

## Consultation on a New Independent Body for Animal Health

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### Overview

This paper is in response to the Defra Consultation Paper (2009) Consultation on a new independent body for animal health. The current consultation is part of the framework strategy set out by Defra in 2004 in *The Animal Health and Welfare Strategy* (2004). The strategy addresses animal health and welfare by hoping to make “joint working between industry and government a reality”. This involves making joint decisions over the prevention, control and elimination of animal diseases under the vision of a clear understanding of the roles and responsibilities that define the relationship between industry and government. In 2007, Defra published its influential *Responsibility and cost sharing for animal health and welfare: next steps Consultation Paper* Defra, December, 2007. This paper addressed the question of how responsibility should be shared between taxpayers and the main stakeholders. Following the 2007 consultation there were calls for the setting up of an independent animal health regulator. One model was the Food Standards Agency but this was not the only way to go forward with regulation. The current consultation process provides an opportunity to set up a new independent body for animal health that allows stakeholders and the government to co-operate in a common regulatory strategy for animal diseases. The main analysis offered in the paper is that the most effective regulation has to be “sound science” led but also incorporate public perceptions about the value of regulation and gain the trust of the main stakeholders. Successful regulation must have clear

regulatory objectives and place the idea of improvement at the heart of regulatory responsibilities<sup>1</sup>.

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<sup>1</sup> The paper draws on a forthcoming publication by GOLD in the *Journal of Law, Science and Policy*. The examples given here are based on cattle because this is the area of our research, and there will be examples from other livestock species that do not fit with the comments made.

## **The governance of animal disease: how diseases are currently managed and how management has arisen**

In broad terms it is possible to distinguish between three forms of governance of animal diseases.

### *Action taken by the individual livestock keeper.*

This action depends on a number of factors, of which the most significant might be: whether the farmer can readily detect the disease in the animal / herd; whether the disease has obvious economic impact relative to the value of the animal / herd and its products; the likelihood of re-infection into the herd (although this often ignores the fact that new strains introduced might be more virulent than existing strains); whether a treatment is readily available and whether it is affordable. In practice, the livestock keeper's decision will also be influenced by the advice that is available. Veterinary surgeons are presumed to be an important source of such advice, but other sources might be other farmers, breed societies and farming organisations<sup>2</sup>.

Particular to infectious disease is that farmers are not independent in terms of the risk of disease and the impact of interventions. One farmer's management (or mis-management) of an infectious disease affects others farmers' livestock by reducing (or increasing) their risk of exposure to the pathogen. This is not only a farm to farm issue, the risk of infectious disease transmission is influenced by hauliers of food and livestock and livestock products, humans who move between farms, and the use of markets that disseminate animals and potentially their pathogens. That is, there are many actors to consider when attempting control of infectious diseases.

### *Self-regulation by a group of farmers but without government intervention.*

Action taken by the individual livestock keeper might be undermined by inaction or actions by other farmers. Hence, there is a classic collective

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<sup>2</sup> Andrew Hindmoor, "Explaining Networks through Mechanisms: Vaccination, Priming and the 2001 Foot and Mouth Crisis" (2009) 57 *Political Studies* 75-94.

action and free riding situation (i.e. the best action for a farmer depends on what other farmers are doing). For example, if all farmers are vaccinating against BVDV, then the rational action for any individual farmer is to cease vaccination since he is protected by the action of the others. There is also a clear ethical component in relation to farmers who take actions (at a cost to themselves) from which other farmers benefit (so-called 'first movers'). Farmers might attempt to overcome this by banding together voluntarily to regulate a disease in a defined geographical area. This may be easiest to achieve in a geographically isolated area such as an island. These activities may be facilitated and in part organised by veterinarians (either in practice or in academic institutions). Government may encourage such actions, but offer no tangible support.

Interestingly, we know of no examples where such governance has developed spontaneously amongst dairy farmers in the UK, and several examples where attempts to develop such governance, through industry or veterinary leadership, have had, at best, muted success (e.g. BVDV in Shetland (Gunn) and United Kingdom (Brownlie) and EU<sup>3</sup>). Understanding why collective action to control endemic cattle disease in United Kingdom is rare would be a major step forward in developing governance of endemic cattle disease. The recent collapse of the Dairy Farmers of Britain co-operative might be instructive in this context. The question of co-ordination between farmers is discussed further below.

### Government intervention

A range of policy instruments have been used at different times to manage and assist control of some diseases at a national level. These include culling of affected animals with compensation to the owner; culling affected wildlife considered to be a disease reservoir; controlling movement of animals,

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<sup>3</sup> Gunn, G.J., Saatkamp, H.W., Humphry, R.W. and Scott, A. (2005) 'Assessing economic and social pressure for the control of bovine viral diarrhoea virus', *Preventive Veterinary Medicine*, 72, 149-162.

including pre-movement testing for presence of infection; research into the transmission of diseases and their treatment; provision of vaccines below cost price and creation of bodies to provide advice and mediate between conflicting interests and perspectives. In the case where a pathogen has a wildlife reservoir, some form of public (government) control is likely to be critical, especially if the reservoir species has legal protection, as in the case of badgers and bovine TB.

Animal diseases are generally considered separately. As we discuss below, the motivations for government intervention are different for different diseases, and presumably there is similar heterogeneity between diseases in the motivation for farmers to take individual or collective action. However, diseases are not themselves independent, so that an intervention that is designed to address a particular disease (e.g. pre-movement testing for bovine TB) will, generally, change farmer behaviour in terms of animal movement, and consequently alter the epidemiology of other diseases for which animal movement is an important factor. Consequently, in considering governance of animal disease, it is an error to consider them separately when the actual target for regulation and improvement is animal health. However, it is usual for individual diseases to receive different treatments – it is perhaps only the individual farmer than takes a more holistic view (i.e. considers all diseases, health, welfare and economics simultaneously). It could be that one of the sources of failure of animal health policy at the aggregate levels of government and industry is the difficulty of taking a holistic perspective.

## **Motivations for government intervention**

Motivations for government led control arise from the impact of the disease on humans and animals and the nature of the pathogen. Public health was a major driver for action on bovine TB in the 1930s. A Medical Research Council reported stated: '2,000 human deaths each year may be ascribed to bovine tuberculosis derived from cows' milk, and at least 4,000 (a most conservative estimate) fresh human cases infected with bovine tuberculosis probably occur.' This particular route of infection is overcome by pasteurisation, although transmission could occur through an aerosol or

consumption of raw milk from an infectious animal. Bovine TB is therefore no longer a major zoonosis, but this has not diminished political interest in the subject. This may in part suggest the importance of 'path dependency' effects resulting from the initial classification of a disease, and, in the case of bovine TB, the role of international legislation. It would also, of course, become a much more serious animal disease if it returned to its early 20<sup>th</sup> century levels when 30 per cent or so of cattle died from TB.

Other factors include the political costs of taking / not taking action on the disease; in particular, whether key stakeholder groups hold positions for or against intervention. The economic impact of the disease, including its impact on international trade, is also a major driver. This seems to have been important in relation to FMD but less so for Johne's disease or BVD. Johne's disease was one of the four diseases included in the wartime scheme known as the Panel Scheme or Four Diseases Scheme and it was recognised as a disease that 'has presented a serious problem in our cattle herds for many years' leading to considerable loss. 'This may suggest that the disease ought to have been tackled earlier. The fact is, however, that it has no public health significance' (J.N. Ritchie, 13 December 1963, National Archives: MAF 287/184). The prevalence of the disease is now much lower, but this probably has as much to do with changes in cattle demography (especially reduced life expectancy) than any concerted action.

It is important to have a readily usable and reliable diagnostic test for a disease and some strategy for treatment, e.g. through vaccination. In the case of bovine TB, an effective vaccine has been promised for a long time, but is yet to be achieved because of the nature of the infection process. We also lack uncontested knowledge about the reservoirs for transmission of the disease and persistence in the environment. 'Johne's disease presents several problems; carriers are difficult to identify; much effort may be required to reduce the spread of the disease, and there is no effective treatment or

wholly effective vaccine.<sup>4</sup> In the case of BVD the technical tools and knowledge for elimination are available, but it has not been accorded a high priority in England.

The political costs of controlling a disease include the public expenditure costs of the measures taken; the time taken by decision-makers (ministers and civil servants) in reaching decisions; personal abuse or threats to those taking the decisions; and the political costs in terms of unfavourable publicity and criticism by stakeholder groups. All these elements have been present in the case of bovine TB. The public expenditure costs of attempting to manage the disease over a seventy year period have been, and remain, considerable. It is estimated to cost approximately £1 billion between 2008 and 2013 and 'takes up 40 per cent of the Animal Health Agency's resources.' (House of Commons, 2008: 12<sup>5</sup>). Considerable ministerial time, up to prime ministerial level, has been taken up with the issue and special working groups have had to be formed by the civil service. Those involved in reports and other studies have been subjected to considerable hostility and personal abuse, including threats against them. Media treatment of policy has been generally highly critical and there has also been outspoken criticism by stakeholder groups, including a private prosecution launched against a minister. The whole topic is highly politicised in an emotional fashion because measures to control the disease have involved the killing of badgers, a highly valued wild animal. The management of bovine TB may be characterised as one of policy failure. The high political profile has also influenced research into TB hugely with many years of work, post the 1970 discovery of TB in a badger carcass, funded only on badgers and a strong belief that this was the area where research was needed. It is only since the Krebs' report in 1996 has research into cattle

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<sup>4</sup> Stott, A. Jones, G. , Humphry, R. and G. Gunn (2005) Financial incentive to control paratuberculosis (Johne's disease) on dairy farms in the United Kingdom *The Veterinary Record* **156**:825-831.

<sup>5</sup> House of Commons (2008) Environment, Food and Rural Affairs Committee, Fourth Report of Session 2007-8, *Badgers and cattle TB: the final report of the Independent Scientific Group on Cattle TB* (London: The Stationery Office Limited).

been highlighted to get a more rounded portfolio of research, through the Independent Scientific Group (ISG). In contrast, Johne's disease and BVD have had a very low political profile.

It might be expected that a cost-benefit analysis could be conducted to determine the economically optimum level of control for any disease, as is attempted for human disease by the National Institute for Health and Clinical Excellence (NICE). In the light of such an analysis, a social planner might decide to live with the disease if the cost of elimination outweighs its benefit (Sumner, 2005). However, the impact of any intervention is unknown at the outset (although the probabilities of its possible outcomes can be predicted), so that stating an objective to eliminate, especially by a particular date, has a clear risk of failure, which will have political and economic consequences. On the other hand, a clear, politically-articulated, date-stamped intention has been suggested to be critical for success of elimination or eradication of human disease, despite the fact that the date is continually moved.

What is evident is that decisions about animal disease management are highly political, although more so in relation to some diseases than others. Although technical advice from vets and scientists is an important component of the decision-making process, that advice is viewed through a political lens which involves a calculation of the costs and benefits to decision-makers of action or inaction.

Once a disease is eliminated, that is removed from a defined region, resources are required to prevent re-introduction into the region. Once a pathogen is eliminated, the perceived threat to productivity and welfare are greater, and may be actually greater since immunity to infection will be lost. Such prevention measures are required until the pathogen is eradicated from the globe. These resources include border control and trade barriers that control any likely source of animal / animal product or human traffic that could lead to accidental or deliberate re-introduction. Consequently excellent monitoring and accurate testing are required to prevent re-entry of a pathogen



and rapid response is required if a re-introduction occurs to prevent the pathogen becoming endemic again. There is a critical timeframe within which this response has to occur and be successful before the pathogens mechanisms for persistence become active and elimination becomes much more difficult.

## **Coordination success and coordination failure**

Disease elimination results in a public good. However, it involves commitments by producers that are difficult to monitor even in the presence of regular monitoring and of financial incentives provided by the public veterinary service. For instance, Great Britain has been following a policy of paying compensation to farmers who report certain types of disease incidence on their farms (see, for instance, SVS, 2006 for sheep scrapie related payments). However, such compensation has not resulted in elimination of the diseases for which the scheme works. Kuchler and Hamm<sup>6</sup> (2000) make a similar observation in relation to compensation payment to encourage elimination of sheep scrapie in the US for the period, 1952-1992. It is not that farmers do not respond to such incentives; they do, but there are other incentive structures at work which counter the effect of such a compensation scheme. In particular, it should be noted that such compensation schemes incentivise reporting, but not elimination – the infected animal has a protected value.

Hennessy<sup>7</sup> (2007) makes the point that farmers have the incentive to make commitments that, if implemented simultaneously by a critical mass, have the potential to eliminate a disease from a country but only if they believe that others also have the incentive to do so. In a market where such a belief is missing, however, an individual farmer might not foresee a benefit but rather a cost from a private action to eliminate disease from their own farm. This

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<sup>6</sup> Kuchler, F. and Hamm, S. (2000), "Animal disease incidence and indemnity eradication programs", *Agricultural Economics*, 22: 299-308

<sup>7</sup> Hennessy, D. (2007), "Coordinating to eradicate animal disease and the role of insurance markets", *Working paper 07-WP 45*, Iowa State University

produces a situation where the disease remains endemic whereby some farmers have to contend with a regular risk of herd infection from neighbours. This points to the importance of signals which indicate the level of commitment among different farmers to disease elimination. According to Hennessy<sup>8</sup> (2007), one way of making such signals available to farmers is through coordination of farmers' efforts which can be achieved, if, for instance, the level of effort expended by individual farmers on disease control is monitored overtime and made publicly available.

Thus, farmers face a coordination problem; both elimination and non-elimination could exist as equilibrium behavioural *conventions* but the efficient outcome may emerge only if it is possible for farmers to commit to contingent (or matching) behaviour or if elimination is not only efficient but *risk-dominant* – in other words if it takes more simultaneous errors or shocks to undermine the elimination regime than the non-elimination regime. This, in turn, may depend on the (social) network structure linking farmers (which e.g. reinforces 'good' behaviour) *and* the epidemiological network linking their herds (which determines the fragility or otherwise of progress towards elimination in local areas). Additionally, robustness depends on the correlation of these two networks; a favourable local epidemiological situation may produce demonstrated success which encourages the diffusion of elimination behaviour (or ambitions) through social networks. Conversely, a favourable social climate (e.g. a cluster that lies also at the heart of the epidemiological network) can change underlying infectivity and thus encourage other parts of the social network to evolve towards elimination.

Hennessy<sup>9</sup> (2007) argues that concentrated farmers are more likely to believe in (and implement) effective coordination than small and scattered farmers as they stand to gain more – both from improved market access and from enhanced productivity as a result of disease elimination. As the above makes evident, one explanation why a certain disease will exist in one country as

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<sup>8</sup> *Ibid.*,

<sup>9</sup> *Ibid.*

endemic emanates from failure to coordinate farmers' and government's efforts to eliminate the disease. Some evidence of these processes can be found by comparing between livestock species. The pig and poultry industry in United Kingdom is configured very differently from the sheep and cattle sectors, and there is a marked difference in the approaches to endemic disease control between the two.

## **Insurance**

An alternative approach to control and elimination of disease is to reduce the economic impact of disease via insurance. Even if a disease is eliminated, then should an outbreak occur, costs will be incurred by all levels (farmers, industry and government) if the disease is to be removed. There are several insurance products which are relevant to the agricultural sector two of which are of particular relevance to livestock diseases<sup>10</sup>. These are:

1. Livestock production insurance: protects farmers from loss and business interruption due to illness or death as well as recover veterinary costs due to on-farm diseases
2. Net revenue insurance: protects farmers against losses from the market place (from productivity loss resulting from livestock disease, from fall in feed quality, and from fall in prices of input and output)
3. Catastrophe insurance: protects farmers against extreme price losses due to the emergence of a disease that correlates with rapid decreases in market prices<sup>11</sup>.

There are five insurability conditions which need to be met in order for a private insurance market to be viable. These are: (1) accidental and unintentional loss; (2) homogeneous and independent loss; (3) feasible private premiums; (4) determinable and measurable loss; and (5) calculable probability of loss.

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<sup>10</sup> Turvey, C.G. (2003) "Conceptual issues in livestock insurance" Food Policy Research Institute, Rutgers University, Working Paper No. WP-0503-005.

<sup>11</sup> However, it is worth noting that both endemic and epidemic disease may increase prices and value of animals, and that price losses need not be caused by disease.

The viability and type of private insurance market depends on the nature of disease and of the potential economic loss specific to the livestock market in question<sup>12</sup>. Firstly, if the disease in question (be it endemic or epidemic) is controllable with proper management then a private insurance market will not be justifiable as all the insurability conditions fail to hold. In this particular instance, the livestock owner can take charge of disease management. This is based on the argument that self-insurance (self-protection) and market insurance are substitutable<sup>13</sup>. Secondly, if the disease is an epidemic with localized outbreaks, then all the insurability conditions are met. In this particular instance, an insurance policy that is appropriate to the disease in question can be designed and marketed. Thirdly, if the disease in question is an epidemic which is geographically widespread then insurability conditions (2) and (3) will not hold but the other three will. In this particular instance, in some cases where the government has already put in place indemnity programmes to cover direct losses, then a private insurance market which caters for livestock owners willing to purchase “wrap around” insurance policies to cover consequential (indirect) losses is possible. In other cases where the government has not put such an indemnity program in place to cover even direct losses in the event of a widespread epidemic, then catastrophe insurance will be appropriate. Fourthly, if the disease is endemic and results in persistent non-random losses, insurability conditions (1), (2) and (3) will not be met for certain even if the last two will be. In this particular instance, private insurance will not be a viable solution. If such a persistent non-random loss forces farmers to exit the industry the most feasible solution might be a scheme which helps make the exit less painful.

In the above discussion, the assumption has been that the insurance cover to be claimed in the case of an epidemic is based on the number of unhealthy animals that are identified and condemned and on the extent of business

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<sup>12</sup> Coble, K.H. and Anderson, J.D. (2009) “Insuring against market disruptions caused by animal disease outbreaks”, mimeo, Mississippi State University

<sup>13</sup> Ehrlich, I. and Becker, G.S. (1972) “Market Insurance, self-insurance, and self-protection”, *The Journal of Political Economy*, 80(4): 623-648.

disruption that results from the epidemic. However, even if there are no animals condemned due to the epidemic, there certainly will be a short term-loss in market value of the healthy animals that are still alive. When this obtains, if the loss is due to a localized quarantine or buyer response, then business interruption insurance can be implemented as all the insurability conditions are met. If, on the other hand, the loss in value is due to a widespread quarantine or buyer response then insurance will not be appropriate. The most appropriate instrument will be a standing market loss (or stabilization) program. The viability of either option, however, rests on the assumption that market prices are observable to allow the calculation of determinable and measurable losses. If, lastly, there occurs a long term loss in market value of the animal resulting from an endemic disease, then insurability conditions (1), (2), (3) and (5) will not be met even though (4) can be. If such a loss triggers exit from the farming industry then private insurance will not be appropriate. To help farmers either to make a smooth transition out of the industry or to undertake restructuring in their enterprise in order to remain in the industry, the government can consider industry exit assistance as an option.

Issues which limit risk insurability from the insurer's side are (1) information asymmetry, i.e. the would-be insured knows more about the risk being insured than does the insurer; and (2) correlation of risk among the insured (**systemic risk**), i.e. many policy holders can face losses at the same time due to livestock epidemics. Insurers can deal with these issues in a number of ways. Firstly, they can insure losses that are not only accidental or unintentional but are also determinable and measurable based on sufficient and reliable data, both real and simulated. Secondly, they can minimize correlated risks by developing adequate reinsurance capacity above a certain catastrophic threshold. This capacity can be developed either by involving the government as a guarantor or by increasing the 'securitization' of reinsurance in the capital market. Issues which limit the demand for insurance, wherever there is potential for acquiring a private insurance policy by farmers, are inaccurate perception of risks and of associated economic costs and existence of

disease related indemnity payments. To deal with these issues the government can consider either subsidizing premium rates and administrative costs or making indemnity payments from the insurance company tax free.

Goodwin and Vado<sup>14</sup> summarize the arguments in favour of government subsidy through reinsurance (1) that it is more efficient as the government has to deal with a handful of banks rather than with many farmers; (2) that by providing reinsurance governments can use the experience and capacity of insurance companies in dealing with moral hazard and adverse selection problems and in handling large numbers of claims; (3) that financial involvement by government might reduce political pressure to provide ad hoc disaster payments; (4) governments have substantial advantages because of their deep credit capacity and their unique position as the largest social entity in a country to name just a few.

It is possible to learn practical lessons from other countries that have had policies of commercial disease insurance<sup>15</sup> for instance, Spain, the Netherlands, Germany, Australia and the US. Even though commercial disease insurance can be viable once the right institutional infrastructure is in place, it is not the only risk management scheme available. Other countries have tried other forms of risk management that are not related to insurance. These include Canada's National Income Stabilisation Accounts (NISA) where the government contributes a dollar for every dollar contributed by the farmer; Australian Farm Management Deposits (AFMD) which does not involve government matching but which allows private deposits into the account to be set against taxable income. These schemes need to be studied in detail to

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<sup>14</sup> Goodwin, B.K. and Vado, L. (2007) "Public responses to agricultural disasters: rethinking the role of government", *Canadian Journal of Agricultural Economics*, 55, 399-417.

<sup>15</sup> Bielza, M., Diaz-Caneja, Conte, C.G., Catenaro, R., and Pinilla, J.G. (2008) "Agricultural Insurance Schemes II, Index insurances", European Commission, EUR 23392 EN/2; Goodwin and Vado, *ibid*

see if there are practical lessons that can be learnt and applied to the UK livestock industry.

## **International trade**

Diseases differ between countries in terms of presence, prevalence and impact. The countries which have eliminated the disease (or in which it was never endemic) have a comparative advantage in international trade because of, all else being equal, a larger volume of animal products they can trade and of a smaller excess burden associated with the disease<sup>16</sup> which they have to bear. Given this economic alignment in international trade, those countries which have not yet eliminated the disease have a relatively lower incentive to avoid engaging in animal trade that facilitates the re-entry of the disease to countries with disease-free status. In this particular case, unless countries with disease-freedom coordinate with those who have not declared such a freedom, they will find it difficult to maintain freedom indefinitely. Therefore in the same way that coordination of farmers' efforts plays a significant role in ensuring disease elimination at the local level, so coordination of countries' efforts plays a role in ensuring regional elimination and global eradication. Such a global coordination is difficult to achieve unless there are international organizations which set disease control standards and enforce them (Barrett<sup>17</sup>, 2003). The formation of the World Organization for Animal Health (OIE) was a result of such calls for standards and enforcement, and, as a consequence of this coordination, the global eradication of rinderpest has been imminent for a number of years.

## **Regulating animal diseases**

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<sup>16</sup> Excess burden is defined as a burden beyond the case reports of disease incidence collected by the public health authority if costly disease prevention occurs (Philipson, 1995).

<sup>17</sup> Barrett, Scott (2003) "Global Disease Eradication", *Journal of the European Economic Association*, 1(2-3): 591-600.

The classification of disease as endemic or exotic, especially for economically significant diseases, is complex and more quantitative than qualitative. It also may give rise to legal implications in terms of controls and procedures. A disease may be classified from (at a minimum) epidemiological, political, policy, legal and economic perspectives. Moreover, the classification may be limited in time, location<sup>18</sup>, species, strain, managed vs. wild populations, etc. Social scientific (e.g. legal, policy, political and economic) classification may further need to distinguish between evidence based assessments and beliefs, perceptions and expectations which may diverge from the available evidence in ways that can affect disease policy and its impacts.

Analysis of animal diseases in terms of prevention and cure is interlinked with the question of how best to regulate animal health. Defra has been actively engaged in a number of consultations and deliberations. Beginning with the inquiry into the foot and mouth outbreak in 2001 under Sir Iain Anderson<sup>19</sup>, there have been a number of working parties and public consultations, some of which are ongoing<sup>20</sup>. The current Consultation on a new independent body for Animal Health (June, 2009) should take account of the main issues outlined above. Designing the most appropriate regulatory regime for animal health and welfare requires careful consideration to ensure the “right fit” between the design of the best regulation and the requirements for animal health and welfare<sup>21</sup>. It is clear from the Government’s consultation process that there are a number of goals in the regulation and governance of animal health. These are to:

- Reduce the overall levels and total costs of animal diseases;
- Ensure that investment in disease prevention and management is effective, efficient and economical;
- Share costs between main beneficiaries and risk managers;

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<sup>18</sup> Market segment, geographical or political region, epidemiological area, etc.

<sup>19</sup> Foot and Mouth Disease, 2001: *Lessons to be Learned Inquiry Report*, 22<sup>nd</sup> July 2002 HC 888.

<sup>20</sup> Public consultations are in 2006 and 2007 and there is a United Kingdom Responsibility and Cost Sharing Consultative Forum.

<sup>21</sup> See: Peter J. May, “Regulatory regimes and accountability” (2007) *Regulation and Governance* 8-26. C.Scott, “Accountability in the Regulatory State”, (2000) 27 *Journal of Law and Society* 38-60.



- Improve confidence of the livestock industry and that of other stakeholders in the way disease risks are managed.

It is clear that sharing costs and introducing any form of independent regulator will substantially alter the largely self regulatory nature of the current arrangements. Cost sharing is likely to mean that livestock owners gain financial responsibilities that were hitherto largely held by government through subsidy and support. This will empower livestock awareness but also require a much more open debate and informed decision-making; a substantial departure from the lobbying stance taken by stakeholders in the past. The Government has an expectation that any new regulatory structure will have the following benefits:

- ensure more independent and better informed decision making;
- increase the involvement of livestock awareness amongst farmers and other key stakeholders;
- provide incentives to reduce the cost of managing disease;
- provide incentives for better risk management and;
- ensure greater financial transparency and accountability in the livestock industry.

The regulatory proposal is to transfer Defra's current animal health policy responsibilities to a new regulatory body. The new body is likely to have a Regulatory Board with the Government Chief Veterinary Officer as an adviser and employed by the regulatory body. Decision making is intended to be based on the best evidence and a proportionate response to risk, balanced by costs and benefits.

A number of aspects of the proposed regulatory body are to be continued as is currently the case within Defra, such as the doctrine of ministerial accountability to Parliament and public funding through public funds as a grant in aid. There is, however, an expectation, on the part of the Government, that there should be accompanying funding for the regulatory body to support 50% of the costs of tackling exotic disease outbreaks. The Government's agenda to create a regulatory agency provides an important

opportunity. In terms of animal health and welfare, it is essential to locate scientific advice at the heart of policy making. In that respect the key proposals are that:

- Animal health and welfare policy will be the responsibility of an independent board;
- The Chair and Chief Executive of the proposed new regulatory body will make decisions about how to tackle disease outbreaks based on advice from the Chief Veterinary Officer. This will include advice on vaccination and controls over animal movements;
- The decision-making and policy making underlying strategies to control exotic diseases are transparent and open.

The above proposals are worthwhile. Their significance is that if properly implemented it will be possible for scientific advice to be at the heart of decision making. There is also a link between prevention and treatment of diseases and also a prospect of greater coherence in how animal health policy responsibilities are reached and communicated to the public. One of the key elements of the new proposals is that welfare policy is to be made "... balancing a wide range of different societal interests, and taking into account ethical as well as scientific concerns"<sup>22</sup>. This will also include close working relations between Defra and the new regulatory body. There must also be appropriate and effective communication with farmers. It will also have to engage with the public and the public interest. How are scientific decisions likely to be made? The Consultation Paper is clear as to the principles that should govern the operation of the new regulatory body. These are:

- Action informed by the best available scientific evidence and advice;
- Decisions and actions should be consistent, clear and proportionate to the risk; pay due regard to costs as well as benefits to those affected by them; take into account Government's wider objectives, particularly related to welfare; and assist better regulation;

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<sup>22</sup> Defra, *Consultation on a new independent body for animal health* (Defra, 2009) P. 15.

- Action should be independent of special sectoral interests.

There are also principles of ministerial accountability, the role of EU law and also the significance of value for money through effective and efficient operations.

There are a number of additional matters that should be directly addressed in the new regulatory framework<sup>23</sup>. These are:

- protecting and promoting the public interest;
- supporting and encouraging an independent, strong and effective profession surrounding the provision of animal health and welfare primarily through the State Veterinary Service;
- increasing public understanding of animal health and welfare;
- to set performance targets for the regulator that take account of the public interest and engagement with stakeholders;
- to provide financial and administrative transparency in the use of public and private money in the provision of animal health and welfare;
- to engage with sound science and through the public understanding of science engage with public understanding of animal health and welfare;
- to consult with relevant stakeholders and the public.

Creating the central role for scientific analysis and advice is critical to the success of the new agency. Ensuring that science is based on the best available scientific evidence and analysis requires care and may be partly achieved through peer group review. Sound science is likely to be contested and overshadowed when it is at the centre of policy and economic considerations. It is therefore essential that safeguards are in place to ensure

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<sup>23</sup> One example of creating a new regulatory framework is the Legal Services Act 2007 and the creation of the Legal Services Board that requires engagement with the current regulatory system under the Law Society and the Solicitors' Regulation Authority (SRA). Another example is the recent regulation of Forensic Science.

that the science operates in an environment that allows and creates interdisciplinary collaboration successfully.

### *Designing the Regulatory Regime*

There are significant regulatory issues at the forefront of animal health and welfare policy strategies. These relate to the independence of the regulators, regulation policy and implementation strategies. The Government's proposal is for the new body to follow the model of the Food Standards Agency and fall within the category of a Non- Ministerial Department. This would mean that funding would be voted directly by Parliament and the new agency would operate through the Treasury or Defra. The advantages of this model are that it provides the agency with an independence from the sponsoring government department and a direct link to Parliament in terms of accountability and transparency. It is estimated that the costs of the new body will initially be £2 million with running costs of £100,000 annually. There are major issues about funding vaccinations and treatments of diseases and whether an animal insurance scheme might provide animal owners with the requisite protection. In order to secure adequate supervision of animals and disease control, there will have to be a registration scheme. This will be based on livestock keepers providing an annual fee, which will contribute some of the necessary finance to the regulatory agency. Raising levies in this way will provide a link between costs of keeping the animals and the associated intervention to prevent or treat diseases. The basic assumption is that risk management will be inbuilt into the financial scheme. Registration and payments will be interlinked with risk factors associated with the keeping of different animals.

The regulation of animal health and welfare will be connected to a “light touch” regulatory system that follows the Hampton<sup>24</sup> and Macrory Review. The Macrory Review<sup>25</sup> that followed the Hampton Report, was asked to look at the role of sanctions and the functioning of criminal sanctions in

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<sup>24</sup> Philip Hampton, *Reducing Administrative Burdens: Effective Inspection and Enforcement Final Report* London: HM Treasury, 2005.

<sup>25</sup> R. Macrory, *Regulatory Justice: Sanctioning in a post-Hampton World: A Consultation Document* London: Cabinet Office, May, 2006 and *Regulatory Justice: Making Sanctions Effective* London: Cabinet Office, November, 2006.

regulatory justice. This is a critical part of the regulatory system. Regulators require access to a range of incentives and sanctions in order to be effective. The Macrory Review accepted that the existing use of criminal sanctions for regulatory offences was required. He also recommended that a new punitive regulation system was necessary rather than reliance on simple moral persuasion or good behaviour. He recommended an extension of the range and variety of penalties available to regulators. He adopted the principle that a regulators' own sanctioning powers should be used rather than requiring recourse to the formalised use of the criminal courts. Macrory's recommendations were largely accepted by the government. New compliance codes and greater managerial controls are also favoured, in his review, as a way of making the compliance arrangements more effective. The implementation of many of the Macrory Review's recommendations may be found in the Regulatory Enforcement and Sanctions Act 2008. This underlines the shift beyond the criminal courts for the application of sanctions to regulator based systems of sanctions and enforcement. The Act underlines the five principles of regulation set out in Hampton namely enforcement action should be transparent, accountable, proportionate, consistent and targeted. The impact of the Hampton and Macrory Reports is important in setting the future direction for regulation in the United Kingdom and for the new animal health and welfare agency. The Hampton Report reinforces and encourages a targeted approach to regulation that requires all regulators to perform risk assessments and to adopt an effective, efficient and proportionate response which does not place unnecessary burdens on business. The underlying philosophy is that information should only be sought when required. Intervention should be targeted and not invasive to the detriment of market conditions.

The use of scientific data and evaluation in the light touch regulatory regime assumed for the new agency by the government raises issues about enforceability and effectiveness. There is a strong ethos post Hampton and Macrory that unreasonable or excessive regulation may lead to burdens and costs on the regulated activity. The need for prescription has to be balanced by the use of incentives. Linked to costs and burdens are questions about

accountability. Democratic governance requires transparency and public confidence in science and its use by politicians is not high in the wake of BSE, the foot and mouth crisis and perceived high costs and public health concerns over animal diseases. The need for accountability includes:

- high standards in the veterinary profession and public confidence in regulation of the profession, including professional accreditation;
- the accessibility of scientific data and its explanation to the public;
- forms of political accountability that are effective.

Addressing such issues also brings to the fore a long-standing concern amongst critics of regulatory agencies that there is potential for regulatory capture in the operation of the regulator. This may be due to a number of factors such as private interest or lobby groups dominating the operational decisions made by the regulator. This may be particularly the case if one group or sector has a monopoly over the prescription of standards and their enforceability<sup>26</sup>. The solution to concerns about regulatory capture is to ensure transparency and openness in decision-making, the registration of vested interest and the creation of a healthy interface between the different sectors within the regulatory body. There is a key element of consistency in approach in setting and enforcing standards and the enhancement of professional standards within the accountability mechanisms. It is probably impossible to eliminate regulatory capture when the stakes are high amongst farmers, pharmaceutical and chemical companies, vets and supermarkets. Enhancing professional standards may require a close look at the legal regime that accompanies each profession to ensure that professional accountability is strengthened and that codes of conduct are properly enforceable<sup>27</sup>.

### *Approaches to Assessing Regulatory Burdens*

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<sup>26</sup> I Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* Oxford: Oxford University Press, 1992.

<sup>27</sup> M. Dowdle, ed., *Public Accountability: Designs, Dilemmas and Experiences* Cambridge: Cambridge University Press, 2006,

Budgetary costs can be directly estimated using management data sources. Transaction costs for public bodies are not always directly measured, but can often be captured either under indirect costs or from other budget lines (identified on the basis of key informant interviews or written queries). Beneficiary transaction and administrative costs stem from their 'legal obligations to provide information on their action or production, either to public authorities or to private parties.' These are generally evaluated using variations of the Standard Cost Model (SCM)<sup>28</sup>. This is the most widely applied methodology for measuring administrative costs, providing a simplified, consistent method for measuring administrative costs imposed on business by central government. It is based on an activity-based measurement of a business's administrative burdens, and thus provides estimates that are consistent across policy areas and directly attributable to government simplification and other initiatives.

The SCM decomposes the business burden of individual regulations into constituent parts known as information obligations. An information obligation refers to part of a regulation for which a business is required to submit information or data to the competent authority in order to demonstrate compliance with a regulation (e.g. completing forms, complying with inspections or applying for licences for specific activities). The information obligation does not measure costs of complying with the regulation – only the administrative cost associated with demonstrating compliance.

This decomposition makes it possible to measure the actual administrative cost associated with each activity at a detailed level. Costs are generally determined through interviews or surveys of the time required to fulfill regulatory activities of an administrative nature. The SCM estimates the cost of completing each activity on the basis of a few basic cost parameters:

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<sup>28</sup> Ref: Annex 10 of the EU Impact Assessment Guidelines, at:  
[http://ec.europa.eu/governance/impact/docs/key\\_docs/iag\\_2009\\_annex\\_10\\_en.pdf](http://ec.europa.eu/governance/impact/docs/key_docs/iag_2009_annex_10_en.pdf)

- Price: wages plus overhead costs for activities conducted by the business;
- Time: time required to complete the administrative activity;
- External costs: cost of goods or services required to carry out the activity; and
- Quantity: the number of affected businesses and the frequency of the activity.

Combining all of these elements gives the basic SCM formula: Cost (of information obligation) = (Price x Time + External costs) x Quantity

The SCM distinguishes between information obligations derived from the EU and from national legislation using three categories.

- Category A - obligations that are exclusively and completely a consequence of EU rules or other international obligations (for example EU Regulations that specify the information businesses need to produce.)
- Category B - obligations that are a consequence of EU and international obligations whose purpose is formulated in the international rules, but whose implementation is left to Member States (for example EU Directives that let Member States determine how to assess compliance).
- Category C - obligations exclusively a consequence of rules formulated at national level<sup>29</sup>.

The costs of some activities that farms, etc. would carry out regardless of regulatory requirements are known as business as usual costs, and may be included in the SCM data, though to date good data are scarce. The Standard Cost Model is designed to indicate the administrative burdens imposed on business. The estimates are not statistically representative, and should not be treated as such in analysis. Administrative burden data may not always produce accurate, robust results at the individual regulation level, but it

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<sup>29</sup> Although the situation in the UK is complicated by the Devolved Administrations so that rules can be formulated at a sub-national level.



provides a good indication of the relative costs of individual regulations. The benefits of the SCM reside in its ability to produce illustrative data, demonstrating the major 'peaks and troughs' in administrative burdens, and therefore the priority areas for simplification. Furthermore, it enables stakeholders and regulators to set clear targets for the reduction of red tape from an established baseline. As such it is a useful political and administrative tool.

Compliance costs are not captured by the SCM, but can be measured either by interviews or (more rigorously) by econometric estimates. Because regulations and other burdens differ between countries and over time, these costs are best measured using a panel econometric approach, which should take into account changes in business behaviour that can be linked to the policy or regulation. Again, incremental impact is the key; it is not appropriate to attribute to a standard or regulation Information Security measures that businesses would undertake as a matter of course. As with administrative costs, the coverage of direct measures is limited; this is why the panel econometric approach is suggested.

Opportunity cost is the value of the best alternative forgone to comply with the policy requirements. The resources used to implement the changes (e.g. to participate in alternative arrangements for managing security issues) need to be 'priced' in an appropriate way. In general, this is done by means of a suitable external comparator. For investments, this is generally the riskless rate of interest; for labour, it is a (suitably skill-adjusted) wage rate in the local market. As with the administrative costs of compliance, the assessment of opportunity costs must take into account the fact that management of security and related risks is a necessary function for many of the business entities affected, and that this function will have to be supplied in some way. Therefore, the opportunity cost needs also to include an estimate of the costs of changed levels of collective security and the scale and scope economies (if any) associated with the option under consideration. To make this realistic, of course, a suitable counterfactual is required. In general, this is provided by the baseline projection that forms the forward-looking part of the problem

definition.

Finally, third party cost estimates must generally be based on modelling, especially forecasting models of the sectors upstream and downstream from those addressed by the new organisation's activities. In tackling this, it is appropriate to consider the extent of vertical integration and the consequent 'bundling' of disease management with other services.

## Conclusions

We have reviewed animal disease from a number of perspectives, but mostly from the presumption that it is, like human disease, a suffering that should be avoided where possible. An alternative approach would have been to consider the value or worth of animals and what is lost by disease. However, we believe that any approach would reveal the same central message: that animal disease and its control involves a complex interaction between biological and human spheres, of which economics, politics and law are key. To argue from an extreme, it is theoretically possible to eradicate any infection with current scientific understanding and technology – what is missing is the necessary political will and legal framework. Endemic diseases especially, persist biologically, but only because the economic, legal and political frameworks allow them to. These human activities do respond to animal disease, sometimes resulting in elimination of infection, so the “successful” endemic disease is one that (unconsciously) creates its own environment in all spheres. If the ultimate aim is to remove animal disease<sup>30</sup>, then a system needs to be created that is able to appropriately manipulate the biological, political, economic, legal and social factors. However, control of animal endemic disease typically suffers from two opposing problems. First, it does not have the political profile to attract research and surveillance funding to demonstrate the burden of disease, and its economic impact. This lack of data and knowledge prevent its political profile being increased.

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<sup>30</sup> There are biological arguments (the “hygiene hypothesis”) that would argue that infection has beneficial effects, and an economic perspective would argue that this should only be an aim if the benefits outweigh the costs. Consequently, the desired outcomes of an idealised animal disease control system are not simply defined.

Placing the best scientific advice available at the heart of animal health and welfare is fundamental to the success of any new regulatory system. This entails prioritising scientific methodology and ensuring transparency so that accountability mechanisms are in place. Cross-disciplinary and collaborative studies are essential. This creates the most appropriate relationships within a regulatory system, and supports professional judgment and responsibility. At the apex of any new regulatory body for animal health and welfare are the political, economic and societal issues that make up decision-making. At the outset public accountability requires that sound science is openly discussed and available; that political choices are fully explained and justified and that when choices are wrongly taken there is an appropriate feedback to ensure that better decision making takes place in the future.

The Government's consultation paper offers a unique opportunity to set the terms of the relationship between public and private sectors in the financing of the surveillance, detection and prevention of animal diseases. Co-ordination of various policies and strategies is essential if regulation is to be effective. Increasing the scope and variety of regulation over the keeper of animals and the various stakeholders must be accompanied by an extensive "tool-kit" of regulatory ideas and devices. Regulating animal health and welfare through a new regulatory agency brings the potential of a new approach to governance. This will enable stakeholders and the public to be engaged in an important collaboration at a period when science is doubted, government and politicians are not trusted and various regulators under the light touch regimes of the past, have been thought inadequate<sup>31</sup>.

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<sup>31</sup> M. Lodge, "Accountability and Transparency in Regulation: Critiques, Doctrines and Instruments" in J. Jordana, D. Levi-Faur, eds., *Politics of Regulation: Institutions and Regulatory Reforms for the Age of Governance* Cheltenham: Edward Elgar, 2004 pps 124-144.