

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION (DG HEALTH AND CONSUMER PROTECTION)

1.1. Epidemiology

Porcine brucellosis is a disease affecting domestic and feral pigs which constitute the main reservoirs. It is also a zoonosis, acquired from handling infected pigs. It is caused by a bacterium called *Brucella suis*. There are five different types of this bacterium, called biotypes, which behave in slightly different ways outside the pig.

In most parts of the world where *B. suis* infects pigs, the most common biotypes causing disease are 1 and 3, with the addition of biotype 2 in Europe. Biotype 2 is enzootic in wild boar and hare populations in Northern, Central Europe and South-Eastern Europe and these animal species transmit it to pigs. Porcine brucellosis has also been reported in Austria, France, Belgium, Germany, Croatia, Portugal and Spain.

B. suis is not present in the United Kingdom or Ireland. It is assumed that it is still enzootic in the hare populations of Scandinavia and Central Europe, but there is insufficient evidence to define the precise area where infected hares live. It is also present in the USA, South America, parts of Asia and Australia.

Once porcine brucellosis is introduced into a pig herd, it is difficult to eliminate. It causes long-term reproductive losses and some biotypes (1 and 3 particularly) also cause a very serious disease in humans. Fortunately, the hare biotype-type 2 is less pathogenic to humans when transmitted.

1.2. EU Legislation

1.2.1. Food Law ("Hygiene Package")

In EU Food Law, brucellosis in animals is listed as a specific hazard and detailed provisions for the disease to ensure safety of meat and to protect public health have been established therein. Chapter IX(F) of Section IV of Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption² *i.e.*:

1. When animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcasses, the slaughter line and staff present in the slaughterhouse.
2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute infection with brucellosis is to be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood must be declared unfit for human consumption, even if no such lesion is found.

1.2.2. Imports to the Community of live pigs and pig meat

Moreover, Council Decision 79/542/EEC of 21 December 1979 drawing up a list of third countries or parts of third countries, and laying down animal and public health and veterinary certification conditions for importation into the Community of certain live animals and their

² OJ L 155, 30.4.2004, p206

fresh meat³ as regards imports of pigs for breeding and production⁴ and fresh pig⁵ meat, sets up specific regimes to be applied with respect to porcine brucellosis.

1.2.3. Intra-Community trade in pigs

As regards intra-Community trade in porcine animals, Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁶ introduced the obligation to certify pigs as originating from brucellosis-free herds and substantiating a test regime to be applied in order to obtain such a status.

However, due to the technical development in pig husbandry, those requirements were removed from that Directive by Directive 97/12/EEC of 17 March 1997 amends and updates Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine⁷.

The disease was thought to have disappeared from some Member States as no clinical cases had been diagnosed for a number of years. Then, over recent years, outdoor breeding pig herds were established which were exposed to wild hares. As a result pigs have caught brucellosis from infected hares.

1.2.4. Reporting and results

Currently, *Brucella suis* infection is listed in Annex E(II) of Directive 64/432/EEC as a notifiable disease and Member States are obliged to report annually on its occurrence within their territory in accordance with Article 8 of the Directive. In the last few years the tendency to reporting more cases has been observed.

<i>Reporting period</i>	<i>Number of cases</i>	<i>Reporting Member States</i>
2004*	58	AT, DE, HU, IT
2005**	72	FR, HU, IT
2006***	2	FR
2007****	39	IT

* 55 isolates obtained from wild boars within a surveillance programme in place in Italy (regions of Piemonte and Liguria)

** 63 isolates obtained from wild boars within a surveillance programme in place in Italy (regions of Piemonte and Liguria)

*** no data provided by Italy.

**** 22 isolates obtained from wild boars within a surveillance programme in place in Italy (regions of Piemonte and Liguria)

There are no cases and positive tests for BS infection in BG in 2007

Taking into account this trend and due to the recent enlargement of the European Union with new Member States where the free range system of keeping pigs is common, the risk of contact of domestic pigs with wild boars and hares is very high.

Porcine brucellosis is a rarely reported disease in the EU. Seventeen Member States reported testing of 37,819,547 pigs, of which 21 pigs were positive for *Brucella* spp.⁸ In Hungary, *Brucella* was not detected in 5,730 tested pig herds.

In 2006, *Brucella suis* was isolated from domestic pigs by bacteriological tests in Belgium and Germany. In addition, *Brucella suis* was also detected in hares in the Czech Republic, Hungary and Spain and isolated from wild boars in Italy.

³ OJ L 146, 14.6.1979, p. 15. Decision as last amended by Decision 2008/61/EC (OJ E 15, 18.1.2008, p. 33).

⁴ Annex I, Part 2, Point 10.4.C and 10.5 of the health certificate POR-X

⁵ Annex 11, Part 2, point 10.3(b) and (c) of the health certificate POR

⁶ OJ L 21, 29.7.1964, p. 1977/64

⁷ OJ L 109, 25.4.1993, p. 1-37

⁸ http://www.efsa.europa.eu/EFSA/Documentset/Zoon_rep_2006_en,0.pdf

1.2.5. Porcine semen

Moreover, Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species⁹ establishes compulsory testing schemes for donor boars with respect to porcine brucellosis in the semen collection centres. Testing methods should be assessed taking into account new technical developments.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION (DG HEALTH AND CONSUMER PROTECTION)

In view of the above, and in accordance with Article 29 of Regulation (EC) 178/2002 and Article 20(2) of Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, the Commission asks EFSA to provide scientific advice on:

- the significance of the presence, origin and occurrence of brucellosis in pigs (*Brucella suis*) in the EU for a better understanding of the impact of the disease in the context of the new epidemiological situation;
- the risk of porcine brucellosis (*Brucella suis*) being introduced into domestic pig herds, in particular through movement of and trade in pigs and contact with wildlife; and assessment of the risk factors for such introduction and spread of the disease;
- the appropriateness of the current measures, different elements and possible strategies that can be used to control and fight against brucellosis in pigs (*Brucella suis*);
- the suitability of available tests for porcine brucellosis (*Brucella suis*).

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⁹ OJ L 224, 18 .X. 1990, p. 62-72

ASSESSMENT

1. Introduction - Approach for this Mandate

The mandate for this scientific assessment focuses on *Brucella (B.) suis* as hazard is addressed in the following steps. A brief description of the hazard is given with emphasis on aspects relevant for a qualitative risk assessment of the current situation of *B. suis* in the European Union (EU) Member States (MS) (Chapter 2). This is to address the 1st ToR on the relevance of *B. suis* in the EU. The epidemiology of *B. suis* is described in terms of geographical occurrence, the role of wildlife and routes of transmission under acknowledgment of uncertainties arising from incomplete scientific information (Chapter 3). The pathogenesis (Chapter 4), clinical signs (Chapter 5) and diagnostic tools (Chapter 6) are a summary, again with emphasis on aspects relevant for the risk assessment. A systematic review of available scientific data on the diagnostic performance of tests for *B. suis* in pigs along with a statistical meta-analysis of the diagnostic sensitivity and specificity has been conducted by the working group and it is reported in the document (Chapter 7). Chapters 6 and 7 address the 4th ToR on the suitability of tests. Risk pathways for the hazard of concern have been elaborated using expert knowledge available in the working group. In relation to these pathways, risk factors have been identified and assessed qualitatively (Chapter 8). Despite the qualitative approach, efforts were made to capture variability (*e.g.* due to different epidemiological situations encountered in MS) and uncertainty (*e.g.* as evident from scores elicited independently from the experts) of this assessment. The results of the qualitative risk assessment address the 2nd ToR on risk factors for introduction and spread of the hazard. Finally, conclusions will be drawn from material presented in various Chapters to assess the potential value of control options (Chapter 9). These science-based conclusions will address the 3rd ToR on the appropriateness of current measures, different elements and possible strategies. For the purpose of this Opinion, a case definition of Brucellosis for domestic or wild pig (*Sus scrofa*) populations has been adopted by the WG, which is further elaborated in Chapter 8.

2. Description of the causative agent (*B. suis*)

Hutyra as early as 1909 isolated a species of *Brucella* from foetuses of aborting sows in Hungary (Huddleson, 1929). The agent was also isolated from aborted porcine foetuses in the USA in 1914 (Traum, 1914). For many years it has been thought to be caused by an exceptionally pathogenic form of *Brucella abortus* (Alton, 1990). In 1929, *Brucella suis* was nominated as a separate species (Huddleson, 1929). To date (June 2009), there are five recognised biovars of *B. suis* (1-5) (OIE, 2008a).

2.1. Morphology (and biovars)

Brucella organisms are Gram negative, coccobacilli, usually arranged singly, but they may be in pairs or small groups. The length varies from 0.6 µm to 1.5 µm and the width from 0.5 µm to 0.7 µm. The morphology is fairly constant and pleomorphic forms are rare except in old cultures. The disease caused by biovars 1 and 3 is similar, while that caused by biovar 2 differs from the others in its host range and pathogenicity. Biovar 2 is very rarely pathogenic for humans, whereas biovars 1 and 3 are highly pathogenic causing severe disease (Alton, 1990; OIE, 2008a). These three biovars usually occur in nature in the smooth form.