Opening Statement, Professor Simon More, UCD, 26-02-19

Oireachtas Joint Committee on Agriculture, Food and the Marine

The bovine tuberculosis eradication programme in Ireland

Written submission from

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UCD Centre for Veterinary Epidemiology and Risk Analysis (CVERA)

1. CVERA provides scientific evidence to support policy decision-making in Ireland on a diverse range of issues relevant to animal health & welfare and public health, including:

   - Bovine tuberculosis (TB),
   - Cattle health issues managed by Animal Health Ireland[1], a public:private partnership, including CellCheck (focusing on national milk quality), the eradication of bovine viral diarrhoea (BVD) and the control of Johne's disease, and
   - Other issues of national importance, including specialist support for emergency disease incursions such as foot and mouth disease, animal welfare, standards in animal health & welfare, and farmed salmon production.

   With each issue, the research of CVERA is generally highly applied and undertaken in response to a clear policy need, as identified by the Department of Agriculture, Food and the Marine (DAFM).

2. The work of CVERA is undertaken by a dedicated team of scientists from diverse scientific disciplines including veterinary epidemiology, biostatistics, geographic information systems (GIS) science, database management and ecology.

3. CVERA is fully funded by DAFM and located within the UCD School of Veterinary Medicine at University College Dublin.

4. Professor Simon More, the CVERA Director, also chairs the Scientific Committee of the European Food Safety Authority (EFSA) where scientific evidence from EU member states and elsewhere is reviewed and distilled, to assist with policy decision-making by the European Commission.

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[1] http://animalhealthireland.ie

A. Background to Ireland's bovine tuberculosis eradication programme

Research in support of the national TB eradication programme

5. The national TB eradication programme is informed by detailed ongoing research, conducted by CVERA and others, with a focus on two broad issues:

- An improved understanding of constraints to national eradication, and
- Practical solutions to address these constraints.

6. In broad terms, research has focused in three key areas (and objectives):

- *Cattle* (improving detection of infected herds, improving clearance of TB from infected herds),
- *Wildlife* (clarifying the role played by badgers in TB infection in cattle, gaining an improved understanding of badger ecology and TB epidemiology in this species, identifying appropriate control strategies to limit infection in badgers and to cattle), and
- *The overall programme* (evaluating appropriate models of governance and cost-sharing, gleaning lessons from international experiences of success and failure).

7. The national programme has evolved substantially over time in response to new knowledge.

Substantial national progress

8. There has been an ongoing decline in TB in Ireland, with levels now among their lowest since the programme started (*Figure 1,* trends from the countries of the UK are included for comparison) (Abernethy et al., 2013; More et al., 2018).

9. Although good progress is being made, TB has yet to be eradicated.

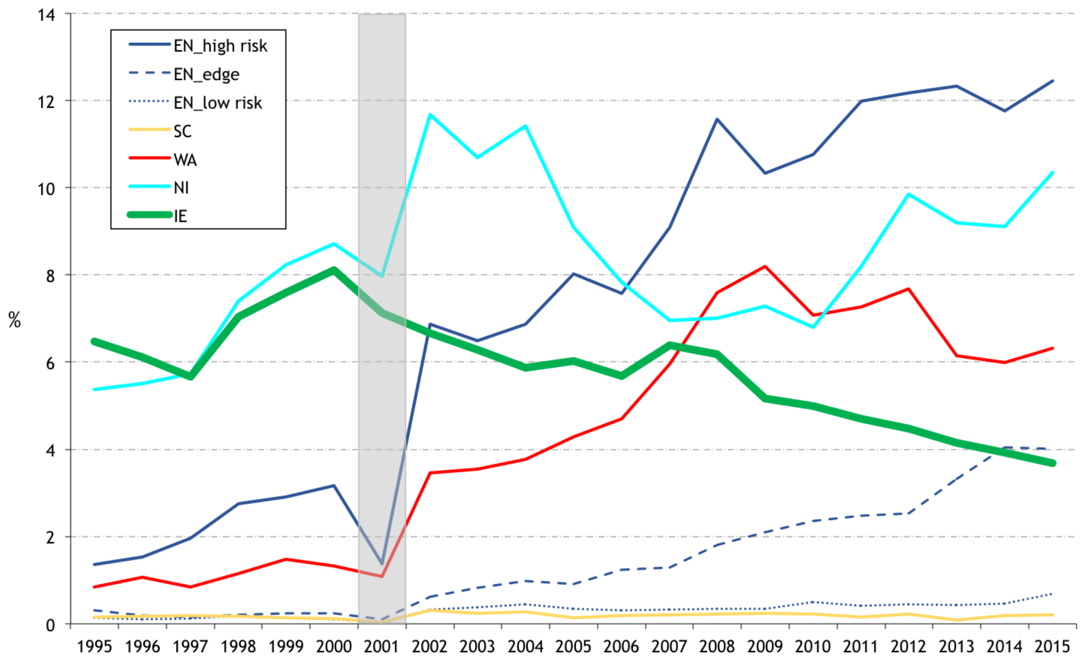

Figure 1. New cases of TB in Irish cattle herds during 1995-2015 (green line) (measured as standardised annual herd incidence), in comparison with the countries of the UK, including England (EN, High Risk Area, Edge Area and Low Risk Area), Northern Ireland (NI), Scotland (SC), Wales (WA). Modified from More et al. (2018)

B. Are we doing enough to successfully eradicate TB from Ireland by 2030?

Broad overview

Prior to the introduction of badger vaccination

10. Until very recently, Ireland has lacked key tools required for eradication, including the ability to sustainably prevent the drift of infection from wildlife to cattle. In such circumstances, it has been appropriate to control TB as effectively as possible (essentially a progressively improving 'holding pattern') whilst seeking to fill critical gaps in knowledge.

Once badger vaccination has been established nationally

11. The ongoing roll-out of badger vaccination is a very important addition to the national programme.

12. Even with this addition, however, there is robust evidence to suggest that all current strategies plus badger vaccination may not be sufficient to successfully eradicate TB from Ireland by 2030. A national target for TB eradication of 2030 was established in Ireland several years ago. This evidence is drawn from:

    a. General national research,

    b. International experiences, and

    c. Results of a recent modelling study.

a. General national research

13. As part of the large body of research conducted in Ireland, a number of challenges have been identified, including some that may substantially constrain progress towards eradication. These include:

    - *Aspects of the disease itself*, including the presence of residual infection (infected animals that test negative to current diagnostic tests) and the prolonged (but variable) period of heightened risk that occurs in herds following infection,

- *The presence of a multi-host system (that is, cattle and badgers),* which requires a multi-faceted strategy to adequately control infection in all animal species of epidemiological relevance (that is, animal species that contribute to both the maintenance and spread of TB infection in Ireland),
- *Programme fatigue,* noting that there have been ongoing eradication effort since the late 1950s,
- *Commercial realities*, including both the substantial and ongoing movement of cattle in Ireland and the need for minimal disruption from the programme to allow ongoing commerce, and
- *Limited industry engagement*, as reflected in the current models of programme governance and cost-sharing.

b. International experience

14. TB has been successfully eradicated from only a small number of countries, primarily Australia and several countries in northern Europe.

15. Ireland can learn lessons from efforts in other countries to control or eradicate TB. Like Ireland, efforts towards eradication have been lengthy in Australia (a 27-year programme) and in New Zealand and the UK (many decades). Similarly, wildlife contribute (or have contributed) to the epidemiology (disease dynamics) of TB in many countries, including Australia (feral buffalo and feral pigs), France (badgers, deer), New Zealand (brush-tailed possum), Spain (wild boar and deer), UK (badgers) and USA (white-tailed deer in Michigan). Lessons learned from the success eradication of TB from Australia have been documented (More et al., 2015).

16. In comparison with Australia (where eradication has been successful) or New Zealand (where substantial progress is being made), there are clear differences in the Irish programme in terms of cattle controls and industry engagement. This is discussed further below. Ireland is not dissimilar to Australia and New Zealand as all three countries are tackling or have tackled TB eradication over a prolonged period with clear wildlife involvement.

c. Results from a recent modelling study

17. In partnership with Wageningen University (the Netherlands), work has recently been completed within CVERA to assess the effectiveness of current control strategies to eradicate TB from cattle and badgers in Ireland, both prior to and following the inclusion of badger vaccination (Aznar, 2018).

    - Central to this work is the concept of the 'reproduction ratio' (termed *R*), this being the average number of secondary cases caused by each primary case. An epidemic can only be sustained if *R* is greater than one. Therefore, the efficacy of control measures can be assessed based on whether or not they are capable of reducing *R* below one.
    - Therefore, *R* = 1 can be considered the *'threshold for eradication'*.

18. The key results from the Wageningen-CVERA study suggest that:

    - Eradication would not have been achieved with all current control strategies, prior to the introduction of badger vaccination. In these circumstances, it is estimated that *R* for the cattle-badger system lies between 1.07 and 1.16, depending on the assumptions used.
    - Following the introduction of badger vaccination in addition to all current control strategies, *R* for the cattle-badger system will be reduced below 1, but not substantially (that is, *R* = 0.93-0.97). Although eradication is likely to be achieved, it will take a very long time (that is, many decades, possibly 60-90 years).

19. From this work, we conclude that:

    - TB eradication is likely to be achieved with the addition of badger vaccination to all current control measures, however, it will take a very long time (that is, many decades).
    - Further measures will be needed, in addition to current controls plus badger vaccination, if Ireland is to eradicate TB within a reasonable time frame.

A critical decision point

20. In my view, we face a critical decision point in the programme, specifically the scope and intensity of control measures from this point forward. Decisions made now will have long-term implications in terms of:

    - *Time-to-eradication*, including whether the 2030 target is at all realistic, and
    - *The cumulative cost of the eradication programme*, from now to the point of eradication and beyond.

21. This decision point is well illustrated from experiences gained in the national BVD eradication programme, which is another animal disease eradication programme in Ireland, coordinated by Animal Health Ireland. Recently completed research has highlighted the long-term impact, in terms of time-to-eradication, of the retention of BVD persistently infected (PI) animals on Irish farms (Thulke et al., 2018).

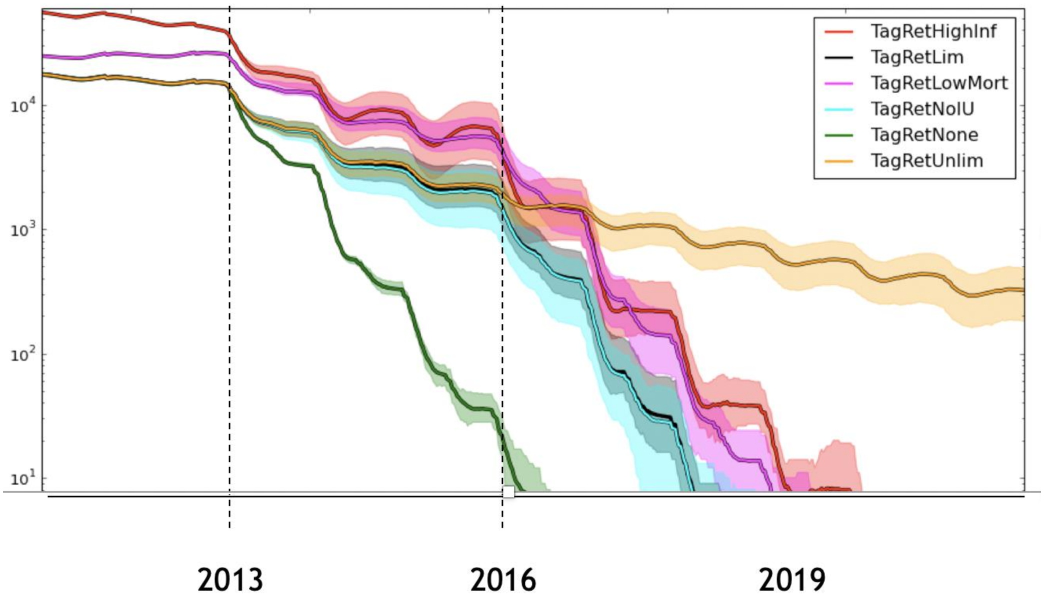

Figure 2. Estimated decline in the total number of persistently infected (PI) animals in Ireland in the years following the start of the compulsory national bovine viral diarrhoea (BVD) eradication programme under differing levels of PI retention. Adapted from Thulke et al. (2018). In particular note:

- *The green line*: the predicted fall in total PI numbers assuming all PIs are removed from farms immediately following testing (that is, without any PI retention). Estimated time to eradication: 3-4 years from programme start (2016-17)
- *The yellow line:* predicted fall in PI numbers given high levels of PI retention (that is, PI retention continues at a high level each year). Unlikely to eradicate
- *The purple line:* the predicted fall in PI numbers, assuming high levels of PI retention during the first three years of the programme, but no PI retention subsequently. Estimated time to eradication: 6-7 years from programme start (2019-20)

Additional measures

The aforementioned Wageningen-CVERA modelling study (Aznar, 2018) has highlighted the need for further measures, in addition to all current controls and badger vaccination, if Ireland is to eradicate TB within a reasonable time frame. Drawing on research findings, international experience and a detailed understanding of the situation in Ireland, it is my view that this is best achieved by:

a. Adequately addressing TB risks from wildlife,
b. Implementing additional risk-based cattle controls, and
c. Enhancing industry engagement.

a. Adequately addressing TB risks from wildlife

Badgers

22. Based on available evidence (including Aznar, 2018; Aznar et al., 2018; Gormley et al., 2018), a national programme of badger vaccination will substantially contribute to national eradication efforts.

23. Ongoing research should focus on critical evaluation of this programme, both on the dynamics of TB infection in badgers and of changes in the risk posed to cattle, with particular emphasis on:

    - Drawing conclusions from the non-inferiority trial (where comparison is being made of badger vaccination and ongoing culling),
    - Detailed monitoring and evaluation of ongoing badger vaccination, particularly in areas where problems arise, and
    - Relevant aspects of badger ecology.

    Each of these issues is an area of active national research, and a range of methods will be used, including whole genome sequencing of the TB organism.

Wild deer

24. Concern has been raised in the Joint Committee about a potential role for deer.

25. Infected wildlife can play differing 'epidemiological roles' with respect to TB in cattle. Wildlife species can act as either:

    - *a spillover host*,
    - *a maintenance (or reservoir) host* [allowing infection to self-sustain in that wildlife species], or
    - *a maintenance host with spillback to cattle* (Haydon et al., 2002; Corner, 2006).

    A spillover host is likely of little concern for national TB eradication, whereas wildlife that act as a maintenance host with spillback to cattle, such as badgers in Ireland, pose substantial challenges.

    - During the Australian TB eradication programme, feral pigs[2] became infected whilst scavenging on infected cattle carcasses. However, infection was not maintained in these populations, and it disappeared from feral pigs once it had been eliminated from cattle (Corner, 2006).

26. In some countries, there is evidence that wild deer act as a maintenance host, playing an important role in the epidemiology of TB in cattle.

    - In Spain, in some populations of red deer (*Cervus elaphus*), TB has been found at high prevalence (up to 50%), with more than 50% of infected animals presenting with generalised infection (Vicente et al., 2006).
    - Based on detailed work conducted over many years, in one region of Michigan (USA) white-tailed deer (*Odocoileus virginianus*) are recognized as a maintenance host for TB, posing an ongoing TB risk to neighbouring cattle (O'Brien et al., 2002, 2011; Ramsay et al., 2016; VerCauteren et al., 2018). Several factors were crucial to the establishment of self-sustaining TB in this deer population, including intensive baiting and supplementary feeding of deer during winter (O'Brien et al., 2002). It is well recognised

[2] Currently, there are an estimated 24 million feral pigs in Australia, which is greater than the human population. The feral pig (*Sus scrofa*). Department of Sustainability, Environment, Water, Population and Communities, Australian Government, Canberra. https://www.environment.gov.au

that increased population density and population aggregation each facilitate TB transmission.

- In New Zealand, transmission within wild deer populations is rare, and wild deer are not recognised as maintenance hosts for TB. However, transmission from wild deer carcasses to scavengers, including brush-tailed possums (*Trichosurus vulpecula*), can occur, creating a 'spillback risk' that could persist for some years after transmission of new infection to wild deer has been halted (Nugent et al., 2014).

27. In Ireland, data are sparse and the epidemiological role played by wild deer (predominantly Sika (*Cervus nippon*) or Sika hybrids) is currently uncertain.

- Using occurrence data (that is, presence or absence in defined areas, based on confirmed deer sightings), Carden et al. (2011) found a considerable expansion in the range of several deer species in Ireland between 1978 and 2008. Trends in deer density are not available.
- Based on available data (all unpublished, except Dodd (1984) and Doyle et al. (2018)), TB prevalence in wild deer is very low in most areas of Ireland:
  - Based on the results of passive surveillance of deer – that is, wild deer which were shot and submitted to Regional Veterinary Laboratories for TB testing – from areas outside Co. Wicklow during 2017 and 2018, 73 wild deer were tested and three were reported to have had TB (4.1%) (unpublished).
  - Of 17 wild deer that were examined during a large outbreak of TB in north Co. Sligo, none were found to be infected (Doyle et al., 2018).
- Higher TB prevalence has been observed in several hot-spot areas of Co. Wicklow (those with high TB prevalence in cattle):
  - An unpublished DAFM research study carried out in the Calary area of Wicklow in 2014 and 2015 found that 16% of deer had TB in that area. Sampling was non-random, using fresh full carcasses. The same (local) TB strain was identified in cattle, badgers and deer.
  - An ongoing follow-up study by DAFM, from the same area, recently reported that 8.3% (10/121) of deer shot on farmland had TB, whereas 0% (0/32) of deer from a nearby control area (in National Park) were infected. Sampling was again non-random, but using frozen heads and plucks.

28. In most areas of Ireland, there is no evidence in support of deer acting as a maintenance host for TB.

29. In hot-spot areas of Co. Wicklow, the epidemiological role played by deer is uncertain. Higher TB prevalence has been observed, however, this does not provide conclusive evidence that TB is self-sustaining in local deer populations, nor – if it is – of the relative contribution of infected deer to local TB epidemiology (establishment and spread).

30. Clarifying the epidemiological role of wildlife species is not straightforward (Palmer, 2013), and the methodologies used in Michigan are not directly transferable to Ireland. The following two recommendations are made[3]:

    - In geographical areas of concern, deer should be managed to minimise risk factors that are known to facilitate the establishment and perpetuation of deer as a maintenance host for TB. Based on international experience and general principles, these include increased population density and circumstances that facilitate aggregation (both of deer *per se*, and of deer with other known infected species).
    - Concurrently, deer removed during these management operations should be utilized to maximise their scientific value in clarifying the epidemiological role being played by deer in these localities. Using this material, and building on earlier research, the following approaches are relevant:
        - ecological and epidemiological studies to address questions relevant to TB establishment, pathogen transmission/spread/persistence, both within and between relevant species (cattle, badgers, deer), and
        - laboratory studies (pathology, microbiology) to further clarify the natural history of infection in this species (including route(s) of infection, the anatomical location of lesions, the route(s) and levels of excretion) (Corner et al., 2006).

    Emerging technologies, including whole genome sequencing (WGS), may assist in tracking the TB-causing pathogen in time and space, to determine the direction and relative frequency of spread between cattle, badgers and deer in the same locality (Kao et al., 2014, 2016). WGS has been used in a number of settings relating to TB in cattle and wildlife, including Germany (Kohl et al, 2018, in a wildlife park), New Zealand (Crispell et al., 2017; Price-Carter et al., 2018), UK (Trewby et al., 2016) and the USA (Salvador et al., in press) (in the latter three countries, as part of their national TB eradication programme). WGS is currently being applied to TB samples from cattle,

[3] I gratefully acknowledge input from Dan O'Brien (Wildlife Disease Laboratory, Michigan Department of Natural Resources, Lansing, Michigan, USA), Stephen Gordon and Joseph Crispell (UCD School of Veterinary Medicine, University College Dublin) when considering these recommendations

badgers and deer in the Calary area of Co. Wicklow, seeking a better understanding of the epidemiological role played by deer in this locality.

b. Implementing additional risk-based cattle controls

TB herd risk

31. In endemic countries (where TB is present), it is not possible using current technologies to determine with 100% confidence whether a herd is TB infected or not. Rather, it is more appropriate to consider herds to be at differing levels of TB risk, from very low to very high.

32. Infected herds are at greater TB risk for an extended period (up to 10 years) after TB derestriction (that is, following release after a TB restriction) (Clegg et al., 2015), depending on factors including the size of the initial breakdown, herd size and herd location (Skuce et al., 2012; More and Good, 2015). Persistent TB risk contributes to herd recurrence and local persistence of TB (More and Good, 2015).

33. There are two main drivers of persistent TB herd risk including:

- *Infection in the locality,* associated with neighbouring cattle and local wildlife, and
- *Infection in the herd,* due to residual infection (More and Good, 2015).

Persistent TB herd risk due to residual infection

34. Residual infection refers to the presence of infected – but undetected – animals. This is of particularly concern at the time of TB derestriction, noting that residually infected animals can pose a future infection risk to the index or neighbouring herds, or to herds to which the animal subsequently moves.

35. Multiple studies from a range of countries have highlighted the contribution of residual infection to TB persistence in a herd or locality (including Karolemeas et al., 2011; Dawson et al., 2014; More and Good, 2015; More et al., 2015). Further, difficulties in clearing infected herds, leading to herd TB recurrence, has been identified as a key challenge to TB eradication, both in Ireland (More and Good, 2015) and New Zealand (Dawson et al., 2014).

36. The problem is essentially technical, but exacerbated by current legislation:

- *Technical.* It is not possible with current diagnostic tools (including the use of interferon-γ) to identify all infected animals within known infected herds.
- *Legislative.* Under relevant EU legislation (Council Directive 64/432[4]), restricted herds are free to trade (and considered at no greater risk than non-infected herds) once two consecutive clear full-herd skin tests are achieved. In other words, herds are free to trade within 4 months after the last known infected animal has been detected[5]. This legislation does not adequately mitigate the aforementioned heightened TB risk associated with these herds.

Cattle movement

- There is very substantial movement of cattle in Ireland. In 2016, there were 1.3 million movement events, this being all journeys travelled by vehicles (such as trailers) to transport cattle to marts, new herds, slaughter plants or export facilities. These movement events covered a cumulative distance of 46 million kilometres in a single year (equivalent of circumnavigating the Earth 1,015 times or travelling to the moon and back 60 times) (McGrath et al., 2018). *See Figure 3*.

[4] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31964L0432
[5] For comparison, in the successful Australian programme, all animals present during a breakdown were considered at risk for the rest of their life, and infected herds took a minimum of 8 years to attain the lowest herd risk status (More et al., 2015).

Figure 3. Screenshot of cattle movement events in Ireland, in this case from 12 August 2016. From McGrath et al. (2018). The blue lines depict movements to slaughter or export, and the red lines from farm to farm including via a mart. The movement video is available on YouTube at *https://youtu.be/PTCdPMnenBw*.

Ongoing recycling of infection in the national population

37. The problem of residual infection coupled with substantial cattle movement leads to ongoing *'churn'* or recycling of infection within the national population. This problem will greatly constrain efforts towards successful TB eradication.

A risk-based approach

38. A risk-based approach is currently the only method available internationally to adequately address the problems caused by residual infection and animal movement, whilst also facilitating ongoing commerce within the farming community. This approach was central to the national eradication programmes in Australia (More et al., 2015) and New Zealand

(Livingstone et al., 2015), and was also recently recommended for introduction in Great Britain[6].

39. Using this approach, TB risk is assessed at the level of the herd (not the animal), with herds progressively moving from a *high* TB herd risk score (at the time of derestriction) to a *low* TB herd risk score over a series of years. A broad range of measures are used to assist *high* TB risk herds to clear infection, and risk-based trading allows ongoing commerce whilst limiting the potential for infection to spread from herds of *higher* to *lower* TB risk through animal movement. This is achieved by allowing:

    - Farmers to sell cattle *to herds of equivalent or higher* TB herd risk
    - Farmers to source cattle *from herds of equivalent or lower* TB herd risk (More et al., 2015).

c. Enhancing industry engagement

40. In Ireland, TB is widely considered a government problem. This is in contrast to international examples of success, where TB eradication has been very reliant on models of programme governance/management and cost-sharing that encourage high level of industry engagement.

41. In the successful Australian TB eradication programme, one commentator suggested that the programme *'enjoy[ed] industry "ownership" and involvement at all levels of management'* (More et al., 2015). Another indicated *that 'the involvement of industry in both funding and policy development was an essential factor in achieving the outcome of the campaign'* (Radunz, 2006). The Australian TB eradication programme led to the formation of Animal Health Australia[7] which now oversees much of national animal health in Australia. In New Zealand, governance of the national TB eradication programme is underseen by OSPRI[8], a non-government organization that manages both TBfree New Zealand and NAIT (the national animal identification and traceability system).

[6] https://www.gov.uk/government/publications/a-strategy-for-achieving-bovine-tuberculosis-free-status-for-england-2018-review/bovine-tb-strategy-review-summary-and-conclusions
[7] https://www.animalhealthaustralia.com.au
[8] https://www.ospri.co.nz

42. Cost-sharing by government and industry has been a key feature of both the Australian and New Zealand programmes, although different models are used:

- In Australia, the programme was funded 50:50 by government and industry, with the latter funded through a cattle transaction levy[9]. If TB were ever to recur (the last known TB case in Australia was in 2002), a cost-sharing model of 20:80 (government:industry) has been legally agreed[10], reflecting a shared understanding of the perceived public:private good associated with this disease.
- In New Zealand, cost-sharing is guided by principles outlined in national biosecurity legislation (Biosecurity Act 1993), with cost-sharing allocated after identifying both:
    - *The beneficiaries* (who will benefit from the control/eradication efforts), and
    - *The exacerbators* (who is perpetuating the problem, essentially constraining eradication)[11].

43. The Bovine TB Stakeholder Forum is an important national initiative, seeking broad stakeholder engagement in the future of the national TB eradication programme. Discussions are informed by the National Farmed Animal Health Strategy[12] which is underpinned by four key enabling principles:

- Working in partnership
- Acknowledging roles and responsibilities
- Reflecting costs and benefits
- Applying the principle of 'Prevention is better than cure'

44. Established in 2009, Animal Health Ireland[13] (as referenced on p1) provides one model where enhanced industry engagement has been facilitated in an Irish context.

[9] http://www.agriculture.gov.au/ag-farm-food/levies/rates/cattle-livestock-transaction
[10] https://www.animalhealthaustralia.com.au/what-we-do/emergency-animal-disease/ead-response-agreement/
[11] https://treasury.govt.nz/publications/risa/regulatory-impact-statement-bovine-tuberculosis
[12] https://www.agriculture.gov.ie/media/migration/animalhealthwelfare/nationalfarmedanimalhealthstrategy/NFAHS110717.pdf
[13] http://animalhealthireland.ie

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