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ADVISERS TO MANAGEMENT

Animal Health Australia

Review of
the National Bovine Johne's disease ('BJD') Strategy:
First Discussion Paper
on a recast National BJD Strategy

Draft for discussion purposes only
Not for release or publication

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Foreword and Introduction

1

This document is the first of a series of iterative and cumulative discussion papers intended to lay the substance and structure of a recast, national bovine Johne's disease ('BJD') strategy as part of a thorough review of current arrangements surrounding the management and control of the disease.

2

The document and the positions expressed in it are intended for consultation and discussion purposes only. No statement expressed in it has executive force any more than they represent agreed policy.

3

That said, the document puts forward a number of important propositions for debate and active consideration as part of the national BJD strategy review and reconstruction process. The propositions, and the rationale for those propositions, will provide the reference material for a critique by the Expert Reference Group during forthcoming workshops.

3

4

Together with the material generated as part of the wider consultation process, the Reference Group critique will serve to formulate increasingly detailed versions of the recast, national BJD strategy that will ultimately take the place of current BJD management and control arrangements.

5

The propositions contained in this document make reference, as appropriate, to the current, Animal Health Committee-endorsed, *Standard Definitions, Rules and Guidelines for the control of cattle strains of mycobacterium paratuberculosis in cattle and for goats, deer and camelids*, 8th edition, May 2012 (the 'SDR&Gs').

6

The various propositions put forward in this discussion paper have their roots in the views and comments offered during two earlier workshops. The first, a widely-attended forum, was held on 16 February 2015; its outcomes were recorded in a *Record of Proceedings* (12 March 2015), since circulated to participants and interested parties by Animal Health

Australia. The second, directed at the Reference Group, was held on 17 February 2015; its proceedings were recorded in the same manner in a document dated 31 March 2015 and subsequently released to members of the Reference Group.

7

Frequent reference is made in the present document to the two *Records* mentioned above, as their substance provides much of the raw material upon which the propositions offered in this paper are based. That notwithstanding, the propositions extend the reasoning and extrapolate from the views advanced in the two *Records* in order to produce what will be, if accepted, the foundation of the recast national BJD strategy.

8

As with any call for change (particularly where the contemplated change is extensive, as is the case here), a measure of open-mindedness and a willingness to suspend disbelief until the entire proposal is heard are pre-requisites for success. Readers are therefore asked to consider the *sum* of the propositions set out in this document. As in any edifice, physical or conceptual, the strength of the whole derives from the sum of its parts. Equally, there should be recognition that the matters offered for review in this document represent a work in progress rather than definitive positions.

BENOIT TRUDEAU
Managing Director,
Trudeau & Associates
13 April 2015

4



Essential Reference Marks

1

The material set out in the next section of this paper rests on widely-recognised calls for change to current arrangements for the management and control of BJD nationally. Appearing below are key extracts from the two Records of Proceedings mentioned earlier. They are restated here because all else proceeds from them.

On the effectiveness of current arrangements

2

*'It is recognised that the National BJD Management Strategy, as it is applied, is fostering behaviours contrary to the interests of participants in the production chain by driving the disease (and information about it) underground. The consequences of the phenomenon are significant: obfuscation, dissimulation and perversion of the system; compromised disease surveillance programs; corruption of the integrity of information and knowledge about the disease; compromise of the quality assurance system; discouragement of participation in surveillance and disease monitoring and management programs; and a general increase in disease-related risks.'*¹

5

On the need for change

3

*'There is strong support for a thorough review and recasting of the present strategy in favour of a better-considered, better-framed, better-targeted, simpler and more consistent BJD management regime than the present one – one based less on regulatory interventions than it would be on producer-driven management of BJD situations, within a wider biosecurity-inspired and trade-reconciled perspective.'*²

On the desired general attributes of a recast BJD strategy (Item 1)

4

'The strategy must be recast so that it promotes open, consistent, science-driven, risk-based, producer-empowering and voluntary participation in a disease containment effort that nonetheless gives trade imperatives and sensible, light regulation their due. Put succinctly, the recast BJD

¹ Record of Proceedings, Open Workshop of 16 February 2015, item 17, p7

² Ibid., p8

management strategy must be demonstrably consistent (with itself and with the treatment of other similar diseases) and 'fit-for-purpose' (i.e. cognisant of all costs and benefits of its application).³

On the desired general attributes of a recast BJD strategy (Item 2)

5

'[The strategy should]...act as a positive, supportive and effective instrument towards the management of a disease with limited clinical impact – i.e. that it works to enhance producer participation in disease monitoring, management and control, rather than discouraging it through the onerous, draconian and punitive regime it can visit on the owners of properties where the disease is found.'⁴

On the more specific objectives of a recast BJD strategy

6

'[The strategy should]...

- *Bring about greater consistency as to the manner in which the management strategy addresses BJD compared with other listed, notifiable diseases*
- *Approach the management of BJD as part of a wider, better-integrated biosecurity promotion, education and management effort*
- *Take a clear position on the pernicious issue of a possible tie between BJD and Crohn's disease given the absence of conclusive evidence in the matter, so that the existence of a relationship between the two is set aside until such time as compelling evidence positively and conclusively warrants otherwise*
- *Recognise explicitly the different sets of interests at work in the management of BJD, from the economic, commercial and political to the scientific and epidemiological, giving them their appropriate due, yet anchoring the strategy in sensible, 'light-touch' regulation*
- *Remove as many as possible of the inconsistencies and discrepancies that exist in the interpretation of the national BJD management framework between jurisdictions in favour of simpler, uniform approaches and measures*
- *Produce a better, more positive balance between the interests of the producer and those of the jurisdiction (via its regulators), in favour of the former – effectively redressing the current skew to the latter and lessening the weight of the regulatory burden in the process*

6

³ *Record of Proceedings*, Reference Group Workshop of 17 February 2015, item 6, p7

⁴ *Ibid.*, item 8, p9

- *Make clear the connection between BJD and trade requirements, taking care to explain (a) the nature and reach of the obligations associated with each of the links in that chain and (b) the connection of jurisdiction-based regulation with those obligations and their interpretation. In short, the strategy should recognise the stakeholders involved, their particular interests and the instruments that reflect the nature, extent and limits of their participation in the production chain*
- *Take a producer's property as the reliable (i.e. 'verifiable') point of reference in disease management approaches (e.g. certification) rather than the less reliable, more open-ended (and thus contentious) 'zone' concept⁵*
- *Recognise the benefits and limitations of testing for BJD and the reliability of the results it produces to give testing its appropriate weight in the disease management armoury*
- *Settle on the approach to be taken with regard to the manner in which the different strains of Johne's Disease ('B', 'C' and 'S') are dealt with under the recast strategy*
- *Encourage and support well-targeted, on-going research into BJD, in search of meaningful advances in the management of the disease*
- *Recognise the commercial, social and personal costs visited on producers whose properties are BJD-affected through the application of the BJD management strategy, to ensure that approaches and measures assist a return to normal operations rather than isolate under a long, often imprecise 'sentence' of isolation.'⁶*

7

The statements above are a fair record of the views arrived at through the discussions held during the February 16 and February 17 workshops. As such, they represent valid starting points for the propositions set out in the pages that follow.



⁵ That being said, there may be support, in well-defined circumstances, for some low-risk areas to be designated as 'low-risk', *provided* herds within these areas can be verified as 'test negative' and the designation and on-going maintenance of the low-risk status are industry-driven (rather than regulation-driven).

⁶ ⁶ Ibid., item 8, p8

Towards a Recast National BJD Strategy: Four Propositions concerned with fundamentals

Purported Link to Crohn's Disease (1-2)
Consistency of Approach (3-5)
Consistency of Application (6-11)
Strains of Johne's Disease (12-20)

Purported Link to Crohn's Disease

1

A supposed link to Crohn's disease has woven its way into the BJD management argument, a vague fear-shadow that indirectly adds weight to (and has frequently underpinned) arguments in favour of restrictive policy. Good strategy, like good policy, rests on fact – not supposition, and not unsupported hypothesis.

2

As no conclusive evidence has yet come to light as to the existence of any such link, we propose that:

The updated national BJD strategy set aside any reference to a putative link between BJD and Crohn's disease until compelling evidence of such a link is brought forward.

Consistency of Approach

3

We like logic to be the hallmark of policy and regulation. Logic, however, demands consistency. Where consistency fails in an argument, so do its strength and its defensibility.

4

The approach taken to the management and control of BJD under current SDR&Gs (and the associated jurisdictional interpretations) is not consistent with that taken to other endemic animal diseases in this country. The present approach is more interventionist and regulation-heavy than is the case for other endemic diseases, with questionable justification for the marked difference in that approach.⁷

5

As consistency of approach makes for credibility – and credibility, in turn, for the readier adoption of recommended management and control approaches, we propose that:

The updated national BJD strategy should treat BJD in a manner analogous to that with which we apply to the management and control of other endemic animal diseases.⁸

Consistency of Application

6

The current 'SDR&Gs'⁹ rest '*...on **nationally-accepted definitions, standards and guidelines for the management and control of bovine Johne's disease in Australia.***' They are designed '*...to assist disease control and management in a **nationally-coordinated manner.***' They describe '*...the tools and how they must be **consistently applied** to regulatory control and how they may be applied for risk-based management.*¹⁰

9

7

The 'national' character of their intent notwithstanding, the SDR&Gs are but '*...guiding principles and practices upon which industries and state and territory governments can formulate **disease control and management programs to suit their circumstances.***' The SDR&Gs also allow that '*...supplementary detailed operating procedures for implementation of Johne's disease control programs **may be developed by animal health authorities in each state and territory.***¹¹

⁷ The statement assumes, of course, the recognition of BJD as an *endemic* rather than *exotic* disease. The distinction is a material one, as the approach to the management and control of an endemic disease will differ significantly from that of an exotic one, with the latter often invoking far more stringent, emergency-like responses than those called upon to deal with an endemic disease.

⁸ Alternatively, if variation in approach there is to be, that the rationale for such a variation be sounder in logic, more transparent in its rationale and national in its application than is the case at present.

⁹ Animal Health Australia, 8th edition, 2012

¹⁰ Introduction, *BJD Standard Definitions, Rules and Guidelines for the control of cattle strains of Mycobacterium paratuberculosis in cattle and for goats, deer and camelids*, Animal Health Committee, Edition 8, May 2013

¹¹ Ibid.

8

The spirit and intent of the present SDR&Gs are avowedly national. Their practice, however, is undeniably and materially jurisdiction-driven in accordance to various imperatives, many of them trade-inspired and motivated.

9

Jurisdictional imperatives act as the prism through which the SDR&Gs are interpreted and adapted. Varieties in interpretations translate to significant differences in the approach taken to the management and control of BJD from one jurisdiction to the next, thereby weakening the notion of a national framework while producing inconsistencies in the treatment of parties whose herds are affected by the same disease.¹²

10

These inconsistencies in treatment give rise in turn to damaging perceptions of inequity (and, by inference, of policy failure) among affected producers: some are seen to pay dearly for the misfortune of a BJD visitation upon their herd, while others are able to manage the same event with far fewer ill effects. Not all are thus 'equal at law', and the injustice weighs heavy on the minds of those affected.

11

In the same manner that we argued earlier for greater consistency of approach, we now propose that:

10

The updated national BJD strategy should significantly reduce (and ideally remove altogether) inconsistencies of approach between jurisdictions – inconsistencies that produce material disparities in the treatment of producers whose herds are touched by BJD, irrespective of geographic location.

Strains of Johne's disease

12

Reference is made to the following statement in the Record of Proceedings from the Reference Group workshop:

¹² Some of the differences may also stem from a view that considers BJD to be an exotic rather than endemic disease. See item 4 above and its accompanying footnote (7).

'The strategy must articulate its position on Johne's disease with regard to its 'B', 'S' and 'C' strains and, in particular, the underlying assumption as to the inclusion or exclusion of strains other than bovine from its ambit.'^{13 14}

13

Mycobacterium paratuberculosis has three major strains: the 'C' strain affects cattle, the 'S' strain, sheep while a 'B' strain has been found in bison.

14

While the strains are different and generally 'stick to their host kind', there is evidence of cross-species infection.

15

To quote Animal Health Australia:

*'While cross-infection between species can occur, different strains of the bacteria cause infection in different animals. The strain of bacteria mainly affecting cattle, goats, camelids and deer in Australia is known as bovine Johne's disease (BJD). The sheep strain of the bacteria is called ovine Johne's disease (OJD). It has also infected goats in Australia.'*¹⁵

And further:

*'Bovine Johne's disease is genetically and epidemiologically a different disease entity to that in sheep under Australian grazing conditions. On the basis of ongoing monitoring of the cross-infectivity of strains of *M. paratuberculosis*, cross-infection between sheep and cattle in Australia is considered to be a rare event.'*¹⁶

11

16

Under current policy and arrangements (including the present SDR&Gs), the strains are addressed individually (i.e. separately), even though cross-infection (a) is possible and (b) has occurred.

¹³ *Record of Proceedings*, Reference Group Workshop, 17 February 2015, item 13, p13 and accompanying note (see also footnote below)

¹⁴ The decision requires separation of epidemiology considerations from those that inclusion of other strains would pose to zone designations and associated certifications for certain lines of overseas exports. This is one of the reasons behind the call for the strategy to identify the different sets of forces and interests at work in BJD management and map their interplay, so that the strategy can answer each according to its type, rather than have them work unrecognised in a clouded mix of imperatives (see items 23 to 25 later in this section)

¹⁵ *What is Johne's Disease?*, Animal Health Australia Web site, April 2015

¹⁶ *SDR&Gs*, Animal Health Committee, Edition 8, 2012, p2/59

17

The 'S' strain is considered endemic in the sheep flock. Since 2007, management and control of the disease is no longer subject to regulation in any Australian jurisdiction. Contrary to the situation with beef, ovine Johne's disease is not an inhibiting factor in the export trade of live sheep.

18

A 'pure' biosecurity focus might see cause to widen the ambit of the present *bovine* Johne's disease program to have it become a national, 'all-strains' *Johne's disease* program, effectively 'admitting' the 'S' strain of the disease into the 'C' strain 'arena'.

19

The consequences of such a shift would have extensive ramifications for many properties and producers where co-grazing of sheep and cattle have occurred. Technically speaking, the producers in question could well find themselves unable to access the export markets they presently trade with on the basis of (a) cattle grazing on acreage where infested sheep have grazed, and (b) the risk of strain cross-infection.

20

The recast policy should make clear its position on the matter. In that regard, and considering (a) the number of instances of cross-species infections, (b) the extent of changes already contemplated in respect of the management and control of bovine Johne's disease and (c) the extent of the ramifications involved in making the present bovine strategy an 'all-strains' strategy, we propose that:

12

The updated national BJD strategy should, in its next iteration, (a) maintain the separation between bovine and ovine Johne's disease – and thus the separation of the associated management and control strategies; (b) acknowledge the risk of such cross-infections occurring; and (c) encourage the active management of the risks involved through biosecurity education and practice improvement initiatives.



Towards a Recast National BJD Strategy: Four propositions concerned with operational matters and their underlying constructs

Distinguishing disease management and control priorities from trade priorities (1-6)
Re-balancing state responsibility and producer responsibility
and the question of self-determination (7-16)
Territorial constructs, risk ownership and risk management regimes (17-29)
Recognising export trade requirements:
Exploring the responsibilities of the producer and those of regulatory authorities (30-36)
In closing... (37)

13

Distinguishing disease management and control priorities from trade priorities

1

Reference is made to the following statements in the Records of Proceedings from the Open Workshop and Reference Group workshop:

*'The answer to a problem must match the nature of that problem. In the eyes of many however, present BJD management arrangements fail to do that, offering instead a mixed and confusing response that seeks to shoehorn and reconcile political, jurisdictional, economic, trade and commercial considerations into what is, in essence, a science-based, epidemiology-driven solution.'*¹⁷

And

*'The recast strategy must make clear the influence and interplay of political, economic, commercial and epidemiological imperatives on the management of BJD and on the weighting of some factors over others (as a matter of practice) between jurisdictions, particularly where trade considerations come into play (whether concerned with overseas trade or inter/intra-state trade).'*¹⁸

¹⁷ Record of Proceedings, Open Workshop, 16 February 2015, items 28, p12

¹⁸ Record of Proceedings, Reference Group Workshop, 17 February 2015, item 23, p15

And

*'Without prejudice to the legitimacy of trade considerations, it is important to the quality and integrity of the new strategy that the influence of such considerations on the BJD management regime is made clear and differentiated from epidemiological considerations. Failure to distinguish the two engines at work in the BJD management regime weakens the underlying logic of the construct, dilutes the clarity of purpose and makes for potentially significant variations in application.'*¹⁹

2

A significant proportion of the difficulties associated with the current national management strategy for BJD and its translation in various jurisdictions arises from the failure to distinguish epidemiology considerations on the one hand and trade considerations on the other – or, if they are recognised, allowing them to be subsumed one into the other without distinction.

3

The resulting 'entanglement' of the two types of imperatives compromises the appropriateness of the response by satisfying neither effectively. Response to the management and control of a disease is one thing; response to an economic threat, another – even if the second proceeds from the first.

4

That the two matters (i.e. disease management and trade considerations) tangle in practice is well demonstrated by the line of reasoning which argues that:

*'...the higher the risk of loss of market access in the future due to BJD, the more appropriate the Protected Zone scenario becomes. The lower the risk of loss of market access, the more appropriate the management zone scenario becomes.'*²⁰

5

One of the consequences of the interaction is that, under present arrangements, the unexpressed overlap between the two makes for a contest between them, with the producer at the centre of the conflict and his or her property the battleground for it.

6

When it comes to distinguishing disease management and control from trade priorities, we propose that:

¹⁹ *Ibid.*, item 24, p16

²⁰ *Bovine Johne's Disease Program Review: Future Directions*, Independent Review, Finlay, B. and Hill, J. Prof., April 2013

The updated national BJD strategy should articulate a clear and crisp definition of its intent and focus by: (a) distinguishing disease management and control matters, which are its unquestioned remit, from trade-related imperatives, which will vary from one jurisdiction to another as well as by type of trade; and (b) giving trade considerations their due and proper place by explaining the link (and separation) between the two.

*Re-balancing regulator responsibility and producer responsibility
and the question of self-determination*

7

Reference is made to the following statements in the Records of Proceedings from the Open Workshop and Reference Group workshop:

*'The present strategy places the onus and the primary responsibility for the management and 'control' of BJD situations largely in the hands of regulatory bodies, with the producer whose property is affected relegated in the main to a reactive role. The future strategy should shift the disease management responsibility (and the associated management choices) to the producer, effectively returning to him or her the ability to consider well-defined (regulation-backed, as appropriate) options (i.e. the 'ways forward' referred to earlier) and choose between them, should BJD manifest in the herd.'*²¹

15

And

*'One of the chief contributions of a recast national BJD strategy must be its emphasis on the producer and, in particular, the ways by which the owner of a BJD-affected property can return to his trading of choice (or, failing that, make use of such trading opportunities as may remain open to him or her) as quickly and effectively as possible – i.e. with minimum emotional trauma, disruption to business, financial hardship and social dislocation.'*²²

8

One of the chief ramifications of a high-regulation system is its proportionately negative effect on individuals' ability to take responsibility for their actions and manage the situation in which they find themselves, generally through no fault of their own. Put succinctly: the higher the degree of regulation, the higher the likely need for regulator intervention, and the lesser the degree of self-determination the parties whom the regulations affect can exercise.

²¹ Record of Proceedings, Open Workshop, 16 February 2015, item 39, p15

²² Record of Proceedings, Reference Group Workshop, 17 February 2015, item 3, p10

9

The application of quarantine orders is the severest of jurisdictional interventions. The lineage of quarantine orders is two-fold. First, quarantine has a long association with dangerous epidemics; its use thus seems out of place in the case of BJD, a last-resort instrument drawn in response to a generally low-grade, slow-moving and slow-burning threat – epidemiologically-speaking at least.

10

Second and more specifically, the recourse to quarantine in the BJD scenario is the direct product of the zone construct: a territory that is deemed ‘free’ of BJD or ‘protected’ from it will demand intervention from its guardians when a suspected threat to that status arises. When this occurs, the response to the threat is often a quarantine order, with its trace-back and trace-forward implications.

11

In practice, quarantine-driven interventions are immediate and stringent in their effect; they are also far-reaching, long-lasting – indeed punitive – in a range of non-disease related ways: for the producer’s business, for the reputation of that business and for its financial viability; and for the social and personal consequences the persons involved endure. Significantly, producers under quarantine orders lose the greater part of their ability to determine their business future.

12

One of the important conclusions from the two February workshops is that the recast BJD strategy should give preference to self-determination over regulation-driven intervention. Essential to the success of such an approach is, of course, the availability of informed guidance to the individual (the producer in this instance) as to the courses of action open to him or her in their particular BJD circumstances via approved pathways to a range of trading options:

‘[The strategy] should maintain the ability of the owners of BJD-affected properties to continue trading (selling and purchasing) in line with the opportunities still open to them, albeit that they, the owners, would do so under a requirement of full disclosure as to the state of health of their cattle to prospective trading partners, through an appropriate form of verifiable (i.e. evidence-based) health statement.’²³

13

Where the balance of responsibility between regulator and producer in the management of BJD is concerned, we propose that:

²³ Record of Proceedings, Open Workshop, 16 February 2015, item 9, p12

The updated national BJD strategy should: (a) rest on a basic tenet and default position of self-determination for producers whose herds are BJD-affected; (b) guide and assist producer self-determination through science-based, jurisdiction-consistent and trade-adjusted pathways that, if followed, allow producers to manage and control BJD in their herd; limit the spread of the disease (typically as part of biosecurity practices); and, most importantly, allow the producer to manage his or her future with neither penalty nor stigma.

14

The principle of self-determination should be a cornerstone of the recast national BJD management and control strategy. Joined to a different construct in regard to risk management (see below), the combined effect of a different approach to disease management and disease risk management will provide the foundation for a fairer, simpler, more consistent, more transparent, more effective and much less onerous approach (for both producers and regulators) to the management and control of BJD nationally.

15

As noted in earlier documented discussions, a collaborative approach between regulators and producers is a pre-condition of the success of a voluntary scheme. At the heart of such a scheme and collaboration lie clear, science-based, regulation-cognisant decision trees ('pathways'):

*'The new strategy should, among other things, offer as clear and straightforward as possible a clear, science-based 'decision-tree of choices' which, besides informing the affected parties as to the options before them, would also empower them to respond, within defined parameters, to their situation.'*²⁴

And

*'Specifically, the strategy should protect the ability of affected parties to settle on a preferred course of action within a sound risk-based, property-focused framework. The BJD status of a property notwithstanding, it should enable producers and purchasers to transact business within understood parameters.'*²⁵

16

Risk management matters and the associated territorial constructs are discussed in the next section.

²⁴ *Record of Proceedings*, Reference Group Workshop, 17 February 2015, item 4, p10

²⁵ *Ibid.*, item 5, p11

Territorial constructs, risk ownership and risk management regimes

17

‘Territorial constructs’ refers to the range of bounded overlays intended to reflect the prevalence, however assessed or measured, of BJD in certain *geographic* areas.

18

Under current arrangements there are four major types of territorial constructs. Variouslly termed zones, areas and compartments, they are defined in the SDR&Gs. They are:

- ‘Free’ zones
- ‘Protected’ zones
- Beef-protected areas, and
- Management areas.

19

In addition, the four constructs admit a further, secondary, species-driven distinction, i.e. between cattle and dairy, with the latter finding its place in the taxonomy as a ‘dairy compartment’ within a beef-protected area.

20

From management areas to free zones, the constructs are intended to reflect the relative prevalence of BJD. As such, they relate to the perceived risk of BJD infection in a given space, from a higher, prevalence-defined risk rating in management areas to a lower one in protected zones and an even lower-to-negligible one in the areas identified as ‘free zones’.

18

21

For all their conceptual nature, these territorial overlays are powerful constructs. Under current arrangements, they invoke significant differences in the type or ‘style’ of the regulatory regime they attract: compulsory versus voluntary in approach, regulation-heavy versus regulation-light in application and focussed on regulator interests versus producer interests, all depending on the associated risk rating.

22

In short, the use of the territorial constructs has major implications for the manner in which producers in different parts of the country experience the supposedly uniform framework designed to manage and control the one, common, endemic disease: *mycobacterium paratuberculosis*, principally in its ‘C’ strain manifestation.²⁶

²⁶ We return to the question of strains later in this document.

23

The difficulty, of course, lies with the ongoing struggle to reconcile the widely and fundamentally different nature of the two conflicting realities at play: on the one hand, the evolving spread of BJD, now contracting or expanding subject to a host of factors, some of them man-made and thus more 'controllable' (like disease awareness and good biosecurity practices of producers, for instance) than others; and, on the other hand, the artificial application of lines to maps and an administrative apparatus that behaves according to their delineations: harsher treatment on this side of the line, easier treatment on that side of it, and yet the identical disease on both.

24

It is a matter of fact that BJD is more prevalent in some areas than it is in others – even a rare occurrence in a few. It is also fair to advance that the greater the prevalence of the disease in an area, the greater will the likelihood be that other animals will contract it; and fair as well to recognise different exposure risks between dairy and beef cattle, given the epidemiology of the disease.

25

When all is said and done however, and stripping the disease management framework of its trade-related overtones, the fundamental question for an incurable, relatively common but low-toll and low local financial impact disease like BJD is one of risk management. Specifically, the manner in which – or the system by which – we opt to manage the risk of the disease spreading to more animals, or from one property to another, coupled with the progress we might make it reducing its general incidence.

19

26

The current framework is a risk management one, albeit a two-tier one: at one level, 'producer-owned' (and driven), biosecurity-supported risk management is the preferred approach to the management and control of BJD in areas of medium to high prevalence. In areas of low prevalence (i.e. the existing protected or free zones), it is the jurisdiction that owns and manages the risk on behalf of cattle-producer constituents; it does so through regulation and intervention, and an eye to the significant value within its borders of the export trade (including the conditions that govern that trade).

27

This shift in the ownership of (or responsibility for) the management of the risk associated with BJD is profoundly consequential and, we argue, the source of much of the difficulties we currently experience and of the observed inequities in producer treatment when BJD is found to be active in their herd(s).

28

In regard to the approach taken to the management of the risk posed by BJD (and the management of the disease when it manifests, we propose that:

The updated national BJD strategy should: (a) recognise the producers (rather than regulators) as owners and managers of the BJD risk in their herd(s) irrespective of jurisdiction – and thus obviate the need for the zone system in a scheme designed for disease management and control (rather than trade); (b) have government resources (including CVOs) and industry assist producers in managing the risk of BJD manifesting in a herd through biosecurity-driven education; (c) have government resources (including CVOs) and industry assist producers in managing the disease, should it manifest nonetheless; and (d) have government resources (including CVOs) and industry support producers' viability through the use of trading pathways that recognise export trading requirements where appropriate.

29

Adoption of this proposition would have four significant advantages:

- It would introduce a single, universal point of focus for the management and control of the disease – i.e. the producer
- It would remove the complexities associated with the current zone- and area-based patchwork of risk sets and subsets, each with its regulatory and administrative regime. In so doing it does away with troublesome differences that emanate from management regime and the inequities that flow from them
- It would remove one of the chief obstacles to the introduction of a genuinely national system of disease management and control
- It would effectively recognise – and separate – two 'tangled' imperatives that, while related, should nonetheless be dealt with separately (i.e. disease management and control on the one hand, and trade requirements on the other).

20

Recognising export trade requirements:

Exploring the responsibilities of the producer and those of the regulatory authorities

30

Let us assume that:

- In any BJD-related scenario (i.e. BJD-free, suspect or infected herd), producers maintain the right to trade their stock in accordance with the tested/declared health status of their herds
- Zones and their associated regulation-driven apparatus (as they exist at present) have been set aside
- Export trade requirements continue to require that animals presented for export must show no evidence of a certifiable disease (and satisfy certification requirements).

31

In the BJD scenario framed by these three assumptions, producer and regulator responsibilities would be as follows:

Producers – Generally

- It is the producer's responsibility to see to the good health of his or her animals and keep diseases like BJD at bay through good biosecurity practices, with the support and assistance of industry and relevant state departments
- Where BJD manifests, it is the producer's responsibility to manage and control that disease by reference to approved, science-based, trade-informed and regulation-backed pathways – again with the assistance of industry and relevant state or territory departments.

21

Producers – When trading

- The producer must meet whatever (BJD-related) health requirements apply to the animal trade he or she wishes to conduct locally, nationally or internationally
- To conduct that trade, the producer must produce to the regulatory authorities the necessary test-based, independent evidence that the animals (herds) offered for a given type of trade to meet the regulatory health requirements for that trade, whether the trade is local, regional, national or international.

Regulatory Authorities – General

- The regulator would provide and disseminate information on BJD (i.e. its prevention, management, control, eradication) and relevant trade-related information (all trade types), in collaboration with industry

- The regulator would assist and support producers in their endeavours to trade in accordance with regulatory requirements, in collaboration with industry
- In cases where BJD manifests, the regulator would respond to the necessary notifiability requirements and assist and support producers in managing and controlling the disease – as well as in managing their on-going operations, in accordance with pathways to BJD eradication (if deemed achievable) *and* to the types of trade that remain open to a BJD-suspect or BJD-infected herd
- The regulator would conduct, in consultation with industry, such animal or herd BJD-related ‘audits’ as it sees fit based on risk profiling – and trace-backs or trace-forwards in those instances where BJD is found in a herd, not with a view to quarantine but in the same spirit of assistance and support as outlined above
- The regulator would ensure that the best science and latest technology are brought to bear on BJD-related matters, including the provision of the necessary testing infrastructure and resources, along with the provision of support for BJD-related support.

Regulatory Authorities – Trading Activity

- The regulator would verify that animals or herds presented for trade (and export trade in particular) are independently certified as meeting applicable (BJD-related) requirements
- The regulator would conduct such confirmation testing as may be deemed necessary or appropriate to complement the independent testing and satisfy (BJD-related) certification requirements.

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The statements offered in (31) above are illustrative and indicative rather than authoritative. They are neither exhaustive nor do they constitute expert statements. They are to be used as working material for subsequent review discussions.

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The model the statements speak to redistributes responsibilities in accordance with the principles and propositions set out earlier. In the process, it does away with a relatively complex and unwieldy BJD management construct and replaces it with a universal, lighter but likely as effective (and far less draconian) approach than that which avails under present arrangements – and one that has two key underpinnings: informed producer self-determination in those instances where BJD manifests and a risk-focussed, trade-supportive, limited-intervention yet regulation-backed role for jurisdictions.

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In regard to the role and responsibilities of producers and regulators in a model based on the principles enunciated so far, we propose that:

Consistent with the producer, property and herd- focussed principles enunciated earlier, the updated national BJD strategy should rely on a producer-centric responsibility structure (a) in which, in ordinary circumstances, producers are required to satisfy authorities, through independent testing, as to the fitness of their herd (or property) for the trade in which they propose to engage – particularly where export trade is concerned; and (b) in which the role of the authorities is to verify that testing and certification, and conduct supplementary, risk-based audits as they see fit; generally, provide assistance and support to producers in understanding and fulfilling the conditions that apply to the type of trade in which they wish to engage; and, where BJD manifests, to assist affected producers in maintaining such operating capacity as is open to them under the regulations governing the trading that can take place in their circumstances.

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The discussion has purposely not dwelt in this iteration on a range of issues associated with export trade requirements as they apply to cattle, including the requirements of foreign trading partners where certain diseases are concerned, the degree to which these requirements are as 'binary' (i.e. 'go/no-go') in effect and practice as they are held to be, the application of such requirements to competitors in other countries where BJD is present, and so on.

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The question is relevant to the recast BJD management and control strategy, insofar as much of the regulatory measures taken in certain jurisdictions respond to such export requirements. It will be examined as part of the next discussion paper.

In closing...

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Subsequent discussion papers will integrate other matters and questions (such as those relating to research and development requirements) canvassed in workshop discussions and documented in the two Records. The propositions raised in this paper are fundamental ones that warrant discussion, refinement and enhancement on the way to their ultimate integration into a recast strategy. As such, they constitute the first 'port of call' in the Reference Group's next deliberations.

