BIOSECURITY NEW ZEALAND

Review of the Biosecurity (Ruminant Protein) Regulations 1999

Regulatory Impact Statement

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Ministry of Agriculture and Forestry
Te Manatū Ahuwhenua, Ngāherehere

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Contents

Page

Executive Summary

The Ministry of Agriculture and Forestry (MAF) Biosecurity New Zealand administers the Biosecurity (Ruminant Protein) Regulations 1999 (the Regulations), which aim to protect New Zealand's bovine spongiform encephalopathy (BSE)-free status, preserve market access and provide risk mitigation measures as required by those markets. The Regulations prohibit the feeding of ruminant protein (such as meat and bone meal) in any form to ruminant animals such as cattle, sheep, deer and goats.

Requests from trading partners have led to the need for increased detail in the Regulations. Livestock industries in New Zealand have agreed that the current Regulations need to be amended and more precisely defined control measures are necessary to ensure trading partners are satisfied and that the protection of domestic and international consumers is assured.

Amendments to the Regulations will improve their effectiveness by:

- imposing the requirement for the use of dedicated equipment for producing feed for ruminants directly in the Regulations, rather than relying on the exercise of the MAF Director-General's discretionary power, to give more certainty to overseas markets about our precautionary measures;
- requiring that Ruminant Protein Control Programmes are audited by people appointed by a MAF Chief Technical Officer as Inspectors under the Biosecurity Act 1993, rather than by auditors approved as third-party service providers, to ensure quality control of the skills and knowledge of auditors;
- enabling the recovery of costs for audits by government employees, agents and contractors from operators of Ruminant Protein Control Programmes through the Biosecurity (Costs) Regulations 2006, so that those benefiting from the audits pay for them;
- clarifying the definitions for "ruminant", "operator" and "ruminant protein" to improve enforcement of the regulations; and
- clarifying labelling requirements for feed so that they are more easily implemented.

Adequacy Statement

MAF has reviewed this Regulatory Impact Statement and considers it to be adequate.

Objective

To improve the efficiency and enforceability of New Zealand's Ruminant Protein Regulations, so as to ensure our BSE-free status.

Dedicated Ruminant Feed Processing Requirements

STATUS QUO AND PROBLEM

The MAF Director-General currently has discretion over whether to require the use of dedicated equipment for producing ruminant feed. In 2006 the Director-General issued a requirement that feed for ruminants must be produced on equipment lines separate from those used to process feed for non-ruminants, to limit the possibility of there being cross-contamination from products containing protein made from ruminants.

PREFERRED OPTION

It is proposed to remove the Director-General's discretion and make the requirement part of the Regulations.

This will not put any cost on industry currently, as the requirement is already in practice. There are approximately twelve feed manufacturers who will be required to continue to maintain separate processing lines. These are costs that feed manufacturers are able to pass onto the livestock industry that receives the trade benefits.

The benefit of this change is to the domestic livestock industry and overseas markets, which prefer certainty in regulation when making contracts, and do not want the risk that the Director-General could remove the requirement at a later time.

Auditing Ruminant Protein Control Programmes

STATUS QUO AND PROBLEM

Premises that produce feed for ruminant animals as well as those that render, use or store ruminant protein are required by the Regulations to have a MAF-registered Ruminant Protein Control Programme (RPCP). Each programme specifies how the operator will manage and minimise the risk of contamination of ruminant feed by ruminant protein, and names an independent auditor who supplies annual verification audit reports to MAF Biosecurity New Zealand. There are currently ten RPCPs in operation in New Zealand.

A pre-registration audit of a facility is carried out by a New Zealand Food Safety Authority Verification Agency (NZFSA VA) Inspector once a draft RPCP has been sent to MAF for review. Once the programme is up and running, an annual audit is carried out by an independent auditor who has been named in the RPCP and approved by MAF Biosecurity New Zealand as part of approving the entire programme. The annual audits are paid for by the facility operator.

Auditors are required to submit statements of independence and are unable to participate in drafting or amendment of RPCPs. They must agree to undertake audits for the premises concerned and inform MAF Biosecurity New Zealand of the results of audits, and of any change in their independence. MAF Biosecurity New Zealand assesses the qualifications and experience of auditors at the time the RPCP is submitted to ensure they have relevant experience in quality management auditing and the feed industry or related industries.

The naming of an independent auditor in a RPCP may lead someone to question whether the auditor had some part in developing the RPCP. This results in the perception of a potential conflict of interest, where there may be none.

RPCP operators are uncertain, prior to commencing the registration process, whether their proposed auditor is suitable, as they are assessed by MAF Biosecurity New Zealand at the same time as approving the whole RPCP.

If competency issues arise with an annual auditor and a new one is sought, the entire RPCP has to be audited by the new auditor, at the operator's cost, before they can be approved. This is because each auditor is only familiar with the one RPCP they are attached to at any one time.

PREFERRED OPTION

It is proposed that the process of appointing an annual auditor is separated from the process of registering a RPCP. An application for registering a RPCP will be placed without naming an auditor. An auditor will be chosen outside of this process.

It is also proposed that auditors carrying out annual audits are appointed Inspectors under the Biosecurity Act, which is currently the case for the pre-registration and compliance auditors. Auditors could be government or non-government employees, agents or contractors. MAF Biosecurity New Zealand would hold a list of approved auditors, which RPCP operators could choose from. As part of the training process to be appointed an Inspector, auditors would be required to be competent in the generalities of the requirements of the Regulations and auditing RPCPs, rather than just being familiar with the RPCP they are attached to.

Auditors will be required to go through MAF Biosecurity New Zealand's statutory appointment process in order to be appointed an Inspector under the Biosecurity Act. This process includes submitting proof of competency in the understanding of the relevant powers to be exercised under the Biosecurity Act, submitting proof of relevant training, and undergoing a police check. Auditors would also be required to undergo periodic competency reviews and training.

Auditors will still be required to submit statements of independence and would continue to be unable to participate in drafting or amendment of RPCPs.

Costs

RPCP operators will have to update their programmes to reflect the change in how auditors are approved. Operators do this regularly whenever anything changes, such as a postal address. Some operators update these more frequently than once a year, so they will be able to incorporate these changes along with other changes at very minor administrative costs. For others who update their RPCPs less frequently than annually, they will incur administration costs of less than one hour on average.

The changes will mean more work for auditors initially, as they will be required to be competent in the generalities of the Regulations and RPCP audits rather than being familiar with just the RPCP they are attached to.

There will be some costs to government when MAF Biosecurity New Zealand decides what training and competency processes are required. These costs, as well as the costs of processing statutory appointments of auditors will be met within MAF Biosecurity New Zealand's baseline. At present, there are ten operators of RPCPs, each with an independent auditor attached. These auditors, as well as others, may choose to be appointed Inspectors under the Biosecurity Act to continue auditing RPCPs. Each appointment will take approximately two hours of an administrator's time to process, once an application has been lodged. It is not anticipated that there will be any change in the amount of time required to approve an auditor, but there will be an increased cost to MAF Biosecurity New Zealand in conducting periodic reviews, training and assessments of competence. The increased time involved could be in the order of 0.05 FTE, to prepare, deliver and assess training, and review and assess competence of all auditors, on an annual basis.

Benefits

Separating the process of appointing an annual auditor from the process of registering a RPCP would minimise the perception of any potential conflict of interest, where there may be none. Even where there is a conflict, it is very difficult to follow up on and prove. With the other changes to approving auditors as Inspectors, the potential for genuine conflicts of interest is limited. Even when there are still remaining conflicts, the greater oversight MAF Biosecurity New Zealand will have will limit the chances that these will result in damage.

This change will also decrease the uncertainty RPCP operators currently have over the suitability of an auditor when looking for one, as they would be able to choose from a list of already approved auditors.

This process of appointing auditors as Inspectors under the Biosecurity Act would allow MAF Biosecurity New Zealand greater oversight of the ongoing competency of auditors. As appointments under the Biosecurity Act require periodic review (not currently required for RPCP annual verification auditors), this would ensure robust and ongoing quality control of

the skills and knowledge of auditors, and greater assurance of a standard audit approach. Such a change would ensure that trading partners have greater confidence in the quality of audits conducted under the Regulations.

Training auditors in the generalities of RPCP auditing would allow more flexibility in the long run for RPCP operators, auditors and MAF Biosecurity New Zealand, as any auditor would be able to audit any programme when required.

For those premises operating RPCPs and other risk management programmes, it may be possible for audits for both to be conducted simultaneously, which may result in a reduction in compliance costs. For other premises, having the audits conducted by persons authorised under the Biosecurity Act is unlikely to cause any significant change in compliance costs.

Recovering Audit Costs from Operators

STATUS QUO AND PROBLEM

This is related to the previous proposal that auditors carrying out annual audits are appointed as Inspectors under the Biosecurity Act. Because some of these auditors could be government employees, agents or contractors, a method for MAF Biosecurity New Zealand to recover the costs of providing the service is required.

Section 12(a) of the Biosecurity (Ruminant Protein) Amendment Regulations 2004 allows MAF Biosecurity New Zealand to recover the costs of registering a new, revised, amended or replacement Ruminant Protein Control Programme. These registration costs are to be payable in accordance with the Biosecurity (Costs) Regulations 2006. The Regulations do not specify, however, how the audit costs would be recovered if audits were carried out by government employees, agents or contractors.

PREFERRED OPTION

It is proposed that the Regulations be amended to allow for the costs of government employees, agents or contractors involved in auditing RPCP operators to be recovered from operators in accordance with the Biosecurity (Costs) Regulations 2006. The Biosecurity (Costs) Regulations would be amended to insert an appropriate line item for RPCP inspections and travel that is consistent with other cost regulations under which government audits are conducted.

Government employees appointed Inspectors under the Biosecurity Act would include NZFSA VA staff. The NZFSA also conduct inspections under the Animal Products and Agricultural Compounds and Veterinary Medicines (1997) Acts, which is charged out at approximately $135 an hour (excluding GST). If they also conducted RPCP annual audits, the rate would be the same. Audits carried out by other government Inspectors will likely be charged out at the same or a comparable rate. An audit takes approximately two to eight hours. The time depends on the complexity of the RPCP, the location of the property, and whether travel and write-up time is included.

Costs

Current auditors would be negatively affected, as there will be greater competition for their work, especially as the government would only be cost recovering, not making a profit. This is not likely to be a big risk to current auditors, however, as there are only ten RPCPs, and auditing of these programmes is unlikely to be a core part of their business.

Benefits

Inserting this provision will ensure that, should a government employee be asked to perform this service, the government will provide the service.

The change may result in improved access to auditors in some places, especially in remote areas. Several NZFSA VA staff are currently approved to conduct auditing and verification for the Ruminant Protein Regulations, and these staff are spread widely across New Zealand.

MAF Biosecurity New Zealand would be able to recoup the cost of providing the service (the inspection) from those who receive it (the operators). Cost recovery is good in this case because it makes operators determine whether the benefits of a RPCP outweigh the costs.

Operators would have more choice and audits conducted by government staff will likely be at a lower cost as the costs would be recovered with no profit. It is likely that introducing this competition will drive down market rates.

Definitions

STATUS QUO AND PROBLEM

The Regulations define "ruminant" as "an animal of the order Artiodactyla that chews the cud regurgitated from its rumen, for example, cattle, sheep, deer, alpacas, and goats." However, although alpacas chew cud, they do not belong to the taxonomic group of the Suborder Ruminantia. There is no scientific basis to suggest that alpacas (and other South American camelids) might contract BSE through consumption of contaminated ruminant protein, unlike with ruminants. Therefore, the Regulations affect business or processes where there are no known risks.

The Regulations define "operator" as "the occupier of premises where ruminant protein is rendered, used, or stored and where non-ruminant mammalian, avian, or fish tissue is rendered for feeding to ruminants, or feed intended for ruminants is produced."

The phrase "occupier of premises" is ambiguous. It can be argued that it does not include mobile feed manufacturers because they are not strictly "occupiers of premises". This makes it difficult to enforce compliance with the requirement that all operators need an RPCP.

The Regulations define "ruminant protein" as "protein derived from the tissue of a ruminant, except dairy produce". The definition of "feed" excludes protein-free tallow and any derivative, rennet, dicalcium phosphate, peptides and amino acids. This means that feed comprised of these components is not required to be labelled as possibly containing ruminant protein. Fertilisers produced with these same components are not specifically exempt under the Regulations, though this is not enforced as this was not an intention of the Regulations. At the moment the Regulations unintentionally regulate fertilisers more strongly than feed.

PREFERRED OPTION

It is proposed that the definition of "ruminant" is amended to specifically refer to all animals that belong to the suborder Ruminantia, rather than including all animals that chew cud. This amended definition would exclude alpacas and other South American camelids. This would make the definition of "ruminant" clearer and more specific, making the regulations easier to interpret. This would require a change in product labelling, which would be included in the wider changes to product labelling proposed. The changed definition would allow feed for alpacas and other camelids to be produced on the same equipment as feeds containing ruminant protein. The finished feed would still be required to be labelled as possibly containing ruminant protein.

It is proposed that the definition of “operator” is amended to include mobile feed manufacturers. This would remove the ambiguity, making the regulations easier to interpret and enforce. It would also ensure all applicable enterprise types are subject to the Regulations.

It is proposed that the definition of “ruminant protein” is amended to exclude protein-free tallow and any derivative, rennet, dicalcium phosphate, peptides and amino acids. This would make it clear that all products produced with these components, including fertilisers, are exempt from having to be labelled as possibly containing ruminant protein.

Wording of Product Labels and Labelling Requirements

STATUS QUO AND PROBLEM

The Regulations provide three options for labelling and require feed suppliers to use the most appropriate of the following notices:

1. "*Notice: Suitable for feeding to [insert ruminant species or type]"*;
2. "*Notice: Suitable for inclusion in feed intended for ruminant animals"*; or
3. "*Notice: not to be fed to sheep, cattle, deer, alpacas, goats, or other ruminant animals"*.

Requiring some but not all feeds to be labelled, whether they contain ruminant protein or not, and having multiple labelling choices is confusing and leads to non-compliance with the Regulations. For example, a feed that doesn't contain ruminant protein and has had no contact with it during manufacturing is required to be labelled with either of the first two options above, if it is produced in a premises where ruminant protein is used. This feed may be perceived as being safe for all ruminant animals, when it may not be. While it is safe from the perspective of BSE risk, some other ingredients used may be poisonous to particular animals. For instance, horse feed normally does not contain ruminant protein, but it often contains copper supplements at levels toxic to sheep. Some feed manufacturers were applying the third label to ruminant protein-free feed to prevent this type of poisoning. This label implied that there was ruminant protein present in this feed when there wasn't. This inappropriate labelling not only contravened the Regulations, but also created extra work for retailers who re-bag bulk feed into smaller packages, as extra precautions are required when handling feed containing ruminant protein. In addition, some feeds do not require labelling at all (feeds that do not contain ruminant protein and are produced in premises where ruminant protein is not used or stored), and the existence of unlabelled feeds was cause for confusion when feeds labelled as suitable for feeding to ruminants also existed.

The Regulations require notices on feed bags to "occupy at least five percent of the total area covered by all labelling" of the feed or fertiliser. The definition of what constitutes "the total area covered by all labelling" has created confusion and has long been the subject of differing interpretations. While industry has interpreted the "total area" to exclude the words in logos and graphics, MAF Biosecurity New Zealand has considered the "total area" to include all words, including those in logos and graphics.

The Regulations require that every label be "conspicuous and easily legible". The words "durable" and "legible" are somewhat open to interpretation and require more specificity. Some labels currently in use were legible when printed, but insufficiently durable, e.g. printed in ink that smudged with handling, or with paper stuck on labels that came off when damp. Some are also insufficiently conspicuous, e.g. hidden on the back of the package at the bottom where it may not be easily seen by people buying the product.

PREFERRED OPTION

The preferred option is to amend the Regulations so that only products which may contain ruminant protein (i.e. ruminant protein is an ingredient, or the product or its components are produced on or using equipment where ruminant protein is used) must be labelled to declare their ruminant protein status. The proposed wording is:

"Notice: Do not feed to sheep, cattle, deer, goats, buffaloes and other ruminant animals. This product contains/may contain ruminant protein."

The proposed wording is in line with the proposed new definition for "ruminant" and includes the major types of ruminant animals.

To remove the confusion around the size of regulatory notices, it is proposed that the requirements will specify a minimum regulatory notice size based on the surface area of the bag or container. The Regulations would be amended to require that the size of the regulatory notice should be the smaller of the following two options. Either:

- the notice must occupy a minimum area defined in the Regulations, based on the total area of the unfolded flattened packaging, as circumscribed by the end stitch lines/folds; or
- the letters in the notice must be at least 20 mm high.

It is also proposed to amend the positioning and durability requirements of the label to clarify the existing requirement that every regulatory notice is to "be conspicuous and easily legible". The Regulations would be amended to require that:

- the regulatory notice must be permanently stamped, affixed, or marked on "to the front of the package or container for the feed or fertiliser, immediately below the top stitch line or fold"; and
- the regulatory notice should be of durable material for the lifetime of the stored and used packaged product.

Changes will come into force twelve months from the date of notification in the Gazette.

Costs

The changes to labelling requirements will have small costs to approximately 120 feed manufacturers, blenders or re-baggers, 4 fertiliser manufacturers, and 48 renderers. Allowing twelve months for the changes to come into force will minimise these cost impacts by ensuring there is sufficient time to organise new labelling and use up existing stocks of packaging materials.

Benefits

The changes will remove confusion associated with having to choose between labels, and the unintended consequence of the wording of the current regulations, where some feed did not require labelling at all. The changes will also ensure that labels are durable and obvious, and ambiguities about the size of label required are removed, which will assist with compliance. There will also be a benefit to end users, as the minimum size of labels will be big enough to be easily read.

The changes will remove the confusion around the required minimum size for regulatory notices and will ensure that it is clear in the Regulations that labelling has to be durable as well as legible, and that it has to be on the front of the package at the top, so that it is easily seen by those intending to purchase the product.

Alternative Options

CHANGING THE DEFINITION OF "FEED"

Some submissions on the recent public discussion paper considered that the current definition of "feed" in the Regulations does not reflect the commonly understood definition.

The Regulations apply to feed in a specific context, and the definition in the Regulations indicates this context. Changing the definition may broaden the scope of the Regulations beyond what was intended unless other substantial changes were made. The changes to the requirements for labelling will remove some of the complexities arising from the definition of feed under the Regulations. This will be communicated to stakeholders along with the rest of the changes and their implications.

COMPULSORY AUDITS

Another option was to implement a compliance reporting regime for all feed manufacturers and retailers, which would have required every business in New Zealand that sells or handles feed or fertiliser to submit an annual return indicating whether they were complying with the Regulations. This would have provided MAF Biosecurity New Zealand with the opportunity to ensure that all businesses were aware of the compliance requirements. It would have also provided MAF Biosecurity New Zealand with the opportunity to undertake targeted audits to those submitting statements indicating non-compliance. Compulsory audits at end-user cost were the proposed response to enterprises not returning the compliance statement. However, the alternative methods of monitoring compliance in the sector (conducting random audits on a regular basis) were considered more appropriate due to the additional administrative burden on government and businesses from this proposal. A change in the Regulations is not required for conducting random audits.

REQUIRING OPERATORS TO PAY FOR RANDOM COMPLIANCE AUDITS

Another option considered was to require those operators selected for random compliance audits to pay for the audit. However, auditing that is not requested by the enterprise being audited (i.e. audits not associated with a RPCP) is considered to contain a lot of public benefit in terms of human and animal welfare, as it helps to ensure that the programmes work and are complied with. The programmes ensure the BSE-free status of New Zealand. Therefore, it is considered appropriate to fund these audits publicly. Industry also benefits from the Regulations in terms of trade impacts. This, however, was unintentionally omitted from the analysis, but will be considered as part of cost recovery reviews in the future.

REQUIRING ALL AUDITS TO BE CONDUCTED BY THE GOVERNMENT

Another option considered was to require all audits (including annual audits of RPCPs, currently conducted by independent auditors) to be conducted only by government staff. This would have helped to increase consistency and quality control of audits, but would have

reduced market competition and was not signalled as a problem by trading partners or domestic industry. Alternative methods of ensuring consistent quality and review of audit standards were developed and proposed (i.e. the requirement for auditors to be appointed Inspectors under the Biosecurity Act).

Implementation and Review

The changes will come into force twelve months from the date of notification in the Gazette. This will allow sufficient time for industry to use up packaging stock, design new packaging and have it printed, for auditors to be appointed as Inspectors under the Biosecurity Act, and for registered operators to update their RPCPs. It will also allow time for communication with industry and end users to ensure they are aware of the changes and new requirements.

MAF Biosecurity New Zealand will contact all RPCP operators and their auditors, and all known feed and fertiliser industry enterprises, by letter, to ensure they are aware of the changes and their implications. MAF Biosecurity New Zealand will supply point of sale education materials to retailers to ensure end users are aware of the changes, and will also communicate changes through rural media as appropriate.

To minimise compliance costs, the cost recovery changes will be included in a wider review of the Biosecurity (Costs) Regulations 2006 currently being conducted.

Consultation

STAKEHOLDER CONSULTATION

The changes will affect ten operators within New Zealand who currently have registered Ruminant Protein Control Programmes. The changes will also affect approximately 120 other feed manufacturers, blenders or re-baggers, 48 renderers, 250 feed retailers, five feed importers, four organic fertiliser manufacturers and 20 feed transport and storage firms, as well as those who purchase animal feed.

MAF Biosecurity New Zealand met with industry representatives in February 2006 to discuss the future direction of the Regulations. There was unanimous support for requiring feed manufacturers to use separate equipment for handling ruminant feed.

MAF Biosecurity New Zealand had further consultations with the New Zealand Feed Manufacturers Association in July 2006, May 2007 and May 2008 to inform them of progress and the changes under consideration. The recommended amendments to the Regulations presented in the discussion paper were informed by and developed as a result of these meetings.

In September 2008, MAF Biosecurity New Zealand released a public discussion document with proposed amendments to the Regulations. Twelve submissions were received from feed millers, organic fertiliser manufacturers, industry associations and farming organisations. Submitters were generally supportive of the intent of the proposed changes to strengthen the Regulations around the use of ruminant protein. Some submitters raised additional issues that they considered required further analysis. The proposed amendment to the definition of

"ruminant protein" was included and the proposed new wording requirements for labelling were altered in light of issues raised in submissions.

Auditors were targeted in consultation, but no feedback was received, which suggests that the changes are unlikely to have significant impacts on them. As there are currently only ten RPCP operators in New Zealand, it is unlikely that the annual audits of these programmes are a core part of an auditor's business.

GOVERNMENT DEPARTMENT/AGENCY CONSULTATION

The following agencies have been consulted on the proposal: the Department of the Prime Minister and Cabinet, the Treasury, the Ministry of Economic Development, the Ministry of Foreign Affairs and Trade, the Ministry of Health, the Department of Conservation, Te Puni Kokiri, and the New Zealand Food Safety Authority.

The Ministry of Health supports the recommendations.

The Department of Conservation expressed support for the intention of these precautionary measures to maintain New Zealand's BSE-free status. They agreed that the changes will tighten up the manufacturing and use of ruminant protein feed, and will remove the uncertainty around issues such as labelling and compliance.

No concerns were raised by any government agency or department.