Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade

OIE Headquarters, Paris, 11-14 June 2001

Conclusions and key recommendations

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Background information

The identification in 2000 of bovine spongiform encephalopathy (BSE) in native-born cattle in European countries previously thought to be free of the disease has led to increased concern about the extent of the BSE epidemic and raised questions about the possible risks for public health. The concern extends beyond Europe, partly as a result of uncertainty about risks that may result from past international trade of cattle and cattle products from BSE-affected countries.

On 21 December 2000, the World Health Organization (WHO) organised a joint informal meeting between representatives from the WHO, the Food and Agriculture Organization (FAO), the Office International des Epizooties (OIE) and twelve consultants. Representatives from the World Trade Organization (WTO) and the European Commission (EC) also participated. The participants at this meeting concluded that while there were no breakthroughs in the scientific understanding of BSE and variant Creutzfeldt-Jakob disease (vCJD), there is a much greater awareness of the issues involved. These widespread concerns have resulted in demands from countries for science-based and independent advice to create reliable policy for public health. It was recognised, as a principle, that the fundamental measures for the protection of public health would have to include measures to protect animal health, as well as measures applicable to international trade. Hence, it was determined that the three organisations would hold a 'Joint Technical Consultation on BSE: public health, animal health and trade' at the OIE Headquarters in Paris (France) from 11 to 14 June 2001.

Objectives

The principal goal of the Consultation was to provide more quality information to Member Countries, especially for those that do not have experience of BSE and vCJD. This would enable national authorities to determine the actions necessary within their own borders to avoid or reduce risk to human and animal populations, and to export trade. Furthermore, it is important from the international perspective that countries should not export materials that could be contaminated with the BSE agent.

A secondary goal of the Consultation was to provide a forum for the review of some of the most compelling problems in international BSE control, namely: detection, prevention and elimination of the disease, coupled with appropriate risk management.

Certain key policy and communications issues were identified in advance. These included the following:

a) identification of the most effective policies to minimise human exposure to the BSE agent

b) identification of the global risk of BSE resulting from trade in live animals and certain products and by-products containing bovine tissues

c) the resulting recommendations for international trade

d) the global need for trade-related action

e) the need for countries to conduct risk assessments

f) the need for countries to implement surveillance systems for BSE and vCJD

g) the need for countries to act before witnessing their first case of vCJD or BSE

h) the difficulties in communicating risks and the true impact of safety measures in the face of incomplete scientific knowledge.

The Consultation did not intend to review issues relating to biologicals, medicines or pharmaceuticals produced from human or animal tissues, or to review issues regarding possible transmission of vCJD between individual human beings.

Consultation logistics and organisation of this document

Professor Robert Will, Director of the United Kingdom (UK) National CJD Surveillance Unit, kindly chaired the Conference. The first two and a half days of the Consultation were spent in plenary presentations, designed to establish the baseline knowledge from which the participants would work. After this, five Working Groups met to discuss specific issues, as follows:

a) risk assessment

b) risk management – international

c) risk management – national

d) BSE in sheep and other animal species

e) risk communication.

The Consultation closed with a joint session during which the principal recommendations were presented to the full assembly. On 15 June 2001, following the formal Consultation, the Chairs, Rapporteurs and Secretariat met to review the recommendations and to incorporate feedback gathered during the final joint session.

This document contains the key recommendations of the Consultation.

Editing to remove duplication and to improve the readability of the document was performed by the Secretariat and reviewed and agreed to by the Chairs of the Working Groups.

Conclusions and key recommendations

Bovine spongiform encephalopathy: public health, animal health and trade

This Consultation confirmed that BSE is a risk to animal and public health, as follows:

a) the disease is transmissible to humans; scientific consensus confirms that food is the main avenue of exposure

b) bovines, bovine products and by-products potentially carrying the BSE agent have been traded world-wide, giving this risk a global dimension

c) the exchanges mentioned above have or can have repercussions on public health, animal health and trade.

Protection of public health is the overarching goal of BSE risk management and, at this time, protecting public health is primarily accomplished through preventing and eliminating BSE in livestock populations. The Consultation reiterated existing WHO recommendations, namely: 'countries should not permit tissues that are likely to contain the BSE agent to enter any food chain (human or animal)'[1].

Food can be regarded as safe from BSE only if all appropriate measures to minimise human exposures to the BSE agent are fully implemented and monitored. Although much is known and considerable efforts have been made to control BSE, scientific uncertainty remains and it is important for governments to recognise that consumers will make individual decisions regarding the level of risk they consider acceptable.

In order to introduce appropriate measures to protect public and animal health, national authorities require information on two aspects, as follows:

a) the risk of BSE infection in cattle populations

b) the risk of human exposure to the BSE agent.

[1] Report of a WHO Consultation on Public Health Issues related to Human and Animal Transmissible Spongiform Encephalopathies. WHO/EMC/DIS/96.147 Geneva, Switzerland 2-3 April 1996

With regard to human exposure, it is recognised that although the infectious dose for humans is not known and not every exposure necessarily results in infection, it is nevertheless essential to minimise exposure.

The Consultation reviewed the commodities that are currently listed in the OIE *International Animal Health Code* (OIE *Code*) as 'unrestricted in terms of international trade' and concluded that there was no new scientific information to justify modifications to the list. The OIE *Code* also establishes a list of tissues and products that, depending upon the BSE-status of a country, should not be traded internationally. The Consultation concluded that, for the time being, there is no need to modify this list. However, there is a global risk and thus a global need for action, which is reviewed in the following sections.

Global risk and global need for action

Materials potentially infected with BSE have been distributed throughout the world through trade in cattle and certain cattle products and by-products. These products include rendered animal proteins and compound animal feed containing meat-and-bone meal (MBM)[2].

All countries are encouraged to evaluate their potential exposure through systematic assessment of trade data and possible risk factors. These assessments are essential to identify risks that need to be addressed to protect public health and prevent further national and international dissemination of infectivity among susceptible species.

In most cases, the likelihood of a case of vCJD occurring in a country that does not currently have BSE is dependent upon the extent to which people were exposed outside their own country, or were exposed to contaminated imported commodities such as BSE-infected bovine meat products and by-products. It is clear that even countries that do not have BSE cases can potentially experience cases of vCJD in their human population. It must not be automatically assumed that finding a case of vCJD in a country is evidence that BSE is present, even though the likelihood of this must be assessed. Countries must be prepared to investigate vCJD cases with careful regard to possible internal and external exposure. If, and only if, this investigation indicates

[2] According the OIE *Code*, 'meat-and-bone meal means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids'

external exposure as the sole explanation, will there be no need to implement emergency domestic procedures relating to BSE in animals.

The original source and movement of animals and animal products, including MBM, can be masked by international trading patterns which often include the processing and re-exportation of products. Consequently, importing countries should be aware of the risks generated by these trading patterns. The risks from illegal trade must also be considered.

Countries should not become complacent about their risk from BSE. The extremely low initial incidence and the low within-herd incidence of BSE cases, long incubation period and non-specific nature of the early clinical signs of BSE can delay the detection of the first cases of disease and so, may mask the severity of the problem.

International risk management strategies should be commensurate with the level of BSE risk for regions, countries and zones. Risk management strategies must be science-based, transparent and not more trade restrictive than necessary for health protection. The choice of the specific risk management strategies must consider the practicality of implementation and means of auditing compliance in each country.

The WHO, FAO and OIE should work to increase world-wide awareness of the clinical signs, epidemiology and relevant risk factors for BSE and vCJD.

Co-ordination and assistance at the international level

Additional resources should be made available to assist nations, particularly developing nations, to assess their potential exposure to BSE-infected materials and to identify measures which may be necessary to manage the risks associated with this exposure. International organisations, such as the WHO, FAO and OIE, have mandates to protect and improve global public and animal health. Co-ordination of efforts among the WHO, FAO and OIE within their specific mandates should optimise the utilisation of any existing and new resources.

All countries should be encouraged to conduct national risk analyses according to appropriate international guidelines (for example, those provided in the OIE *Code*, Chapter 1.3.2. and Article 2.3.13.1.). The aim should be to enable reliable

categorisation of countries on the basis of risk[3]. It is noted that the current OIE *Code* provides categories based on the incidence of disease but that the OIE is considering an approach that would categorise countries on the basis of risk. This approach is strongly supported.

It is recognised that conducting risk assessments may be difficult for some countries[4]. The process of risk analysis is technically complex and potentially expensive. If a country finds that it faces too large a barrier to accomplish this task, solutions should be sought from international organisations and from countries with greater expertise and resources (especially risk assessment and active surveillance expertise). Countries should be aware that their trading status may be dependent upon conducting a risk assessment for BSE and upon their undertaking of appropriate measures to manage the level of risk identified.

Risk assessment for vCJD and BSE

Risk assessments should be based on the present state of knowledge about the agent, its transmission, the relevant risk factors and currently available diagnostic methodologies.

It is essential to remember that scientific evidence advances and that there is a need to further our understanding of the spread and biology of both BSE and vCJD.

The Consultation concluded that human exposure to BSE depends upon the following internal and external factors:

a) internal – the geographical risk of BSE infectivity in cattle and the domestic consumption patterns of bovine-derived products

b) external – human exposure to the BSE agent through the importation of infected animals or animal products or through exposure while travelling within geographic areas where BSE is present in the cattle population and where appropriate controls have not been implemented.

[3] As specified in OIE *Code* Article 2.3.13.2. to 2.3.13.6. inclusive

[4] Countries are invited to examine relevant *Codex Alimentarius* guidelines and draft guidelines for risk analysis and risk assessment

Hazard identification[5]

Although the BSE agent has not been isolated, substantial experimental evidence has accumulated regarding the distribution of infectivity throughout cattle tissues. The Consultation discussed the list of bovine tissues that are known or suspected to carry BSE infectivity. The Consultation noted that the OIE has published a list of specified risk materials (SRMs)[6], as has the EC Scientific Steering Committee (SSC). The SSC list includes the rationale for their selection[7]. According to current scientific knowledge, BSE infectivity has been demonstrated in the following list of tissues to varying degrees: brain, eyes (retina), trigeminal ganglia, the spinal cord, the dorsal root ganglia and the distal ileum.

Table I provides an estimate of the cattle infectivity dose $(ID)_{50}$ associated with each tissue at the height of infectivity for that tissue type.

Table I
Scientific Steering Committee estimate of cattle infectivity dose $(ID)_{50}$

Tissue	Cattle infectivity dose $(ID)_{50}$ per BSE case	Percentage of total infective load per bovine
Brain	5,000	64.1%
Spinal cord	2,000	25.6%
Trigeminal ganglia	200	2.6%
Dorsal root ganglia	300	3.8%
Ileum	260	3.3%
Spleen[8]	26	0.3%
Eyes	3	0.04%

Source: Opinion of the European Union SSC: Human Exposure Risk (HER) via food with respect to BSE, 10 December 1999, page 11

[5] The *Codex Alimentarius* defines 'hazard identification' as the 'identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods'

[6] The relevant section of the OIE *Code* is Article 2.3.13.22.

[7] Listing of Specified Risk Materials: a scheme for assessing relative risks to man: Opinion of the Scientific Steering Committee adopted on 9 December 1997, re-edited version adopted by the Scientific Steering Committee during its third Plenary Session of 22-23 January 1998

[8] The SSC hypothesised that the spleen could contain some infectivity based on other TSEs. However, no such infectivity has since been found after intracerebral inoculation of cattle (personal communication, G.A.H. Wells), Joint WHO/FAO/OIE Technical Consultation on BSE: animal health, public health and trade, Paris, 11-14 June 2001

Other tissues that might be infected (such as tonsils and the entire intestine from duodenum to rectum) or that could be contaminated by SRMs (such as might occur during the slaughter process under certain circumstances) should also be considered for removal and destruction. The Consultation recommended a regular review of the list of tissues in the light of emerging scientific evidence and of information on the practical aspects of their exclusion.

Risk assessment may also determine that particular categories of animals no longer represent a risk in relation to all tissues or a particular category of tissue (e.g. the dorsal root ganglia from cattle born after the fully effective implementation of an MBM ban, provided they are not the last born progeny of confirmed cases).

Exposure assessment of BSE risk to humans – vCJD

To better assess the risk of human exposure to BSE, the Consultation recommended an analysis of the pathways along which the BSE agent could be transferred from animals to humans, in particular via food. The evaluation of the pathways should include a comprehensive approach that would include both public health policy and livestock management. Such a pathway analysis will provide the basis for assessing the human exposure risk and to manage that risk, even if an exact quantification remains unlikely. The EC SSC has provided an opinion on the human exposure risk[9]. That opinion suggested that from a single infected animal entering the food chain, existing pathways could lead to exposure of either a relatively small number of consumers to high doses of BSE-infectivity, or of a large number of consumers to small doses.

Risk factors of relevance to a human exposure risk analysis include the following:

a) biological (tissue infectivity, pathogenesis, i.e. influence of age on infective load and tissues affected)

b) epidemiological (incidence of BSE in a country, as well as BSE-related risks)

[9] Opinion of the Scientific Steering Committee on the Human Exposure Risk (HER) via food with respect to BSE, adopted on 10 December 1999, Brussels, Belgium. Opinion oral exposure of humans to the BSE agent: infective dose and species barrier, adopted by the Scientific Steering Committee on 13 and 14 April 2000, Brussels, Belgium

c) importation of BSE contaminated commodities and recycling (see the SSC Geographic BSE Risk assessment [GBR][10] and OIE *Code*[11])

d) human factors (slaughter methods, industry practice, cross-contamination, dietary patterns, compliance with sanitary measures, training and education, awareness, surveillance and monitoring, animal husbandry practices)

e) technical (rendering processes, feed production, transport).

The relevant human exposure pathways are likely to differ significantly between countries and it is therefore recommended that whenever a country identifies a risk of BSE, it should take immediate steps to identify the fate of the SRM. International trade in food products may disseminate tissues containing BSE. Therefore, a standardised approach, including a continuous international review process for food in international trade is recommended. The three Organisations should play an instrumental role in this standardisation[12].

BSE in cattle

To assess the risk of bovine infection, the Consultation welcomed the fact that the OIE International Committee has invited the all Member Countries to establish the necessary documentation and to carry out an assessment of the risk of BSE being present in its domestic cattle herd. To this end, the Foot and Mouth Disease and other Epizootics Commission of the OIE has the mandate to provide specific guidelines in line with the OIE *Code* chapter on BSE and to determine if countries meet the OIE criteria to be recognised as BSE-free. It is recommended that these new guidelines take due account of the experience from the application of the GBR assessment exercise carried out by the SSC advising the EC. Countries are encouraged to utilise these guidelines for their own internal assessments, bilateral negotiations and third-party independent assessments.

Hazard characterisation

In the risk assessment process, hazard characterisation has the role of establishing dose response. At this time, information is not sufficient to

[10] Final Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR), adopted on 6 July 2000, Brussels, Belgium
[11] The relevant sections of OIE *Code* are Article 2.3.13.1. to 2.3.13.6.
[12] The OIE *Code* offers a standardised approach to zoonotic diseases

estimate the shape of the dose response curve, and no information is available to determine the level of infectivity required to cause disease in human beings, or in any animals, except bovines. In bovines, one gram of brain from a clinically ill cow is sufficient to cause infection[13].

Risk characterisation

Risk characterisation is the area of risk assessment that, according to the *Codex Alimentarius*, establishes the probability of infection. At this time, there is a substantial lack of information, which is seriously impeding the production of accurate risk characterisation for both humans and animals.

Risk management

The prevention of BSE is a responsibility shared among all those involved in the food and feed chains from farm to fork. Risks are dynamic. Therefore, to detect changes in risk, risk assessment must be ongoing and risk management must be based on the results of these risk assessments.

Meat-and-bone meal

Meat-and-bone meal of ruminant origin must not be fed to ruminants.

In countries where ruminant MBM is fed to other food animal species, all possible measures must be implemented to ensure avoidance of cross-contamination of ruminant rations with feed for non-ruminant species (e.g. by using species-dedicated MBM production premises and/or feed production premises dedicated to ruminants and non-ruminants). Where such avoidance cannot be guaranteed, MBM from any species should not be fed to ruminants. To ensure compliance, it may also be necessary to ban all mammalian protein-based animal feed from ruminant feeds or even from all farm-animal feeds. If cross-contamination cannot be avoided, countries should not trade in these materials.

If a country has identified BSE or, on the basis of a risk assessment, a BSE risk, then MBM for use in non-ruminants should be prepared from non-SRM material by the method prescribed in the OIE *Code* (Article 3.6.3.1.), or by a method that achieves equivalent or enhanced inactivation.

[13] Experiments are under way to examine the infectivity of smaller amounts of cattle brain

Guarantees on the quality, condition of production, the source of the ingredients and the composition of MBM, must be a part of international risk management to prevent the introduction or spread of BSE infectivity. International monitoring of compliance with the feed bans needs further development, including reliable certification programmes and screening tests to guarantee the absence of BSE infectivity in ruminant feedstuffs traded internationally. Emphasis must be placed on the development of rapid and reliable tests for the detection of ruminant protein in animal feeds.

Specified risk materials

This Consultation had no reason, at the time of the meeting, to modify the basic list of SRMs as identified earlier in the section entitled 'Risk assessment for vCJD and BSE: hazard identification'.

Issues such as slaughter methods, cross-contamination during and after slaughter, and difficulties in the identification of specific tissues or organs under slaughterhouse conditions should be taken into account when determining whether products are free of known sources of infectivity. For this reason, risk management options may include the identification and removal of entire bovine heads, as opposed to only removing the brain and eyes, or may include the prohibition of the harvesting of all mechanically-recovered meat (MRM), rather than just the elimination of MRM from the vertebral column.

Whenever the possibility that slaughtered animals may be infected with BSE cannot be excluded, all tissues that have been proved capable of carrying BSE infectivity should be removed and destroyed, i.e. an SRM ban should be imposed. Where this risk is higher, those tissues that under certain conditions are suspected to carry infectivity should also be considered for removal and destruction. If the risk is high, all possible additional precautions should be taken, such as prohibiting cattle over a certain age from entering food or feed chains. The Consultation recommended that the WHO, FAO and OIE review this approach specifically in relation to public health issues. Finally, consideration may be given to applying separate SRM bans for human food and animal feed.

Animals with confirmed or suspected BSE

Clinically confirmed cases in bovines and any progeny born in the two preceding years to female cases should be destroyed.

Given the limitations of the current knowledge concerning the human infective dose and concerning the pathways for human exposure to infected tissues, the Consultation underlined that, as a precaution, all animals suspected of being infected with BSE should be destroyed.

Where a case has been confirmed, cohort animals, i.e. animals exposed to the same risk, should be destroyed[14]. For this purpose, adequate, individual animal identification and records of movement of cattle must be in place. In some circumstances, consideration may be given to more extensive slaughter by some authorities, even though no evidence for horizontal transmission exists. This action may be considered for social, political, economic or trading reasons and should be judged on a case-by-case basis.

Surveillance

Surveillance data is fundamental for the safe trade of animals and animal products. Ongoing surveillance data provides an indicator of the effectiveness of risk management measures and monitors the effect of any changes in the overall BSE risk of a region, country or zone. Surveillance strategies should be commensurate with the BSE risk, but surveillance should include both active and passive components, as outlined in Appendix 3.8.3. of the OIE *Code,* using methods described in the OIE *Manual of Standards for Diagnostic Tests and Vaccines*.

Countries should strongly consider, on the basis of the risk assessment, the use of appropriate tests on target populations, conducted regularly and on a sufficiently significant number of animals, to provide the necessary confidence that any risks are identified. Contingency planning for action following the identification of the first case of BSE in a country previously without reported cases should be established.

Compliance

Experience in countries with BSE has demonstrated that failure of implementation of adequate measures can lead directly to the failure of BSE control programmes. Implementation of the chosen risk management options

[14] The OIE *Code* Article 2.3.13.4., paragraph 2b, subparagraph iii, provides the following definition, 'all cattle either born in the same herd as, and within 12 months of the birth of, the affected cattle or reared together with the affected cattle during the first year of their life, and, in both situations, which may have consumed the same potentially contaminated feed as that which the affected cattle consumed during the first year of their life'

must be enforced strictly to protect global health and trade. Efforts by authorities must be directed at ensuring full compliance. Governments must pay particular attention to ensuring all risk reduction measures are actively established, implemented, enforced and audited. In particular, attention should be paid to the prevention of fraud.

Awareness

An ongoing education and extension programme for all those involved in the food and feed chains should be introduced to encourage, in particular, the following:

a) prevention of exposure

b) methodologies that can be audited

c) traceability of raw materials and compound feed

d) traceability of animals

e) identification of cohorts of cattle fed batches of potentially contaminated feed

f) identification and reporting of suspect BSE cases.

Animal and human health authorities should work together closely for these purposes.

To facilitate animal and public health protection from BSE, incentives should be considered (including financial aid and compensation) and disincentives should be eliminated.

Risk of BSE in sheep and other animal species

Risk assessment in sheep

The Consultation noted that it is possible that BSE could be present in some small ruminants because there is evidence that BSE-contaminated MBM has been fed to some sheep and goats[15]. In recent years, millions of sheep were exported from countries in the European Union (EU). In addition, even where grazing is the normal practice, in some cases MBM from EU countries has

[15] Based on the EC SSC document, Opinion on the pre-emptive risk assessment should BSE in small ruminants be found under domestic conditions, dated 8-9 February 2001, Brussels, Belgium

been imported as a feed supplement for animals, particularly during periods of drought. Consequently, the Consultation concluded that the issue of possible BSE infectivity in sheep is, potentially, global in scope.

The distribution of infectivity in sheep experimentally infected with BSE has been shown to be similar to that of scrapie. Although this idea is speculative, should BSE be present in sheep, the disease may spread laterally between sheep as is the case for scrapie. Should this occur, feed bans would not be sufficient to prevent transmission in sheep populations.

To date, there is no confirmation that BSE is present in small ruminants. However the extent of investigations to detect BSE in sheep has been limited.

Risk management in sheep

It is recommended that individual countries assess the risk that BSE infection could be present in their native sheep and goat populations. Each country should determine the level of risk from both internal and external sources. The Consultation encouraged all countries to require notification and surveillance for transmissible spongiform encephalopathies (TSEs) of sheep and goats and to take steps to mitigate the risks identified. The OIE, FAO and WHO should help to provide and standardise guidance, advice and training for the above if requested. The OIE should complete its draft OIE *Code* chapter on scrapie of sheep and goats, and should address the specific issue of BSE in sheep and goats. The Consultation further recommended that efforts to investigate and detect the presence of natural BSE in sheep and goats be pursued.

In countries where sheep and goat populations have been potentially exposed to BSE infectivity, measures should be taken to minimise the exposure of humans to infectivity from small ruminants.

Other ruminants

Meat-and-bone meal contaminated with BSE may have been fed to water buffalo, cervids, camelids and other ruminants. There is no evidence of neurological disease caused by the BSE agent in these animals, but there is limited knowledge on the full range of susceptibility. Countries should assess the risk and conduct surveillance on water buffalo, cervids, camelids and other domestic ruminants that may have been exposed to potentially contaminated

feed. Research should be conducted to fill existing gaps in knowledge regarding susceptibility in these species.

In the meantime, water buffalo, cervids, camelids and other domestic ruminants should be included in any ruminant feed bans.

Other farmed animals

The research available to date indicates that experimental oral BSE challenge of pigs and poultry with brain material from cattle with BSE does not result in disease and that there is no evidence for residual infectivity present in tissues; there have been no reports of a naturally occurring TSE in these species either[16].

In the case of ostriches, there have been reports of a naturally occurring spongiform encephalopathy in red-necked ostriches. However, the disease has not been transmitted experimentally. Consequently, there is some doubt regarding the true nature of this disease. After appropriate precautions, including all those that may result from cross-contamination, have been taken to mitigate risks, rendered animal protein derived from BSE-free materials may be fed to pigs and poultry (see the section above entitled 'Risk management: meat-and-bone meal'). The EU ban on feeding rendered animal protein to farmed animals was presented as an emergency measure to protect ruminants by avoiding risk of cross-contamination of the ruminant feed system at any level. No experimental study has been performed on horses but, to date, no neurological disease similar to BSE has yet been detected in horses in the UK, where, presumably, any exposure would have been greatest.

Fur-bearing mammals

Under research conditions, BSE has been shown to infect farmed mink by both the oral and intracerebral routes. It is essential that fur-bearing animals must not be re-cycled to food animal species.

[16] Transmission experiments have shown that pigs are susceptible to intracerebral challenge with the BSE agent (seven of ten pigs died of disease after intracerebral inoculation). There is no evidence to date that pigs are susceptible to BSE following oral challenge, and there is no epidemiological evidence in the UK that BSE has been naturally transmitted to swine

Fish

There is ongoing research regarding the susceptibility of fish to the BSE agent. One species of fish has been inoculated with BSE. Results are pending.

Companion animals

It is well recognised that cats are susceptible to BSE (over 85 cats are known to have died from BSE-caused feline spongiform encephalopathy). Dogs in the UK and EU must have been exposed to the BSE agent, yet BSE has not been detected in dogs. Experimental challenges have not been performed on canines.

Passage of infectivity

Laboratory experiments show that mice orally challenged with scrapie have detectable infectivity that passes through the gut. Gut contents and faecal material may therefore contain infectivity, and it is noted that in experimental oral challenges in cattle conducted in the UK, faeces must be treated as medical waste for one month following the challenge. It is concluded that digestive contents and faecal material from livestock or poultry currently being fed with MBM potentially contaminated with BSE should not be used as a feed ingredient for animal feed.

Risk communication

Preamble

In this setting, risk communication is the exchange of information between regulators and those who have a 'stake' in the process, with the objective of building a consensus on the appropriate management of risk[17].

Stakeholder consultation is a two-way process that includes consumers, industry and all interested parties in the food and feed chain. Risk communication is a critically important aspect of risk analysis because 'safety' is a negotiation about the acceptability of risks by those who are the bearers of

[17] The *Codex Alimentarius* defines 'Risk communication' as 'An interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk related factors and risk perception, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions'

the risks. Risk communication is the process by which this acceptance is established and maintained. Effective risk communication takes concerns about the need for regulation of risk and so builds public confidence in the risk management process. Maintenance of public confidence is essential for the effective management of risks. Even the most comprehensive risk assessment and the most reliable risk management practices can be undermined and fail if public confidence in risk regulators is eroded. Stakeholders should be involved early, especially when there is debate.

Consumer risk perceptions often differ dramatically from those of the experts. For this reason, an important task of risk communication is to develop a clear understanding, through consultation, of the aspects of the risk that are of greatest concern to stakeholders. These may not be aspects of the risk that experts would be most likely to identify or respond to. Experts, for example, tend to focus on the quantifiable aspects of risks, while non-experts tend to be more concerned about qualitative aspects of risks (the degree to which risks are voluntary, who takes the risk versus who gets the benefits, the degree of certainty in the knowledge about risk, as well as its familiarity and controllability). Experts prefer to withhold judgement on potential hazards when there is a lack of scientific evidence, but to the lay person this gives the appearance of favouring industry and looks like a preference for risk-taking rather than safety. However, exercising precaution requires action to be taken when significant levels of uncertainty remain in science. Consequently, regulatory decisions may be required before sufficient scientific data are available. This is especially true in the most contentious and perturbing risk issues, such as BSE/vCJD. Uncertainty is one of the most critical issues in risk communication. How the proper messages can be communicated when risks are unclear should be addressed.

General principles

Four contexts for typical risk communication messages were identified, as follows:

1. Issues where we think we know the answers (high certainty contexts), recognising that new data can change the conclusions in which you have the highest confidence. For example: is food exposure the cause of vCJD?

2. Issues where we don't know (high uncertainty contexts). For example: how many people might get vCJD in the future?

3. Issues where there is debate or controversy (moderate uncertainty). For example: has BSE spread to the rest of the world?

4. New emerging issues of potential risk. For example: sheep and goats may have been infected with BSE.

Principles identified

The seven principles listed below were identified:

1. Consult all stakeholders at the outset to address their concerns in an open and transparent dialogue.
2. Frame the question and address the full range of concerns about the risk.
3. Frame the response in the context of the full story. The audience may be poorly or well informed. It is important to translate and summarise the story for different audiences.
4. Explain:
   - what measures are being taken to reduce the risks, and why
   - what is known, what is unknown and explain why this is the case; be open and honest
   - what is being done to fill the knowledge gap
   - what precautionary measures are being taken in the interim.
5. Give regular updates, even when there is no new information.
6. Be proactive, take the initiative to communicate new information about risks, even though it may be unsettling to the public. Explain what is being done to address these risks.

Dealing with controversial science

Ordinarily, the quality of science is ensured through the peer-review process, but new and important scientific information can, in some cases, merit early communication because it may be relevant to the formulation of new precautionary measures. It is important to present such information within the context of the scientific status of the information, i.e. non peer-reviewed, peer-reviewed, or peer-reviewed *and* confirmed *or* supported through repeated investigation. Care needs to be exercised in the treatment of minority scientific

opinions; they sometimes prove to be right – an important early claim that BSE was likely to cross the species barrier was dismissed by mainstream science.

Guidelines to regulators on good media communications

- Simplify the scientific message but maintain accuracy
- Use the media as partners to achieve your goal of communication develop; seek a dialogue and an ongoing relationship
- Respond quickly, be candid and understand how the media work; if you decide not to discuss an issue during an interview, explain why
- The media want 'news', so know how to frame the message without allowing the process to distort the message
- Be consistent, but be prepared to revise your message in the light of new data
- Prepare a written statement to ensure the media get the message and be able to respond to questions
- Try to get journalists to repeat back the message to see that they have understood and that you have communicated your points clearly.

The communication needs of Member Countries

The Consultation recommended that the WHO, FAO and OIE should collaborate on better communication strategies with their constituencies. They should make every effort to keep all Member Countries informed of developments of BSE and measures for the management of the related risks appropriate to their context. It is especially important to take into account the different perceptions and capacities to respond to risks in different cultural contexts, especially in the developing world.

Specific recommendations to the International Organisations: WHO, FAO and OIE

1. The WHO, FAO and OIE should work to increase world-wide awareness of the epidemiology and relevant risk factors for BSE and vCJD.

2. Additional resources should be made available to assist nations, particularly developing nations, in assessing their potential exposure to BSE-infected materials and in identifying measures which may be necessary to manage the risks associated with this exposure. International organisations such as the WHO, FAO and OIE have mandates to protect and improve global public and animal health. Co-ordination of efforts among the WHO, FAO and OIE within their specific mandates should optimise the utilisation of any existing and new resources.

3. Whenever the possibility that slaughtered animals may be infected with BSE cannot be excluded, all tissues that have been proved capable of carrying BSE infectivity should be removed and destroyed, i.e. an SRM ban should be imposed. Where this risk is higher, those tissues that under certain conditions are suspected to carry infectivity should also be considered for removal and destruction. If the risk is high, all additional possible precautions should be taken, such as prohibiting cattle over a certain age from entering food or feed chains**.** The Consultation recommended that the WHO, FAO and OIE review this approach specifically in relation to public health issues.

4. To assess the risk of bovine infection, the Consultation welcomed the fact that the OIE International Committee has invited all OIE Member Countries to establish the necessary documentation and to carry out an assessment of the risk of BSE being present in its domestic cattle herd. To this end, the Foot and Mouth Disease and other Epizootics Commission of the OIE has the mandate to provide specific guidelines in line with the OIE *Code* chapter on BSE and to determine if countries meet the OIE criteria to be recognised as BSE-free. It is recommended that these new guidelines take due account of the experience from the application of the GBR assessment exercise carried out by the SSC advising the EC.

5. The relevant human exposure pathways are likely to differ significantly between countries and it therefore is recommended that whenever a country identifies a risk of BSE, it should take immediate steps to identify the fate of the SRM. International trade in food products may disseminate tissues containing BSE. Therefore, a standardised approach, including a continuous international review process for food in international trade is recommended. The three Organisations should play an instrumental role in this standardisation.

6. The Consultation encouraged all countries to require notification and surveillance for TSEs of sheep and goats and to take steps to mitigate the risks identified. The OIE, FAO and WHO should help to provide and standardise guidance, advice and training for the above if requested. The OIE should complete its draft OIE *Code* chapter on scrapie of sheep and goats, and should address the specific issue of BSE in sheep and goats. The Consultation further recommended that efforts to investigate and detect the presence of natural BSE in sheep and goats be pursued.

7. The WHO, FAO and OIE should collaborate on better communications strategies with their constituencies. They should make every effort to keep all Member Countries informed of developments of BSE and measures for the management of the related risks appropriate to their context. It is especially important to take into account the different perceptions and capacities to respond to risks in different cultural contexts, especially in the developing world.

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