prevalence ~~based on the outcomes of surveillance~~;

      ii) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

      iii) imported *meat-and-bone meal* or *greaves*;

      iv) imported live ruminants ~~animals~~;

      v) imported animal feed and feed ingredients;

      vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 2.3.13.13. and may have been fed to cattle;

      vii) imported products of ruminant origin for *in vivo* use in cattle.

      The results of any ~~surveillance and other~~ epidemiological investigations into the disposition of the *commodities* identified above ~~(especially surveillance for BSE conducted on the cattle population) relevant to the above~~ should be taken into account in carrying out the assessment.

   b) Exposure assessment

      If the release assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

      i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

ii) the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

iv) the level of surveillance for BSE conducted on the cattle population to that time and the results of that surveillance;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all *cases* showing clinical signs consistent with BSE in target sub-populations as defined in Appendix 3.8.4.;

3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) the examination in an *approved laboratory* of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above)~~ demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix 3.8.4.

When the *risk assessment* ~~(which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible~~ fails to demonstrate negligible risk, the country should conduct Type A surveillance in accordance with Appendix 3.8.4.

Article 2.3.13.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent, should the following conditions be met:

1) a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;

2) the country has demonstrated that Type B surveillance, in accordance with Appendix 3.8.4, is in place and the relevant points target, in accordance with Table 1, has been met;

3) ~~EITHER~~:

a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated, through an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

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~~OR~~AND

b) ~~the last indigenous *case* of BSE was reported more than 7 years ago~~ no indigenous *case* of BSE has been born within the past 8 years; and

i) the criteria in points 2) to 4) of Article 2.3.13.2. have been complied with for at least 7 years; and

ii) it has been demonstrated, thorough an appropriate level of control and audit, that for at least 8 years *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants; and

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent, should the following conditions be met:

1) a *risk assessment*, as described in point 1) of Article 2.3.13.2., has been conducted in order to identify the historical and existing risk factors, and the country has demonstrated that appropriate generic measures are being taken, but have not been taken for the relevant period of time to manage all risks identified ~~the country has not demonstrated that appropriate generic measures have been taken for the relevant period of time defined below to manage all risks identified;~~

2) the country has demonstrated that Type A surveillance in accordance with Appendix 3.8.4. is in place; type B surveillance may replace type A surveillance once the relevant points target, in accordance with Table 1, is met;

3) EITHER

a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit, that *meat-and-bone meal* and *greaves* derived from ruminants has not been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for 8 years;

OR

b) there has been an indigenous *case* of BSE ~~reported~~, the criteria in points 2) to 4) of Article 2.3.13.2. are complied with, and it can be demonstrated, through an appropriate level of control and audit that *meat-and-bone meal* and *greaves* derived from ruminants have not been fed to ruminants, but at least one of the following two conditions applies:

i) the criteria in points 2) to 4) of Article 2.3.13.2. have not been complied with for 7 years;

ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* and *greaves* derived from ruminants to ruminants have been in place for 8 years;

AND

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and
- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 2.3.13.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 2.3.13.6.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for all *commodities* from cattle not listed in point 1) of Article 2.3.13.1.

the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.

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Article 2.3.13.7.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;

2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 3) b) iii) of Article 2.3.13.4.;

3) in the case of a country, *zone* or *compartment* with an indigenous *case*, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 2.3.13.8.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2) all BSE *cases*, as well as:

   a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

   b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

   b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 2.3.13.9.

When importing from a country, *zone* or *compartment* posing a negligible BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.3.;

2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate.

Article 2.3.13.10.

When importing from a country, *zone* or *compartment* posing a controlled BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1) the country, *zone* or *compartment* complies with the conditions in Article 2.3.13.4.;

2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;

3) cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

4) the *fresh meat* and *meat products* do not contain:

   a) the tissues listed in Article 2.3.13.13.,

   b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

   all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

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Article 2.3.13.11.

When importing from a country, *zone* or *compartment* with an undetermined BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle (other than those listed in point 1) of Article 2.3.13.1.)

the presentation of an *international veterinary certificate* attesting that:

1) the cattle from which the *fresh meat* and *meat products* originate:

   a) are not suspect or confirmed BSE *cases*;

   b) have not been fed *meat-and-bone meal* or *greaves*;

   c) were subjected to ante-mortem and post-mortem inspections;

   d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;

2) the *fresh meat* and *meat products* do not contain:

   a) the tissues listed in Article 2.3.13.13.,

   b) nervous and lymphatic tissues exposed during the deboning process,

   c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age,

   all of which have been completely removed in a manner to avoid contamination of the *fresh meat* and *meat products*.

Article 2.3.13.12.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5. should not be traded between countries.

Article 2.3.13.13.

1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 2.3.13.4. and 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle that were at the time of slaughter over 30 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

3) From cattle that were at the time of slaughter over 12 months of age originating from a country, *zone* or *compartment* defined in Article 2.3.13.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1) a country, *zone* or *compartment* posing a negligible BSE risk; or

2) a country, *zone* or *compartment* posing a controlled BSE risk; and

   a) skulls and vertebrae (except tail vertebrae) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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the presentation of an *international veterinary certificate* attesting that it originates from:

1) a country, *zone* or *compartment* posing a negligible BSE risk; or

2) a country, *zone* or *compartment* posing a controlled BSE risk, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspection and has not been prepared using the tissues listed in point 2 of Article 2.3.13.13.

Article 2.3.13.16.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1) they originate from a country, *zone* or *compartment* posing a negligible BSE risk; or

2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

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APPENDIX 3.8.4.

SURVEILLANCE FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 3.8.4.1.

Introduction

1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), surveillance for BSE may have one or more goals:

   a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;

   b) monitoring the evolution of BSE in a country, *zone* or *compartment*;

   c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;

   d) supporting a claimed BSE status;

   e) gaining or regaining a higher BSE status.

2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:

   a) cattle not exposed to the infective agent;

   b) cattle exposed but not infected;

   c) infected cattle, which may lie within one of three stages in the progress of BSE:

      i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;

      ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;

      iii) the smallest number will show clinical signs.

3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a surveillance programme but should be determined in accordance with all the factors listed in Article 2.3.13.2. The surveillance programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.

4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for surveillance purposes:

Appendix XXXIII (contd)

Appendix IV (contd)

a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE;

b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty, emergency slaughter or downer cattle);

c) cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock);

d) cattle over 36 months of age at routine slaughter.

5) A gradient is used to describe the relative value of surveillance applied to each subpopulation. Surveillance should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. ~~All countries should sample at least three of the four subpopulations.~~ This approach is consistent with Appendix 3.8.1. on general guidelines for animal health surveillance.

6) When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implications. Authorities must find ways to overcome these difficulties.

Article 3.8.4.2.

Description of cattle subpopulations

1) Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation~~, particularly cattle over 30 months of age,~~ is the one exhibiting the highest prevalence. ~~The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio economic repercussions.~~ The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and laboratory examination systems (Article 2.3.13.2), implemented by the *Veterinary Services*, are essential for the credibility of the surveillance system.

2) Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3) Cattle over 30 months of age which are found dead on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4) Cattle over 36 months of age at routine slaughter

Experience in countries where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

~~Within each of the above subpopulations, countries may wish to target cattle identifiable as imported from countries or *zones* not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE, offspring of BSE affected cows and cattle which have consumed feedstuffs potentially contaminated with other TSE agents.~~

~~When establishing a surveillance strategy, authorities must take into account inherent difficulties of obtaining samples on farm. These difficulties include higher cost, necessity for education and motivation of owners, counteracting potentially negative socio-economic implication. Authorities must find ways to overcome these difficulties.~~

Article 3.8.4.3.

~~1)~~ **Implementation of ~~Type A~~ surveillance**

In order to implement efficiently a surveillance strategy for BSE, a country must use ~~good quality data (or reliable estimates)~~ documented records or reliable estimates of ~~concerning~~ the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. ~~The application of the following procedure will allow the detection of BSE at a prevalence of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.~~

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

Appendix XXXIII (contd)

Appendix IV (contd)

A country should design its surveillance strategy to ensure that samples are representative of the herd of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for 7 years.

The points targets and surveillance point values in this appendix were obtained by applying the following factors to a statistical model:

a) ~~a~~ the design prevalence for Type A or Type B surveillance ~~of one case per 100,000 of the adult cattle population~~;

b) a confidence level of 95%;

c) the pathogenesis, and pathological and clinical expression of BSE:

   i) sensitivity of diagnostic methods used;

   ii) relative frequency of expression by age;

   iii) relative frequency of expression within each subpopulation;

   iv) interval between clinical pathological change and clinical expression;

d) demographics of the cattle population, including age distribution;

e) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;

f) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

a) cattle population numbers stratified by age;

b) the number of cattle tested for BSE stratified by age and by subpopulation.

This Appendix utilises Tables 1 and 2 to determine a desired surveillance points target and the point values of surveillance samples collected.

Within each of the subpopulations above, countries may wish to target cattle identifiable as imported from countries or *zones* not free from BSE, cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE, and offspring of BSE affected cows.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1) Type A surveillance

The application of Type A surveillance will allow the detection of BSE around a design prevalence[1] of at least one case per 100,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.

2) ~~Maintenance (~~Type B~~)~~ surveillance

The application of Type B surveillance will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern.

Type B surveillance may be carried out by Member Countries of negligible BSE risk status (Article 2.3.13.3) to confirm the conclusions of the risk assessment, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through surveillance targeted to maximise the likelihood of identifying failures of such measures.

Type B surveillance may also be carried out by Member Countries of controlled BSE risk status (Article 2.3.13.4), following the achievement of the relevant points target using Type A surveillance, to maintain confidence in the knowledge gained through Type A surveillance.

~~For countries which have demonstrated through risk assessment (including surveillance) that they meet the requirements for 'negligible risk', should continue at a reduced maintenance level.~~

~~In order to implement efficiently a maintenance surveillance strategy for BSE, a country must use good quality data (or reliable estimates) concerning the age distribution of its adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation. The application of the following procedure will allow the detection of BSE prevalence of at least one case per 50,000 in the adult cattle population, at a confidence level of 95% in the country, *zone* or *compartment* of concern. This Appendix utilises Tables 1 and 2 to determine a desired surveillance point target and the point values of surveillance samples collected.~~

~~Maintenance surveillance should focus on the higher prevalence subpopulations (especially clinical suspects). The number of clinical suspect samples taken annually should approximate the number of samples taken annually from clinical suspect cases during the time taken to reach the country, *zone* or *compartment*'s BSE status (to a maximum of 7 years).~~

Article 3.8.4.4.

1) Selecting the points target

The desired surveillance points target is selected from Table 1, which shows target points for adult cattle populations of different sizes. A country's adult cattle population size may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size. The target depends on the design prevalence chosen by the country.

[1] DP (design prevalence) is used to determine the magnitude of a testing survey expressed in terms of target points. If the actual prevalence is greater than the selected design prevalence, the survey is highly likely to detect disease.

Appendix XXXIII (contd)

Appendix IV (contd)

Table 1 Points targets for different adult cattle population sizes in a country, *zone* or *compartment* ~~which has not identified any BSE cases~~

Points targets for country, zone or compartment with ~~0 cases,~~ 95% confidence		
Adult Cattle Population Size (24 months and older)	**Type A surveillance**	**Type B surveillance**
≥ 1,000,000	300,000	150,000
800,000 – 1,000,000	240,000	120,000
600,000 – 800,000	180,000	90,000
400,000 – 600,000	120,000	60,000
200,000 – 400,000	60,000	30,000
100,000 – 200,000	30,000	15,000
50,000 – 100,000	15,000	7,500

~~DP is the maximum possible prevalence or "design prevalence".~~

2) Determining the point values of samples collected

Table 2 can be used to determine the point values of the surveillance samples collected. The approach assigns point values to each sample according to the likelihood of detecting infection based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of surveillance described in Appendix 3.8.1. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the disease and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle herd of the country, *zone* or *compartment*.

If a Member Country determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the surveillance point values accorded to the combined subpopulation would be that of 'fallen stock'.

~~In addition, Countries should sample at least three of the four subpopulations.~~

The total points for samples collected may be accumulated over a period of a maximum of 7 consecutive years to achieve the target number of points determined in Table 1.

Table 2 Surveillance point values for samples collected from animals in the given subpopulation and age category

Surveillance subpopulation			
Routine slaughter[1]	Fallen stock[2]	Casualty slaughter[3]	Clinical suspect[4]
Age ≥ 1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥ 2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥ 4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥ 7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥ 9 years (aged)			
0.0	0.1	0.2	45

1 See point 4) of Article 3.8.4.2.
2 See point 3) of Article 3.8.4.2.
3 See point 2) of Article 3.8.4.2.
4 See point 1) of Article 3.8.4.2.

Surveillance points remain valid for 7 years (the 95th percentile of the incubation period).

~~Article 3.8.4.5.~~

~~**To monitor the evolution of BSE in a country, zone or compartment once it is detected**~~

~~To monitor the evolution of BSE in a country, *zone* or *compartment* once it is detected, a more intensive sampling method needs to be used to determine disease prevalence. For countries that have determined that BSE exists within their cattle population, the goal of surveillance shifts from one of detection to one of monitoring the extent and evolution of the disease, and monitoring the effectiveness of control measures such as feed bans and policies for the removal of specified risk materials.~~

— text deleted

BSEに関する国際基準の改正について

OIEコードとは？

WTO協定上の位置づけ

- 動物の健康及び人獣共通感染症に関する国際基準

国際基準としてのOIEコード

- 「国際基準」の意義
  - 国際基準に適合する措置は、WTO協定に適合しているものと推定される。
  - 国際基準より高いレベルの措置をとることは可能であるが、科学的に正当な理由があることを立証すること等が必要。

OIEコードの策定手続き

アドホック委員会（事務局長が任命する専門家で構成。議論はクローズ、会議要旨を配布。）

↓

科学委員会（総会で選出する専門家で構成。議論はクローズ。会議報告書は後日、加盟国に配布。）

↓

コード委員会（総会で選出する専門家で構成。議論はクローズ。会議報告書は後日、加盟国に配布。）

↓

加盟国からの意見受付

↓

総会（加盟国（167カ国）の首席獣医官（CVO）が代表。）

現行のBSEコードの概要

・無条件物品

・BSEリスク・ステータスの決定基準

・各カテゴリーの要件

・各カテゴリーの貿易条件
(貿易すべきでない部位(SRM)の定義を含む)

・BSEサーベイランス基準

無条件物品

無条件物品

BSEステータスに関わらず「条件を課さずに輸入を承認すべき物品」

① 牛乳及び乳製品
② 精液及び一定の要件を備えた受精卵
③ 獣皮及び皮革
④ 獣皮又は皮革のみから調製されたゼラチン及びコラーゲン
⑤ タンパク質を含有しない獣脂及び獣脂由来製品
⑥ 第2リン酸カルシウム(タンパク質及び脂肪を含まないもの)
⑦ 骨なし骨格筋肉(機械的除去肉を除く)注
⑧ 血液及び血液製品(ピッシング等せず)

注：以下の条件を満たしていることが必要

- 30か月齢以下であること
- ピッシング等がされていないこと
- と殺前／後検査を受けたこと
- BSE感染の疑いがなく、もしくは、感染が確認されていないこと
- SRMによって汚染されないように処理されていること

BSEリスク・ステータスの決定基準

BSEリスク・ステータスの決定基準

1　リスク評価の結果
（1）侵入リスクの評価
（2）暴露リスクの評価

「無視できるリスク」とは言えない場合 ⇨ A型サーベイランス
「無視し得るリスク」 ⇨ B型サーベイランス

2　獣医師、農家等を対象とした教育プログラムの実施

3　BSE様症状牛の調査及び届出義務

4　研究所での検査の実施

リスク評価に当たって考慮すべき事項

1　侵入リスクの評価

（1）TSE病原体の存在の有無（存在する場合、サーベイランスの結果に基づいた有病率）
（2）自国産反すう動物由来の肉骨粉・獣脂かす
（3）輸入された肉骨粉・獣脂かす
（4）輸入された生体動物
（5）輸入された飼料・飼料原料
（6）牛に給与された可能性のあるＳＲＭを含有する食用の反すう動物由来製品
（7）牛への体内利用に供される反すう動物由来の輸入製品

⇨ サーベイランス・疫学調査を考慮

リスク評価に当たって考慮すべき事項

2 暴露リスクの評価

(1)肉骨粉・獣脂かす及びこれらにより汚染した飼料を牛が摂取したことによるBSE病原体の循環と増幅

(2)反すう動物のと体、副産物及びと畜場廃棄物の利用等

(3)反すう動物由来の肉骨粉・獣脂かすの反すう動物への給与(交差汚染防止措置を含む)

(4)実施されたBSEサーベイランスの程度とその結果

各カテゴリーの要件

各カテゴリーの要件

カテゴリ	リスク評価	サーベイランス	BSE発生状況	リスク低減措置	感染牛等の処分
無視できるリスク	実施	B型サーベイランスを実施中	発生なし	①報告・教育等が7年以上 ②フィードバンが8年以上	ー
			輸入牛のみで発生		感染牛の処分
			国内発生あり	①最終発生から7年以上経過 ②報告・教育等が7年以上 ③フィードバンが8年以上	感染牛、コホート牛の処分
管理されたリスク	実施	A型サーベイランスを実施中	発生なし	報告・教育等が行われ、フィードバンが効果的に実施されているが、 1)報告・教育等が7年未満、又は 2)フィードバンが8年未満	ー
			輸入牛のみで発生		感染牛の処分
			国内発生あり		感染牛、コホート牛の処分
不明なリスク	上記のいずれにも該当しない場合				

各カテゴリーの貿易条件

各カテゴリーの貿易条件

生体牛を輸入する際に要求すべき事項

1. 無視できるリスク国から輸入する場合

・ な し

2. 管理されたリスク国から輸入する場合

当該牛が備えるべき要件

① 母牛及び由来牛群が恒久識別制度によって識別。
② コホート牛でないこと。
③ 国内発生がある場合、フィードバンの効果的実施日以降に出生。

各カテゴリーの貿易条件

生体牛を輸入する際に要求すべき事項

3. 不明のリスク国から輸入する場合

国内対策に係る要件

① フィードバンの効果的な実施。
② 患畜・コホート牛の処分。

当該牛が備えるべき要件

① 母牛・由来牛群が恒久識別制度により識別。
② コホート牛でないこと。
③ フィードバンの効果的実施日から2年経過した後に出生。

各カテゴリーの貿易条件

骨付き牛肉等を輸入する際に要求すべき事項

1. 無視できるリスク国から輸入する場合

・と殺前後の検査(inspection)が実施。

2. 管理されたリスク国から輸入する場合

由来する牛・当該肉などが備えるべき要件

① と殺前後の検査(inspection)が実施。
② ピッシング等が行われていないこと。
③ SRMを含まないこと。
④ 30か月齢超の牛由来の機械的除去肉を含まないこと。
⑤ ③及び④による汚染が無いよう完全に除去されること。

各カテゴリーの貿易条件

骨付き牛肉等を輸入する際に要求すべき事項

3. 不明のリスク国から輸入する場合

由来する牛・当該肉などが備えるべき要件

① 患畜・疑似患畜でないこと。
② 肉骨粉等が給与されていないこと。
③ と殺前後の検査(inspection)が実施。
④ ピッシング等が行われていないこと。
⑤ SRMを含まないこと。
⑥ 12か月齢超の牛由来の機械的除去肉を含まないこと。
⑦ 脱骨の過程で露出する神経組織、リンパ組織を含まないこと。
⑧ ⑤～⑦による汚染が無いよう完全に除去されること。

SRM（特定危険部位）の定義

カテゴリ	全月齢	12か月以上	30か月以上
無視できるリスク国	-	-	-
管理されたリスク国	扁桃・回腸遠位部	-	脳・目・脊髄・頭蓋骨・脊柱
不明のリスク国		脳・目・脊髄・頭蓋骨・脊柱	-

BSEサーベイランス基準

サーベイランス基準の概要

1. 対象範囲

次の4つの牛群のうち、少なくとも3つの牛群からサンプリング。

① BSE様症状牛（30か月齢超）
② 歩行困難牛、緊急と殺牛等（30か月齢超）
③ 死亡牛（30か月齢超）
④ 通常と殺牛（36か月齢超）

サーベイランス基準の概要

2. サーベイランスの種類

(1) A型サーベイランス

① リスク評価の結果、「無視できるリスク」とは評価されなかった場合に実施。
② 95%の信頼性で、成牛群における有病率（十万頭に1頭）の検出が可能。

(2) B型サーベイランス

① リスク評価の結果、「無視できるリスク」と評価された場合に実施。
② 特に臨床症状牛を対象に実施。
③ 95%の信頼性で、成牛群における有病率（5万頭に1頭）の検出が可能。
④ 現在のカテゴリー（無視できるリスク）に分類されるまでの間（最大7年）実施されたサーベイランスのサンプル規模を維持。

サーベイランス基準の概要

(1)国における成牛群のサイズと目標ポイント数の関係

成牛群のサイズ (24か月齢以上)	目標ポイント数 想定される有病率	
	10万頭に1頭の場合 (A型サーベイランス)	5万頭に1頭の場合 (B型サーベイランス)
1,000,000頭以上	300,000	150,000
800,000頭～1,000,000頭	240,000	120,000
600,000頭 ～800,000頭	180,000	90,000
400,000頭～600,000頭	120,000	60,000
200,000頭～400,000頭	60,000	30,000
100,000頭～200,000頭	30,000	15,000
50,000頭～100,000頭	15,000	7,500

サーベイランス基準の概要

(2)牛群別・年齢別のポイント数

	牛群の範囲			
	通常と殺牛	死亡牛	緊急と殺牛等	症状牛
1歳～2歳	0.01	0.2	0.4	N/A
2歳～4歳	0.1	0.2	0.4	260
4歳～7歳	0.2	0.9	1.6	750
7歳～9歳	0.1	0.4	0.7	220
9歳以上	0.0	0.1	0.2	45

OIEコード改正案の概要

①骨なし骨格筋肉の条件の変更
②「無視できるリスク」の要件の変更
③サーベイランス基準の変更
④その他（BSE発見時に処分が必要な牛の範囲の変更、リスクアセスメントの対象の変更等）

＊総会前に加盟国からの意見、OIE専門家による議論を踏まえた若干の修正の可能性あり。

骨なし骨格筋肉の条件の変更

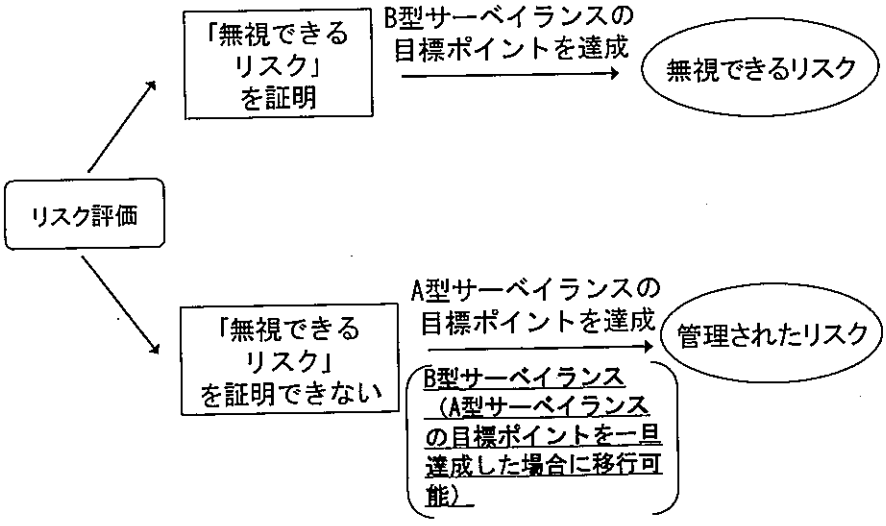
BSEステータスに関わらず「条件を課さずに輸入を承認すべき物品」

骨なし骨格筋肉（機械的除去肉を除く。）
以下の条件を満たした骨なし骨格筋肉であることが必要
- ~~30ヶ月齢以下であること~~
- ピッシング等がされていないこと
- と殺前／後検査を~~受け~~合格していること
- ~~BSE感染の疑いがなく、もしくは感染が確認されていないこと~~
- SRMによって汚染されないように前処理されていること

「無視できるリスク」の条件の変更

カテゴリ	リスク評価	サーベイランス	BSE発生状況	リスク低減措置	感染牛等の処分
無視できるリスク	実施	B型サーベイランスを実施中	発生なし	①報告・教育等が7年以上 ②フィードバンが8年以上	-
			輸入牛でのみ発生		感染牛の処分
			国内発生あり	~~①最終発生から7年以上経過~~ 8年以内に国内で出生した牛で発生なし ②報告・教育等が7年以上 ③フィードバンが8年以上	感染牛、コホート牛の処分

サーベイランス基準の変更



サーベイランス基準の変更

・累積ポイントにかかわらず、全ての臨床的に疑わしい牛に対する検査を実施する旨の規定を新設

・各加盟国の判断で、「緊急と殺牛等」と「死亡牛」の統合を可能とする旨の規定を新設

その他①

・BSE発生時に処分が必要な牛の範囲の変更

1. 全てのBSE感染牛

及び

2. (1) ~~BSE臨床症状発病前2年以内又は発病後にBSE感染雌牛から生まれた全ての産子~~

(2) 生後1年の間に、生後1年までBSE感染牛とともに飼育され、かつ、調査により当該期間に同じ汚染した可能性のある飼料を摂取したことが示された全ての牛

(3) 感染牛と同じ群において、感染牛が生まれた前後12ヶ月の間に生まれた全ての牛（調査の結果が得られない場合）

その他②

・リスクアセスメントの対象の明確化

侵入リスクの評価

（１）~~TSE~~BSE病原体の存在の有無（存在する場合、サーベイランスの結果に基づいた有病率）
（２）自国産反すう動物由来の肉骨粉・獣脂かす
（３）輸入された肉骨粉・獣脂かす
（４）輸入された~~生体~~反すう動物
（５）輸入された飼料・飼料原料
（６）牛に給与された可能性のあるＳＲＭを含有する食用の反すう動物由来製品
（７）牛への体内利用に供される反すう動物由来の輸入製品

⇒　**サーベイランス・疫学調査を考慮**

参考資料 ②

食肉のと畜検査を通じた家畜衛生及び公衆衛生上のハザードコントロールのためのガイドライン（概要）

1．経緯

・　コーデックスは、昨年、リスク・ベースド・アプローチにより、これまでの食肉関連の規範を一つにまとめた、食肉衛生規範（Code of Hygeienic Practice for Meat:CHPM）を採択（注）。

・ＯＩＥは、今般、と畜検査のガイドラインの新設を提案（参考）。

2．概要

・　家畜に係る家畜衛生、公衆衛生のリスクは地域や飼養管理システムによって大きく異なり、と畜検査は各国の状況と家畜衛生、公衆衛生上の目的に応じて個別に構築される必要がある。

・　獣医サービスが、食肉のと畜検査プログラムの開発に一義的な責任を有する。検査に関する所管官庁として獣医サービスの責任には、以下の事項が含まれる
- リスクアセスメント
- 政策及び基準の確立
- 検査プログラムのデザインと管理
- 保証と証明
- 情報の流布

（注）CHPM 採択に伴い、以下の規範を廃止。

- Recommended International Code of Hygienic Practice for Fresh Meat (CAC/RCP 11-1976, Rev. 1-1993)
- Recommended International Code of Hygienic Practice for Game (CAC/RCP 29-1983, Rev. 1-1993)
- Recommended International Code for Ante-Mortem and Post-Mortem Inspection of Slaughter Animals and for Ante-Mortem and Post-Mortem Judgment of Slaughter Animals and Meat (CAC/RCP 41-1993)
- Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products (CAC/RCP 13-1976, Rev. 1-1985)
- Recommended International Code of Hygienic Practice for Poultry Processing (CAC/RCP 14-1976)
- Recommended International Code of Practice for the Production, Storage and Composition of Mechanically Separated Meat Intended for Further Processing (CAC/RCP 32-1293)

（参考）

CODE OF HYGIENIC PRACTICE FOR MEAT

1. INTRODUCTION

3. At the national level the activities of the Competent Authority having jurisdiction at the slaughterhouse (usually Veterinary Administrations[2]) very often serve animal health as well as public health objectives. This is particularly the case in relation to ante- and post-mortem inspection where the slaughterhouse is a key point in animal health surveillance, including zoonoses. Regardless of jurisdictional arrangements, it is important that this duality of functions is recognized and relevant public
health and animal health activities are integrated.

2 OIE is currently working on guidelines on application at national level addressing 'ante- and post-mortem activities in the production of meat to reduce hazards of public and animal health significance'.

APPENDIX X.X.X.

GUIDELINES FOR THE CONTROL OF HAZARDS OF ANIMAL HEALTH AND PUBLIC HEALTH IMPORTANCE THROUGH ANTE- AND POST-MORTEM MEAT INSPECTION

Introduction

Foodborne disease and zoonoses are important public health problems and important causes of decreased economic productivity in developed and developing countries. Similarly, transmission of hazards of animal health importance via the food chain and associated by-products can result in significant economic loss in livestock. Inspection of animals at slaughter can provide a valuable contribution to surveillance for certain diseases of animal and public health importance. Control and/or reduction of hazards of animal and public health importance by ante- and post-mortem meat inspection are a core responsibility of *Veterinary Services.*

Purpose

These guidelines provide a basis for future development of OIE standards for animal production food safety.

Hygienic practice throughout the food chain

The Codex Alimentarius Code of Hygienic Practice for Meat[50] (CHPM) constitutes the primary international standard for meat hygiene and incorporates a risk-based approach to application of sanitary measures throughout the food chain. Ante-mortem inspection is described as a primary component of meat hygiene pre-slaughter, and post-mortem inspection is described as a primary component of process control in post-slaughter meat hygiene. The CHPM specifically recognises the dual objectives that slaughterhouse inspection activities deliver in terms of animal and public health.

The CHPM does not provide inspection measures for specific hazards or organoleptically detected abnormalities, which remain the responsibility of national competent authorities. The animal and public health risks associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

The CHPM provides a platform for development of meat hygiene systems that are based on risk assessment. There are few risk assessment models or relevant scientific information available on public health hazards, making difficult the development of risk-based standards for food-borne zoonoses. While this scientific information is being accumulated, ante- and post-mortem inspection systems will remain dependent on traditional approaches.

[50] Code of Hygienic Practice for Meat, CAC/RCP 58-2005

Veterinary Services and meat inspection programmes

Veterinary Services are primarily responsible for the development of ante- and post-mortem meat inspection programmes. Wherever possible, inspection procedures should be risk-based and management systems should reflect international norms. In respect of ante- and post-mortem inspection as a component of meat hygiene, responsibilities of *Veterinary Services* include:

- Risk assessment
- Establishment of policies and standards
- Design and management of inspection programmes
- Assurance and certification of appropriate delivery of inspection and compliance activities
- Dissemination of information throughout the food chain

Risk assessment

Veterinary Services should utilise risk assessment to the greatest extent possible in the development of sanitary measures. *Veterinary Services* should give priority to addressing microbiological contamination, rather than gross abnormalities detected at ante and post-mortem inspection, as this has been found to be the most important source of hazards.

Microbiological, serological or other testing at single-animal and herd level as part of ante- and post-mortem inspection should be used to support surveillance, as well as risk assessment of prioritised foodborne hazards. The information gathered should be linked to human disease data to allow an assessment of the effectiveness of various management options, as well as a general evaluation of food sources of foodborne disease.

Application of a generic framework should provide a systematic and consistent process for managing all biosecurity risks, while accommodating the different risk assessment methodologies used in animal and public health.

Establishment of policies and standards

The national competent authority(s) should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.

As well as meeting public health objectives, policies and standards relating to ante- and post-mortem inspection should aim to detect and remove hazards of animal health significance from the food chain. This may be achieved by the removal of live animals at ante-mortem inspection or by the removal of specific tissues at post-mortem inspection.

Veterinary Services should integrate their activities to the maximum extent possible and practicable so as to increase the efficacy of policies to prevent duplication of effort and unnecessary costs e.g. within the process of international certification.

Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Veterinary Services* contribute through the direct performance of some veterinary tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector. To this end, *Veterinary Services* provide assurances domestically and to trading partners that safety and suitability standards have been met.

Veterinary Services should allow flexibility in meat inspection service delivery through an officially recognised competent body operating under its supervision and control. In recognition of the contribution of industry to food safety, quality assurance systems may be extended in the case of ante- and post-mortem inspection to systems that integrate industry and *Veterinary Services* activities. Nevertheless, *Veterinary Services* should take into account the factors identified in Chapter 1.3.3 on the Evaluation of *Veterinary Services*. For example, if personnel from the private sector are used to carry out ante- and post-mortem inspection activities under the overall supervision and responsibility of the *Veterinary Services*, the *Veterinary Services* should specify the competency requirements for all such persons and verify their performance.

Assurance and certification

Assurance and certification of appropriate delivery of inspection and compliance activities is a vital function of *Veterinary Services*. International health certificates providing official assurances for trading of meat must engender full confidence to the country of importation.

Dissemination of information

Organisation and dissemination of information throughout the food chain involves multidisciplinary inputs. To ensure the effective implementation of ante- and post-mortem inspection procedures, *Veterinary Services* should have in place systems for the monitoring of these procedures and the exchange of information gained. Animal identification and traceability systems should be integrated in order to be able to trace slaughtered animals back to their place of origin, and products derived from them forward to processors.
