



Better Training for Safer Food *Initiative*

EU provisions related to monitoring and surveillance

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EU LEGAL PROVISIONS

- **BSE surveillance in cattle**

BSE surveillance: different goals based on the epidemiological situation

Testing animals is first of all a tool of knowledge of the current situation (Reg. EU 999/2001 Annex III)

Objectives of surveillance in cattle

For **countries where BSE cases have already been detected**, the main goal of surveillance is monitoring the effectiveness of control measures by following the evolution of BSE prevalence and incidence.

The results of surveillance activities lead to a periodical (re)evaluation of the epidemiological situation in the countries and possibly a (re)planning of control measures.

In **countries with no autochthonous BSE cases occurred**, the final goal of surveillance is to demonstrate that the infection is below an agreed threshold.

Strategies in BSE surveillance

Passive vs. active surveillance (1/2)

Passive surveillance

Passive surveillance is based on the reporting of all animals clinically suspected of being infected by BSE and, where BSE cannot be excluded by clinical investigations, the laboratory testing of such animals.

Severe limitations made it inappropriate as the unique mean for BSE surveillance. In fact, passive surveillance abilities to detect BSE cases appeared to be strongly biased due to the incubation period of clinical disease and the sensitivity of the notification system greatly influenced by the farmers and veterinarians knowledge and awareness.

Strategies in BSE surveillance

Passive vs. active surveillance (2/2)

Active surveillance

Active surveillance is based on testing animals not reported as suspected of being infected by BSE, such as emergency slaughtered animals, animals with clinical signs other than BSE at ante mortem inspection, fallen stock, healthy slaughtered animals. This type of surveillance is fundamental for determining the evolution and prevalence of BSE in a country or a region.

Strategies in BSE surveillance

Targeting surveillance through streams: subpopulations and age limits)

At risk subpopulations

From 2001 to 2012, 75% of all BSE cases was detected in at risk population (fallen stock or animals subject to 'special emergency slaughtering' or showing symptoms at ante mortem inspection or slaughtered in the context of a disease eradication campaign).

Age classes

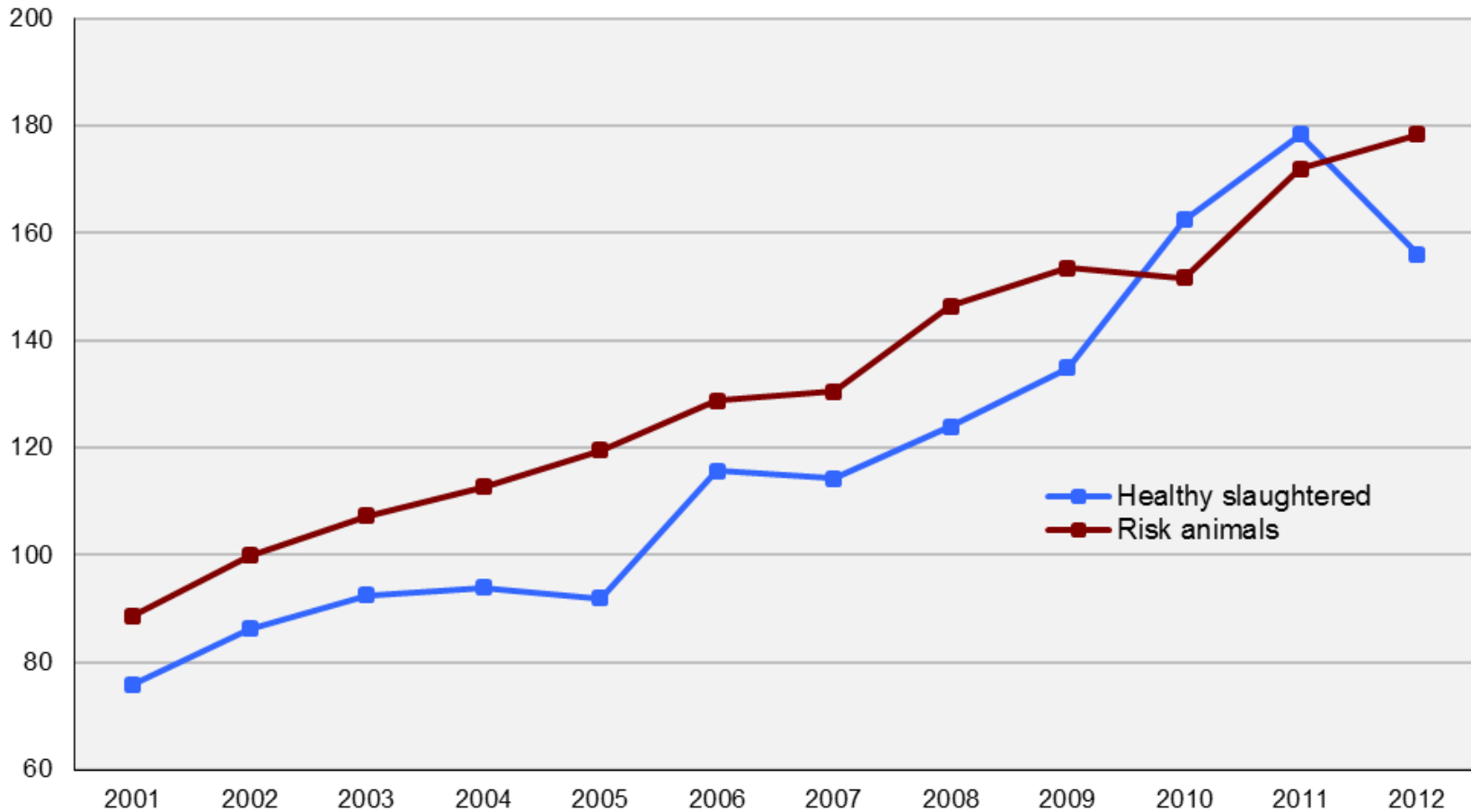
Since 2001 only 2 BSE cases younger than 24 months of age were reported in 1989 and 1992 in UK. Therefore an age limit of 24 months was suggested in 2001 for at risk population when the active surveillance provisions came into force.

For healthy bovine animals regularly slaughtered, the age limit was set at 30 months of age.



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Strategies in BSE surveillance



Average age (in months) of BSE positive cases detected in the EU from 2001 to 2012. From: *EC 2013, Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2012.*

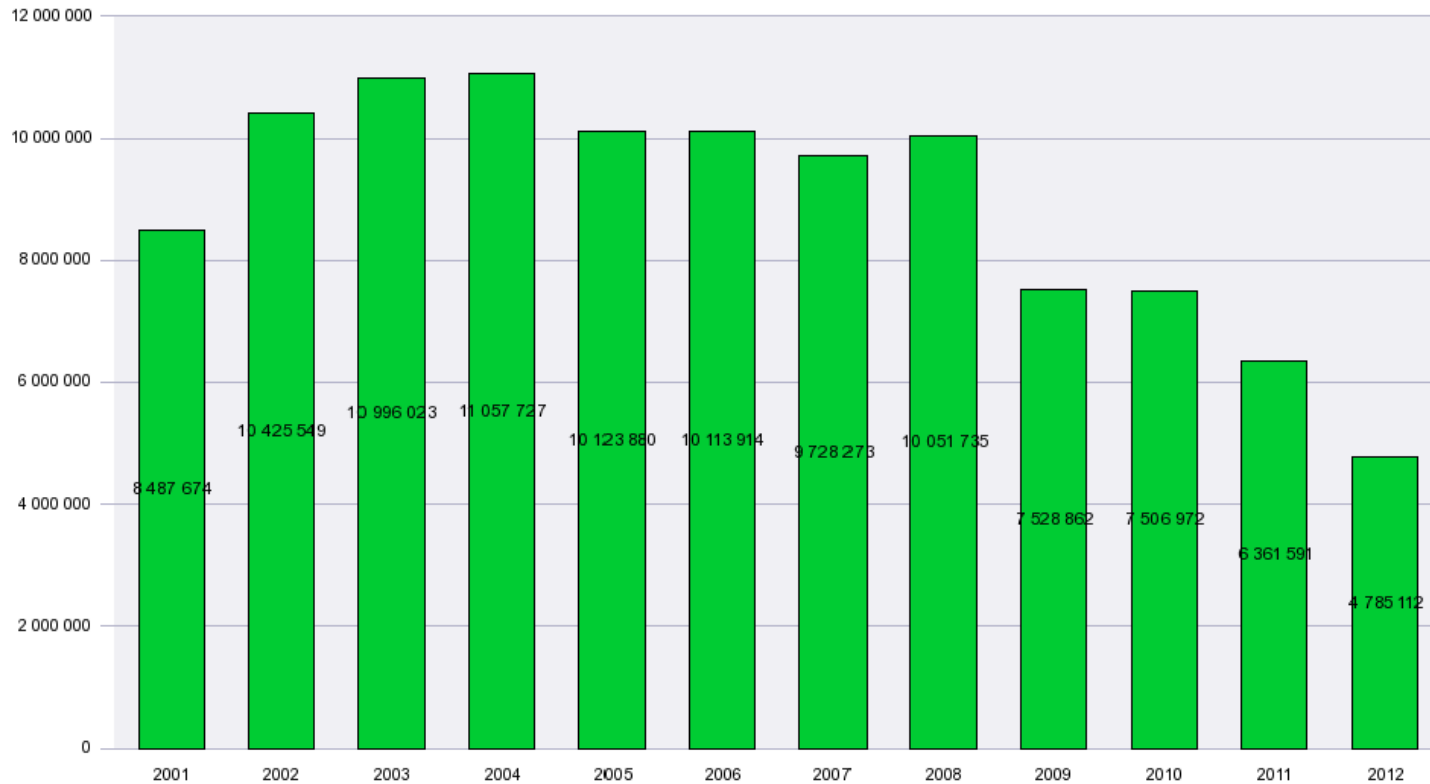
Strategies in BSE surveillance



Evolution and current legal provisions

The active surveillance came into force in January 2001 for healthy slaughtered cattle and in July 2001 for at risk cattle.

In total over 107 million cattle have been tested in the EU since 2001.



Total tests performed in the EU between 2001 and 2012.

From: EC 2013, Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2012.

Strategies in BSE surveillance



Evolution and current legal provisions

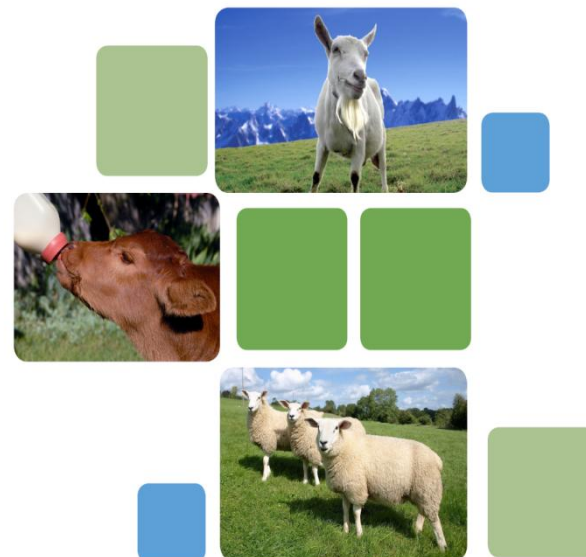
On 15 July 2005 the European Commission published a first TSE roadmap document in which it presented the outcomes of discussions on the next steps in the BSE policy on different points such as the definition and removal of Specified Risk Material (SRM), the feed ban and the BSE surveillance. A new version (The TSE Roadmap 2) has been released in 2012.

In relation to the revision of national monitoring programmes a strategic goal was identified in the reduction of the numbers of tests of bovine animals and at the same time to continue to measure the effectiveness of the measures in place with a better targeting of the surveillance activity.



The TSE Roadmap 2

Brussels, 16.7.2010
COM (2010) 384 final



Strategies in BSE surveillance



Evolution and current legal provisions

Since 2005 a constant process of control measures revision was applied, based on scientific opinions provided by the European Food Safety Authority (EFSA) (on 10 July 2008, 22 April 2009, 9 December 2010, 13 April 2011) on the risk for human and animal health related to the revision of the BSE monitoring regime in EU.

The results of these risk assessments based on the outcomes of the national surveillance systems led to the adoption of the Commission Decision 2009/719 in which the revision of criteria of national monitoring programmes was authorised for 25 MS (all EU MS except Bulgaria, Romania and Croatia).

According to Decision 2009/719/EC, as lastly amended by Decision 2013/76/EU, these 25 MS may decide not to test healthy bovine animals subject to normal slaughter.



Rapid Tests:

Since January 2001: all cattle aged over 24 months

Since April 2005:

- subject to special emergency or difered slaughtering (RISK ANIMALS) aged over 24 months
- subject to normal slaughter for human consumption, aged over 30 month

Since January 2009:

- all categories aged over 48 months

Since July 2011

- subject to special emergency or difered slaughtering (RISK ANIMALS) aged over 48 months
- subject to normal slaughter for human consumption, *aged over 72 month*

Since July 2013

ONLY RISK ANIMALS aged over 48 months .

BSE Passive Surveillance

(Definitions article 3 of Reg 999/2001)

A suspected animal is an animal that shows (or has shown) such behavioural disorders or neurological symptoms that BSE cannot be ruled out (on basis of clinical examination, response on treatment, pm examination or following on a rapid test)

BSE Passive Surveillance

Passive surveillance: a clinical suspect

- **Following the notification, the Official veterinarian seizes the suspect animal and performs a neurological clinical examination, filling the proper form with the necessary clinical data**
- **If the Official veterinarian confirms the clinical suspicion, the holding is seized and the suspected animal culled in order to exclude or confirm the presence of the disease**
- **In Italy, if a clinical suspicion was officially confirmed the entire milk production of the holding was destroyed until November 2007 and – where it is possible – the sole cohort of the suspected animal.**

Age Determination

- ***Documentation (birth certificate, cattle passport, etc.).***
- ***If there are serious concerns about the establishment's records, the PHV will conduct an examination of the cattle's teeth.***
- ***When the examination of the detention of the animal shows at least one of the second set of permanent incisors, the animal will be deemed to be 30 months of age or older.***



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Cattle Passports

IMPORTANT: Please keep this document safe – it must accompany the animal when moved. It is an offence to destroy this document in any way.

Cattle Passport

Eartag UK AB1231 54321




Electronic Id For future use

Animal Details British Cattle
Movement Service

Breed:	BELGIAN BLUE	Genetic Dam Id:	UK AB1201 10301
Sex:	MALE	Issue / Version:	20 10 1998 / 1
Date:	10 10 1998	Re-issue / Version:	

Specimen

Beef Special Premium Scheme

8 months old: 10 06 1999

21 months old: 10 07 2000



UK AB1231 54321 Page 1 CPP-13 2/98



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Dentition for Cattle That Are Under 30 Months of Age

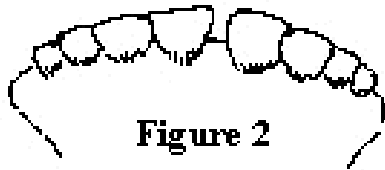


Figure 2

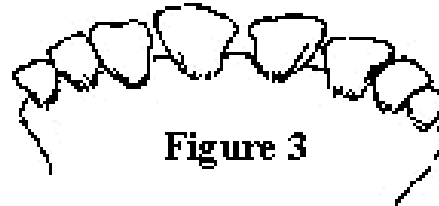


Figure 3



Figure 4



Figure 5

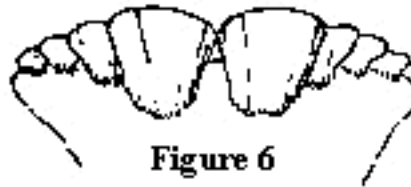


Figure 6

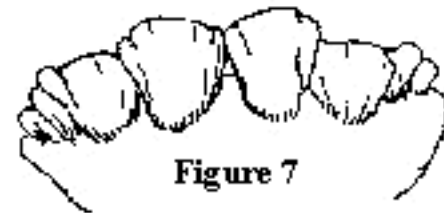


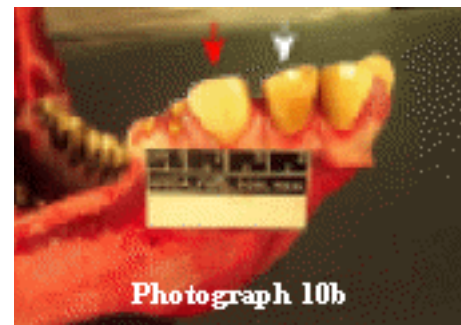
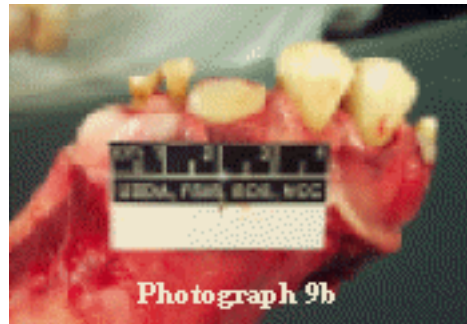
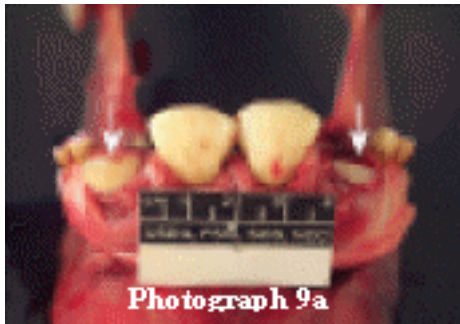
Figure 7

Source: USDA, FSIS—Using Dentition to Age Cattle



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Cattle That Are 30 Months of Age or Older



Source: USDA, FSIS—Using Dentition to Age Cattle



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Control Measures and their effects

B T S F

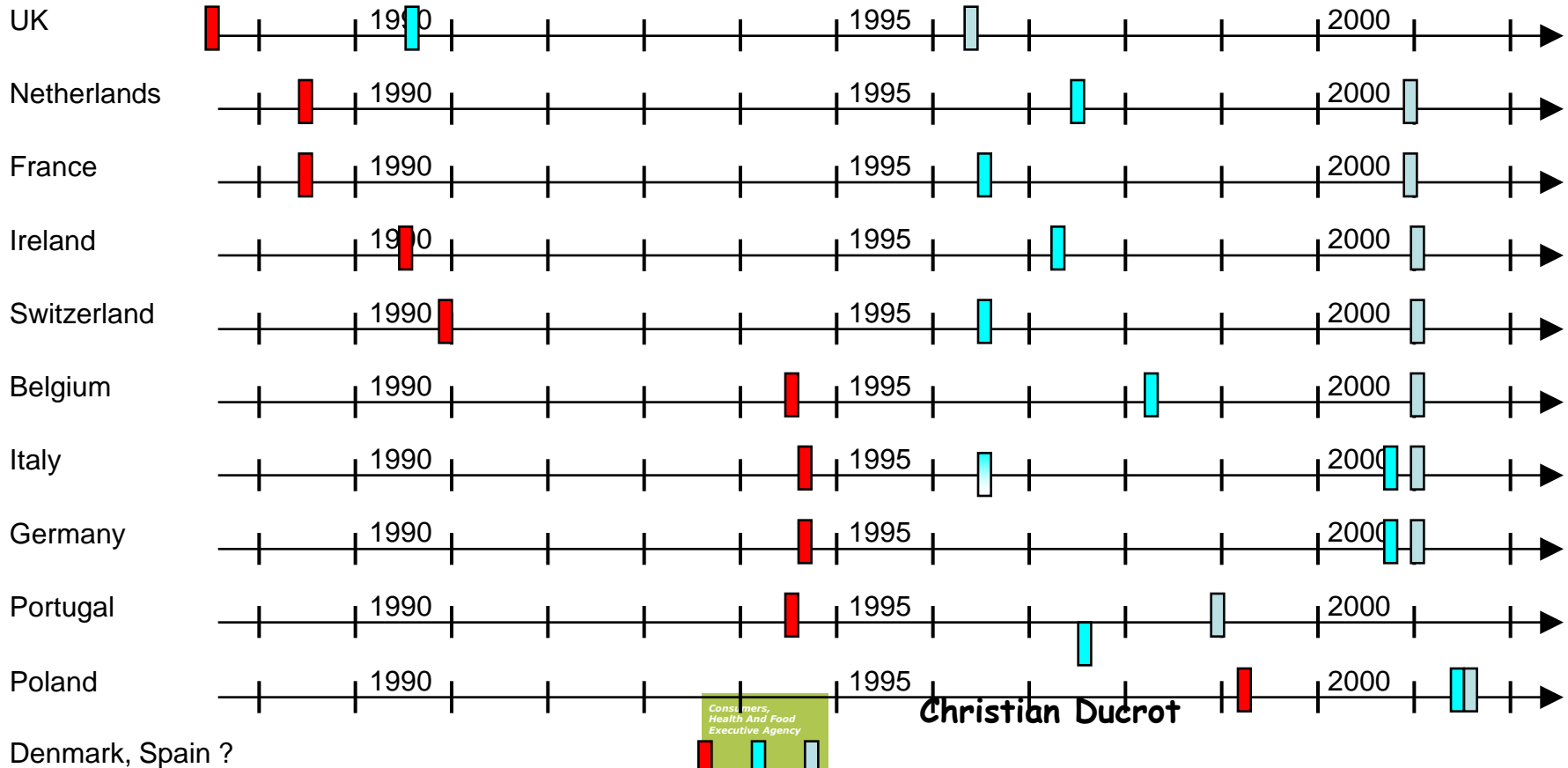
Main Control Measures

Removal of Specified Risk Material is the key public health control measure for BSE rather than BSE testing

MBM ban is the second best measure introduced to fight the BSE epidemic

Main Control Measures for BSE

█ MBM ban for cattle
 █ SRM removal from MBM
 █ MBM ban for all farm animals





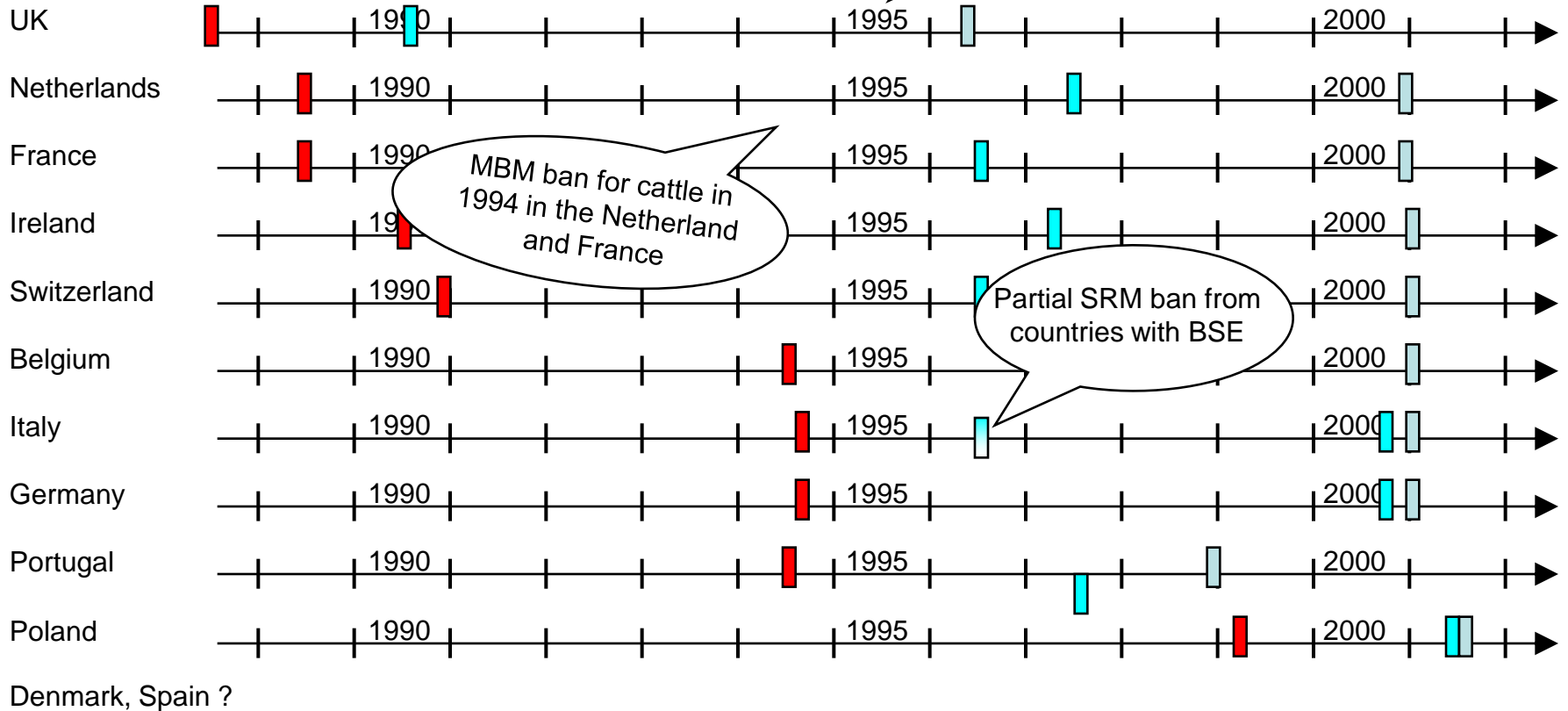
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█ MBM ban for cattle
 █ SRM removal from MBM
 █ MBM ban for all farm animals

Dedicated line for rendering SRM in the UK in 1995

MBM ban for cattle in 1994 in the Netherland and France

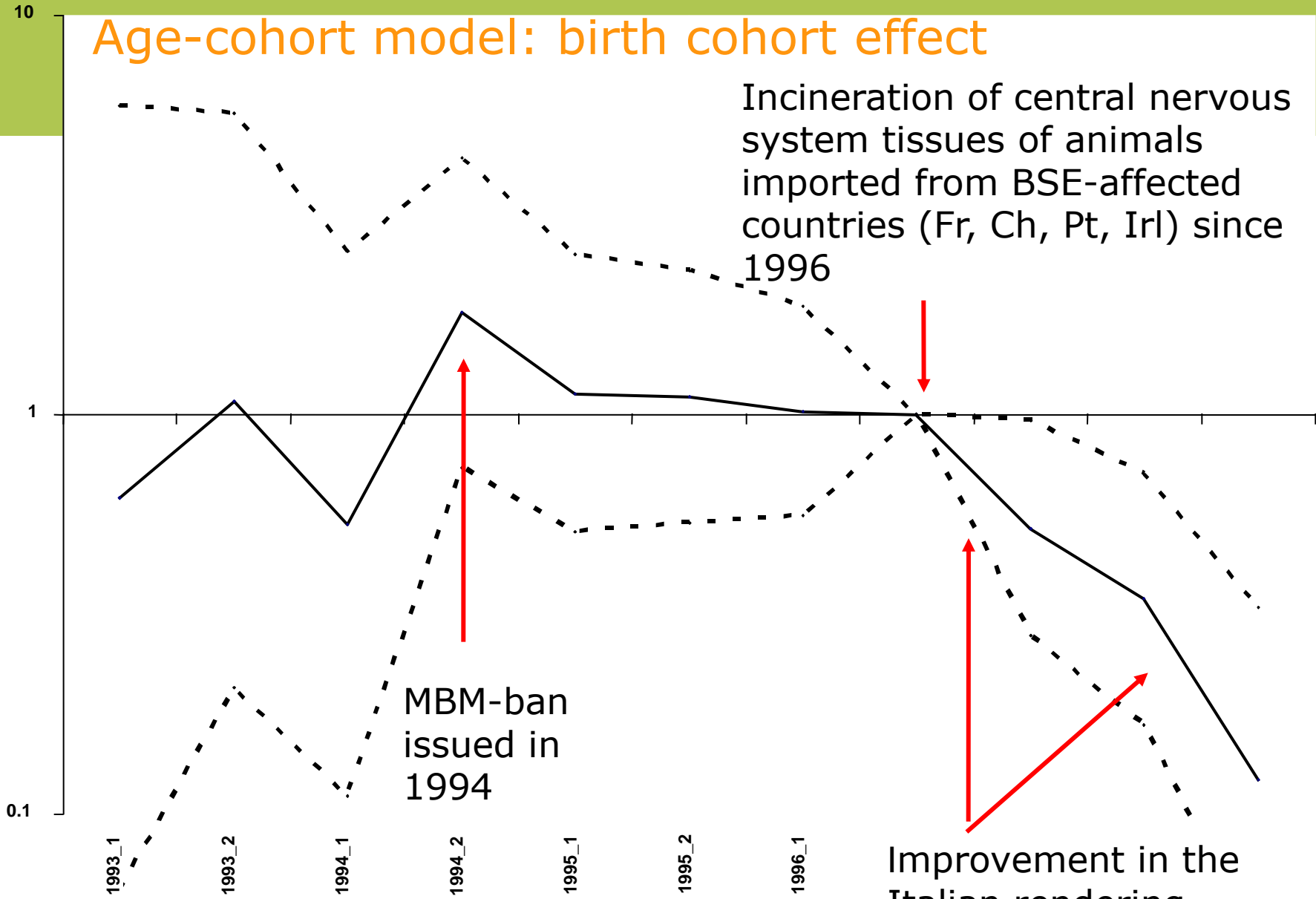
Partial SRM ban from countries with BSE



Age-cohort model: birth cohort effect

Incineration of central nervous system tissues of animals imported from BSE-affected countries (Fr, Ch, Pt, Irl) since 1996

Prevalence ratios



MBM-ban issued in 1994

Improvement in the Italian rendering system between 1996-1999

Italy: Risk by semester of birth

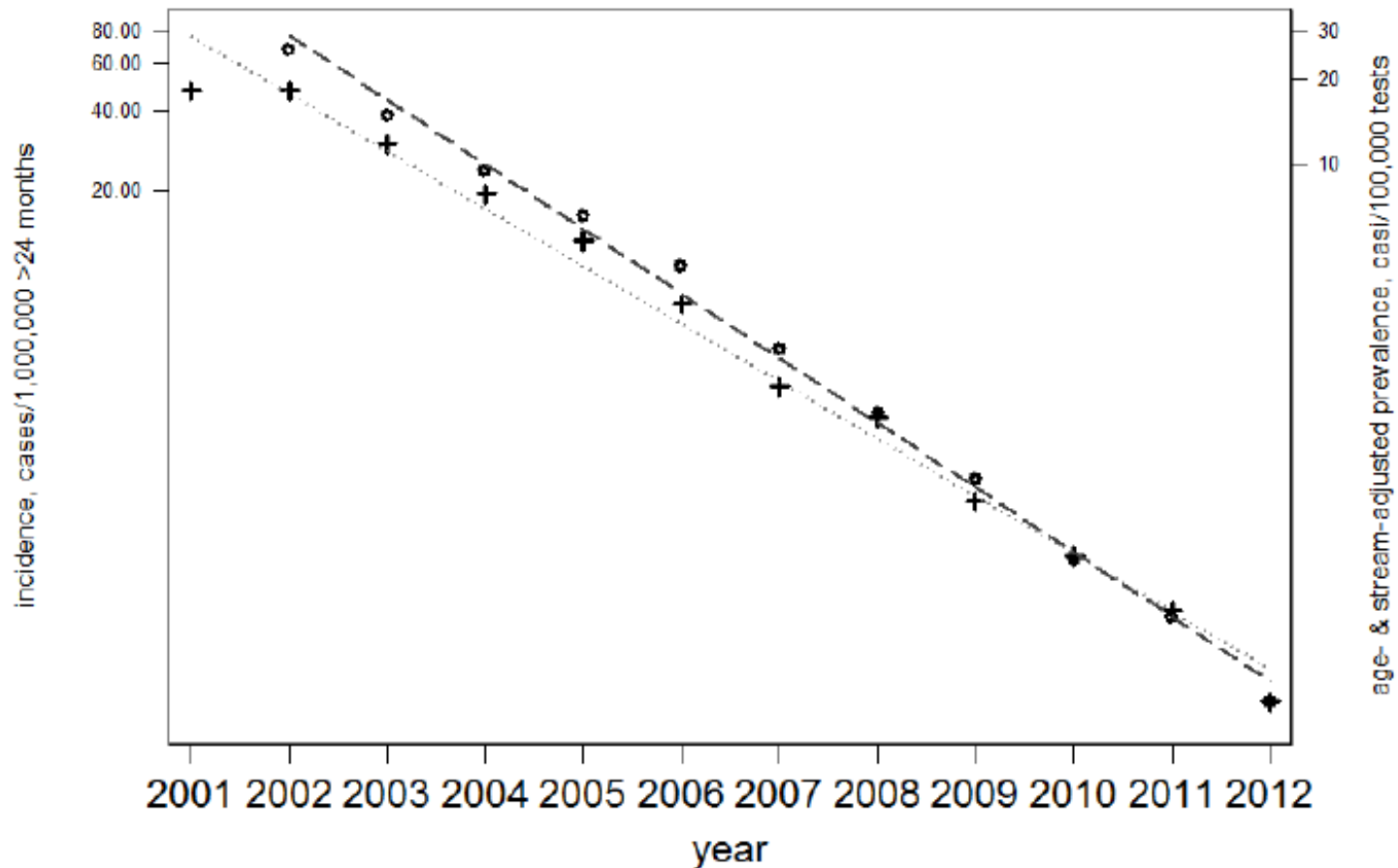


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Number of classical BSE cases detected during 2001-2012

Target Group	No of detected BSE cases per testing year												Total
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	
Active Surveillance													
Healthy slaughtered	280	292	264	177	115	81	39	29	28	15	9	5	1 334
At risk animals													
Emergency slaughter	321	509	316	172	123	31	8	7	3	0	0	0	1 490
Fallen stock	400	610	406	313	219	165	95	75	32	29	19	6	2 369
Presenting Clinical signs at <i>ante mortem</i> inspection	35	24	31	11	16	9	4	2	0	0	0	0	133
Total Active Surveillance	1 036	1 435	1 017	648	446	273	133	107	57	41	27	11	5 326
Passive Surveillance													
Suspects subject to lab	1121	674	304	172	74	37	15	8	2	0	0	0	2 407
Eradication Measures	9	10	3	5	16	1	1	3	0	0	0	0	48
Total	2 166	2 119	1 324	850	564	324	162	124	65	44	28	11	7 781

EU27-wide crude incidence (cases/million cattle > 24 months) and standardised prevalence by year (cases/100,000 tests)

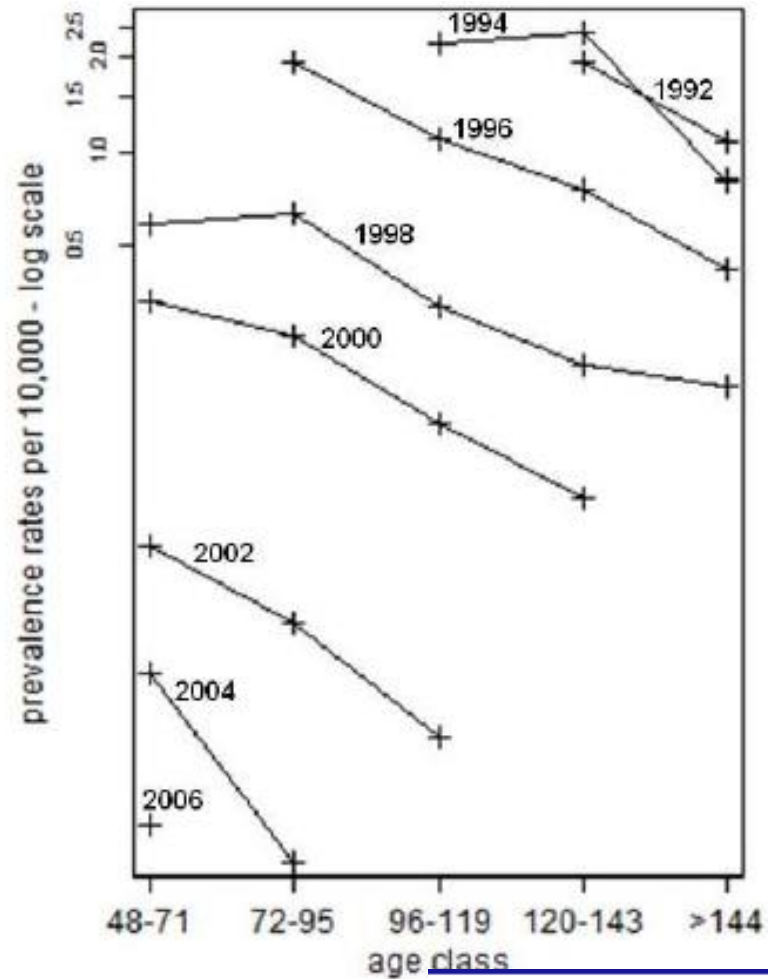
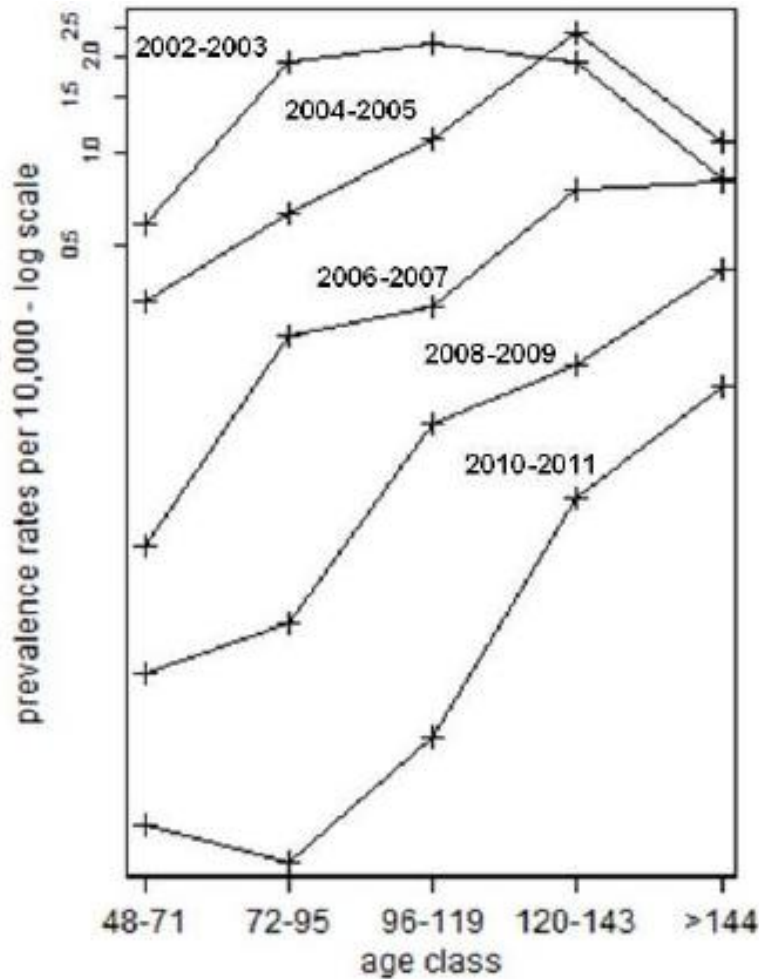


(o) — prevalence; (+) ... incidence

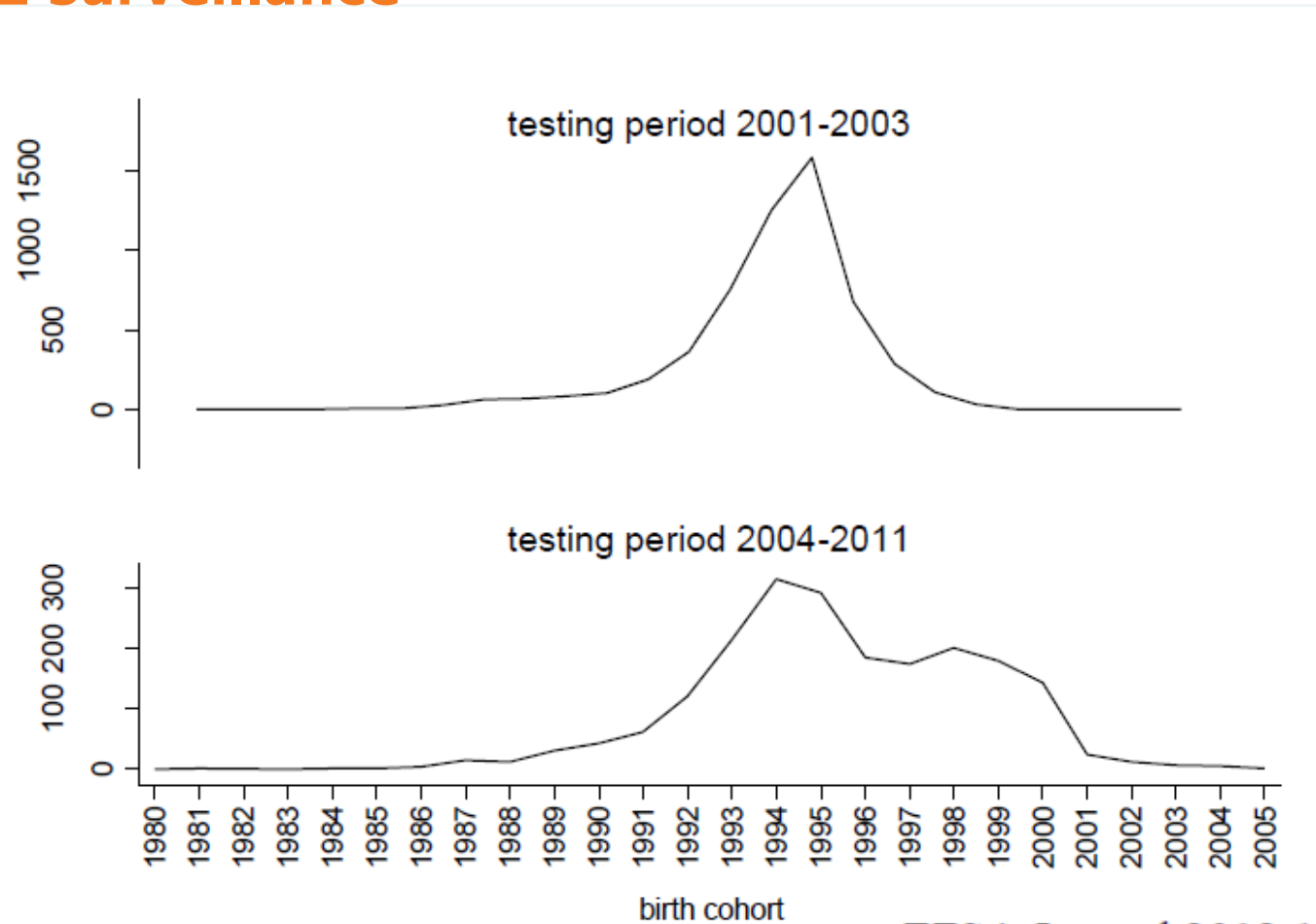


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Observed age-specific prevalences of BSE by two-year periods of diagnosis (a) and by birth cohort (b)



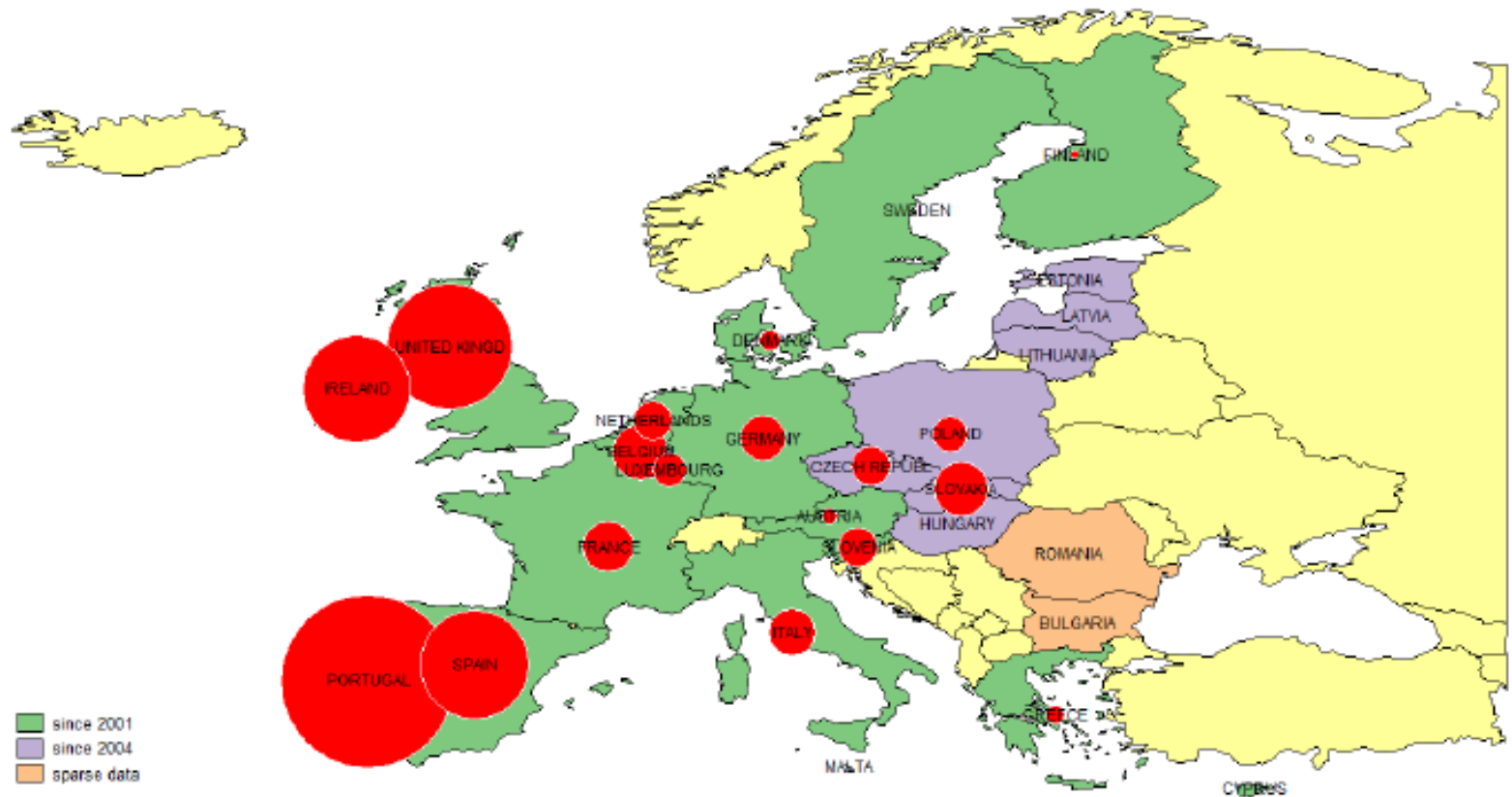
Number of BSE cases per birth cohort detected through BSE surveillance





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Geographical distribution of BSE within EU. Prevalence by country standardised on stream



Estimated total number of infected animals in two streams missed between 2007-2011

Infected cattle missed (EU27) in HS and ES Mean (2.5th and 97.5th)

Year	
2007	6816 (6438, 7214)
2008	4382 (4253, 4511)
2009	2533 (2436, 2630)
2010	1665 (1586, 1744)
2011	1031 (970, 1093)
2012	613 (566, 661)

Identification of a second bovine amyloidotic spongiform encephalopathy: Molecular similarities with sporadic Creutzfeldt-Jakob disease

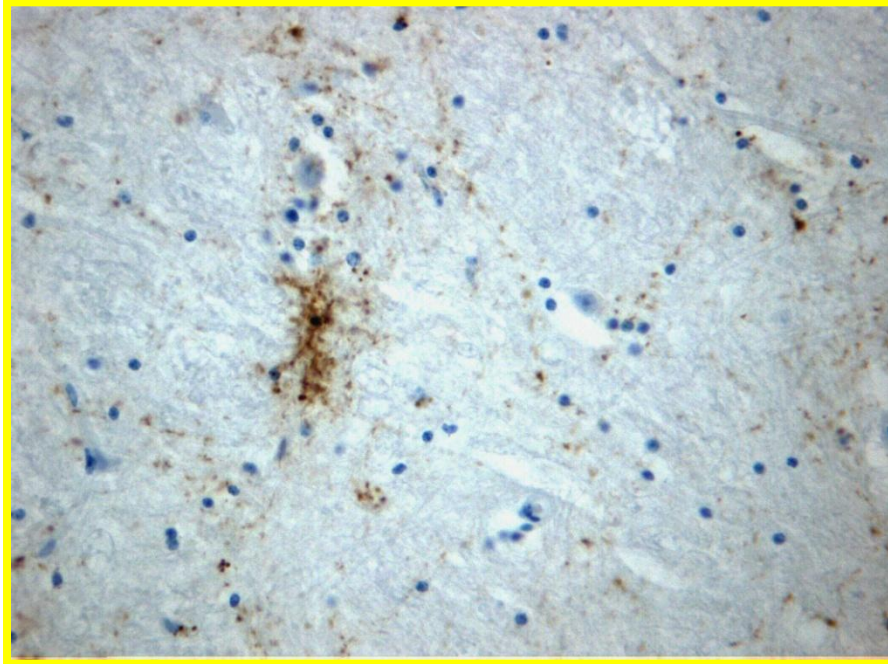
C. Casalone, G. Zanusso, P. Acutis, S. Ferrari, L. Capucci, F. Tagliavini, S. Monaco, and M. Caramelli

vol.101: 3065-3070 (2004)

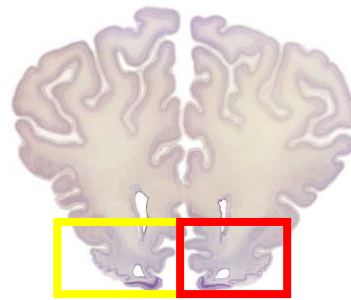
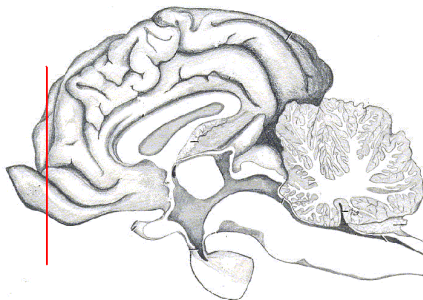
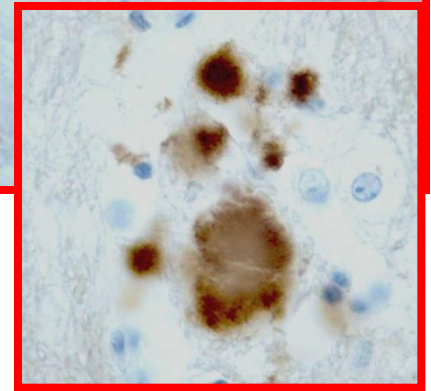
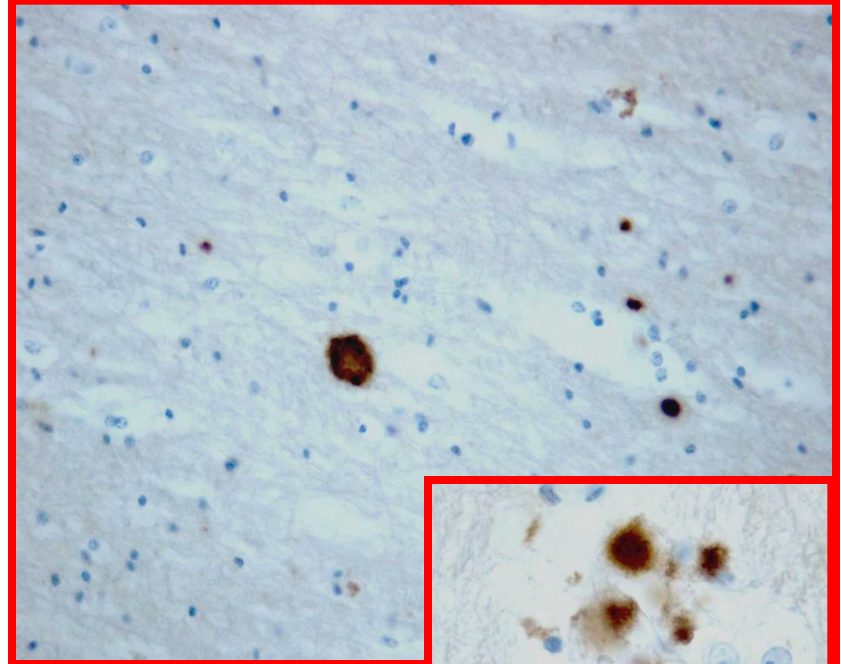
Pattern of PrP immunoreactivity



BSE



BASE

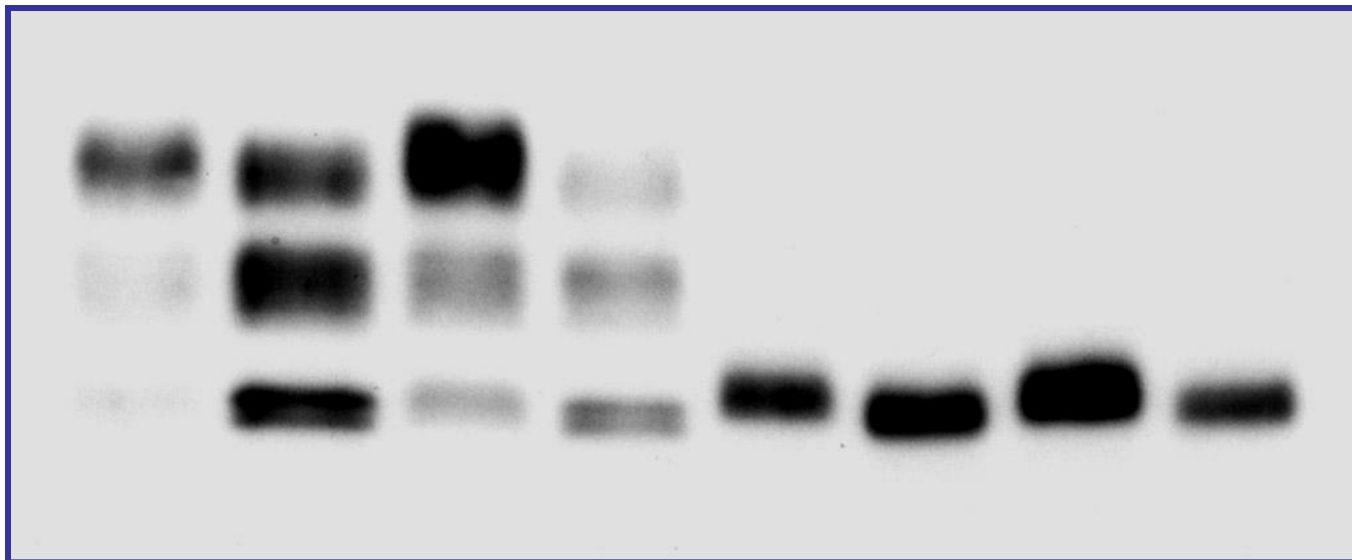




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Distinct types of PrP^{res} are associated with BSE and BASE

PK	+	+	+	+	+	+	+	+
PNGase	-	-	-	-	+	+	+	+



BSE

BASE

BSE

BASE

BSE

BASE

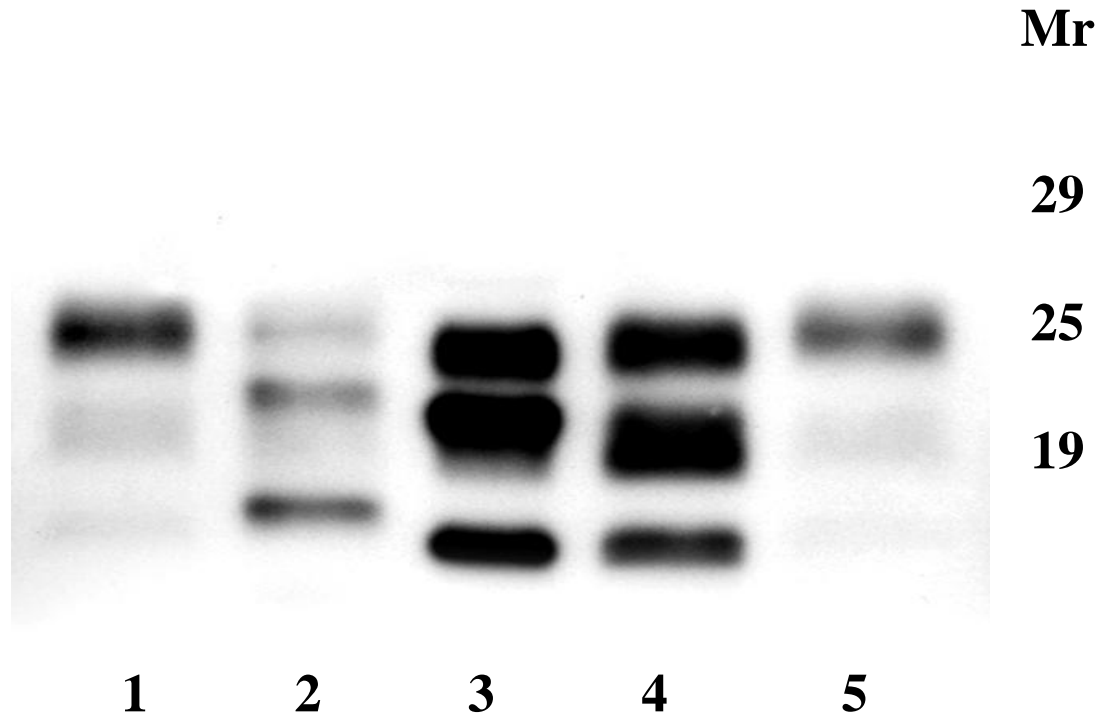
BSE

BASE



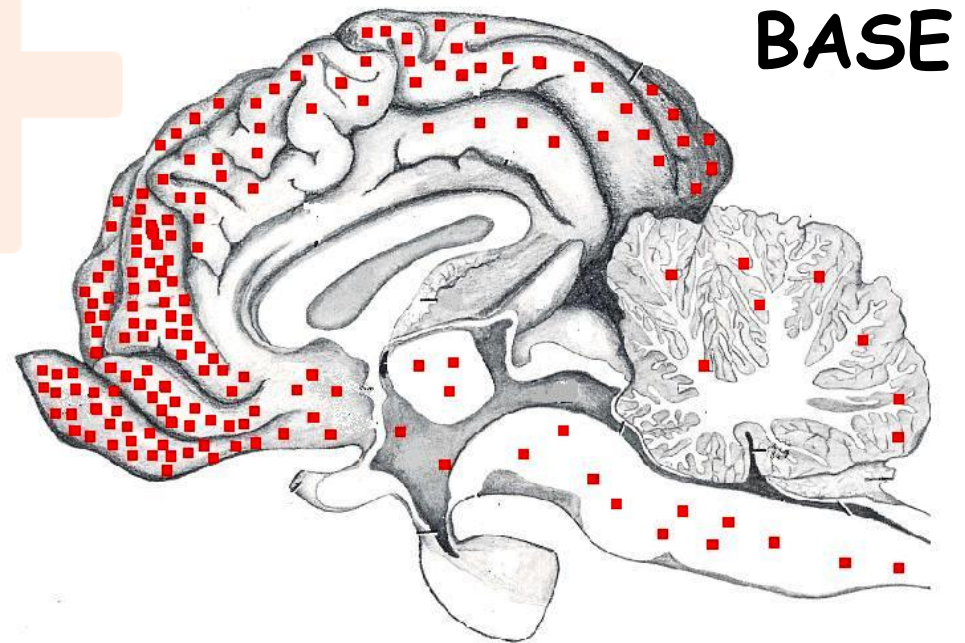
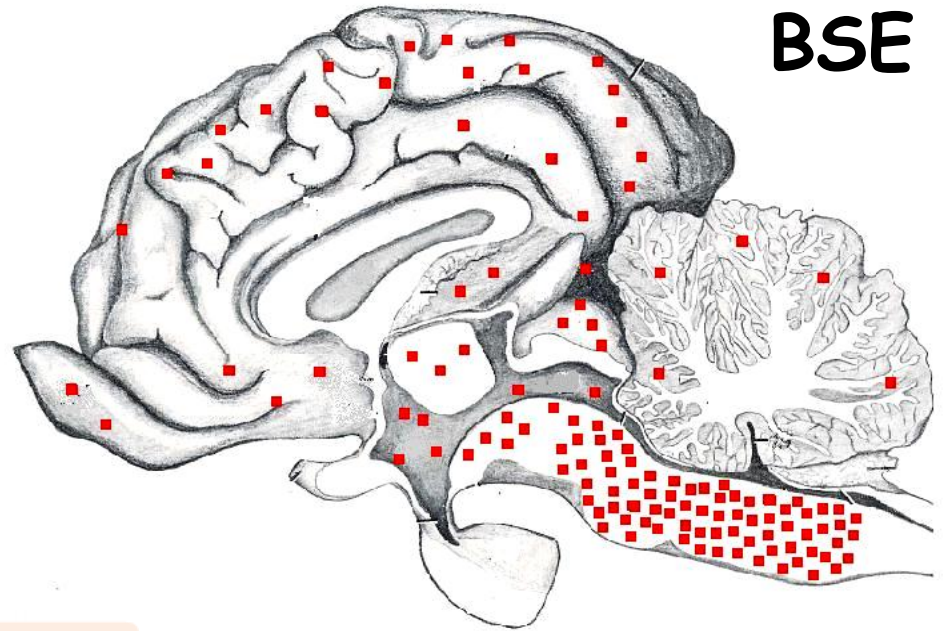
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Comparison of BSE and BASE cases with sCJD



**Lanes 1 and 5: Typical BSE; Lane 2 sCJD Met/Met;
Lane 3 sCJD Met/Val; Lane 4 BASE**

Brain regional distribution of PrP in BSE and BASE



Number of Atypical BSE cases

N° of detected Atypical BSE cases per testing year

2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
2	8	6	5	16	5	8	5	7	8	6	7	83



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BTSF **SCRAPIE**

Passive surveillance → compulsory reporting of suspected animals

Active surveillance → Reg. 999/2001 (EC)

Rapid tests on:

Healthy Slaughtered ovine and caprine aged more than 18 months (Italy 10.000 heads)

Fallen stock: all aged more than 18 months

Ovine and Caprine Animals That Are 18 Months of Age or Older

A permanent incisor erupted through the gum



> 18 months

TSE surveillance in small ruminants

Targeting surveillance through streams in small ruminants: subpopulations and age limits in the active monitoring for TSEs

Subpopulations

The following subpopulations are considered:

- ovine and caprine animals slaughtered for human consumption
- ovine and caprine animals not slaughtered for human consumption i.e. animals which have died or been killed, but which were not slaughtered for human consumption nor killed in the framework of a disease eradication campaign

Age classes

Only animals older than 18 months are included in the surveillance of TSE in small ruminants.



Surveillance in small ruminants



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Evolution and current legal provisions

- 1. animals slaughtered for human consumption:** The animals (sheep and goats) must be randomly selected, avoiding to over-represent any group as regard the origin, age, breed, production type or any other characteristic. At least 10,000 slaughtered sheep and 10,000 slaughtered goats must be annually tested in each MS. For MSs which have difficulties to collect sufficient numbers of healthy slaughtered ovine and caprine animals, they may replace a maximum of 50% of their sample with died animals over 18 months of age, and a maximum of 10% of their sample with animals over 18 months of age killed in the framework of a disease eradication campaign
- 2. animals not slaughtered for human consumption:** The animals have to be died on farm or killed (fallen stock) but not killed in the framework of a disease eradication campaign or slaughtered for human consumption. The minimum number of animals not slaughtered for human consumption to be annually tested for each MS is reported in the tables
- 3. animals in infected flocks:** a random sample (min 68 and max 150 according to flock size) of animals over 18 months of age to be killed must be tested in each infected flock

Member State population of ewes and ewe lambs put to the ram	Minimum sample size of dead ovine animals ⁽¹⁾
> 750 000	10 000
100 000-750 000	1 500
40 000-100 000	100 % up to 500
< 40 000	100 % up to 100

⁽¹⁾ Minimum sample sizes are set to take account of the size of the ovine populations in the individual Member States and are intended to provide achievable targets.

Member State population of goats which have already kidded and goats mated	Minimum sample size of dead caprine animals ⁽¹⁾
> 750 000	10 000
250 000-750 000	1 500
40 000-250 000	100 % up to 500
< 40 000	100 % up to 100

⁽¹⁾ Minimum sample sizes are set to take account of the size of the caprine population in the individual Member States and are intended to provide achievable targets.

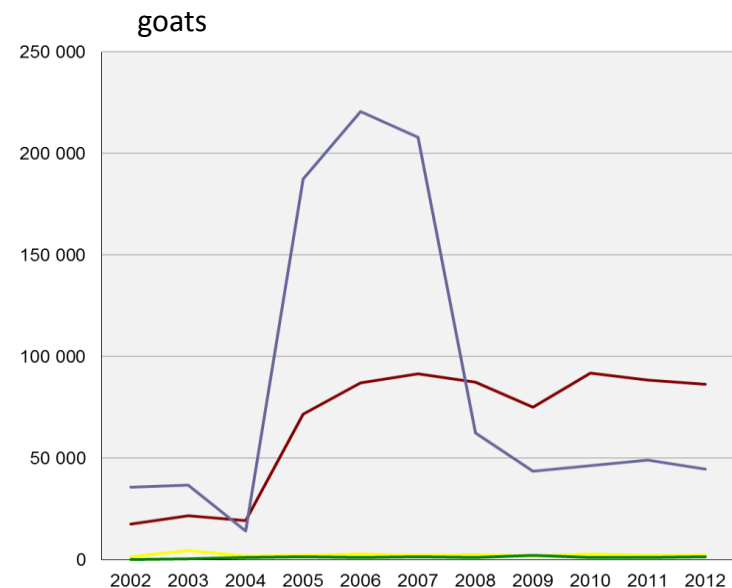
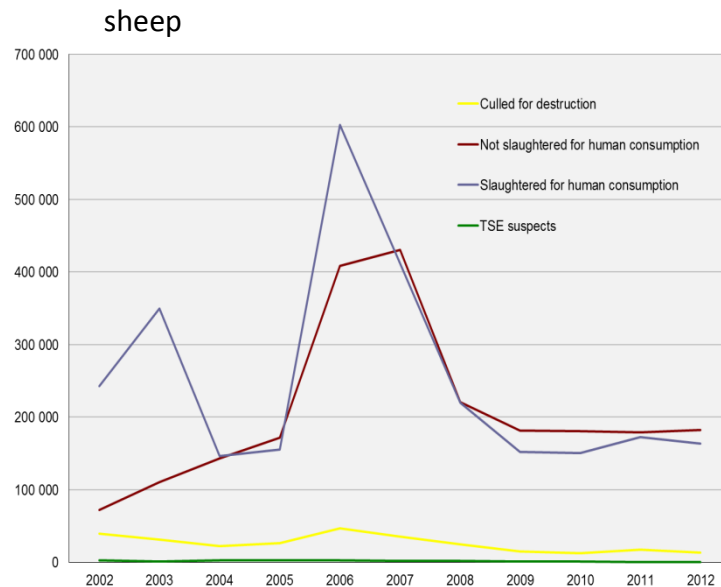
Surveillance in small ruminants



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Evolution and current legal provisions

The active surveillance came into force in 2002 and up to 2012 over 6.7 million ovine and caprine animals have been tested in the EU. Slightly more than half of tests (55%) have been performed in regularly slaughtered animals for human consumption. Only 0.5% of all tests have been performed in clinically suspected animals. The confirmation of a case of bovine spongiform encephalopathy (BSE) in a goat in France in 2005 led to a 3-year period (2005 and 2007) of extended monitoring without any new BSE case detection.



Total tests performed in the EU between 2002 and 2012.

From: EC 2012, Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2011.



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SAMPLING TECHNIQUES

B T S F



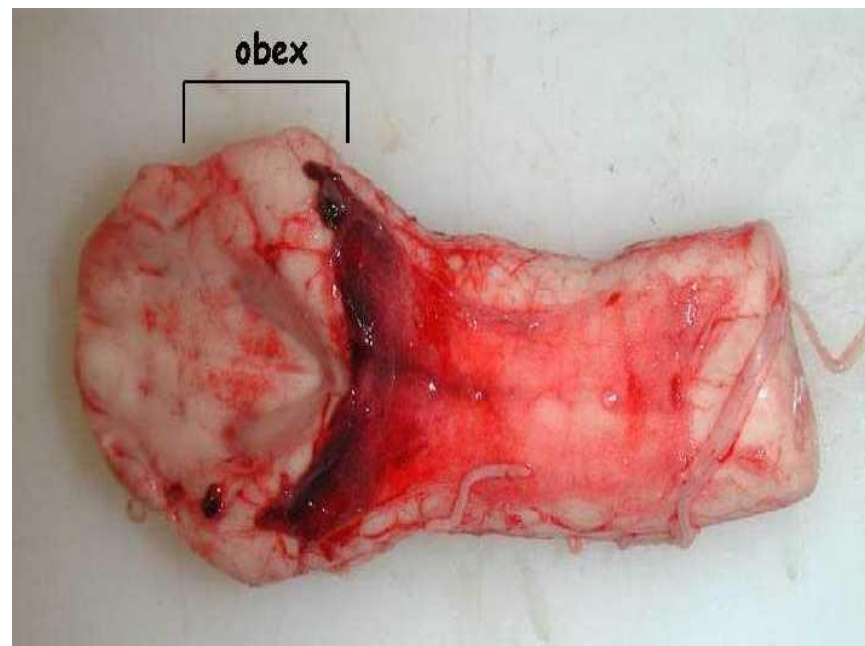
What, where, and how sampling

Rapid screening tests

Only post-mortem diagnosis is possible.

The available rapid tests are validated to detect PrP^{sc} in the Central Nervous Tissues: in particular the target region where the PrP^{sc} accumulation gets its maximum is, within the BRAINSTEM, the obex.

However the tests are rapid but not early, i.e. the disease is detectable only few months before the onset of the clinical signs



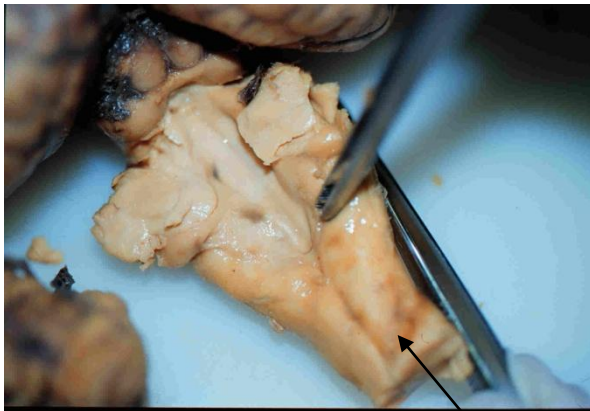
BRAINSTEM

Practical application of TSE surveillance: sampling



What, where, and how sampling

**Usual sampling technique:
bovine animals**



Cattle: Collection of the brainstem throughout the *foramen magnum* using the sample extraction tool



Rapid testing

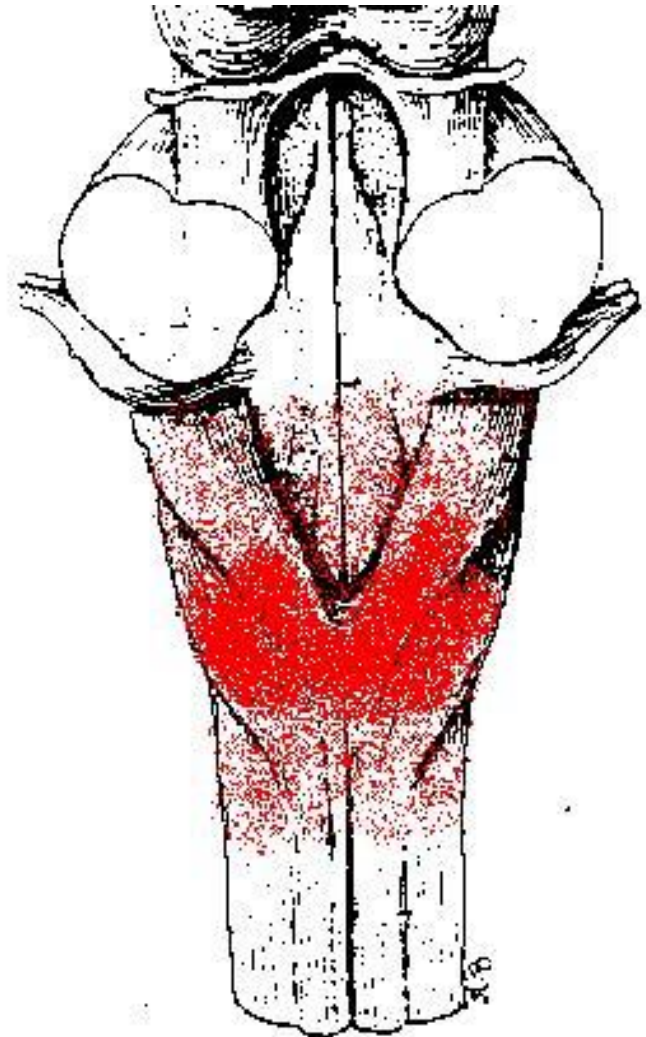
EU Regulation 999/2001 ANNEX - CHAPTER C

Sampling and laboratory testing

Any samples intended to be examined for the presence of a TSE shall be collected using the methods and protocols laid down in the latest edition of the Manual for diagnostic tests and vaccines for Terrestrial Animals of the International Office for Epizooties.

In particular the competent authority shall collect the appropriate tissues, according to the available scientific advice and the guidelines of the Community Reference Laboratory.

The samples shall be correctly marked as to the identity of the sampled animal.

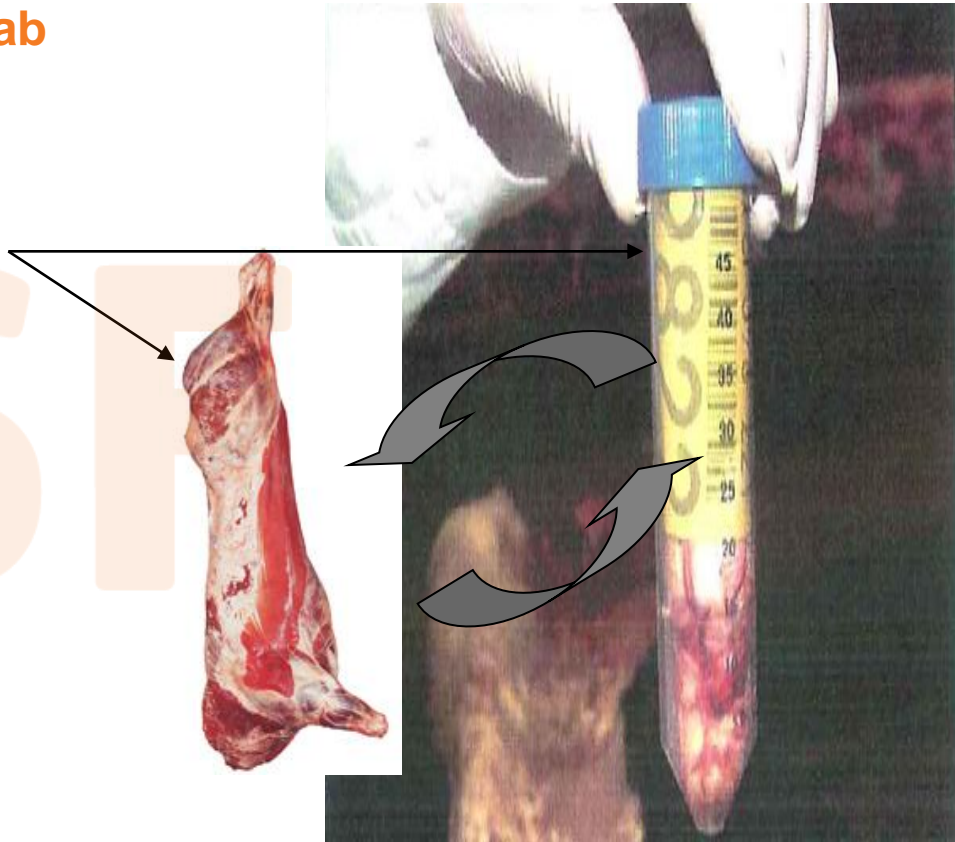


Practical application of TSE surveillance: sampling

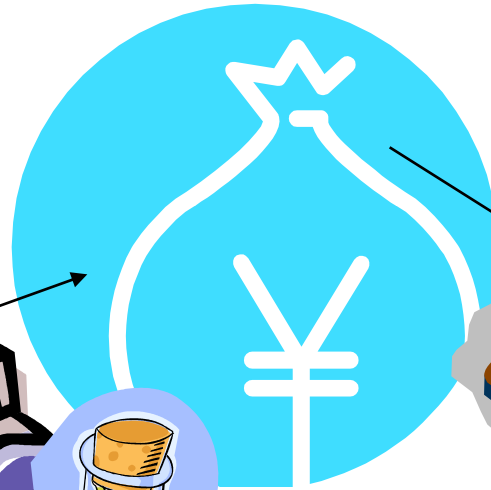
Transferring the sample to lab

Identification: a remarkable issue

It is fundamental to comply with traceability by reporting an unequivocal identification number linking the specimen to the carcass of origin



Transferring the sample to lab - packaging



The sample has to be put in a watertight hard-set container and, subsequently, in a plastic bag and kept refrigerated

