

(イ) 血液成分採血装置を用いて、適当な血液保存液を混入しながら血液を体外循環させて特定の血液成分を採取する方法

(3) 輸血用血液製剤の原材料は、別に定める場合を除き、(2)で定められた採血法によって採取した次のいずれかを用いる。

ア 全血採血で採取した血液

イ 血液成分採血で採取した多血小板血漿又は濃厚血小板血漿

ウ 血液成分採血で採取した血漿

(4) 輸血用血液製剤の原材料を保存する場合は、1～10℃の温度で保存しなければならない。ただし、血小板製剤を製造する場合又は血液成分を分離する場合は、常温に置くことができる。

(5) 輸血用血液製剤の原材料として用いる血液については、一の献血者から採取された血液ごとに、少なくとも梅毒トレポネーマ、B型肝炎ウイルス(HBV)、C型肝炎ウイルス(HCV)、ヒト免疫不全ウイルス(HIV-1及びHIV-2)及びヒトTリンパ球向性ウイルス1型(HTLV-1)の血清学的検査を行わなければならない。これらの検査の結果、不適格と認められた場合は、生物学的製剤基準(平成16年厚生労働省告示第155号)医薬品各条に規定されているものを除き、輸血用血液製剤の原材料として用いてはならない。

(6) 輸血用血液製剤の原材料として用いる血液については、少なくともB型肝炎ウイルスDNA、C型肝炎ウイルスRNA及びヒト免疫不全ウイルスRNAに対する核酸増幅検査を行わなければならない。これらの検査の結果、B型肝炎ウイルスDNA、C型肝炎ウイルスRNA又はヒト免疫不全ウイルスRNAが検出された血液は、輸血用血液製剤の原材料として用いてはならない。

(7) 輸血用血液製剤の原材料として用いる血液については、一の献血者から採取された血液ごとに、ABO血液型及びRh式血液型の判定用抗体を用いて血液型を判定しなければならない。

ABO血液型の試験は、既知のA型及びB型の赤血球を使用し、その血清又は血漿についても試験して、血液型を判定しなければならない。また、血液型判定用抗体基準(平成6年厚生省告示第204号)に適合する抗A血液型判定用抗体又は乾燥抗A血液型判定用抗体及び抗B血液型判定用抗体又は乾燥抗B血液型判定用抗体を用いて行わなければならない。

Rh式血液型の試験は、血液型判定用抗体基準に適合する抗D血液型判定用抗体又

は抗D血液型判定用混合抗体を用い、所定の使用法に従って行い、D(Rho)陽性又は陰性の別を判定するものでなければならない。この試験の結果が陰性の場合には、更に血液型判定用抗体基準に適合する抗ヒトグロブリン抗体(多特異性抗体)を用いて試験を行わなければならない。

(8) 輸血用血液製剤の原材料として用いる血液についての、品質及び安全性の確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。

ア 採血した採血所名

イ 採血した年月日

ウ 診療録等献血者の検診に係る記録

エ 血清学的検査及び核酸増幅検査の結果

オ 当該血液を採取する作業の経過

カ 当該血液の献血者を特定する番号

キ アからカまでに掲げるもののほか、輸血用血液製剤の品質及び安全性の確保に關し必要な事項

## 2 血漿分画製剤総則

(1) 血漿分画製剤(医薬品等の製造工程において添加剤、培地等として用いられるものを含む。以下同じ。)に用いる血液の提供者(以下血漿分画製剤総則において「供血者」という。)は、問診等により、血液によって伝播される疾患にかかっている疑いがなく、血漿分画製剤の原材料となる血液を提供するに十分な適格性を有するものであると認められる者でなければならない。ただし、血液によって伝播される病原体が製造過程において不活化又は除去されることが確認され、その旨が、薬事法に基づく当該血漿分画製剤の製造販売の承認の際に交付される承認書に記載されているものについては、この限りではない。

(2) 採血は、1輸血用血液製剤総則(2)に定められた採血法によって行わなければならない。

(3) 血漿分画製剤の原材料は、別に定める場合を除き、(2)で定められた採血法によって採取した次のいずれかを用いる。

ア 全血採血で採取した血液

イ 血液成分採血で採取した多血小板血漿又は濃厚血小板血漿

ウ 血液成分採血で採取した血漿

- (4) 血漿分画製剤の原材料を保存する場合は、(3)アに該当する原材料については凍結を避けて10℃以下の温度で保存し、(3)イ又はウに該当する原材料については、10℃以下の温度で保存しなければならない。
- (5) 血漿分画製剤の原材料として用いる血液については、少なくともB型肝炎ウイルス(HBV)、C型肝炎ウイルス(HCV)及びヒト免疫不全ウイルス(HIV-1及びHIV-2)の血清学的検査を行わなければならない。これらの検査の結果、不適格と認められた場合は、生物学的製剤基準医薬品各条に規定されているものを除き、原材料として用いてはならない。
- (6) 血漿分画製剤の原血漿については、少なくともB型肝炎ウイルスDNA、C型肝炎ウイルスRNA及びヒト免疫不全ウイルスRNAに対する核酸増幅検査を行わなければならない。ただし、その原血漿の原材料である血液について、B型肝炎ウイルスDNA、C型肝炎ウイルスRNA及びヒト免疫不全ウイルスRNAが検出されないことが核酸増幅検査により確認されている場合は、この限りではない。これらの検査の結果、B型肝炎ウイルスDNA、C型肝炎ウイルスRNA又はヒト免疫不全ウイルスRNAが検出された血漿は原血漿として用いてはならない。
- (7) 原血漿を保存する場合は、6℃以下の温度で保存しなければならない。
- (8) 血漿分画製剤の原材料として用いる血液及び原血漿についての、品質及び安全性の確保に必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。
- ア 原材料を採取した採血所名
  - イ 原材料を採取した年月日
  - ウ 診療録等原血漿に用いた血液の供血者の検診に係る記録
  - エ 血清学的検査及び核酸増幅検査の記録
  - オ 原材料を採取する作業及び原血漿を製造する作業の経過
  - カ 原材料及び原血漿の製造番号
  - キ 原血漿に用いた血液の供血者を特定する番号
  - ク アからキまでに掲げるもののほか、血漿分画製剤の品質及び安全性の確保に関し必要な事項

### 第3 人由来製品原料総則

#### 1 人細胞組織製品原料基準

- (1) 人細胞組織製品(人に由来する原料又は材料(血液及び血液から製造される成分を

除く。)から構成される医薬品又は医療機器をいう。以下同じ。)の原料又は材料として用いる細胞及び組織については、採取するために必要な衛生管理を行うのに十分な人員及び設備を有する施設で採取されたものでなければならない。

- (2) 人細胞組織製品の原材料として用いる細胞又は組織を採取するに当たっては、次に掲げる措置が講じられていなければならない。
- ア 当該細胞又は組織を採取する過程における病原微生物その他疾病の原因となるものによる汚染を防止するために必要な措置が講じられていること。
  - イ 採取された細胞又は組織について、必要に応じて感染症に関する最新の知見に照らして適切な検査が行われ、病原微生物その他疾病の原因となるものに汚染されていない旨が確認されていること。
- (3) ドナーは、次のいずれにも該当し、人細胞組織製品の原材料として用いる細胞又は組織を提供するにつき十分な適格性を有するものでなければならない。なお、人細胞組織製品の使用の対象者とドナーが同一の者である場合は必ずしもドナースクリーニングを必要としない。
- ア 当該細胞又は組織を採取するに当たって、それらの利用の目的に応じ、問診、検診、検査等により、細菌、真菌、ウイルス等の感染が否定されていること。
  - イ アの検査項目及び検査方法が感染症等に関する最新の知見に照らして適切なのであること。
  - ウ アの検査項目、検査方法等に応じた再検査がウインドウペリオドを勘案して適切な時期に行われていること。
- (4) 上記のほか次に掲げる疾病等について、問診、検診、検査等を行うとともに、輸血又は移植医療を受けた経験の有無等を勘案して、ドナーとしての適格性があると判断されていなければならない。
- ア 梅毒トレポネーマ、クラミジア、淋菌、結核菌等の細菌による感染症
  - イ 敗血症及びその疑い
  - ウ 悪性腫瘍
  - エ 重篤な代謝及び内分泌疾患
  - オ 膠原病及び血液疾患
  - カ 肝疾患
  - キ 伝達性海綿状脳症及びその疑い並びにその他の痴呆症
- (5) 細胞又は組織の採取を行う者が、ドナーとなる者に対して、ドナースクリーニン

グの実施前に細胞及び組織の利用目的、個人情報の保護、その他採取に関する事項について当該者の理解を得るよう、文書を用いて十分に説明し、自由な意思による同意を文書により得たものでなければならない。なお、説明に当たっては、同意の拒否及び撤回の権利があり、拒否又は撤回することにより当該者が不利益を受けないことが明らかにされていなければならない。

(6) ドナー本人が説明を受け同意を与えることが困難な場合又は単独で完全な同意を与える能力を欠いている場合において、下記の要件を満たす場合に限り、代諾者(本人に対して親権を行う者、配偶者及び後見人その他これらに準じる者であって、本人に代わって説明を受け、本人に代わって同意をする権限を有するものをいう。以下同じ。)の同意により細胞又は組織の採取を行うことができる。

ア 当該ドナーからの細胞又は組織の採取が人細胞組織製品の品質、有効性及び安全性の確保の観点等から必要とされる合理的理由があること。

イ 代諾者がドナーの意思及び利益を最もよく代弁できると判断される者であり、かつ、代諾者の同意に際しては、ドナーと代諾者の関係についての記録が作成され、同意書とともに保存されていること。

ウ 細胞又は組織を採取する者は可能な限りドナーにその理解力に応じた説明を行うとともに、ドナー本人からも同意を得るよう努めること。

エ 採取を行う施設の倫理委員会等において、当該ドナーからの細胞又は組織の採取の科学的及び倫理的妥当性が審査され、了承されていること。

(7) 死体から細胞又は組織の提供を受ける場合には、遺族に対して(5)に従って説明し同意を得たものでなければならない。細胞又は組織の採取は、当該ドナーが細胞又は組織の提供を生前に拒否していない場合に限る。また、ドナーに対する礼意の保持に留意したものでなければならない。

(8) 手術等で摘出された細胞又は組織を利用する場合においても、(5)及び(6)に従って同意を得たものでなければならない。なお、この場合にあつては、当該手術等が細胞又は組織の採取の目的を優先して行われたものであってはならない。

(9) ドナーからの細胞又は組織の採取が無対価で行われたものでなければならない。ただし、細胞又は組織の提供により生じるドナーの負担につき、交通費等実際にかかった費用を勘案しつつ、倫理委員会等の了承を得た上で、適切な補填がなされることは、この限りではない。

(10) 細胞組織製品の原材料となる人の細胞又は組織についての、品質及び安全性の確

保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。

ア 当該細胞又は組織を採取した施設

イ 当該細胞又は組織を採取した年月日

ウ ドナースクリーニングのための問診、検診、検査等による診断の結果及び状況

エ 当該細胞又は組織を採取する作業の経過

オ 倫理委員会等の審議結果

カ 同意説明文書及び同意文書

キ ドナーに関する識別番号

ク アからキまでに掲げるもののほか、人細胞組織製品の品質及び安全性の確保に關し必要な事項

## 2 人尿由来原料基準

(1) 原材料として人の尿が用いられる医薬品等については、人尿由来原料基準を適用するほか、1人細胞組織製品原料基準(9)の規定を準用するものとする。

(2) 原材料として用いる尿又はプール尿(提供者ごと又は複数の提供者から提供された尿を集めて混合したもの。以下同じ。)の適切な段階において、感染症に関する適切な検査が行われ、病原微生物等に汚染されていないことが確認されていなければならない。ただし、病原微生物その他疾病の原因となるものが製造過程において不活化又は除去されることが確認され、その旨が薬事法に基づく当該製品の製造販売の承認の際に交付される承認書に記載されているものについては、この限りではない。

(3) 原材料として用いる尿については、プール尿の適切な段階において、少なくともB型肝炎ウイルスDNA、C型肝炎ウイルスRNA及びヒト免疫不全ウイルスRNAに対する核酸増幅検査を行わなければならない。ただし、B型肝炎ウイルスDNA、C型肝炎ウイルスRNA及びヒト免疫不全ウイルスRNAが検出されることが適当な核酸増幅検査により確認されている尿を原材料として用いる場合は、この限りではない。

(4) 原材料として用いる尿について、製造過程において、細菌、真菌、ウイルス等が不活化又は除去されることが確認されていなければならない。

(5) 原材料として用いる尿についての、品質及び安全性の確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。

ア プール尿を作製した機関名

イ プール尿を作製した年月日

ウ プール尿の検査等の結果

エ プール尿を作製する作業の工程

オ プール尿のロットの番号

カ アからオまでに掲げるもののほか、当該医薬品等の品質及び安全性の確保に関し必要な事項

### 3 人由来原料基準

(1) 血液、尿及び人細胞組織製品の原材料以外の人に由来する原料又は材料(細菌又はウイルスの感染リスクが否定されていることが科学的に公知のものとされるものを除く。以下人由来原料基準において同じ。)の原材料については、人由来原料基準によるものとする。ただし、人に由来するセル・バンクによる原材料であって、本基準の適用の際現に構築され、かつ、品質及び安全性の確保の観点から、原材料として用いることについて(2)の規定と同等以上の妥当性を有することが確認され、その旨が、薬事法に基づく製品の製造販売の承認の際に交付される承認書に記載されているものにあつては、(2)の規定は適用しないものとする。

(2) ヒトに対して感染性及び病原性を示す可能性のあるウイルスの存在の有無を確認するために、原材料として用いる細胞又は組織(セル・バンクを出発基材とし細胞培養により生産される製品については、細胞株や培養終了後の細胞を含む。)に対して、ウイルスを検出するために必要な試験(以下「ウイルス試験」という。)を行わなければならない。更に、未加工又は未精製バルクの段階において、適切にウイルス試験を実施しなければならない。ただし、工程をごく一部進めることによってウイルスを検出する試験がより高感度に行えることとなる場合にはこの限りではない。これらの試験において、外来性ウイルスが検出された場合には、原則として、医薬品等の原材料として用いてはならない。

(3) 原材料について、製造過程において、細菌、真菌、ウイルス等を不活化又は除去する処理を行わなければならない。

(4) 原材料についての、品質及び安全性の確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。

ア 原材料を作製した機関名

イ 原材料を作製した年月日

ウ 原材料の検査等の結果

エ 原材料を作製する作業の経過

オ 原材料のロットの番号

カ アからオまでに掲げるもののほか、当該製品の品質及び安全性の確保に関し必要な事項

### 第4 動物由来製品原料総則

#### 1 反芻動物由来原料基準

(1) 反芻動物に由来する原料又は材料(脂肪酸、グリセリン、脂肪酸エステル、アミノ酸、合成オリゴペプチドその他高温及びアルカリ処理により製するものを除く。)については、反芻動物由来原料基準によるものとする。

(2) 反芻動物の次に掲げる部位を医薬品等の原材料に用いてはならない。

ア 下垂体

イ 胸腺

ウ 硬膜

エ 三叉神経節

オ 松果体

カ せき髄

キ せき柱骨

ク 胎盤

ケ 頭骨

コ 腸

サ 脳

シ 脳せき髄液

ス 背根神経節

セ 脾臓

ツ 副腎

タ 扁桃

チ 眼

ツ リンパ節

(3) 反芻動物に由来する原材料(乳を除く。)を医薬品等に用いる場合には当該反芻動物の原産国は次に掲げる国でなければならない。ただし、羊毛、ラノリン並びに皮由来ゼラチン及びコラーゲン並びにアメリカ合衆国又はカナダを原産国とする反芻動物由来原材料(以下「アメリカ産又はカナダ産原料」という。)を使用して細胞培養によ

り製造される注射剤(セルバンクにのみアメリカ産又はカナダ産原料を使用しているものに限る。)その他これに準ずるもの、アメリカ産又はカナダ産原料から製造されたコール酸類を使用して製造される経口剤その他これに準ずるもの、アメリカ産又はカナダ産原料を使用して製造されるワクチン(経口ワクチンに限る。)、アメリカ産又はカナダ産原料を使用して微生物培養により製造される注射剤(種培養にのみアメリカ産又はカナダ産原料を使用しているものに限る。)若しくは経口剤その他これに準ずるもの又はアメリカ産又はカナダ産原料を使用して製造される外用剤については、この限りではない。また、乳を原材料として用いる場合には当該反芻動物の原産国は、英国及びポルトガル以外の国でなければならない。

- ア アルゼンチン
- イ インド
- ウ ウルグアイ
- エ エルサルバドル
- オ オーストラリア
- カ ケニア
- キ コスタリカ
- ク コロンビア
- ケ シンガポール
- コ スワジランド
- サ ナイジェリア
- シ ナミビア
- ス ニカラグア
- セ ニューカレドニア
- ソ ニュージーランド
- タ パキスタン
- チ パナマ
- ツ バヌアツ
- テ パラグアイ
- ト ブラジル
- ナ ボツワナ
- ニ モーリシャス

(4) 反芻動物に由来する原材料についての、品質及び安全性の確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていなければならない。

- ア 原産国
- イ 原材料を作製した年月日
- ウ 原材料の由来となる反芻動物の飼育又はと畜の状況
- エ 原材料について伝達性海綿状脳症を防止するための処理及び作業の経過
- オ 原材料のロットの番号

(5) 医薬品、医療部外品及び医療機器については、治療上の効果が当該原材料を用いることによるリスクを上回る場合その他必要な場合において、(2)又は(3)に適合しない原材料をやむを得ず使用する場合は、その妥当性について、薬事法に基づく製品の製造販売の承認の際に交付される承認書に記載することとする。

(6) 化粧品については、(3)に適合しない原材料をやむを得ず使用する場合は、厚生労働省医薬食品局長が定める必要な条件に適合するもののみを使用することができる。

## 2 動物細胞組織製品原料基準

(1) 動物細胞組織製品(人以外の動物に由来する原料又は材料から構成される医薬品又は医療機器をいう。以下同じ。)の原材料となる細胞又は組織の採取に当たっては、採取の過程における病原微生物その他疾病の原因となるものの汚染を防ぐために必要な措置を講じなければならない。

(2) ドナー動物は、次のいずれにも該当し、動物細胞組織製品の原料又は材料となる細胞又は組織を提供するに十分な適格性を有するものでなければならない。

- ア ドナー動物を選択するに当たっては、動物種ごとの微生物学的特性が考慮されていること。
- イ ドナー動物の受入れ時及び受入れ後の試験検査が、当該試験検査の項目及び当該試験検査の結果を評価する基準をあらかじめ設定した上で行われていること。特に、感染症等に関する試験検査については、動物種ごとに検査すべき項目が異なる点に留意すること。
- ウ ドナー動物の受入れに際して、感染症等の伝播を防止するための措置が適切に行われていること。
- エ ドナー動物の飼育管理に関する実施方法及び手順を記載した標準操作手順書が作成されていること。
- オ 感染症等の伝播を防止するため、ドナー動物の飼育管理が封じ込めの設備その他

の適切な設備を有する施設で行われていること。

カ ドナー動物が動物福祉の精神に基づいて取り扱われていること。

- (3) 動物の生きた細胞又は組織を用いる場合にあっては、ウイルス感染リスクの検証を行わなければならない。
- (4) (3)以外の場合にあっては、無菌性が担保されていること及びウイルス感染リスクの検証が行われていることを確認しなければならない。
- (5) 動物細胞組織製品の原料又は材料となる動物の細胞又は組織についての、品質及び安全性確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていないなければならない。
  - ア 当該細胞又は組織を採取した施設
  - イ 当該細胞又は組織を採取した年月日
  - ウ ドナー動物の受入れ並びに試験検査及び飼育管理の状況
  - エ 当該細胞又は組織を採取する作業の過程
  - オ 当該細胞又は組織のロットの番号
  - カ アからオまでに掲げるもののほか、当該動物細胞組織製品の品質及び安全性の確保に関し必要な事項
- (6) 動物細胞組織製品の原料又は材料として用いる細胞及び組織については、採取するために必要な衛生管理を行うのに十分な人員及び設備を有する施設で採取されたものでなければならない。

### 3 動物由来原料基準

- (1) 動物細胞組織製品の原材料以外の動物に由来する原料又は材料(細菌又はウイルスの感染リスクが否定されていることが科学的に公知のものとするものを除く。以下動物由来原料基準において同じ。)の原材料は、薬事法に基づく製品の製造販売の承認の際に交付される承認書に別に記載されている場合を除き、健康な動物に由来するものでなければならない。健康な動物に由来することが確認できない場合にあっては、無菌性が担保されていること及びウイルス感染リスクの検証が行われていることを確認しなければならない。
- (2) 原材料について、動物の原産地、使用部位等を明らかにするとともに、細胞又は組織の入手方法について明らかにしなければならない。
- (3) 特性解析された動物(哺乳類、鳥類及び昆虫類)に由来するセル・バンクを出発基材とした細胞培養により生産される製品については、ヒトに交 原性を示

す可能性のあるウイルスの存在の有無を確認するために、細胞株や培養終了後の細胞については、ウイルス試験を少なくとも一度は行わなければならない。さらに、未加工又は未精製バルクの段階において、適切にウイルス試験を実施しなければならない。ただし、工程をごく一部進めることによってウイルス試験がより高感度に行える場合にはこの限りではない。本試験において、外来性ウイルスが検出された場合には、原則として、製品を製造するために用いてはならない。

- (4) 生きた動物全体を出発基材として生産される製品については、(3)及び2動物細胞組織製品原料基準(2)の規定を準用する。
- (5) 細胞、組織又は体液から得られた原材料について、製造工程において、細菌、真菌、ウイルス等を不活化又は除去する処理を行わなければならない。
- (6) 原材料についての、品質及び安全性の確保上必要な情報が確認できるよう、次に掲げる事項が記録され、保存されていないなければならない。
  - ア 原材料を作製した機関名
  - イ 原材料を作製した年月日
  - ウ 原材料の検査等の結果
  - エ 原材料を作製する作業の経過
  - オ 原材料のロットの番号
- (7) 生物由来製品に指定された製品以外の製品については、(2)から(5)までの規定を適用しないものとする。

改正文（平成一六年三月三〇日厚生労働省告示第一五七号）抄

公布の日から適用する。ただし、本告示の適用の際現に同法第十四条(第二十三条において準用する場合を含む。)又は同法第十九条の二の規定による承認を受けている医薬品、医薬部外品、化粧品又は医療用具であって、平成十六年九月三十日までに製造され、又は輸入されるものについては、なお従前の例によることができる。

改正文（平成一六年七月五日厚生労働省告示第二六二号）抄

公布の日から適用する。ただし、インド、ケニア、コスタリカ、コロンビア、ナイジェリア、パキスタン又はモーリシャスを原産国とする反芻動物の三叉神経節、せき柱骨、頭骨又は背根神経節から製造されるゼラチン又はコラーゲン(以下「骨由来ゼラチン等」という。)を使用して製造される医薬品、医薬部外品、化粧品又は医療用具(以下「医薬品等」という。)であって平成十七年九月三十日までに製造され、又は輸入されるもの及びアルゼンチン、ウルグアイ、エルサルバドル、オーストラリア、シンガポール、スワジランド、チリ、ナミビ



OIE による BSE ステータス評価

OIE は、国際的な動物検疫の協調の一環として、BSE について公衆衛生も含めたステータス評価 (BSE リスクの程度に応じた各カテゴリーに分類すること) を実施している。具体的には、ステータス評価を希望する OIE 加盟国から提出されたデータに基づき、OIE の基準により加盟国のリスク等を評価し、各国を「無視できるリスク国」、「管理されたリスク国」(いずれにも該当しない場合は「不明のリスク国」になる) として評価・分類した案を加盟国に示し、毎年5月に開催される OIE 総会で決定している。

OIE Member Countries' official BSE risk status map

Last update May 2013

Click on a specific region to zoom in



Member Countries recognised as having a negligible BSE risk  
 Member Countries recognised as having a controlled BSE risk  
 Countries without OIE recognised BSE risk status

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CHAPTER 11.5.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.5.1.

General provisions and safe commodities

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 Authorities* 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) gelatine and collagen prepared exclusively from hides and skins;
  - e) tallow with maximum level of insoluble impurities of 0.15 percent 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 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 passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.5.14.;
  - 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 Authorities* 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*.
- 3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country, zone or compartment*.

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

Article 11.5.2.

The BSE risk status of the cattle population of a country, zone or compartment

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*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective. Member Countries should review the *risk assessment* annually to determine whether the situation has changed.
  - a) Entry assessment  
 Entry assessment consists of assessing, through consideration of the following, the likelihood that the BSE agent has either been introduced into the country, *zone or compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone or compartment*:
    - i) the presence or absence of the BSE agent in the indigenous ruminant population of the country, *zone or compartment* and, if present, evidence regarding its prevalence;
    - ii) production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
    - iii) imported *meat-and-bone meal* or *greaves*;

- iv) imported cattle, sheep and goats;
- v) imported animal feed and feed ingredients;
- vi) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.5.14. and may have been fed to cattle;
- vii) imported products of ruminant origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

If the entry assessment identifies a *risk* factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, 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 up 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 Articles 11.5.20. to 11.5.22.;
- 3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4) the examination carried out in accordance with the *Terrestrial Manual* in a *Laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member Country should conduct Type B *surveillance* in accordance with Articles 11.5.20. to 11.5.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member Country should conduct Type A *surveillance* in accordance with Articles 11.5.20. to 11.5.22.

Article 11.5.3.

Negligible BSE risk

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

- 1) a *risk assessment*, as described in point 1 of Article 11.5.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
- 2) the Member Country has demonstrated that Type B *surveillance* in accordance with Articles 11.5.20. to 11.5.22. 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, if there has been a case, every 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 11.5.2. have been complied with for at least seven years; and
  - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

OR

- b) if there has been an indigenous case, every indigenous case was born more than 11 years ago; and
  - i) the criteria in points 2 to 4 of Article 11.5.2. have been complied with for at least seven years; and
  - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

- iii) all BSE cases, as well as:

- 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.

The Member Country or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.5.4.

Controlled BSE risk

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

- 1) a *risk assessment*, as described in point 1 of Article 11.5.2., has been conducted in order to identify the historical and existing risk factors, and the Member Country has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;
- 2) the Member Country has demonstrated that Type A *surveillance* in accordance with Articles 11.5.20. to 11.5.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;
- 3) EITHER:
  - a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported and has been completely destroyed, the criteria in points 2 to 4 of Article 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
    - i) the criteria in points 2 to 4 of Article 11.5.2. have not been complied with for seven 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 eight years;

OR

- b) there has been an indigenous case of BSE, the criteria in points 2 to 4 of Article 11.5.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

and all BSE cases, as well as:

- 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.

The Member Country or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

## Article 11.5.5.

## 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 11.5.6.

**Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk**

For all commodities from cattle not listed in point 1 of Article 11.5.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, zone or compartment complies with the conditions in Article 11.5.3.

## Article 11.5.7.

**Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case**

For cattle selected for export

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b)iii) of Article 11.5.3.;
- 2) 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 11.5.8.

**Recommendations for the importation of cattle from a country, zone or compartment posing a controlled BSE risk**

For cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the country, zone or compartment complies with the conditions referred to in Article 11.5.4.;
- 2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.5.4.;
- 3) 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 was effectively enforced.

## Article 11.5.9.

**Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk**

For cattle

Veterinary Authorities should require 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 cattle which, during their first year of life, were reared with the BSE cases which investigation showed consumed the same potentially contaminated year of life, and period, or

- b) 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 in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
  - b) were born at least two 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 11.5.10.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the country, zone or compartment complies with the conditions in Article 11.5.3.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the *fresh meat* and *meat products* were derived 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 11.5.11.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the country, zone or compartment complies with the conditions referred to in Article 11.5.4.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) cattle from which the *fresh meat* and *meat products* destined for export were derived 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* 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 points 1 and 2 of Article 11.5.14.,
  - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

## Article 11.5.12.

**Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk**

For fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.5.1.)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the cattle from which the *fresh meat* and *meat products* originate:
  - a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
  - b) passed ante- and post-mortem inspections;
  - c) 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* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
- the tissues listed in points 1 and 3 of Article 11.5.14.,
  - nervous and lymphatic tissues exposed during the deboning process,
  - mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

## Article 11.5.13.

**Recommendations on ruminant-derived meat-and-bone meal or greaves**

- Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.5.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before 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.
- 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 11.5.4. and 11.5.5. should not be traded between countries.

## Article 11.5.14.

**Recommendations on commodities that should not be traded**

- From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.5.4. and 11.5.5., 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. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.5.4., 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 and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.5.5., 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 and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

## Article 11.5.15.

**Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;
- OR
- they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that
    - vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;
    - the bones have been subjected to a process which includes all of the following:
      - degreasing,

- acid demineralisation,
- acid or alkaline treatment,
- filtration,
- sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds, or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

## Article 11.5.16.

**Recommendations for the importation of tallow (other than as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.5.14.

## Article 11.5.17.

**Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.5.15.

## Article 11.5.18.

**Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.5.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- the tallow derivatives originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
- they are derived from tallow meeting the conditions referred to in Article 11.5.16.; or
- they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

## Article 11.5.19.

**Procedures for the reduction of BSE infectivity in meat-and-bone meal**

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

- The raw material should be reduced to a maximum particle size of 50 mm before heating.
- The raw material should be heated under saturated steam conditions to a temperature of not less than  $133^{\circ}\text{C}$  for a minimum of 20 minutes at an absolute pressure of 3 bar.

## Article 11.5.20.

## Surveillance: 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 11.5.2. 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:
  - 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 or killed 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*. This approach is consistent with Articles 11.5.20. to 11.5.22.
- 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 11.5.21.

## Surveillance: 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 Member 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 is the one exhibiting the highest prevalence. The classification of such *animals* will depend on the ongoing owner/veterinarian assessment, reporting and documentation. This and the

quality of the investigation and *laboratory* examination systems (Article 11.5.2.), 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 Member 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 or killed 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 Member 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 Member 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).

## Article 11.5.22.

## Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member Country should use documented records or reliable estimates of the age distribution of 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 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*.

A *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 seven years.

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

- 1) the design prevalence for Type A or Type B *surveillance*;
- 2) a confidence level of 95 percent;
- 3) the pathogenesis, and pathological and clinical expression of BSE:
  - a) sensitivity of diagnostic methods used;
  - b) relative frequency of expression by age;
  - c) relative frequency of expression within each subpopulation;
  - d) interval between pathological change and clinical expression;
- 4) demographics of the cattle population, including age distribution and population size;
- 5) influence of BSE on culling or attrition of *animals* from the cattle population via the four subpopulations;
- 6) 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:

- 7) cattle population numbers stratified by age;
- 8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter 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 Member 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 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 percent.

#### 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 percent.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.5.3.) 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 11.5.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

#### 3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows the points target for adult cattle populations of different sizes. The size of the adult cattle population 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.

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,000	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

#### 4. 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 Chapter 1.4. 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*. In addition, Member Countries should sample at least three of the four subpopulations.

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

Surveillance subpopulation			
Routine slaughter <sup>1</sup>	Fallen stock <sup>2</sup>	Casualty slaughter <sup>3</sup>	Clinical suspect <sup>4</sup>
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			
0.0	0.1	0.2	45

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'.

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

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

#### Article 11.5.23.

##### BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

##### 1. Entry assessment

Entry assessment consists of assessing the likelihood that a BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with a BSE agent:

- meat-and-bone meal* or *greaves*;
- live *animals*;
- animal feed and feed ingredients;
- products of animal origin for human consumption.

##### 2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- epidemiological situation concerning BSE agents in the country or *zone*;

- 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;
- the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; through epidemiological investigations of any indigenous *case* born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

#### Article 11.5.24.

##### The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 11.5.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

*Assumption:* That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

*Question to be answered:* Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

*Rationale:* Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

##### Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

#### Article 11.5.25.

##### The potential for the entry of the BSE agent through the importation of live animals potentially infected with BSE

##### Assumptions:

- Countries which have imported ruminants from countries infected with BSEs are more likely to experience BSE.
- Cattle pose the only known risk although other species are under study.
- *Animals* imported for breeding may pose a greater risk than *animals* imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than *animals* imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** Have live *animals* been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the *animals* in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

**Evidence required:**

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported *animals*, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

#### Article 11.5.26.

**The potential for the entry of the BSE agent through the importation of products of animal origin potentially infected with BSE**

**Assumptions:**

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with BSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

**Question to be answered:** What products of animal origin have been imported within the past seven years?

**Rationale:** The likelihood of entry is dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.5.14.);
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of geographical BSE risk;
- feeding and management of the *animals* in the country of origin;
- use to which the *commodity* has been put as apart from representing risk of developing clinical *disease*, the *slaughter*, rendering and recycling in *meat-and-bone meal* of imported *animals* represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

**Evidence required:**

- Documentation on the country of origin of imports. This should identify the country of breeding of *animals*, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.

- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

#### Article 11.5.27.

**The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin**

**Assumptions:**

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

**Question to be answered:** Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.5.3. and 11.5.4.)?

**Rationale:** If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

#### Article 11.5.28.

**The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production**

**Assumptions:**

- BSE has a long *incubation period* and insidious onset of signs, so *cases* may escape detection.
- Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.5.19.
- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

**Question to be answered:** How has animal waste been processed over the past eight years?

**Rationale:** If potentially infected *animals* or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

**Evidence required:**

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.5.29.

**Conclusions of the risk assessment**

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.



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**REPORT OF THE MEETING  
OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES**

Paris, 4-8 February 2013

A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at the OIE Headquarters in Paris, France from 4 to 8 February 2013.

**Opening**

The Commission was welcomed by Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department of the OIE, on behalf of Dr Bernard Vallat, Director General of the OIE.

Dr Miyagishima mentioned that a number of Member Countries had applied for the first time for official recognition of freedom from African horse sickness (AHS) after the revision of the relevant chapter in the *Terrestrial Animal Health Code (Terrestrial Code)*, to provide for the first equine disease to be officially recognised by the OIE for country or zonal freedom from disease. He further mentioned that following AHS, *peste des petits ruminants* (PPR) could also be considered as a candidate disease for official recognition of free status. Dr Miyagishima also indicated that the OIE was actively involved in the intended worldwide control of PPR under the umbrella of an OIE/FAO initiative for the "Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs)". A working group had been tasked by the GF-TAD's to work on a PPR Global Strategy, following the model of the Global Foot and Mouth Disease (FMD) Control Strategy.

In respect of FMD, it was mentioned that after the successful Global Conference on FMD Control held in Bangkok in June 2012, the partners involved in the Global Strategy had entered the implementation phase. Dr Miyagishima encouraged the Commission to continue to be involved actively in the Global FMD control programme. Another important development within the OIE was the establishment of an *ad hoc* group on the international movement of high -level competition horses with the collaboration and financial support of the *Fédération Equestre Internationale (FEI)*. It was foreseen that the task of this *ad hoc* Group would include revision of the OIE *Terrestrial Manual* and *Terrestrial Code* chapters on horse diseases. The *ad hoc* Group would report to the two concerned Specialists Commissions (Biological Standards Commission and this Commission) while maintaining coordination with the Terrestrial Animal Health Standards Commission (Code Commission).

On administrative issues, Dr Miyagishima sought the opinion of the Commission on its willingness to work on electronic files of the working documents and discontinue use of hard copies, at least for those members who were ready to do so. He also requested the Commission to evaluate the need for and explore the possibility for extending its meeting beyond one week, in view of the Commission's increasing work load. Another matter discussed was the desirability of including the draft revised chapters of the *Terrestrial Code* developed by *ad hoc* Groups as annexes to the *ad hoc* Groups' reports. This would improve the traceability of documents and increase the transparency in the standard setting process to the benefit of Member Countries, without necessarily leading to confusion. Only the final report as approved by the Scientific Commission would be attached to the *ad hoc* Group's report. The President of the Commission indicated that draft or amended chapters of the *Terrestrial Code* would not be

1 See point 4) of Article 11.5.21.

2 See point 3) of Article 11.5.21.

3 See point 2) of Article 11.5.21.

4 See point 1) of Article 11.5.21.

circulated with the reports of the Scientific Commission but only with the report of the Code Commission as decided by mutual agreement between the two Commissions. The main reason for this arrangement is to avoid confusion by Member Countries and to ensure that comments on draft or amended chapters from Member Countries are directed to the OIE in response to the report of the Code Commission. In view of the increased volume the Commission's report would acquire, Dr Miyagishima advised only the body of the report, containing the deliberation and decisions by the Commission would be printed for the General Session, but the complete version with the annexes would be distributed to OIE Delegates in a CD and through the OIE Delegates' website.

Finally, Dr Miyagishima announced his imminent departure from the OIE and thanked the Commission for its support to the staff of the Scientific and Technical Department. Dr Alessandro Ripani also announced his departure in coming months and thanked the Commission for the opportunity of having worked with them for several years.

In his response the President of the Commission regretted these departures and thanked the significant contribution of the departing staff to the work of the Commission.

#### Statement of the Director General

After joining the meeting at a later stage, Dr Vallat commented on important issues related to the working programme of the OIE. Firstly, the OIE had been requested to increase its involvement in implementing the global strategies to control diseases of importance, namely on FMD, PPR and rabies. For FMD, he reiterated that the Commission's work was essential in ensuring the OIE's involvement in the implementation of the recommendations of the Global Conference on FMD control (Bangkok, June 2012) by among others encouraging the further development of Veterinary Services and through the endorsement of the official control programmes for FMD. The OIE might consider increasing the number of experts involved in the evaluation of FMD dossiers, given the anticipated increase in the number of countries that would apply for endorsement of their control programme and eventually recognition of disease free status. The updated *Terrestrial Code* chapter on FMD was most welcome and would, after approval by the Scientific and Code Commissions, be ready for circulation for comments from Member Countries.

On PPR, there was an on-going project, supported by the Bill & Melinda Gates Foundation, to develop vaccination campaigns in Africa with some focus on backyard small ruminants. Dr Vallat also highlighted the importance of finalising the amended *Terrestrial Code* chapter on PPR that would support the political will of countries and donors to participate in the global control strategy which would include among others convincing animal owners on the need to vaccinate small ruminants for PPR.

On rabies, Dr Vallat urged that the inclusion in the *Terrestrial Code* of an article for the control of rabies in dogs would encourage and mobilise decision makers to invest in mitigating the public health risk by controlling rabies at its source as recommended at the Global Conference on Rabies Control held in Incheon-Seoul (September, 2011). Dr Vallat informed the Commission on the EU-funded rabies vaccine bank in Asia which had been deployed in Lao and Vietnam, and very soon in the Philippines, and that could provide up to 4 million vaccine doses. Other vaccine banks could be eventually created in Africa if the vaccine bank in Asia proved to be successful.

On official disease status recognition, Dr Vallat expressed his satisfaction on the number of country applications received and on the ongoing improvement in the evaluation system. Possible additions to the list of diseases with official status might include, apart from PPR, other diseases such as CSF and Glanders. The future validation of an improved diagnostic method would perhaps enable Glanders to be considered as a candidate disease for official disease status recognition. There were still Member Countries wishing to have CSF as a disease for official status recognition; however the wild and feral animal implication had so far complicated this possibility. Dr Vallat encouraged the Commission to increase the number of expert missions to visit countries not only in relation to FMD free status, but also for other diseases.

Dr Vallat supported the missions to southern African countries and other Member Countries planned for 2013. Finally, Dr Vallat expressed his opinion on how the Commission should deal with Bovine Spongiform Encephalitis (BSE), classical or atypical, stating that atypical BSE could be regarded as a rare disease. He indicated that the resource investment in risk status recognition as well as in standard setting for BSE should gradually be brought to a level proportionate to the real impact of the disease on the society, given the significant global decrease in the number of human and animal cases linked with BSE.

## 1. Adoption of the agenda

The meeting was chaired by Dr Gideon Brückner, President of the Scientific Commission, with the Scientific and Technical Department staff of the OIE, providing the preparation of the draft report.

The President expressed his appreciation for the work of the Scientific and Technical Department in the preparation of the working documents to be in time for the meeting and also commended the *ad hoc* Groups for the scientific quality of their reports.

The agenda, as adopted, and the list of participants, are attached as Annexes 1 and 2, respectively.

## 2. Issues from the last meeting of the Scientific Commission

The Commission reviewed salient points from the report of its previous meeting. The following issues emanating from and related to the previous meeting were discussed:

### 2.1. Principles on Disease Control (proposed new chapter for the *Terrestrial Code*): comments from Member Countries

The Commission had requested Member Countries to comment on the new proposed chapter on disease control for possible inclusion in the *Terrestrial Code*. Comments were received by the African countries and by Switzerland welcoming the chapter with minor suggestions. The Commission, on request of Switzerland, accepted to include "holders" in addition to "producers" in the disease control planning process. The inclusion of "institutional arrangements", as suggested by Delegates from Africa as a factor to consider when planning a disease control programme, was accepted but as a socioeconomic consideration, rather than as a technical tool. Finally, a comment on communication was not accepted because the Commission considered it was sufficiently covered throughout the chapter.

The draft new chapter with the comments of Member Countries addressed was forwarded to the Code Commission for its further processing and possible final adoption by the World Assembly in May 2014.

### 2.2. Decision on the inclusion of the term "risk-based surveillance" in the Glossary

The term "risk based surveillance" had been drafted by the *ad hoc* Group on Epidemiology in 2011 for inclusion in the *Terrestrial Code* Glossary. Noting that the term was not used in the text of the *Terrestrial Code*, the Commission had postponed its decision for inclusion in the Glossary until the matter was discussed with the Code Commission.

The two Commissions agreed that they would discuss this matter at their next joint meeting.

### 2.3. Items consulted with experts to address Member Country comments or requests

#### a) Equine viral arteritis

The Code Commission had forwarded to the Scientific Commission some Member Country comments for discussion by the Scientific Commission at its meeting in August 2012. The Commission sought expert advice on a request by a Member Country on extending the period during which a colt is tested and vaccinated against Equine viral arteritis (EAV) from 9 months to 12 months. The expert advised that colts were considered pre-pubertal and required testing to ensure they had not been exposed, and vaccination following negative testing, to prevent the risk of being permanent carriers of the disease. After considering the expert opinion, the Commission dismissed the proposal, since the average age for puberty was considered to occur earlier and was dependent on breeds and also on seasonality<sup>1</sup>. Vaccinating colts at a later age than that recommended in the *Terrestrial Code* could pose a risk of developing persistent carrier status following EAV infection.<sup>2</sup>

The decision of the Commission was forwarded for information to the Code Commission.

<sup>1</sup> Brown-Douglas, C.G., Firth, E.C., Parkinson, T.J., Fennessy, P.F., (2004), Onset of puberty in pasture-raised Thoroughbreds born in southern hemisphere spring and autumn. *Equine Vet. J.*, 36, 499-504.

<sup>2</sup> Holyoak, G.R., Little, T.V., McCollam, W.H., Timoney, P.J., (1993), Relationship between onset of puberty and establishment of persistent infection with equine arteritis virus in the experimentally infected colt. *J. Comp. Pathol.*, 109, 29-46.

#### b) Porcine Reproductive and Respiratory Syndrome (PRRS)

The Commission had sought an expert opinion on the need to develop a *Terrestrial Code* chapter on PRRS following the requests of several Member Countries. The experts advised that a chapter should be drafted as the disease was widespread worldwide. There were also a number of countries that had achieved disease freedom through the implementation of control measures, and thus, international standards could help preventing the introduction of PRRS virus.

The Commission agreed with the expert opinion and recommended that the Director General convene an *ad hoc* Group to develop a *Terrestrial Code* chapter. The Code Commission was also informed of this proposal.

#### 2.4. Guide on Terrestrial Animal Health Surveillance

The Commission requested the Scientific and Technical Department to provide the Commission with a copy of the draft Guide for final endorsement by electronic correspondence with members of the Commission. The Commission reiterated its request from previous reports of the Commission that the proposed guide was an initiative of the Scientific Commission and thus the Commission maintains the right to finally endorse the proposed text. It was also regarded as essential, as had been previously requested, that a section in the Guide be dedicated to surveillance in respect of official disease status recognition as prescribed in the *Terrestrial Code*, to ensure that Member Countries fully realised the rationale for the specific surveillance strategies for diseases with an officially recognised status by the OIE.

The Commission was informed that, in the final draft, more cross-references to the *Terrestrial Code* Chapter 1.4 would be inserted.

### 3. Reports of *Ad hoc* Groups and Working Group on Wildlife Diseases

#### ■ Meeting reports for endorsement

##### 3.1. *Ad hoc* Group on African Horse Sickness official disease status evaluations: 15-17 January 2013

###### a) Revision of Chapter 12.1. of the *Terrestrial Code*

The Commission reviewed the report of the *ad hoc* Group on African Horse Sickness (AHS), including the amendments suggested to the *Terrestrial Code* Chapter 12.1.

To harmonise Chapter 12.1 with other revised chapters in the *Terrestrial Code*, the case definition and the definition for infection were moved to the beginning of the General provisions in the chapter. The Commission recommended that this approach be followed for all disease specific chapters in the *Terrestrial Code*.

Similarly, in Article 12.1.5, the Commission added provisions for the occurrence of AHS virus (AHSV) within or outside the boundaries of the containment zone. Wording within this article was also harmonised with other chapters. The wording on the extension of the containment zone was removed from the same article because it was an unscientific statement/requirement subject to variable judgement and perceptions on what should be "large enough".

The amended chapter with Member Country comments addressed was forwarded to the Code Commission for further processing together with the *ad hoc* Group's report endorsed by the Commission.

The Commission took note of the *ad hoc* Group's concern regarding a revision of the chapter on AHS in the *Terrestrial Mammal* considering the different purposes for which the tests could be performed. The Commission requested that this issue be forwarded to the Biological Standards Commission for consideration.

#### b) Evaluation of the requests from 59 Member Countries to be recognised as historically free from AHS

The Commission assessed the recommendations of the *ad hoc* Group for country applications for historical AHS freedom. A simplified procedure had been offered to Member Countries applying for historical AHS freedom so that a baseline list of historically free Member Countries could be presented at the 81<sup>st</sup> General Session in May 2013. This shorter procedure would not be applicable once adopted at the 81<sup>st</sup> General Assembly. Member Countries complying with the requirements of the *Terrestrial Code* for historical freedom would still have the possibility to apply for it, but would have to provide evidence of compliance with the *Terrestrial Code*.

The Commission agreed that 57, out of the 59 Member Countries that had applied through this shorter procedure, fulfilled the conditions to be considered historical AHS free countries in accordance with Article 12.1.2. of the *Terrestrial Code*. The list of these Member Countries is in the report of the *ad hoc* Group.

The applications for historical freedom of the two remaining Member Countries were not approved and referred back to the applicant Member Countries with suggestions on actions to be taken to comply with the requirements of the *Terrestrial Code*.

#### c) Evaluation of the requests from 2 Member Countries to be recognised as free from AHS

Portugal and Spain applied for AHS country freedom through the ordinary procedure and the Commission determined that they fulfilled the conditions to be considered AHS free countries in accordance with Article 12.1.2. of the *Terrestrial Code*.

#### d) Evaluation of the request from a Member Country for the establishment of a zone free from AHS

The application of the Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country with the advice to the latter to fully consider the provisions in Article 12.1.2.

The Commission noted that, according to the *Terrestrial Code*, AHS-free countries adjacent to infected countries should have a 100-km surveillance zone, and that countries without an AHS-free status were considered as infected. The Commission did not find any scientific evidence to suggest that this distance be reduced except when geographical or ecological factors contribute to limit the risk of potential incursion. The Commission agreed that this provision should remain unchanged, given that a surveillance programme should be designed according to different factors and tools, including a risk assessment.

The Commission endorsed the report of the *ad hoc* Group on AHS, including the amendments suggested to the *Terrestrial Code* Chapter 12.1. and the procedure for annual reconfirmation form with minor changes. The report and Chapter 12.1 with proposed amendments were forwarded to the Code Commission for further processing. The endorsed report is attached as Annex 3.

##### 3.2. *Ad hoc* Group on Antimicrobial Resistance: 8-10 January 2013

The Commission endorsed the report of the *ad hoc* Group on Antimicrobial Resistance, which had addressed Member Country comments on *Terrestrial Code* Chapter 6.10. The *ad hoc* Group had updated the list of antimicrobial agents of veterinary importance. The Commission endorsed the list and proposed its adoption at the 81<sup>st</sup> General Session by Resolution. The endorsed report is attached as Annex 4.

##### 3.3. *Ad hoc* Group on Bovine Spongiform Encephalopathy: 11-13 September 2012

The Commission reviewed the report, including the proposed amendments to Article 11.5.22 in relation to the point targets for the different adult cattle population sizes in a country, zone or compartment, adjusted for countries with small cattle population. The proposal of the *ad hoc* Group for an amendment to the existing table in the *Terrestrial Code* was approved and forwarded to the Code Commission for further processing. The Commission commended the high quality of the *ad hoc* Group's report.

On atypical BSE, the Commission noted the main differences with classical BSE and considered the possibility of revising the existing *Terrestrial Code* to provide standards on atypical BSE.

The Commission agreed that the current procedure for official recognition of BSE risk status had been conceived with a focus on classical BSE. The Commission suggested that an *ad hoc* Group review the *Terrestrial Code* chapter on BSE to assess if a change to the current chapter on BSE was desirable (e.g. as was done for atypical scrapie).

In addition, the Commission noted that the notion of "compartment" was not applicable to BSE official risk status and agreed to recommend to the Code Commission that the word "compartment" be deleted throughout the Article 1.6.3.

The report of the *ad hoc* Group was endorsed by the Commission and is attached as [Annex 5](#).

The proposed change to Article 11.5.22 was forwarded to the Code Commission.

### 3.4. *Ad hoc* Group on Bovine Spongiform Encephalopathy risk status evaluations of Member Countries: 27-30 November 2012

The Commission considered and endorsed the recommendations of the *ad hoc* Group on the applications from 9 Member Countries for the evaluation of their BSE risk status.

For the dossier related to the request of the United States of America to be considered as a negligible BSE-risk country, the Commission noted that the *Ad hoc* Group could not reach a consensus in making recommendation to the Commission. The Commission considered and discussed the analysis made and opinions expressed by the *ad hoc* Group. The Commission based its assessment on the provisions laid out in the *Terrestrial Code* and agreed that the release risk in the USA was negligible and that the BSE risk mitigating measures put in place by the country were commensurate with the assessed release risk. At the same time, the Commission decided to request the applicant Member Country to monitor annually - through the annual reconfirmation form - the continued implementation of the risk mitigation measures as described in the *Terrestrial Code*, especially those related to preventing the potential recycling and amplification of the BSE agent in the country at the rendering plants.

The Commission agreed to recommend the following Member Countries for adoption as having a negligible risk for BSE by the World Assembly of Delegates at the 81st General Session:

- Israel, Italy, Japan, the Netherlands, Slovenia and the USA

The Commission agreed to recommend the following Member Countries for adoption as having a controlled risk for BSE by OIE World Assembly of Delegates at the 81<sup>st</sup> General Session:

- Bulgaria and Costa Rica.

For the remaining Member Country, the application was not approved and referred back to the applicant Member Country with suggestions to the Member Country on actions to be taken to comply with the requirements of Chapter 11.5 of the *Terrestrial Code*.

The Commission adopted the report of the *ad hoc* Group. The report is attached as [Annex 6](#).

### 3.5. *Ad hoc* Group on Brucellosis: 9-11 January 2013

The *ad hoc* Group on Brucellosis had restructured the *Terrestrial Code* draft chapter on Brucellosis in accordance to the comments received by Member Countries, the Scientific Commission and the Code Commission. The three pathogens, *Brucella abortus*, *B. melitensis* and *B. suis* were kept under the same multispecies chapter (8.x) but the provisions in the chapter were made species-specific. This way, the concept of disease free status at the country or zone level was considered for cattle, sheep and goats, camelids and cervids but not for pigs. Disease free status with vaccination was however currently possible only for cattle, sheep and goats, since there was not an appropriate vaccine for camelids or cervids. The *ad hoc* Group had also harmonised the language throughout the chapter.

The Commission recognised that the amendments proposed by the *ad hoc* Group to the draft *Terrestrial Code* chapter on Brucellosis would facilitate its use by Member Countries and endorsed the report.

The amended chapter was forwarded to the Code Commission for further processing.

The endorsed report is attached as [Annex 7](#).

### 3.6. *Ad hoc* Group on Contagious Bovine Pleuropneumonia (CBPP): 9-10 January 2013

The *ad hoc* Group on CBPP had evaluated by electronic correspondence a single application for free status from a Member Country.

The Commission supported the findings of the *ad hoc* Group, and, after discussions with the Director General, decided, in accordance with the provisions of Resolution 25 of the 80<sup>th</sup> General Session, to request the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

The Commission adopted the report of the *ad hoc* Group. The endorsed report is attached as [Annex 8](#).

### 3.7. *Ad hoc* Group on the inclusion of Classical Swine Fever in the list of diseases with official status: 16-18 October 2012

The *ad hoc* Group had, at the request of the Scientific Commission and the Code Commission, revised the *Terrestrial Code* chapter on CSF and had included a new case definition for domestic and captive wild pigs, as well as reviewed the articles on surveillance for CSF together with the questionnaire that would allow the addition of CSF to the list of diseases for officially recognised status. The *ad hoc* Group had agreed that if a country found a wild boar positive for CSF it would have to be notified according to Chapter 1.1 but that its impact on its official disease status should be determined on a risk assessment, including surveillance and the evaluation of biosecurity measures to separate domestic and captive wild pigs from feral and wild pigs.

The Commission noted that the new case definition was in contradiction with Article 1.4.6 of the *Terrestrial Code* requiring that for official recognition of freedom there should be no evidence of infection in wildlife. In view of this, the Commission recommended that the Code Commission revise Article 1.4.6. to the effect that in points (a) vi) and (b) v) the sentence on wildlife be completed with "unless otherwise stated in the relevant *disease* chapter".

The draft *Terrestrial Code* Chapter 15.2 and the accompanying questionnaire in relation to recognition of official disease status were endorsed by the Commission with some amendments. For example, vaccine strains were excluded from the definition of infection, and the Commission considered that it would be sufficient to detect infection by detection of viral RNA specific to a field strain of CSF virus, without necessarily linking the test result to an epidemiological investigation, since the use of real-time tests and in-tube reading could largely avoid the risk of false positive results. In addition, tests to detect RNA were generally validated and accredited to an appropriate quality standard, with adequate separation from areas where field virus are handled and with the use of positive controls. For these reasons, detection of RNA specific to a field strain of CSF virus was considered sufficient as a stand-alone test to define infection.

In relation to wild and feral pigs, the Commission expanded the requirement on separation of wild from domesticated pigs to include potential geographical barriers in addition to man-made ones. However, they considered that it would not be possible to establish containment zone if wild or feral pigs were infected. The Commission considered that the epidemiological situation within the containment zone should be sufficiently controlled to provide confidence to the capability of the country to control the disease and agreed to require that any new outbreak within or outside the containment zone result in the suspension of the status of the whole country or zone. The requirements on the annual reconfirmation of a CSF free status were also added. For the questionnaire, the *ad hoc* Group had suggested combining in a single questionnaire the requirements for a country/zone application. The Commission agreed to this suggestion and recommended that countries insert a heading in their application that would inform the Commission of the option chosen (country or zone).

Finally, the Commission was informed by the Scientific and Technical Department on the requirements for vaccines in the CSF chapter of the *Terrestrial Manual*, which had been reviewed by an *ad hoc* Group after the request from the Biological Standards Commission in September 2012. The *Terrestrial Manual* chapter had been recently finalised and was making reference to the availability of biotechnology derived marker vaccines and their corresponding tests that would allow for a DIVA strategy and a "vaccination to live" strategy.

The endorsed report, draft chapter and questionnaire were forwarded to the Code Commission for further processing. The endorsed report is attached as [Annex 9](#).

### 3.8. *Ad hoc* Group on Epidemiology: 2-4 October 2012

The report of the October meeting of the *ad hoc* Group on Epidemiology contained the rationale for some of the changes proposed to the revised *Terrestrial Code* chapter on FMD. The revision of the FMD chapter had needed four *ad hoc* Group meetings; the *ad hoc* Group on Epidemiology also revisited the draft chapter with special emphasis on the articles on surveillance. However, the October meeting of the *ad hoc* Group on FMD proposed the final amendments to the Chapter.

The report was endorsed by the Commission and was forwarded to the Code Commission. The endorsed report is attached as [Annex 10](#).

### 3.9. *Ad hoc* Group on Epidemiology: 29 January 2013

The report of the January meeting of the *ad hoc* Group on Epidemiology contained the rationale for the proposed amendments to the new surveillance articles for the *Terrestrial Code* chapter on PPR. It also carried a suggestion to the Commission to draft guidelines for the identification of factors that would guide risk based sampling as part of the horizontal chapters in the *Terrestrial Code*. The Commission endorsed the report and accepted the suggestions of the *ad hoc* Group, requesting the Director General to convene a meeting of the *ad hoc* Group on Epidemiology to address this matter. The report was forwarded to the Code Commission for information. The endorsed report is attached as [Annex 11](#).

### 3.10. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 9-11 October 2012

#### a) Revision of Chapter 8.5. of the *Terrestrial Code*

A merged version of the revised chapter after the work of four *ad hoc* Group meetings was presented to the Commission. The representative of the Commission at those meetings explained the rationale behind the proposed amendments to both the Scientific Commission and the Code Commission.

The main amendments were relative to the management of:

- Wildlife
- The process to be followed when a country/zone free with vaccination wishes to be recognised free without vaccination
- The compartment, which could be free with or without vaccination
- The containment zone: a new case, even within the containment zone, leads to withdrawal of the approval of the containment zone
- The recovery of free status for a zone/country (possibility for a country previously free without vaccination to recover free with vaccination).
- The border areas between a free country/zone/compartment and an infected area (truly infected or undefined)

The Commission also noted that the articles for country and zonal freedom with vaccination and country and zonal freedom without vaccination had been merged.

The Commission agreed to all amendments proposed by the *ad hoc* Group to the chapter on FMD, except for:

- Requiring additional warranties in the border areas between a free country/zone/compartment and an infected area (truly infected or undefined status). The Commission considered this an unnecessary burden, since the maintenance of a free status already require strict preventive measures.
- Differentiating serotypes of FMD virus when importing from vaccinated countries. The Commission did not accept this as it could implicate trade barriers

In addition, the Commission also discussed the duration of the period during which a status of a country or zone could remain suspended and the period for which a containment zone could be implemented. The Commission decided not to indicate a prescriptive duration but amended the corresponding text in the Chapter to indicate that the duration of these periods should be limited in time.

The Commission also suggested that the questionnaire for a country free without vaccination be merged with the questionnaire for a zone free without vaccination, and that the questionnaire for a country free with vaccination be merged with the questionnaire for a zone free with vaccination. The report of the *ad hoc* Group and the revised draft *Terrestrial Code* Chapter 8.5 were endorsed and forwarded to the Code Commission with the explicit request that the draft amended chapter be circulated for Member Country comments. The Commission requested that the OIE Secretariat of the *ad hoc* Group on FMD attend the Code Commission meeting when FMD would be discussed. The endorsed report is attached as [Annex 12](#).

#### b) Evaluation of the request from three Member Countries for the endorsement of their official control programme for FMD

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the endorsement of their official control programmes. These three applications were not approved by the Commission and the dossiers were referred back to the applicant Member Countries inviting them to fully observe the provisions in Article 8.5.48.

The Commission emphasised the need to develop and implement a quality filter to avoid that Member Countries apply for the endorsement of their official FMD control programmes without meeting the requirements of the relevant chapter of the *Terrestrial Code*. In discussions with the Director General, the Commission was informed that the OIE had initiated regional activities to assist in providing a filtering mechanism for applications such as for example the proposed OIE Animal Health Centre dedicated to FMD in Kazakhstan to help the Member Countries of the sub-region.

### 3.11. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 10-14 December 2012

The Commission representative on the *ad hoc* Group provided a summary of the *ad hoc* Group meeting outcomes to the Commission.

The Commission acknowledged that the increased number of Spanish-speaking experts in the *ad hoc* Group would facilitate the evaluation of dossiers submitted in Spanish. The Commission also noted that the expert of the *ad hoc* Group from Africa would be replaced by another expert from the same country (Botswana).

The Commission noted that the *ad hoc* Group had received and evaluated five dossiers for disease status recognition from four Member Countries (one country applied for two zones) and two dossiers to be evaluated for the endorsement of official control programmes for FMD. The *ad hoc* Group had evaluated all the dossiers in detail and requested additional information from some of the applicant Member Countries. The *ad hoc* Group also evaluated the additional information provided by a Member Country that had applied in 2011 and whose evaluation had been suspended awaiting this complement of information.